



Safeguarding Patient Rights: The Role of Informed Consent and Data Protection in Modern Healthcare

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Recommended Citation

Parul Garg and Pankhuri Joshi, *Safeguarding Patient Rights: The Role of Informed Consent and Data Protection in Modern Healthcare*, 5 IJHRLR 714-724 (2026).

Available at www.ijhrlr.in/current-issues/.

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ABSTRACT

Patient rights have become an important issue in the current era of medicine due to the rapid evolution of technology and adoption of digital health care records. The present research will focus on the importance of informed consent and data protection as some of the important ways through which patients' rights can be protected. Informed consent and data protection are important means through which patients' autonomy and privacy rights are respected. The main research problem that will be considered in the current research paper is the problem associated with the successful implementation of patient rights in digital health care. The objectives of the present study include analyzing the meaning of patient rights, assessing the legal and ethical significance of the concept of informed consent, discussing the importance of protecting health care data, and establishing the relationship between these two important concepts. The approach used in this study involves both doctrinal and analytical methodologies based on the use of secondary materials like legislation, case laws, international guidelines, books, and academic articles. Pertinent laws, including data protection laws, have been analyzed to give a clear insight into the topic under consideration. This study reveals that both informed consent and data protection are complementary concepts, which are important in enhancing the level of transparency, accountability, and integrity of healthcare services.

KEYWORDS

Informed Consent, Data Protection, Patient Rights, Healthcare Ethics, Digital Health Privacy

INTRODUCTION

The protection of patient rights has become a fundamental concern in modern healthcare systems, particularly in an age where medical technologies and digital health records are rapidly expanding. Patients today are not only recipients of medical treatment but also active participants in decision affecting their health and personal information. Two important mechanisms that safeguard these rights are informed consent and data protection. These principles remain ethical, transparent, and respectful of individual autonomy.

Informed consent refers to the process through which patients receive adequate information about a medical procedure, including its risks, benefits and alternative, before agreeing to treatment. It promotes patient autonomy by allowing individuals to make voluntary and well informed decisions regarding their healthcare. Without proper consent, medical intervention may violate both ethical and legal obligations.

While on the other hand, the increasing adoption of electronic medical record, telemedicine services and other digital tools has generated major worries over the privacy and security of patient information. In hospitals, there is a lot of sensitive information that needs protection; hence it is important that the necessary data protection mechanisms be put in place.

Thus, the concepts of consent and data privacy operate in synergy with one another within the realm of healthcare. Both these principles serve to establish an atmosphere that promotes autonomy on the part of patients with respect to their own healthcare choices and personal information. The objective of this research is to investigate the significance of these two aspects within healthcare.

CONCEPT OF PATIENTS RIGHTS IN HEALTHCARE

The term patient rights describe the legal and moral rights that safeguard people who receive medical treatment. The rights of patients are grounded on basic principles of human dignity, personal autonomy human equality, and reverence for human life¹. According to international human rights treaties, the right to health is considered an indispensable component of human dignity.²

Patient rights guarantee that opportunity to acquire information concerning their illness and make decisions about their treatments.

Ethical principles such as autonomy, beneficence, non-maleficence, and justice guide the protection of patient rights in healthcare practice³. When healthcare providers respect these principles, patient trust and cooperation significantly improve.⁴

INFORMED CONSENT IN MODERN HEALTHCARE

Informed consent is considered to be one of the essential principles of

¹ World Health Organization, Patients' Rights and Access to Health Information (2018).

² World Medical Association, Declaration of Lisbon on the Rights of the Patient (2015).

³ Eleanor D. Kinney, The International Human Right to Health, 34 Ind. L. Rev. 1457 (2001)

⁴ Tom L. Beauchamp & James F. Childress, Principles of Biomedical Ethics 123 (8th ed. 2019)

ethical practice in medicine. This means that a treatment voluntarily after getting enough information on its nature, risk, advantages and alternatives⁵

Informed consent became a legally recognized term due to judicial decisions like *Canterbury v. Spence* that stated that doctors are required to warn their patients of significant risk that may arise from medical interventions⁶

Similarly, the Indian Supreme Court recognized the significance of informed consent in the case *Samira Kohli v. Dr. Prabha Manchanda*. In this case, it was ruled that carrying out treatment without informed consent is a breach of the law.⁷ According to medical scientists, informed consent is a process rather than a legal act.

