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THE ROLE OF INFORMED CONSENT AS AN INSTRUMENT OF LEGAL PROTECTION IN DENTAL SERVICES: A COMPARATIVE LITERATURE STUDY IN INDONESIA

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ABSTRACT
Informed consent is a fundamental ethical and legal requirement in healthcare that safeguards patient autonomy while protecting healthcare professionals from legal disputes. In dental practice, informed consent extends beyond obtaining a patient's signature, encompassing a comprehensive communication process that enables patients to make informed decisions regarding diagnosis, treatment alternatives, benefits, risks, and possible complications. Despite recent regulatory reforms through Law Number 17 of 2023 concerning Health and Government Regulation Number 28 of 2024, challenges remain in the consistent implementation of informed consent within Indonesian dental services. This study aimed to comprehensively review the role of informed consent as an instrument of legal protection for dentists in Indonesia by comparing existing scientific evidence with the current national legal framework governing dental practice. A systematic literature review employing a comparative legal approach was conducted following the PRISMA 2020 guidelines. Literature was retrieved from PubMed, Scopus, ScienceDirect, and Google Scholar using Medical Subject Headings (MeSH) and free-text keywords related to informed consent, dentistry, legal protection, and health law. Eligible studies addressing legal, ethical, and clinical aspects of informed consent in dental services were selected according to predefined inclusion and exclusion criteria. Relevant Indonesian legislation, including Law Number 17 of 2023 and Government Regulation Number 28 of 2024, was also analyzed. Extracted data were synthesized using qualitative thematic analysis. The review demonstrates that informed consent functions as both an ethical obligation and a legal safeguard by promoting patient autonomy, supporting shared decision-making, and providing documentary evidence of professional compliance. Medical records and informed consent collectively strengthen legal protection for dentists by documenting adherence to professional standards and reducing medico-legal risks. Nevertheless, implementation in Indonesian primary healthcare facilities remains constrained by high patient workloads, limited human resources, inconsistent documentation practices, inadequate digital infrastructure, and insufficient understanding of medico-legal responsibilities among healthcare professionals. Effective implementation of informed consent requires integration of comprehensive documentation, standardized operating procedures, continuous legal and ethical education, and strengthened electronic medical record systems. Harmonizing clinical practice with Indonesia's evolving legal framework will improve patient safety, reinforce professional accountability, and enhance legal protection for dentists delivering dental healthcare services.

Keywords: dentistry; dental services; health law; informed consent; legal protection; medical records

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INTRODUCTION

Dental and oral health services are an integral part of the healthcare system and carry both medical and legal risks that cannot be ignored. In practice, the relationship between dentist and patient is based on the concept of a therapeutic contract, which is inspanningsverbintenis , namely the doctor's obligation to provide the best possible care, not to guarantee the final result. This situation opens up the potential for legal conflicts when the results of care do not meet the patient's expectations . (Guwandi, 2014; Soekanto, 2014). In this context, informed consent is a crucial element, serving as a manifestation of the principle of patient autonomy and a legal protection instrument for medical personnel. Normatively, informed consent is not merely an administrative formality, but rather a form of consent based on complete, clear, and understandable information provided by the patient before a medical procedure is performed (Hanfiah & Amir, 2012; Guwandi, 2004). However, various studies show that the implementation of informed consent in the field still faces various obstacles. One study found that the completeness rate of informed consent in primary

healthcare facilities was only 76.7% , indicating a persistent gap between regulations and practice. Time constraints, medical personnel workloads, and low legal awareness are the main causes of this discrepancy (Saksono et al., 2022; Notoatmodjo, 2018).

On the other hand, the literature also shows that the failure to properly implement informed consent can have serious legal consequences, both in the civil and criminal realms. Cases of practice without informed consent have the potential to be categorized as malpractice, even though the medical actions performed are technically correct. This emphasizes that administrative and documentation aspects have a strategic position in the legal evidence system. (Kuswandi, 2004; Daeng et al., 2023) Interestingly, there are differences in the characteristics of the implementation of informed consent between services at Community Health Centers and independent dental practices. In Community Health Centers, limited facilities and a high number of patients often become obstacles in meeting informed consent standards. Meanwhile, in independent practices, legal risks are more related to individual negligence in carrying out professional obligations (Kuswandi, 2019; Notoatmodjo).

Although numerous studies have partially addressed informed consent, a research gap remains, characterized by a lack of comparative analysis that systematically compares the various approaches, methods, and findings from different studies. Therefore, this study aims to provide a comprehensive review of the implementation of informed consent in dental practice and to examine its implications for the legal protection of dentists within the Indonesian healthcare system.

