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## **Ethical considerations in the use of patient medical records for research**

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**Abstract**--Background: The exchange of data allows major advancements in the medical field and contributes to growth in data research in general. However, these practices also raise ethical concerns such as patient's privacy rights, patients' self-ownership, and reporting and ownership of data. Aim: The custodianship of data; whether it should be one's best to share or collaborate depends on the benefits to be accrued from the research, against the rights of the patients. Methods: A literature review of current literature and major ethical codes was also employed to identify the main hurdles to data sharing and cooperation. Results: The study also revealed explicit threats regarding the dangers which privacy and data integrity of patients may face, especially for de-identified data. It also brought into focus issues on consent procedures, conflicts in ownership particularly where collaborations involve several institutions, and procedural lapses on the part and parity of ensuring compliance to ethics and the law. Conclusion: Ethical issues arising from data-sharing and collaboration call for still stronger measures for protective governance as well as equitable share and open policies for patients' protection as research is enhanced.

**Keywords**--Data sharing, communication, patient's identity, consent, data sovereignty, medical ethics, research compliance.

**Introduction**

Interdisciplinary cooperation in the dissemination of data is a fundamental component of the contemporary scientific process in medicine as well as medical advancements. There is a potential to combine data from different sources within and across institutions, countries and disciplines; this enables researchers to interrogate and answer incredibly difficult questions that cannot be resolved by using individual datasets. However, increased use of technology in the delivery of health care has created increased concern on ethical issues especially when handling patients' medical records.[1,2] Questions concerning privacy, informed consent, ownership and accountability re-emerge more especially when research is being conducted in collaboration with other institutions or across national borders. These challenges simply underscore the need for a credible ethical framework and ethical regulatory safeguards within specific research paradigms to guarantee that credible research progress does not compromise on patient or the public's interests. To that end, this paper examines the various challenges related to data sharing and cooperation, and provides recommendations for increased trust, fairness, and compliance with all legal requirements.[3]

Ethical principles in research form foundation of work, reliability and credibility, as well as the trust in scientific community. They make sure that research does not infringe on the person and group respect, autonomy, and crucial for their wellbeing. Through ethical standards and principles, the rights of participants are protected; their privacy and Identity kept secure; and the principle of 'Do No Harm' as well as 'Do Good and minimize harm but maximize benefits' is achieved. The presented ethic standards are especially important in fields such as healthcare, where patient medical records are used as sources for the research. Since the data with which medical personnel deal with include diagnostics, treatment, and clients' history, such data should be protected. Any misconduct in ethical standard therefore can easily lead to harm of people involved in the research and may also lead to loss of confidence in the research fraternity by people thus reducing willingness of people in research practices.[4]In addition, ethical standard promotes the qualities of the result obtained in research such that it is believable and could be repeated. Cheating in research includes falsifying data, embezzlement or failing to respect informed consent deprives research of credibility and reliability as it provides wrong information, which may have negative impacts. For instance in clinical research, unethical practice yields in the release of dangerous medical practices or could expose people to useless treatments. Ethical research practices also serve a purpose of accountability Since researchers must declare their sources of funding, the things that may cause bias or conflicts of interest, it is instrumental in encouraging fairness in scientific research. The research community, research institutions, and the public equally benefit from such accountability because it encourages cooperation and the sharing of resources on knowledge production processes.[5,6]

Besides the participants and the quality of research, ethical principles serve as the main factor regulating the existing research with reference to the society's and legal norms. Scientific faculty has to deal with multiple ethical issues: self-fulfillment and inter- individual relations; conflicts of interest; social responsibility and impact of new technologies in the context of the increasingly questioning of research benefits, including topics such as artificial intelligence or genetic engineering. For example, where patient medical records are incorporated into big data repositories that feed into Machine Learning applications, issues of data privacy, data justice, and even potential abusive uses of the data are an issue. To these challenges, it is possible to respond in an affirmative manner by showing how acting ethically in accordance with certain norms facilitates the production of benefits and minimizes harm to subjects. In addition, E-Research also serves the interest of promoting ethics in scientific research as well as asserting the ethical imperatives of researchers as guardians of the public interest and good.[7]ethical standards in scholarly research erute the significance beyond scholarly circles and cut across other facets of life. These principles drive the policies, regulations and general norms which people have about science. Each time the researchers embrace ethical conduct, they show the basic human values of honoring the participants' rights as human beings, and the overall societal benefit that scientific endeavor should espouse to enhance the value of its benefits to the society.[8]