Elements of Informed Consent

To have effective consent, some fundamental aspects need to be fulfilled. These principles ensure that the agreement made by the patient was done out of full awareness of the situation, voluntary, and out of their own will.

First, there should be sufficient information disclosure. Doctors need to communicate the kind of treatment the patient needs, the associated risks and benefits, as well as other options for them⁸. They should also inform patients about the consequences of withholding their consent.

The second requirement to fulfill is the comprehension of the information disclosed. Doctors need to communicate in terms that patients can understand.⁹ In cases where complicated terms or explanations are used, patients cannot make an informed decision.

Importance of Informed Consent

Informed consent is vital to protect the right to autonomy of patient and ensuring patient ensuring proper ethical medical practice. The main reason why does so is the fact that it enables the patients to have control over their bodies¹⁰.

Moreover, informed consent is necessary in establishing a good

⁵ Jonathan Herring, *Medical Law and Ethics* 110 (7th ed. 2023).

⁶ *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).

⁷ *Samira Kohli v. Dr. Prabha Manchanda*, (2008) 2 S.C.C. 1 (India)

⁸ Margaret Brazier & Emma Cave, *Medicine, Patients and the Law* 132-148 (7th ed. 2020).

⁹ Michelle Oberman, *Informed Consent and the Ethics of Patient Autonomy*, 25 J. Legal Med. 451 (2004).

¹⁰ Jay Katz, *The Silent World of Doctor and Patient* 1-29 (1984).

connection between the health care practitioner and the patient. When doctors inform patients about what will happen, they create mutual understanding and transparency.¹¹

Finally the informed consent lower the risk of medical disputes or lawsuits against practitioner or hospitals since patients understand the potential consequences of procedure¹². Overall, informed consent not only helps ensure proper ethics of the medical procedures, but it is also needed from the perspective of law.

Data Protection in Healthcare

The quick development in our technology in our worlds means that healthcare organizations are increasingly relying on electronic solutions in order to document and manage patient information. In others words the introduction of electronic health records, telemedicine software, and other others digital health solutions has helped make medical treatment more efficient and convenient¹³

Yet, the above advancements are bringing about issues of data privacy and security. Indeed, medical records typically include extremely sensitive data, namely personally identifiable information and various other information and various other details that could be misused in case this information becomes available to wrong parties, which could lead to discrimination or even loss of money.¹⁴ Data protection is the set of measures that protect personal data from illegal processing or sharing. Solid data protection practices can guarantee that any sensitive patient data is collected and processed in accordance with its purpose.¹⁵

There are a number of international as well as domestic legal frameworks that provide guidelines regarding data protection in the field of healthcare. For instance, the General Data Protection Regulation (GDPR) is a regulation within the European Union which provides stringent guidelines concerning the processing of personal data.¹⁶ Likewise, the Health Insurance Portability and Accountability Act (HIPAA) of the United States provides legal protections for sensitive information.¹⁷

The Digital Personal Data Protection Act, 2023 of India is another

¹¹ Raanan Gillon, Medical Ethics: Four Principles Plus Attention to Scope, 309 Brit. Med. J. 184 (1994)

¹² Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972)

¹³ Nicolas P. Terry & Leslie P. Francis, Health Privacy 55–79 (2013)

¹⁴ Daniel J. Solove, Medical Privacy and Data Protection in the Digital Era, 75 Law & Contemp. Probs. 1 (2012).

¹⁵ Lawrence O. Gostin, Global Health Law 312–330 (2014).

