

## Research Article

# Telemedicine Practice: Current Challenges of Consent and Autonomy, Patient Privacy and Data Security Worldwide

Aqsa Mustafa,<sup>1</sup> Areesha Ahmad,<sup>2</sup> Ali Akram Qureshi,<sup>3</sup> Ansa Naseem,<sup>4</sup> Ali Raza Rana,<sup>5</sup> Marina Akhtar,<sup>6</sup> Alishba Rasool,<sup>7</sup> Umar Sadat<sup>8</sup>

<sup>1-7</sup>Department of Community Medicine, King Edward Medical University/ Mayo Hospital Lahore, Pakistan; <sup>8</sup>Hunterian Professor (2019), Royal College of Surgeons England, University of Cambridge

### Abstract

**Background:** Telemedicine, facilitating medical services remotely, introduces ethical concerns. Safeguarding patient data, ensuring informed consent, addressing access disparities, and managing biases in artificial intelligence-driven diagnoses are critical. Navigating these challenges ethically is essential for harnessing telemedicine benefits while upholding patient trust and welfare.

**Objectives:** To ascertain the primary obstacles affecting global telemedicine practice, including issues concerning patient confidentiality, privacy, autonomy, informed consent, and data security.

**Methods:** Conducted a systematic literature review, for which we searched two databases (Pubmed and Google Scholar) between January 2018 to December 2022. Broad terms such as ethical issues, legal issues, health care providers were used as keyword searches. The authors used a narrative approach according to PRISMA guidelines 2020 (Checklist). The authors did a qualitative synthesis of selected studies according to inclusion criteria. The inclusion criteria required articles that reported ethical and legal concerns associated with the use of telemedicine; the full texts articles were electronically available and published in English. Systematic reviews and papers in other languages are not a part of the study.

**Results:** Results showed that most reported ethical and legal concerns were related to privacy and confidentiality, followed by informed consent, patient autonomy and data security. From the 16 papers reviewed, authors identified or discussed the following ethical concerns faced by healthcare professionals during the use of telemedicine: patient privacy was addressed in 75% (n = 12/16) studies, informed consent 56.25% (n = 9/16), patient autonomy 31.25% (n = 5/16), data security 25% (n = 4/16).

**Conclusion:** In the dynamic landscape of telemedicine, healthcare providers and policy makers play pivotal roles in addressing its ethical and legal concerns. Collaborative efforts are essential to establish clear guidelines, secure patient data, ensure informed consent, and create adaptable regulations, fostering a responsible and effective telemedicine ecosystem.

**Corresponding Author** | Dr. Marina Akhtar | Department of Community Medicine, KEMU, Lahore

**Email:** marinaakhtar88@gmail.com

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### Introduction

The term "telemedicine" is a combination of the Greek word "tele," which means "distance," and "medicine," referring to the practice of medical diagnosis and treatment.

It pertains to delivering healthcare services such as consultations, guidance, education, recovery, and treatment through electronic communication methods. This approach utilizes wireless devices, email, interactive video, smartphones, and other telecommunications technologies. The utilization of telemedicine has grown significantly in recent times. Particularly during the COVID-19 pandemic, there was a substantial surge in the global adoption of telemedicine.<sup>1</sup> A swift embracing of digital healthcare systems was undertaken to reduce limitations imposed by geography and social con-



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straints. Through technology, we can enhance healthcare availability for numerous marginalized groups, including individuals in rural regions, nursing homes, correctional facilities, and less developed regions globally.<sup>2,3</sup> The domain of online health system expands to mobile health applications as well such as remote monitoring apps, clinical and diagnostic apps, clinical reference apps, etc, referred as mHealth.<sup>4</sup> Nevertheless, the emergence of telecare has brought forth novel ethical and legal dilemmas.<sup>5</sup> The major challenges are related to informed consent and autonomy, patient privacy, and data security.<sup>6</sup> It is essential to ensure precise protection of patient information and adhere to the regulations outlined in the Health Insurance Portability and Accountability Act (HIPAA).<sup>2</sup> In telemedicine, informed consent is vital, involving clear communication of virtual healthcare aspects, risks, privacy measures, and alternatives. Providers must obtain explicit consent before remote consultations, respecting patients' autonomy and promoting well-informed decisions in digital healthcare. Data protection in telemedicine is crucial, demanding stringent measures to safeguard patient information during remote medical interactions, upholding privacy and compliance standards.<sup>7</sup> While isolated studies have spotlighted specific facets of these issues, what is lacking is a synthesized and methodical review that comprehensively delves into the multifaceted challenges confronted by practitioners, policymakers, and patients in the domain of telemedicine. By synthesizing existing literature, the study aims to offer a clear understanding of these multifaceted issues, thereby informing strategies and solutions that enhance the ethical, legal, and technical foundations of telemedicine on a worldwide scale.