### **Issues Pertaining to Privacy**

Privacy and confidentiality form core values of research especially when is involved with details of patients' information. These principles are necessary to avoid the community suffering from resultant vices such as identity theft, stigmatization or discrimination from the misuse of their personal information. Privacy protection in the context of medical studies mean that such individual patient data is protected and released to only such other people as have the right to have access to it for research purposes. As a result, the legal and ethical regulation of studies means that researchers have to follow legal and ethic requirements of laws, for example, in the United States the Health Insurance Portability and Accountability Act (HIPAA), and in Europe the General Data Protection Regulation (GDPR). These frameworks give an indication on how to handle patients data in terms of collection, storage, and sharing without infringing on patient's rights.[9]

Measures of ensuring in their work concealment include rigorous data protection measures for maximum seclusion of information such as in the use of encryption for information, secure database, and restricted platform to access information. Further, the data contains identifiers such as name and address, or medical record numbers are completely removed from the data to eliminate re-identification of the individuals. Though, anonymization is not sufficient, as there are ways to identify individuals in contemporary datasets given particular attributes enhanced by artificial intelligence techniques. This raises a key issue which many scholars face in executing their research; how best can one ensure that large samples are used in a research but at the same time ensure that the identity of the participants is protected.[10,11]There are also privacy issues in the dissemination of the research results obtained from the data collected. The authors of any study are ethically responsible for protecting identities of participants, when disclosing the results of their investigations. For example, while writing case studies or qualitative analysis where quantitative data involving human subject may be presented in form of narratives the subject should be disguised. In addition, partnerships between two institutions or two countries require other measures to ensure that data sharing procedures meet differing legal and ethical requirements. Research utilizing cloud storage or computerized systems for medical record storage can have the potential for threats and breaches, as such the researcher has to be cautious.[12]Last but not the least; confidentiality and private to the last detail, is highly important in sustaining the public's confidence in the research. From the study, patients are willing to allow their health records to be used if they are assured their data will be managed with appropriate concern and ethical manner. Scientific research requires this trust because it enables researchers to obtain data from numerous and rich sources needed for study results. Scholars often face new privacy concerns and should refrain from engaging in old practices that are no longer safe for participants' rights and ethical integrity. Maintaining confidentiality and privacy in research, scientists do respect the person and dignity and advance the ethical aspect of science.[13]

### **Informed Consent: Fundamentality Of Ethics**

Informed consent is one of the critical ethical requirement in conducting research that seeks to utilize human subjects in experiments, test, studies and the like. It is going to embrace the principle of autonomy which simply emphasizes that a person has a right to make self-governing decisions in connection with his or her body. It's important to get proper consent, especially when a patient medical record is involved, as such records must contain only personal and health related info. According to the participants, they need to make sure they are aware about the uses, users, and security of data they share with the application. This process however can engender the participants so that they can be in a position to decide whether they should submit their information for research or not. [14] They rightly pointed out that getting informed consent is not just about having participants fill and sign a document. It refer to the openness and clarity of research information exchange between researchers and participants. Information has to be given in a form so that people can comprehend them without having intensive learning background and without struggle due to the difference in their culture. Informed consent demands that participants are not forced to participate and that they are freely able to withdraw from each study at any time. This is especially important in special classes of persons such as the children, the elderly and those whose mental health is not sound to give a proper informed consent for research, extra precautions may be needed to ensure true informed consent was given by the patient.[15]

Informed consent for research incorporating outpatient records can be seen as dynamic in part, most of the time particularly in situations where an investigation continues over a long period of time, or in circumstances where information gathered from patients' records form the basis of additional research. CMS guidelines require that researchers to seek fresh permission where the purposes of the research will be expanded or where the information will be conveyed to other people. This continuous process reemphasizes the ethical requirement of engaging the participants and involving them in the decisions concerning use of their information. For example, suppose patient medical records data is to be used in a multinational study; participants have to be told the meaning of this, possibly, how data on them will operate under the Aegis of different privacy laws of the world. [16]Self imperative also plays a very important role in maintaining and enhancing the relationship between the researcher and the participant in that the Principle of Informed consent enhances trust. If people feel they are in a position to decide on their own without interference, they will feel happier.[17,18]