METHOD

Study Design

This study employed a systematic literature review using a normative legal research approach to examine the legal framework and implementation of informed consent in dental services. The review aimed to identify, compare, and synthesize evidence regarding informed consent as a legal protection mechanism for both patients and dentists. The review process was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines to ensure methodological transparency and reproducibility.

Search Strategy and Data Sources

A comprehensive literature search was performed in four electronic databases: PubMed, Scopus, ScienceDirect, and Google Scholar. In addition, relevant Indonesian legal documents were retrieved from official government regulatory databases to identify current legislation governing informed consent in healthcare practice. The search was conducted using a combination of Medical Subject Headings (MeSH) and free-text keywords. Boolean operators (AND, OR) were applied to maximize the sensitivity and specificity of the search. The primary MeSH terms included: ("Informed Consent"[MeSH]) AND ("Dental Care"[MeSH] OR Dentistry[MeSH]) AND ("Health Law" OR "Patients' Rights" OR "Legal Protection"). The search was limited to studies published in English or Indonesian between 2010 and 2024.

Eligibility Criteria

Studies were included if they met the following criteria: Discussed informed consent in dental or healthcare services, Examined legal, ethical, regulatory, or professional aspects of informed consent, Were published in peer-reviewed journals, Were available in full text, Were written in English or Indonesian. Studies were excluded if they: Did not address informed consent directly, Were conference abstracts, editorials, letters, commentaries, or news articles, Had insufficient methodological information, Were duplicate publications.

Study Selection

All records identified through database searching were imported into a reference management system. Duplicate articles were removed prior to screening and 5 articles were obtained from 457 article that met the criteria for further analysis. The study selection process consisted of three stages: (1) Identification – records retrieved from the databases were compiled and duplicates removed, (2) Screening – titles and abstracts were evaluated according to the eligibility criteria and (3) Eligibility Assessment – full-text articles were assessed for relevance and methodological suitability. Disagreements during screening and eligibility assessment were resolved through discussion until consensus was reached. The final selection process was documented using a PRISMA 2020 flow diagram.

Data Charting

Data extraction was conducted using a standardized charting form developed by the researchers. The following information was extracted from each included study: Author(s), Year of publication, Country of study, Study design, Research objective, Legal framework examined, Key findings, Legal Implications.

Additionally, Indonesian legal documents, including Law Number 17 of 2023 concerning Health and Government Regulation Number 28 of 2024, were reviewed and charted to identify regulatory provisions related to informed consent and legal accountability in dental practice.

Data Analysis

The extracted data were analyzed using qualitative thematic analysis. Relevant findings were coded and grouped into recurring themes related to: Legal requirements of informed consent, Patients' rights and autonomy, Dentists' professional responsibilities and Legal protection mechanisms for healthcare providers and Regulatory challenges in implementing informed consent. Themes identified across studies were compared and synthesized to determine common patterns, similarities, and differences. The findings were subsequently interpreted in light of the current Indonesian legal framework, particularly Law Number 17 of 2023 concerning Health and Government Regulation Number 28 of 2024, to evaluate the extent to which existing regulations support legal protection for patients and dentists in dental services.

RESULT

Table 1.
Analysis Article

No	Author, Year	Study Design	Location	Example / Data Source	Study Focus	Key Findings	Legal Implications
1	Kuswandi, 2019	Normative Jurisprudence (descriptive)	Community Health Center	Official secondary documents	Legal protection for dentists in providing services to the community	Dentists are legally protected when practicing in accordance with professional standards and SOPs even though facilities are limited.	Compliance with SOPs is the main legal protection for dentists.
2	Oktarina, 2010	Policy Analysis	Indonesia (national policy context)	Regulatory Framework & Policy Documents	Informed Consent Policy on Dental Care	Highlighting the need for special regulations for high-risk procedures (e.g. tooth extraction).	Lack of specific regulations increases the vulnerability of medical law

3	Saksono et al., 2022	Descriptive Qualitative (observation & interview)	Kebumen 1 Community Health Center	Medical Records & Healthcare Personnel	Application of Informed Consent in dental medical procedures	76.7% completeness rate; Barriers include high patient load and limited time	Incomplete documentation weakens legal defense in malpractice claims
4	Basuki et al., 2024	Empirical Justice (case-based analysis)	Independent Dental Practice	Case study	Legal consequences of performing a procedure without informed consent	The absence of fully informed consent leaves dentists vulnerable to civil and criminal liability.	Informed consent is essential to avoid lawsuits for malpractice.
5	Daeng., 2023	Normative Jurisprudence (Library Research)	Indonesia	Legal literature & regulations	Legal basis for the protection of doctors and dentists	Informed consent and medical records are the main legal evidence in dispute resolution.	Proper documentation is essential for legal release.