## Methods

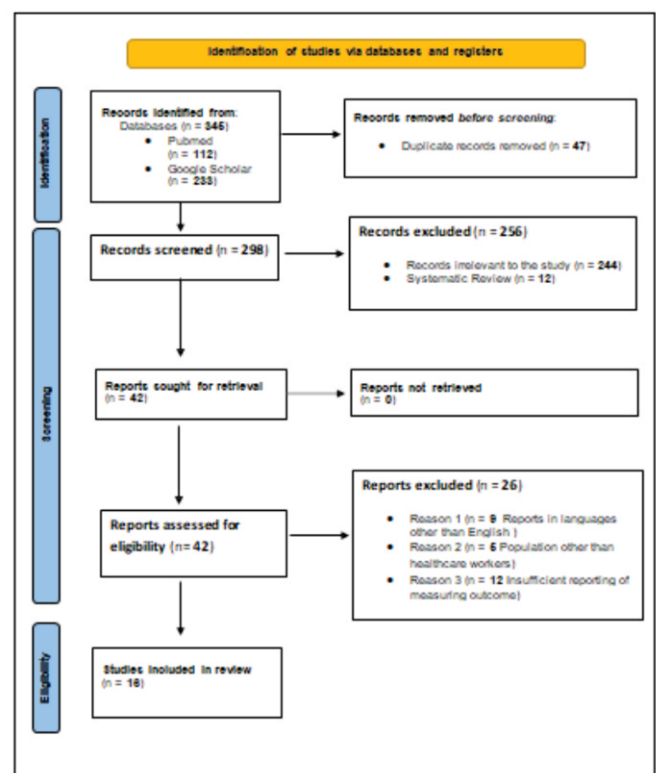
A systematic review was conducted. Systematic reviews serve as valuable tools for staying informed about recent advancements and utilizing them as reference points in medical practice. The examination adhered to the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) guidelines.

The systematic review was carried out by exploring two databases, namely Google Scholar and PubMed. The search was limited to items published between January 2018 and December 2022. Various MeSH and Non-MeSH keywords were used, including telemedicine, ethical issues, legal issues, informed consent, patient autonomy, privacy, and data security. The search procedure used boolean operators like AND and OR.

On the basis of predetermined inclusion criteria, the articles acquired from multiple databases under-went a thorough screening procedure. These requirements included articles that were written in English, were published between January

2018 and December 2022, were easily accessible with free electronic full-texts, and had a common focus in terms of their title, objectives, and content, specifically addressing the ethical and legal issues related to tele-medicine. The chosen publications were in line with the study's scope and objectives.

To assure the caliber and applicability of the chosen literature, the selection procedure for articles included a strict set of exclusion criteria. Articles published before January 2018 were not taken into consideration. To ensure uniformity and make understanding easier, articles written in languages other than English were excluded. Grey literature and systematic reviews were excluded. Additionally, studies that fell short of the study's objectives of thorough analysis and synthesis of pertinent material were excluded since they did not address the ethical and legal issues raised by telemedicine. By ensuring that the chosen articles satisfied the study's requirements for comprehensiveness and relevance, these exclusion criteria helped to streamline the selection process.