### **Data Anonymization as the Measure of Privacy Protection**

De-identification is an important step in any study where attempt is made to make the data unsuitable for identification of the individuals involved in it. It is most relevant when dealing with large data files which contain private information on clients like patients to retain their anonymity while at the same time allowing scientists to analyze the data they need. Database anonymization is usually a process of data obscuring where names, addresses, social security numbers and other attributes that may be used to identify an individual or group of individuals are either deleted or encrypted, or, in the case of other attributes, where large

groups of attributes are combined or their true values hidden. Since the data cannot be linked back to particular individuals, then anonymization can be seen as serving a purpose of putting privacy concerns at par with the concern to use data for research in a rightful way.[19]

The Need for data anonymization has increased with the use of big data and analytics in research work. In healthcare, it established that patient medical records offer unique source of information in disease and treatment process; as well as for identifying general health trends. Nonetheless, if anonymized correctly, only risks of sensitive information disclosure to a third party are retained while the anonymity of a patient could be perilously breached in cases where data is linked with other sources. For example, if some registry or bibliographic database can be linked with another database containing personal profiles from the social networks, the data can be reconstructed in order to identify an individual. This underlines the presence of other anonymization techniques referred as k-anonymity, l-diversity, and differential privacy of anonymizing that are aimed reducing re-identification risks while at the same time enhance the data usefulness. The capabilities of the data analytics technologies are increasing, and researchers need to cautiously respond to their advances and update their anonymization practices.[20,21] In addition to its technical function, data anonymization has an equally if not more important ethical/ legal function in research. Laws such as the General Data Protection Regulation in Europe, and the Health Insurance Portability and Accountability Act in United States set more or less legal standard of handling personal information. According to these frameworks, most of the data are anonymous and therefore can easily be released to the public or put into research without much of a problem concerning privacy. However, it is often difficult to achieve fully anonymized data and this may become a question of the trade off between loss of detail in the data and the level of identification risk. The researchers also need to be careful so that the anonymization process that is being adopted may not bring in biases or inaccuracies which can mess up the research results.[22]

In addition, data anonymization increases confidence between the researcher and the participant, so even more participants contribute to the study. People will be more inclined to provide permission to the usage of their information if they will be informed that their identity will be concealed. This trust is especially high in fields like healthcare because big and diverse datasets are crucial to pushing the boundaries in healthcare knowledge and outcomes. It also helps ethical sharing of data between the institutions and across different countries, as the researchers working with different jurisdictions can anonymize their data and share because they understand that their laws are different. For instance, identified data can help to combat worldwide threats, including pandemics or to find out more about the factors of rare diseases, when data collection from different sources is required.[23] data anonymization, is one of the cardinal practices in ethical research especially within hi-g settings such as patient electronic records. It ensures that people, if not all, have their privacy ensured while at the same time allowing researchers to ask question that are central to society's progress and come up with results that would benefit people. Yet, authors have to keep developing their anonymization strategies for addressing emergent challenges, thus proving their interest for ethical academic practice and correct data usage in

science.. Since the focus is placed on anonymization, the rights of participants are protected, the public is confident in the outcomes, and science and knowledge continue to be developed while respecting peoples' density and privacy.[24]

**Regulations governing the records of patients This section seeks to answer the following questions:**

Polices and laws concerning patient data are crucial in safeguarding and promoting the proper use of all patient medical data in all realms of human life and research. Such frameworks set clear principles on how the data of patients should be acquired, secured, retrieved, and used so as to respect rights and individual privacy of those patients. Among the purposes of such regulations is to protect the personal health information from misuse for purposes that include discrimination, stigmatization or breach of confidentiality. Moreover, all these frameworks offer a basic framework within which patients, providers and researchers may establish trust for patients' information to be well handled and protected.[25]HIPAA in the United States, or GDPR of the European Union are examples of a set of laws that are the foundation for the regulation of records belonging to patients. HIPAA for instance requires that anyone in healthcare, insurance, and other industries protected PHI to observe set administrative, physical as well as technical measures. It also need the consent of the patient for data sharing and also has provision for penalties for non compliance. On the other hand, GDPR is wider in its scope that regulates processing of any personal data, including health-related data of the subjects residing in EU or those Europeans affected while in Member States. It includes basic concepts like openness, proportionality, and responsibility; it provides individuals more ability to manage their data through mechanisms of rights like information, correction and deletion.[26]