¹⁶ Regulation (EU) 2016/679, General Data Protection Regulation (GDPR), art. 5

¹⁷ Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §1320d (2018)

example of legislative frameworks that are being adopted by countries in order to provide adequate protection to personal data, including information pertaining to health¹⁸

Relationship Between Informed Consent and Data Protection

Data protection and informed consent are related concepts which ensure patient rights in contemporary healthcare. On the one hand, informed consent is a right to make independent choices regarding medical treatment. Data protection is aimed at ensuring that patients' personal information is stored and secured properly.¹⁹ Consent is necessary not only for the medical intervention itself, but also for the storage and processing of patient's personal information in many cases. It means that a person who agrees to be included in some medical study give consent for the treatment and processing of his/ her personal information.²⁰

For example, The Declaration of Helsinki recommends providing participants in a study with confidential information and receiving their consent.²¹

ROLE OF HEALTHCARE INSTITUTIONS AND PROFESSIONALS

Medical facilities and doctors are crucial for providing the implementation of informed consent procedures and proper data protection. The obligation of protecting rights of individuals cannot only be guaranteed by laws, but also through the professional work of practitioners.²²

Practically, doctors are supposed to provide all necessary and understandable information about patient's state of health, potential diagnoses and treatment plans. It is required for specialists to translate complicated terms into language of ordinary patients.²³ Moreover, it is critical for hospitals to introduce necessary rules for protecting personal data of clients. All facilities should have restricted access to such databases. Hospitals also need cybersecurity to protect confidential patient information from attacks and leaks²⁴

Finally, training programs are necessary. They help healthcare workers

¹⁸ Digital Personal Data Protection Act, No. 22 of 2023 (India).

¹⁹ Paul M. Schwartz, Privacy and the Economics of Personal Health Information, 76 Tex. L. Rev. 1817 (1998).

²⁰ Council for Int'l Orgs. of Med. Sciences, International Ethical Guidelines for Health-Related Research Involving Humans (2016).

²¹ World Medical Association, Declaration of Helsinki (2013).

²² Mark A. Hall et al., Health Care Law and Ethics 215-230 (9th ed. 2022).

²³ Michelle Oberman, Informed Consent and the Ethics of Patient Autonomy, 25 J. Legal Med. 451 (2004).

²⁴ Nicolas P. Terry & Leslie P. Francis, Health Privacy 55-79 (2013).

better understand their obligations in accordance with law and ethical principles.²⁵ In general, cooperation of both groups is vital for creating a trustworthy healthcare environment.

LEGAL AND ETHICAL FRAMEWORKS GOVERNING PATIENT RIGHTS

Protection of the rights of the patients involves the use of various provisions of law and ethical norms not only in the national context but also internationally. The aforementioned rules define certain requirements that the healthcare practitioners should comply with when providing medical services. For instance, internationally recognized mechanisms such as the Universal Declaration of Human Rights include the right to health among the basic human rights.²⁶ Moreover, ethical regulations such as the Declaration of Helsinki highlight the significance of obtaining informed consent and confidentiality from the research participants. At the national level, judicial decisions can be regarded as one of the most important sources for ensuring that patients' rights are recognized. For example, judicial precedents such as *Samira Kohli v. Dr. Prabha Manchanda* underline the significance of informed consent prior to any medical intervention.²⁷

In addition, it is necessary to take into account legal norms regulating personal data protection, such as the Digital Personal Data Protection Act, 2023.²⁸

TECHNOLOGICAL DEVELOPMENTS AND PATIENT RIGHTS

The introduction of technological innovations has revolutionized the manner in which healthcare services are provided. Innovations such as the electronic health record systems, telemedicine platform, and artificial intelligence software have made healthcare more efficient and effective.²⁹ Nevertheless, these innovations introduce other forms of challenges relating to patient's right. The rise in the utilization of digital technologies has expanded the extent of patient data generation. Therefore, there is a need for greater vigilance regarding the issues of patient confidentiality and consent. This is because patients might not always understand how the information collected is going to be used, stored, or distributed.

The use of blockchain technology has great potential for improving the

²⁵ Lawrence O. Gostin & Lindsay F. Wiley, *Public Health Law* 392–410 (3d ed. 2016).

²⁶ Jonathan Montgomery, *Health Care Law* 211–235 (2d ed. 2003).

²⁷ World Medical Association, *Declaration of Helsinki* (2013).