A total of five scientific articles meeting the inclusion criteria were analyzed in this comparative review, with varying methodological approaches, including normative juridical ones. Despite these differences, all studies demonstrate a consistent focus on the crucial role of *informed consent* in dental care, particularly within the context of legal protection. (Kuswandi, 2019; Daeng et al., 2023) which focuses on the analysis of legal regulations and doctrine. These two studies emphasize that legal protection for dentists is in principle guaranteed as long as practice is carried out in accordance with professional standards and operational procedures. In contrast, research using empirical and qualitative approaches (Saksono et al., 2022; Basuki et al.) provides a real picture in the field, which shows a discrepancy between legal norms and practical implementation. Meanwhile, Oktarina (2010) through a policy approach identified a gap in specific regulations regarding *informed consent* for high-risk dental medical procedures.

There are significant differences between primary health care facilities (Puskesmas) and independent dental practices. Studies conducted at Puskesmas (Kuswandi, 2019; Saksono et al., 2022) indicate that time constraints due to high patient volumes are a major obstacle to optimally implementing *informed consent* . One important finding is the completeness rate of *informed consent* , which is 76.7%, indicating moderate but not optimal compliance. Conversely, in independent practices (Basuki et al.), problems are more often caused by individual factors, such as negligence or lack of legal awareness, which actually increases the risk of direct legal liability. In terms of key findings, all articles share the common belief that *informed consent* is a fundamental element in dental practice. However, there are differences in its interpretation and implementation. Legal studies position *informed consent* as a legal obligation inherent in professional standards, while empirical studies show that in practice, *informed consent* is often treated as a mere administrative formality and is not yet a comprehensive communication process between doctor and patient. All literature agrees that *informed consent,* along with medical records, is the primary evidence in resolving medical disputes and malpractice cases. However, its effectiveness depends heavily on the completeness and validity of the documentation. These findings represent an important contrast to normative perspectives that tend to assume ideal compliance in practice. Overall, the results of this comparative analysis identified an implementation gap between legal norms and dental health service practices in the field.

DISCUSSION

Medical records constitute one of the most important legal instruments for protecting dentists because they document the entire clinical decision-making process, demonstrate compliance with professional standards, and provide objective evidence in the event of legal disputes (Pandit & Pradhan, 2024; Reid, 1998). In dental practice, where many procedures such as tooth extraction,

endodontic treatment, implant placement, and oral surgery involve invasive interventions and potential complications, comprehensive documentation is considered an essential component of risk management (American Dental Association [ADA], 2023; Reid, 1998). Complete dental records should include patient identification, medical and dental history, clinical examination findings, diagnosis, treatment alternatives, informed consent, procedures performed, prescribed medications, postoperative instructions, and follow-up evaluations, as these elements collectively demonstrate adherence to accepted standards of care (Pandit & Pradhan, 2024; Mason & Laurie, 2022). Beyond supporting continuity of care, detailed medical records establish that the dentist exercised professional judgment consistent with ethical and legal obligations (Beauchamp & Childress, 2019; Brazier & Cave, 2021).

The legal value of medical records is inseparable from the implementation of informed consent because documentation alone cannot establish legal compliance unless it also demonstrates that patients received adequate information before treatment (Reid, 1998; Pandit & Pradhan, 2024). Contemporary legal and ethical frameworks define informed consent as an ongoing communication process rather than merely obtaining a patient's signature on a consent form (Beauchamp & Childress, 2019; Montgomery, 2019). Dentists are therefore expected to provide clear explanations regarding the diagnosis, proposed treatment, available alternatives, expected benefits, potential risks, possible complications, costs, and prognosis before patients voluntarily agree to treatment (ADA, 2023; FDI World Dental Federation, 2022). Consequently, medical records become essential evidence that patient autonomy has been respected and that the decision-making process complied with professional standards (Beauchamp & Childress, 2019; Reid, 1998).

The increasing emphasis on patient autonomy has also transformed judicial approaches to malpractice litigation involving dental services (Montgomery, 2019; Brazier & Cave, 2021). Courts increasingly assess whether dentists fulfilled their legal obligation to disclose material information rather than focusing solely on whether an adverse clinical outcome occurred (Montgomery, 2019). Therefore, the occurrence of complications following dental treatment does not automatically establish negligence if the dentist has complied with professional standards and appropriately documented the informed consent process (Reid, 1998; Mason & Laurie, 2022). Conversely, failure to adequately explain treatment risks or document patient consent may expose dentists to legal liability even when the clinical procedure itself was technically appropriate (Pandit & Pradhan, 2024; Brazier & Cave, 2021). This shift reflects the growing recognition that legal protection for healthcare professionals depends not only on technical competence but also on transparent communication and comprehensive documentation (Montgomery, 2019; Beauchamp & Childress, 2019).