Especially in the context of medical research, they may define circumstances, under which patient data can be used without consent, e.g. for public health epidemiology, or if data sensitivity has been reduced to a certain level. For example, HIPAA's Privacy Rule permits the disclosure of PHI to satisfy particular purposes, including receiving an authorization waiver from an IRB or Privacy Board. As with first level research, GDPR allows data processing for research purposes but only under what it considers appropriate measures such as anonymization. These exceptions shed light on the precise balance that is in the middle of which regulations are made to be in relation to the discoverability of scientific information, as well as respecting the privacy rights of persons. However, most nations also have general legal requirements or rules that apply to issues of patient data management in research even as they address specific regulatory frameworks for clinical research. For instance, in the United States, ethical issues are regulate by the Federal Policy for the Protection of Human Subjects known as Common Rule that work hand in hand with HIPAA. Some countries may have general codes like the National Health Service (NHS) Code of Practice for the UK and contains practical working procedure for managing health data legally.[27]Nonetheless, the application of these frameworks might be challenging primarily because of the issues concerning data sharing across border in research that cuts across legal systems of different countries. For instance, even though HIPAA addresses confidentiality mainly in the context of PHI, GDPR applies to all

the processing of personal data irrespective of the location of the organization processing it. These factors present a lot of challenges such to researchers and institutions and may at times demand legal counsel to be observed. Noncompliance with these principles leads to severe legal and financial consequences soon and loss of the public's confidence in research organizations.[28,29]

Finally, legal and regulatory aspects of patient records constitute a very significant part of ethical use of both paper and electronic records in health care provision and research. They put measures as barriers to privacy while facilitating access the information for important health care and research uses. These frameworks have now to adapt to new issues like artificial intelligence and big data due to the progress of technology and data analytics. Thus follows that by observing to these regulations, investigators and physicians shall be in a position to observe ethical standards, to encourage public confidence and to play our part in the progress of science and of medicine in the right manner.

### **Balancing Research Benefits and Patient Rights**

This paper has shown that the problem of striking a balance between research and patient's rights is one of the major ethical issues in healthcare and medical research. On one end, the utilization of patient medical records can help develop fresh knowledge and effective treatments and contributing to the improvement of health for the common populace. On the other, the rights of the patient to privacy, self-rule, and consent should not be violated due to distrust to personal or other's harm. Balancing these two aims is possible only by bringing into effect an approach that is aware of both the scientific missions and the ethical imperatives.[30]If patient information is used in research the gains are numerous and revolutionary. Full clinical records enable the study of diseases' distribution, treatment outcomes, and possibility of individual treatment plans. For instance, a huge database has played a significant role in different diseases with genetic and environmental determinants like diabetes and cancer. Furthermore, records of patients have been of great importance in surveillance and investigation of communicable diseases and for measuring the effect of government legislations. Without such data many of these advances wouldn't be possible. Nevertheless, these kinds of benefits cannot be achieved while compromising the rights of the patients which are provided in ethical and legal norms.[31]

Patients have rights to privacy and confidentiality, this is especially so in the case that health information is sensitive. Privacy violation in an unauthorized or a misuse of medical records can lead to harm such as stigmatization, discriminations or emotional harm. In order to safeguard these rights researchers have to ensure proper measures to protect the data, including anonymization, data encryption, and properly storing it so that data breaches are less of a likelihood. Second, copyright law is as a valuable supplement, as the rights of patients must be protected to the greatest extent possible with regard to the use of their data in research; the principle of informed consent is another important requirement, which guarantees that patients will know the purpose for which their data will be used, as well as the rights and freedoms pertaining to research subjects. Concerning patient's self-Managed preference, this approach not only

meets Ethical requirements but also enhances patient's confidence, hence participation and data sharing among the research fraternity.[32]