²⁸ *Samira Kohli v. Dr. Prabha Manchanda*, (2008) 2 S.C.C. 1 (India).

²⁹ Digital Personal Data Protection Act, No. 22 of 2023 (India).

confidentially of patient information. Through the implementation of blockchain, secure and tamper-proof records of patient information could be created.³⁰ Additionally, artificial intelligence could be employed to enhance cybersecurity in the healthcare industry.³¹

Nonetheless, it is important that patients' rights are not violated through technological innovations.

FUTURE CHALLENGES AND DEVELOPMENT

The development of health care in the future would continue to face challenge related to technology advancement, globalization, and changing patient needs. The key concerns in term of patient rights include the need for patient consent and data protection; however, there are some issues that need to be addressed.³² First of all, it can be noted that new complex treatment techniques and technologies make it harder for patients to understand the provided information. To prevent such problems, patient-centered communication technologies can be used. Such techniques can involve the use of visualization tools and digital technologies.³³

In addition, the threat of cyber attacks is becoming higher with every year that passes. Thus, the development of adequate cybersecurity measures and data protection technologies is needed to secure the patient's information.³⁴ Moreover, the policymakers should focus on working out new legal regulations related to issues such as AI, big data, and other innovative concepts that have been actively implemented into health care recently.³⁵

Finally, promoting patient's awareness and educating people would be extremely helpful in improving the protection of their personal information and other rights.

EMERGING TRENDS IN PATIENT -CENTERED HEALTHCARE

In recent years, the emphasis on creating patient- centered healthcare

³⁰ Nicolas P. Terry, Protecting Patient Privacy in the Digital Age, 48 J. L. Med. & Ethics 24 (2020)

³¹ Daniel J. Solove, Medical Privacy and Data Protection, 75 Law & Contemp. Probs. 1 (2012)

³² Paul M. Schwartz, Privacy and the Economics of Personal Health Information, 76 Tex. L. Rev. 1817 (1998)

³³ Shubha Ghosh, Cybersecurity and Health Data Protection, 39 J. Health Pol. Pol'y & L. 1169 (2014).

³⁴ Mark A. Rothstein, Is Deidentification Sufficient to Protect Health Privacy?, 10 Am. J. Bioethics 3 (2010).

³⁵ World Health Organization, Ethics and Governance of Artificial Intelligence for Health (2021).

systems, where patient preferences, rights, and needs healthcare decisions, has increased greatly.³⁶ In such environment, there is an opportunity for patients to be actively involved in all stage of making decisions related to their health.³⁷ Furthermore, technological progress in the field of digital health, which includes various types of software applications designed for mobile phone as well as different kinds of wearable medical equipment, makes it possible for patients to continuously monitor their health status and receive medical information.³⁸ Yet, it is essential to establish proper measures to protect patient's data and ensure its ethical usage.

The implementation of patient centeredness together with informed consent can greatly improve the overall quality of healthcare services provided to patients.

COMPARATIVE ANALYSIS OF GLOBAL PRACTICES

A number of nations have opted for different strategies towards ensuring patient rights via informed consent and data protection. In a comparison of such strategies, one can appreciate their strengths and weaknesses. The Eu offers one of the best laws regarding data protection in the form of General Data Protection Regulation (GDPR). The GDPR ensures the right of an individual to know how his/her personal data will be used.³⁹ Patients can access, amend, and delete their personal data.

The HIPAA law in United States ensures that medical data is protected but it quit specific compared to the GDPR.⁴⁰

India's Digital Protection Act, 2023 ensures that the government adopts policies towards protecting personal data in the nation. Implementation of this law remains difficult in some regions of India, especially in rural areas.⁴¹

ETHICAL CONSIDERATIONS IN THE DIGITAL AGE

The fast development of technology has created complicated ethical problems in the healthcare industry. As digitalization makes procedures faster and more convenient, it also brings ethical problems associated

³⁶ Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001).

³⁷ Robert M. Veatch, *Patient, Heal Thyself* 72–85 (2009).

³⁸ World Health Organization, *Global Strategy on Digital Health 2020–2025* (2021).