**Figure 1:** PRISMA flowchart (PRISMA, Preferred Items for Systematic Reviews and Meta-Analysis)

As illustrated in Fig. 1, the two databases (PubMed and Google scholar) yielded 345 papers. We eliminated 47 duplicates and screened titles and abstracts of remaining papers (n=298). Records were eliminated on basis of irrelevance and excluded study type, reducing the number of articles to 42. Full-texts

of these 42 articles were examined, leading to elimination of further 26 articles due to unavailability of full texts in English, insufficient reporting of outcomes, or study population other than health care professionals. A total of sixteen studies were analyzed for this systematic review.

The items of data that were extracted included the author names, year of study, the country where the study was conducted, type of study, major medical purpose for the use of technology, and all the major challenges of telemedicine that have been discussed in the articles. The data was entered in a spreadsheet and analyzed.

**Results**

Our results showed that most reported ethical and legal concerns were related to privacy and confidentiality, followed by informed consent, patient autonomy and data security. From the 16 papers reviewed, authors identified or discussed the following ethical concerns faced by healthcare professionals during the use of telemedicine. Patient privacy was addressed in 75% (n = 12/16) studies, informed consent 56.25% (n = 9/16), patient autonomy 31.25% (n = 5/16), data security 25% (n = 4/16). Moreover, a number of other challenges were also identified which are summarized in Table 2.

The issue of privacy was the most discussed outcome in our study. In the realm of online medicine, issues regarding pri-

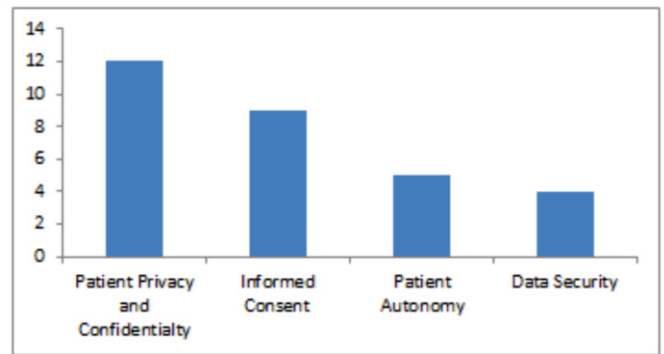
**Table 1: Summary of Outcomes for Studies (n = 16)**

Outcomes	No. of Studies (%)
Patient Privacy and Confidentiality	12 (75%)
Informed Consent	9 (56.25%)
Patient Autonomy	5(31.25%)
Data Security	4 (25%)

**Table 2: Other Ethical and Legal Challenges**

Ethical Challenges
Beneficence
Non-maleficence
Justice
Non-discrimination
Quality of Care
Clinical Governance
Legal Challenges
Malpractice and Professional Liability
Licensure
Encryption of Communication
Cvber security
Legislation and Regulation
Adherence to Cvber Laws

vacancy, confidentiality, security, and safety have arisen. One particular concern involves the utilization of insecure web-sites or communication tools lacking encryption, such as readily hackable commercial software. Additionally, data security vulnerabilities may emerge in the event of technological failures, potentially leading to confidentiality breaches that are beyond the therapist's control.<sup>16,17</sup> In the United States, recommended approaches to telemedicine adhere to HIPAA compliance, and several commercial platforms have been designed to enable healthcare professionals to conduct virtual patient consultations while complying with legal requirements.<sup>22</sup>



**Figure 2: Bar chart showing summary of results**

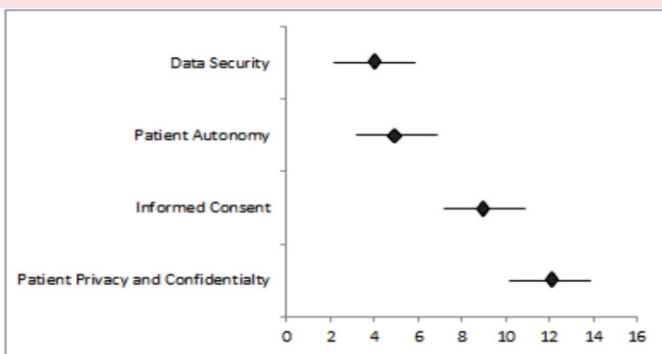
In ethical healthcare, informed consent is a fundamental principle. The informed consent document outlines the data collection subject, treatment objectives, treatment approaches, potential data recipients, the holder's identification details, and data protection methods.<sup>9</sup> Article by Raveesh discusses that in telepsychiatry, consent can be either implied or explicit. If the patient initiates the teleconsultation, it's implied consent. However, if the psychiatrist initiates it, explicit consent is necessary, recorded in the patient's record. Patients should be informed about telepsychiatry's operational aspects, pros and cons, alternatives, and details about the psychiatrist before the service begins.<sup>14</sup> Stoll mentions how telemedicine can pose a challenge to ascertain the patient's legal capacity to provide consent or to evaluate their mental competence for such consent.<sup>16</sup>