These interests also need be balanced taking into account the concerns of regulations and the law. For example the EU General Data Protection Regulation or the US Health Insurance Portability and Accountability Act both regulate the use of patient data and concern itself with a balance between ethical research use of patient data and autonomy of individuals. Such frameworks can have provisions for exigent circumstances such as probably pandemic situations where the rewards of research may overshadow need to follow the consent formalities to the extremity. Nevertheless, certain standards have to be maintained so that patient rights are not sufficiently prejudice during such choices.[33,34]the emergence of a large number of databases and artificial intelligence has introduced new conditions to this balance. Modern technologies can provide solutions and make desirable predictions from enormous patient datasets that would have been impossible just a few years ago; however, these technologies can threaten patient privacy and consent. For instance, it has become possible to identify de-identified data especially using other databases into which such data is merged and this erodes on traditional principles of privacy. There is thus need for researchers to embrace dynamic ethical approaches and tools including differential privacy and secure multiparty computation to combat the challenges while preserving on their research.[22]it is very much a work in progress to find the right calibrations between the assessed benefits of research and patient rights, with constant discourse between researchers, policymakers and society. Being clear about why, how, and what research is being done is important to gaining the public's trust and to making sure that patients consider themselves valuable members of the research team. Another important feature is that the scientific studies of ethic research should be approved by ethic boards and according to institutional regulations preceding the recognition of these projects. By walking this tightrope, the research community will be able to make real progress in medicine while also preserving the worth and the rights of the people whose contribution makes such progress possible. [23,24]

### **Potential Ethical Challenges in Data Sharing and Collaboration**

In this case, data sharing and collaboration are some of the essential activities in progress towards enhancing medical research and future health care services, but they present the following ethical issues: The interdisciplinary and cross-institutional and international aspect of big data promotes innovation, allows for the conduct of large scale studies, and increases the possibilities to replicate the studies. But with it comes certain challenges such legal considerations particularly in areas like privacy or consent or provenance and responsibility which if not well handled compromise the trust of research participations. [25,26]Thus, one of the most pressing ethical questions concerning data sharing is how to protect patients' identity. Medical records are often invasive personal records, and sharing them across different systems raises the privacy stakes of an attack or a breach. Sometimes data is collected and anonymized, nevertheless, a re-identification can be made with the aid of other 'open' data sources. This risk is more apparent in big data and artificial intelligence in which powerful algorithms can establish patterns that are likely reveal particulars about a person. To avoid

any of these risks, researchers need to adopt more enhanced approaches like differential privacy or secure data enclaves. However, such measures are also known to make the process of data analysis more challenging, where both abstractions provide relative privacy protection while preserving data utility.[27,28]

Another daunting task will be to achieve informed consent especially where data sharing is concerned. In some cases, patients may sign a consent to let their data to be used in a particular research but this doesn't include other uses or further studies. Secondary research or secondary analysis may include a population that provided data for one purpose and without prior knowledge about other usage. In response to this, some people suggest converting broad or tiered models, whereby patients consent for various uses of their data. But, such models should not undermine patient self-determination and, therefore, must be coupled with openness. [29] Ownership and control of data are another issue of ethical interest that emerges when working collaboratively. Assigning ownership of the data and controlling access rights and usage or sharing rights are often disputed especially in multi site or multi country studies. Disputes over data ownership are likely to result in delays, conflicts, and unfair distribution of resources especially where institutions from hi-income and low income countries are involved. The exploitation may ensue from differences in power relations where the researchers from institutions of higher resource endowment stand to benefit hugely from data collected in comparatively disadvantaged environments. Implementing ambient privacy and distribution means to maintain oversees are a key to cultivate accountable and co-beneficial research partnerships. [30]

## **Conclusion**

The issues like data sharing, data collaboration and collection are seen ethical issues for the medical research and this is because the researchers need to balance between the medical advancement and the rights of the patients. Necessary preconditions for addressing the most important problem areas such as privacy, informed consent, data ownership, and accountability include proactive approaches and adequate governance solutions. As such, researchers, institutions, and policymakers have to find common ground in establishing fair, open, and culturally sensitive use of data that will be comprehensive and error-free. In this way, the research community is able to build the public and stakeholder trust, support mutually beneficial collaborations and maximize the benefits of data sharing to everyone's benefit in enhancing the global health of societies. Lastly, ethical collaboration serves research by promoting the basic values of respect, fairness and integrity in medical science .

## **References**

1. Rocher, L., Hendrickx, J. M., & de Montjoye, Y. A. (2019). Estimating the success of re-identifications in incomplete datasets using generative models. *Nature Communications*, 10\*(1), 3069.
2. Keyes, K. M., & Westreich, D. (2019). UK Biobank, big data, and the consequences of non-representativeness. *Lancet*, 393(10178), 1297.