³⁹ Regulation (EU) 2016/679, *General Data Protection Regulation (GDPR)*, arts. 12–17.

⁴⁰ *Health Insurance Portability and Accountability Act of 1996*, 42 U.S.C. § 1320d (2018).

⁴¹ *Digital Personal Data Protection Act, No. 22 of 2023* (India).

with the issue of consent, privacy and accountability.⁴²

First of all, one can mention the problem of informed consent within a digital environment. A person may accept some terms on the internet while signing a form that is difficult to understand.⁴³ The concept of informed consent implies full awareness of the terms of cooperation.

Secondly, it should be mentioned that the issue of using artificial intelligence in making decisions is also rather controversial. As far as artificial intelligence contributes to improving diagnostic procedures, its application is not clear for the patient.⁴⁴

Thus, in order to practice ethics in health care, it is essential to make sure that technological developments do not undermine any ethical principles.

ROLE OF GOVERNMENT AND POLICY MAKERS

It is imperative for governments and policymakers to take steps towards ensuring enhanced protection for patient rights. For this, effective Laws, regulations, and policies need to be put in place so that healthcare facilities follow the necessary requirements.⁴⁵

Policymakers need to ensure that their frameworks are capable of addressing all new issues that might arise in terms of digitized health care systems, sharing of data internationally, and use of artificial intelligence.⁴⁶ Regulatory agencies need to ensure strict implementation of data protection laws and penalties for any breach of these rules. Patients themselves can also be informed regarding their rights and responsibilities through public information campaigns.⁴⁷

CONCLUSION

The need to protect the rights of the patient has become one of the most prominent issues in modern times because of technological advancement and the digitization of medical practices. This paper has revealed that informed consent and data protection are two primary ways of ensuring the protection of patients' rights. Informed consent protects the right of

⁴² Lawrence O. Gostin, *Global Health Law* 312–330 (2014).

⁴³ Paul M. Schwartz, *Privacy and the Economics of Personal Health Information*, 76 *Tex. L. Rev.* 1817 (1998).

⁴⁴ World Health Organization, *Ethics and Governance of Artificial Intelligence for Health* (2021).

⁴⁵ Eleanor D. Kinney, *The International Human Right to Health*, 34 *Ind. L. Rev.* 1457 (2001).

⁴⁶ Nicolas P. Terry, *Protecting Patient Privacy in the Digital Age*, 48 *J. L. Med. & Ethics* 24 (2020).

⁴⁷ George J. Annas, *The Rights of Patients* (2004).

the patients by allowing them to make their own decisions regarding their bodies and treatment, while data protection ensures that their medical records remain safe and private. The shift from the conventional healthcare system to a more patient-centered system is an example of how patients are now being recognized for the autonomy and dignity they possess. The law through the cases of *Canterbury v. Spence* and *Samira Kohli v. Dr. Prabha Manchanda* has affirmed the need to obtain proper informed consent before treating a patient. On the other hand, laws like the General Data Protection Regulation and Digital Personal Data Protection Act, 2023 show the world's commitment to protecting patients' sensitive data in the modern era. However, despite these advancements, significant challenges persist. Issues such as lack of patient awareness, communication barriers, technological vulnerabilities, and the growing complexity of medical procedures continue to hinder the effective implementation of these principles. Moreover, the expansion of digital health technologies, artificial intelligence, and cross-border data flows has introduced new ethical dilemmas that require careful regulation and oversight.

To address these challenges, a multi-faceted approach is necessary. Healthcare institutions must prioritize patient education, adopt transparent communication practices, and invest in robust data security systems. Policymakers must ensure the effective enforcement of legal frameworks while continuously updating regulations to address emerging technological risks.

Moreover, safeguarding patient rights is not merely a legal obligation but an ethical imperative that underpins trust in healthcare systems. The effective integration of informed consent and data protection can create a healthcare environment that is transparent, accountable, and respectful of individual autonomy. As healthcare continues to evolve, maintaining a balance between innovation and patient rights will be essential to ensuring equitable and ethical medical care for all.