Patients possess the entitlement to make informed choices regarding their healthcare, which entails comprehending the functioning of telemedicine. The exercise of patient autonomy in selecting a care modality may be balanced with endeavors to optimize benefits for all parties involved.<sup>11,17</sup>

The provider bears a significant responsibility for ensuring the safety, non-invasiveness (to prevent the patient from feeling surveilled), and user-friendliness of the devices used. Conversely, the physician must exercise extreme caution when sharing the patient's data with others (e.g., seeking a second opinion) and in the storage of this data.<sup>12</sup>

**Table 3:** Summary of Selected Studies (n = 16)

Sr. No.	Author (Year)	Title of Study	Location	Type of Article	Medical Purposes For Use of Technology	Ethical, Legal And Regulatory Challenges
1.	Bailo P, et. al (2022) <sup>8</sup>	Telemedicine Applications in the Era of COVID-19: Telesurgery issues	Italy	Review Article	Telesurgery: surgeries carried out by means of computer or satellite links and robotic instruments	Data protection and legal challenges, technical implication, breach of data protection by hackers and regional variations in legal implications
2.	Gioia G, et. al (2019) <sup>9</sup>	Medical and Legal Aspects of Telemedicine in Ophthalmology	Italy	Review Article	Ophthalmology: Visual images for the diagnosis, therapy, and follow-up of the diseases.	Social challenges such as connectivity, need of deviation from standard of care, equity of access, inevitable constraints on patient-provider relationship, tele-responders, Licensing and reciprocity (need for provider to be registered in remote area of service) Ethical challenges such as autonomy, beneficence, non-maleficence and justice
3.	Ferorelli D, et. al (2020) <sup>10</sup>	Medical Legal Aspects of Telemedicine in Italy: Application Fields, Professional Liability and Focus on Care Services During the COVID-19 Health Emergency	Italy	Review Article	Specialized Telemedicine, Tele-healthcare and Tele-assistance.	Clinical governance, Communication technology infrastructure, Data privacy (storage, record keeping, security and confidentiality), Cost of information and communication, Feedback and choices and Reimbursement
4.	Fields B (2020) <sup>11</sup>	Regulatory, Legal and Ethical Considerations of Telemedicine	USA	Review Article	Sleep Medicine: Consultancy, diagnosis, monitoring	Ethical and Legal Challenges such as Patient Privacy and Data Security and Informed Consent, Compliance with Regulatory Requirements, Professional Standards, Accessibility and Equity, Provider-Patient Relationship and Communication, Patient Satisfaction and Experience, Risk Management and Liability
5.	Nittari G, et. al (2020) <sup>12</sup>	Telemedicine Practice: Review of the Current Ethical and Legal Challenges	Italy	Review Article	Adequate clinical care in remote areas, online healthcare services	Ethical Challenges: Confidentiality, Privacy, Informed consent, Professional integrity, and Patient autonomy Legal Challenges: licensure, liability, malpractice, prescribing regulations, accessibility and equity of telemedicine services, potential risks, adverse events, and errors associated with telemedicine encounters



**Figure 3:** Forest Plot of reported challenges of

*Telemedicine*

**Discussion**

One of the most highlighted challenges of Telemedicine in our studies was the maintenance of patient privacy and ensuring confidentiality of patient information. Patient confidentiality was highlighted in the Hippocratic Oath dating back to 3rd century: “Whatever, in the course of my practice, I may see or hear (even when not invited), whatever I may happen to obtain knowledge of, if it be not proper to repeat it, I will keep sacred and secret within my own breast.” The