3. Wachter, R. M., & Cassel, C. K. (2020). Sharing health care data with digital giants: Overcoming obstacles and reaping benefits while protecting patients. *JAMA: The Journal of the American Medical Association*, 323(6), 507-508.
4. Ballantyne, A. (2019). Adjusting the focus: A public health ethics approach to data research. *Bioethics*, 33(3), 357-366.
5. Sadowski, J., Viljoen, S., & Whittaker, M. (2021). Everyone should decide how their digital data are used, not just tech companies. *Nature*, 595(7866), 169-171.
6. Sideri, K., Cockbain, J., Van Biesen, W., De Hert, M., Decruyenaere, J., & Sterckx, S. (2022). Digital pills for the remote monitoring of medication intake: A stakeholder analysis and assessment of marketing approval and patent granting policies. *Journal of Law and Biosciences*, 9(2), Isac029.
7. Richter, G., Borzikowsky, C., Hoyer, B. F., Laudes, M., & Krawczak, M. (2022). Secondary research use of personal medical data: Patient attitudes towards data donation. *BMC Medical Ethics*.
8. Hawkins, J., Wellsted, D., Corps, C., Fluck, R., Gair, R., Hall, N., et al. (2022). Measuring patients' experience with renal services in the UK: Development and validation of the Kidney PREM. *Nephrology, Dialysis, Transplantation: Official Publication of the European Dialysis and Transplant Association-European Renal Association*, 37(8), 1507-1519.
9. Morzywolek, P., Steen, J., Vansteelandt, S., Decruyenaere, J., Sterckx, S., & Van Biesen, W. (2022). Timing of dialysis in acute kidney injury using routinely collected data and dynamic treatment regimes. *\*Crit Care*, 26\*(1), 365.
10. Fu, E. L., Evans, M., Carrero, J. J., Putter, H., Clase, C. M., Caskey, F. J., et al. (2021). Timing of dialysis initiation to reduce mortality and cardiovascular events in advanced chronic kidney disease: Nationwide cohort study. *\*BMJ*, 375, e066306.
11. Van Biesen, W., Van Der Sträeten, C., Sterckx, S., Steen, J., Diependaele, L., & Decruyenaere, J. (2021). The concept of justifiable healthcare and how big data can help us to achieve it. *\*BMC Medical Informatics and Decision Making*, 21(1), 87.
12. McCord, K. A., Al-Shahi Salman, R., Treweek, S., Gardner, H., Strech, D., Whiteley, W., et al. (2018). Routinely collected data for randomized trials: Promises, barriers, and implications. *Trials*, 19(1), 29.
13. Van Acker, P., Van Biesen, W., Nagler, E. V., Koobasi, M., Veys, N., & Vanmassenhove, J. (2021). Risk prediction models for acute kidney injury in adults: An overview of systematic reviews. *PLoS One*, 16(4), e0248899.
14. Vanmassenhove, J., Steen, J., Vansteelandt, S., Morzywolek, P., Hoste, E., Decruyenaere, J., et al. (2021). The importance of the urinary output criterion for the detection and prognostic meaning of AKI. *Scientific Reports*, 11\*(1), 11089.
15. Sawhney, S., Bell, S., Black, C., Christiansen, C. F., Heide-Jorgensen, U., Jensen, S. K., et al. (2022). Harmonization of epidemiology of acute kidney injury and acute kidney disease produces comparable findings across four geographic populations. *Kidney International*, 101(6), 1271-1281.
16. Dehrlein, E. M., Graff, J. S., Harris, J., & Perfetto, E. M. (2019). Patient-community perspectives on real-world evidence: Enhancing engagement, understanding, and trust. *atient*, 12(4), 375-381.