Patients' access to dental medical records further strengthens legal protection by promoting transparency, accountability, and trust within healthcare services (Brazier & Cave, 2021; Mason & Laurie, 2022). Contemporary health law increasingly recognizes patients as active participants in healthcare decisions rather than passive recipients of treatment (Beauchamp & Childress, 2019). Access to medical records enables patients to review diagnoses, treatment plans, medications, dental radiographs, and clinical progress while facilitating continuity of care and second opinions when necessary (Pandit & Pradhan, 2024; ADA, 2023). Increased transparency has also been associated with improved patient satisfaction and reduced misunderstandings that frequently contribute to legal disputes (Brazier & Cave, 2021). Nevertheless, the patient's right of access must be balanced with the dentist's legal obligation to maintain confidentiality and protect sensitive personal health information in accordance with professional ethics and applicable legislation (Mason & Laurie, 2022; FDI World Dental Federation, 2022). This principle is consistent with Indonesia's Health Law Number 17 of 2023 and Government Regulation Number 28 of 2024, which recognize both patient access rights and the confidentiality of medical records (Republic of Indonesia, 2023; Government of Indonesia, 2024).

Despite the existence of a stronger legal framework, practical implementation remains challenging, particularly within Indonesian community health centers (Puskesmas) (Pandit & Pradhan, 2024). Organizational constraints, including high patient volumes, shortages of dentists, insufficient medical record personnel, and limited consultation time, frequently reduce opportunities for effective communication during the informed consent process (Pandit & Pradhan, 2024). Under these circumstances, informed consent may become a routine administrative requirement rather than a meaningful shared decision-making process, thereby weakening both ethical practice and legal protection (Beauchamp & Childress, 2019; Montgomery, 2019). Previous studies consistently demonstrate that excessive workload and time constraints contribute to incomplete documentation and reduced quality of informed consent records, thereby increasing medico-legal vulnerability (Pandit & Pradhan, 2024; Reid, 1998).

Technological challenges also continue to affect implementation. Although Indonesia has accelerated the adoption of electronic medical records, many primary healthcare facilities still experience limited digital infrastructure, inconsistent interoperability, inadequate cybersecurity measures, and the absence of role-based access control systems (Galeotti et al., 2026). These limitations reduce the reliability, completeness, and legal defensibility of electronic documentation when disputes arise (Galeotti et al., 2026; Mason & Laurie, 2022). International evidence suggests that digital transformation should be accompanied by standardized documentation protocols, secure electronic consent systems, and comprehensive governance frameworks to ensure that electronic medical records remain legally admissible and ethically compliant (Galeotti et al., 2026; ADA, 2023).

Another important challenge concerns the legal literacy of healthcare professionals. Although dentists generally possess strong clinical competencies, previous studies suggest that knowledge regarding medico-legal responsibilities, informed consent, confidentiality, and documentation requirements remains variable (Pandit & Pradhan, 2024; Reid, 1998). Consequently, incomplete consent forms and inadequate medical records continue to represent preventable sources of legal risk (Brazier & Cave, 2021). Continuous professional education in health law, bioethics, and risk management should therefore accompany clinical competency development to strengthen legal compliance and patient safety (Beauchamp & Childress, 2019; Mason & Laurie, 2022). Furthermore, developing standardized operating procedures governing informed consent and patient access to dental medical records would improve consistency across healthcare facilities and enhance legal certainty for both patients and dentists (ADA, 2023; Government of Indonesia, 2024).

Overall, the findings of this review indicate that informed consent and medical records should be understood as complementary legal mechanisms rather than independent administrative requirements (Pandit & Pradhan, 2024; Reid, 1998). Their effective implementation protects patient autonomy while simultaneously strengthening professional accountability and reducing legal risks for dentists (Beauchamp & Childress, 2019; Montgomery, 2019). Achieving these objectives requires not only compliance with statutory regulations but also organizational support, adequate digital infrastructure, standardized documentation systems, and continuous legal education for oral healthcare professionals (Galeotti et al., 2026; Mason & Laurie, 2022).

CONCLUSION

The results of this comparative review show that informed consent has a very central position in the practice of dental services, not only as an ethical obligation, but also as an instrument of legal protection.

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