6.	Liem A, et. al (2020) <sup>13</sup>	Ethical standards for Telemental health must be maintained during the COVID-19 Pandemic	Asia	Letter to editor	Mental healthcare services	Ethical Challenges: Confidentiality, Consent, Compliance, Contingency, Competency
7.	Raveesh B, et. al (2020) <sup>14</sup>	Ethical and Legal Aspects of Telepsychiatry	India	Review Article	Telepsychiatry: Consultation, monitoring, counseling	Ethical Challenges: Consent, Patient Privacy Legal Challenges: Identification, Malpractice and Professional Liability, Professional Misconduct Regulatory Challenges and Responsibility of Technology Platforms
8.	Arimany-Manso- J, et. al (2020) <sup>15</sup>	Medico legal Aspects of Teledermatology	Spain	Review Article	Teledermatology: Consultation, diagnoses, treatment and education.	Ethical Challenges: Patient Autonomy, Confidentiality, Informed Consent, Legal Challenge: Professional Liability, Legislation, Responsibility of Healthcare Administration and System, Clinical Security
9.	Stoll J, et. al (2020) <sup>16</sup>	Ethical Issues in Online Psychotherapy-A Narrative Review	Switzerland	Narrative Article	Psychotherapy: Professional mental health counseling	Ethical Challenges: Patient Privacy, Confidentiality, Autonomy Issues, Legal Challenges: Data Security, Informed Consent, Identity and Verification Issues, Increased Liability and Litigation, Absent or Incomplete Guidelines, Practicing Across Borders Technological Competence, , Technical Issues, Therapeutic Relationship Issues, Financial Gain
10.	Shahbaz R, et. al (2021) <sup>17</sup>	Law and Order of Modern Ophthalmology: Teleophthalmology, Smartphones Legal and Ethics	Multiple	Editorial	Ophthalmology: Visual images for the diagnosis, therapy, and follow-up of the diseases	Legal Issues: Data protection, freedom of choice of healthcare provider, costs of cross border healthcare, insurance logistics, Patient rights (informed consent, continuity of care, non -discrimination), licensing/ registration of health professionals, liability] Ethical issues: Justice, Non-maleficence, Beneficence, Autonomy, Confidentiality and privacy, informed consent, disclosure/non-disclosure of medical errors
11.	Chim H, et. Al (2021) <sup>18</sup>	Telepsychiatry in the Age of COVID: Some Ethical Considerations	USA	Review Article	Telepsychiatry: Consultation, monitoring, counseling	Regulatory restrictions, Patient privacy, Quality of care, i.e. proper licensure of eligible clinicians and prevention of fraud, Ease of access
12.	Jalali M, et. al (2021) <sup>19</sup>	Telemedicine, Privacy, and Information Security in the Age of COVID-19	USA	Correspondence	Adequate clinical care in remote areas, online healthcare services	Security concerns: Lack of awareness of cybersecurity among health professionals, cyberattacks, intruders joining video conferences, inadequate encryption of communications
13.	Aneja J, et. al (2021) <sup>20</sup>	Telemedicine and Ethics: Opportunities in India	India	Review Article	Online Healthcare Services	Ethical Challenges: Informed consent, privacy and confidentiality, patient understanding Legal Challenges: scope of practice, medico legal reforms, compliance with existing laws
14.	Intan Sabrina M, et. al (2021) <sup>21</sup>	Telemedicine Guidelines in South East Asia		Scoping Review	Online patient care, diagnosis, management and education	Ethical Challenges: adherence to code of conduct, confidentiality and privacy, clinical governance Legal Challenges: legislation and regulation, jurisdiction of medical councils, compliance with laws, adherence to cyber laws