17. Fiske, A., Degelsegger-Marquez, A., Marsteurer, B., & Prainsack, B. (2022). Value-creation in the domain: A typology of what health data help us do. *Biosocieties*, 1-25.
18. Prainsack, B., El-Sayed, S., Forgo, N., Szoszkiewicz, L., & Baumer, P. (2022). Data solidarity: Governing health futures. *Lancet Digital Health*, 4\*(11), e773-e774.
19. Hernán, M. A., Hsu, J., & Healy, B. (2019). A second chance to get causal inference right: A classification of data science tasks. *CHANCE*, 32(1), 42-49.
20. Nagendran, M., Chen, Y., Lovejoy, C. A., Gordon, A. C., Komorowski, M., Harvey, H., et al. (2020). Artificial intelligence versus clinicians: Systematic review of design, reporting standards, and claims of deep learning studies. *BMJ*, 368, m689.
21. Van Biesen, W., Vanmassenhove, J., & Decruyenaere, J. (2020). Prediction of acute kidney injury using artificial intelligence: Are we there yet?
22. Nephrology, Dialysis, Transplantation: Official Publication of the European Dialysis and Transplant Association-European Renal Association, 35(2), 204-205.
23. Naik, N., Hameed, B. M., Shetty, D. K., et al. (2022). Legal and ethical consideration in artificial intelligence in healthcare: Who takes responsibility? *Frontiers in Surgery*, 9, 862322. <https://doi.org/10.3389/fsurg.2022.862322>
24. Fletcher, R. R., Nakeshimana, A., & Olubeko, O. (2020). Addressing fairness, bias, and appropriate use of artificial intelligence and machine learning in global health. *Frontiers in Artificial Intelligence*, 3, 561802. <https://doi.org/10.3389/frai.2020.561802>
25. Chen, Y., Clayton, E. W., Novak, L. L., Anders, S., & Malin, B. (2023). Human-centered design to address biases in artificial intelligence. *Journal of Medical Internet Research*, 25\*, 0. <https://doi.org/10.2196/43251>
26. Ahmed, Z., Mohamed, K., Zeeshan, S., & Dong, X. (2020). Artificial intelligence with multi-functional machine learning platform development for better healthcare and precision medicine. *Database (Oxford)*, 2020, 0. <https://doi.org/10.1093/database/baaa010>
27. Habli, I., Lawton, T., & Porter, Z. (2020). Artificial intelligence in healthcare: Accountability and safety. *Bulletin of the World Health Organization*, 98, 251-256. <https://doi.org/10.2471/BLT.19.237487>
28. 1. Amann, J., Blasimme, A., Vayena, E., Frey, D., & Madai, V. I. (2020). Explainability for artificial intelligence in healthcare: A multidisciplinary perspective. *BMC Medical Informatics and Decision Making*, 20(1), 1-9. <https://doi.org/10.1186/s12911-020-01332-6>
29. 2. Brown, E. (2020). A healthy mistrust: Curbing biometric data misuse in the workplace. *Stanford Technology Law Review*, 23(1), 252-305.
30. McBride S. Tietze M. *Nursing informatics for the advanced practice nurse: patient safety, quality, outcomes, and interprofessionalism*. Springer Publishing Company; 2022.

## الاعتبارات الأخلاقية في استخدام السجلات الطبية للمرضى في البحث العلمي

### الملخص

### الخلفية:

يسهم تبادل البيانات في تحقيق تقدم كبير في المجال الطبي ويعزز نمو البحث القائم على البيانات بشكل عام. ومع ذلك، فإن هذه الممارسات تثير مخاوف أخلاقية تتعلق بحقوق خصوصية المرضى، وحقهم في ملكية أنفسهم، فضلاً عن الإبلاغ وملكية البيانات.

### الهدف:

يعتمد الإشراف على البيانات، سواء كان من الأفضل مشاركتها أو التعاون بشأنها، على تحقيق التوازن بين الفوائد المتوقعة من البحث وحقوق المرضى.

### المنهجية:

تمت مراجعة الأدبيات الحالية والمدونات الأخلاقية الرئيسية لتحديد العقبات الرئيسية التي تواجه مشاركة البيانات والتعاون.

### النتائج:

كشفت الدراسة عن تهديدات واضحة تتعلق بالمخاطر التي قد تواجه خصوصية المرضى وسلامة بياناتهم، خاصة فيما يتعلق بالبيانات المجهولة المصدر. كما سلطت الضوء على قضايا تتعلق بإجراءات الموافقة، والنزاعات المتعلقة بملكية البيانات، خاصة عند تعاون مؤسسات متعددة، وأوجه القصور الإجرائية المتعلقة بضمان الامتثال للأخلاقيات والقوانين.

### الاستنتاج:

تتطلب القضايا الأخلاقية الناشئة عن مشاركة البيانات والتعاون إجراءات أقوى للحوكمة الوقائية، بالإضافة إلى سياسات مفتوحة وعادلة لضمان حماية المرضى مع تعزيز البحث العلمي.

### الكلمات المفتاحية:

مشاركة البيانات، التواصل، هوية المريض، الموافقة، سيادة البيانات، الأخلاقيات الطبية، الامتثال البحثي.