15.	Tedeschi C (2021) <sup>22</sup>	Ethical, Legal, and Social Challenges in the Development and Implementation of Disaster Telemedicine	USA	Narrative review Review Article	Disaster Telemedicine: emergency services and public assistance during or immediately after a disaster	Ethical Challenges: Autonomy, Beneficence, Non-maleficence, justice Legal Challenges: licensing, privacy and confidentiality
16.	Kaplan B (2022) <sup>23</sup>	Ethics, Guidelines, Standards, and Policy: Telemedicine, COVID-19, and Broadening the Ethical Scope	USA		Online provision of health facilities	Ethical Challenges: Quality of care, Consent, Access, Privacy Legal Challenges: Licensure, liability, Regulatory Compliance, Device Regulation, Policy Guidelines

digital nature of telemedicine introduces new avenues for patient data to be compromised. Privacy breaches and unauthorized access to patient information can lead to identity theft, medical fraud, and other forms of cybercrime. As telemedicine platforms collect a vast amount of sensitive data, ensuring robust privacy protection mechanisms becomes imperative. Moreover, patients may be apprehensive about sharing personal health information through electronic channels, potentially leading to reluctance in using telemedicine services. The privacy of patients is the subject of a research by Mishkin and Zabinski. The authors discuss the challenges of protecting private medical data when using telemedicine, examining the potential repercussions and suggesting solutions to ensure privacy.<sup>24</sup> Laws pertaining to privacy must be applied in a consistent and coordinated manner.

Receiving informed consent from patients is one of the main issues with telemedicine. Traditional medical venues guarantee in-person conversations and signatures, while telemedicine may not have these protections. Patients could not completely comprehend the drawbacks and hazards of online consultations, which could result in misconceptions or decreased decision-making autonomy. Furthermore, consent practices might differ significantly between nations, confusing both patients and healthcare professionals. The importance of informed consent in regard to telemedicine is also discussed in an article by Ingrid Dreezen, which also addresses the difficulties and moral dilemmas associated with getting patient agreement during virtual medical consultations.<sup>25</sup>

Healthcare data has becoming a popular target for cyberattacks as telemedicine becomes more widespread. To access patient records without authorization, cybercriminals may use holes in telemedicine systems, raising the possibility of medical malpractice and legal difficulties. Data breaches can severely impact patients' trust in telemedicine and disrupt healthcare services, demanding the implementation of stringent security measures. Similarly, an article published in 2015 emphasizes on data security. The authors explore the challenges posed by digital accessibility and potential risks to patient data, while also offering insights into strategies for enhancing

data security in telemedicine practices.<sup>26</sup>

Upholding beneficence, ensuring patient welfare, and non-maleficence, preventing harm, is paramount. Justice and non-discrimination must guide access, while maintaining quality of care through clinical governance. Malpractice liability and licensure require adaptation to this digital realm. Robust encryption and cybersecurity safeguard patient data, aligning with legislation, regulations, and cyber laws to ensure ethical and legal integrity.

Telemedicine is pivotal for the future. It enhances healthcare access, empowers patients, optimizes resources, and revolutionizes delivery for efficient and equitable services.<sup>27,28</sup> It emerged as a vital lifeline during the pandemic. It enabled remote medical consultations, curbing virus spread and offering essential care. This modality underscored its adaptability, proving essential in times of crisis and reinforcing its significance in modern healthcare.<sup>29</sup> It alleviates the burden of chronic diseases by providing continuous monitoring, remote consultations, and timely interventions.<sup>30</sup>

Our research on global telemedicine challenges offers strengths such as a comprehensive grasp of issues through systematic review, evidence-backed insights and a worldwide outlook encompassing regulatory, cultural, and technological variations. Limitations of our study include potential geographical bias, language restrictions, and methodological disparities, lack of longitudinal data, ethical considerations, and regulatory variability. These factors can impact the comprehensiveness, generalizability, and relevance of findings.

## Conclusion

In conclusion, this systematic review has illuminated the intricate challenges confronting telemedicine, across the globe. The synthesis of diverse perspectives underscores the urgent need for cohesive strategies to address these issues. By fostering comprehensive solutions, we can cultivate a safer, more patient-centric telemedicine landscape that upholds ethical standards while harnessing the benefits of technological advancement.

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**Authors' Contribution**

All the authors contributed equally in accordance with ICMJE guidelines.

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