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Original Research Paper

Implementation of Electronic Medical Records in Ensuring the Completeness of Informed Consent Forms for Caesarean Section Procedures

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Abstract

Background: Electronic Medical Records (EMR) have been widely adopted to improve the quality and accessibility of medical documentation, including informed consent forms for surgical procedures. **Objective:** This study aims to analyze the completeness and accuracy of informed consent documentation for caesarean section procedures following EMR implementation at Hospital X. **Methods:** This is a qualitative study involving 54 informed consent forms collected from November 2024 to February 2025. Data were obtained through observation, document review, and in-depth interviews with medical record officers and clinical staff. **Results:** The study found that the average completeness rate of informed consent forms reached 96%, with missing elements such as patient address (9%) and witness signatures (15–32%). While key clinical components were fully documented, issues related to data accuracy, return timeliness, and legal authentication remained. Suboptimal utilization of EMR features and limited awareness of legal documentation procedures were contributing factors. **Conclusion:** Despite the benefits of EMR in structuring documentation, its implementation alone does not guarantee complete, accurate, and legally valid informed consent. Enhancing SOP adherence, digital system optimization, and staff training in legal-medical documentation are necessary to improve record quality.

Keywords: Electronic Medical Record; Informed Consent; Caesarean Section; Documentation Accuracy; Legal Compliance.

Introduction

In the era of global digital transformation in healthcare services, Electronic Medical Records (EMRs) have emerged as a fundamental pillar to ensure medical documentation that is secure, accurate, and efficient[1]. Their integration reflects a commitment to improving the quality and legal accountability of healthcare practices[2]. In Indonesia, however, the use of informed consent forms for caesarean section procedures remains problematic, with many still incomplete or recorded manually[3]. Studies at Bhakti Mulia Hospital, Muhammadiyah General Hospital Cirebon, and Nyi Ageng Serang Hospital in Kulon Progo revealed that the completeness of informed consent documentation had not met the minimum standards set by the Ministry of Health[4]. According to the Indonesian Ministry of Health Regulation (Permenkes No. 24 of 2022)[5], every element of the medical record must be fully documented electronically and without omission to be considered legally valid and useful for auditing and quality evaluations. Failure to meet these standards may compromise the legal integrity of medical records, degrade documentation quality, and hinder optimal healthcare delivery[6]. This situation emphasizes the urgency to assess how

EMR implementation can support the completeness of informed consent in the context of caesarean section procedures, which are often high-risk and require meticulous documentation[7].

Previous quantitative studies have highlighted the issue of incomplete informed consent in caesarean section procedures. For instance, Adham et al. (2024)[8] reported an average completeness of 85.75%, while Puspitasari (2023)[9] found notable gaps in authentication and documentation. Despite these findings, limited research has explored the qualitative dimensions of how EMR systems affect the digital completion of informed consent, especially regarding technical barriers, user perceptions, and system–user interactions. While Fitriani & Ulfah (2023)[10] indicated that some forms remain undigitized, their work did not comprehensively address the enablers and barriers to digital implementation. This indicates a significant research gap in understanding how EMR integration can ensure the legal and quality standards of informed consent in caesarean sections, a procedure that also has significant implications for post-operative care and infant health outcomes, such as the incidence of low birth weight[11].

Recent literature further underscores the importance of this topic. Hossain et al. (2025)[12] found that EMR implementation success in Indonesian hospitals largely depends on infrastructure readiness and healthcare workers' digital literacy. They also identified a significant disparity in digital preparedness between hospitals in Java and Sulawesi. At Weda Regional Hospital, Syahrul and Widiyanto (2025)[13] noted that while EMR adoption improved record accuracy and outpatient services, it was constrained by inadequate training and infrastructure gaps. These findings suggest that optimizing EMR features such as auto-fill, data validation, and digital tracking requires not only technical readiness but also sustained human resource development through training and operational standardization[14]. This study, therefore, addresses a crucial gap by investigating the digital legal documentation process in a high-risk procedure through a qualitative lens, considering factors that influence patient outcomes, such as the differences in gut microbiota between infants born via C-section and normal delivery[15].

This study explicitly aims to qualitatively analyze how the implementation of Electronic Medical Records (EMRs) influences the completeness and accuracy of informed consent forms in caesarean section procedures at Hospital X. Using in-depth interviews with medical record officers and surgeons, as well as direct observations of the documentation process, the study investigates various aspects including the completeness of informed consent documentation, frequently omitted sections such as patient address or witness signature and their implications for record quality, and the accuracy of patient identification and clarity of medical information. Additionally, it evaluates the timeliness of form completion and return, examines legal compliance regarding the validity of signatures, and assesses the extent to which digital features within the EMR system such as auto-fill, automatic validation, and document tracking are utilized, along with the challenges that hinder their optimal implementation.

Theoretically, this research contributes to the development of digital clinical governance concepts and EMR quality models by adding empirical depth to predominantly quantitative studies[16]. It enhances current models by focusing on user experience, legal compliance, and human–technology interaction in clinical documentation. Practically, the findings are expected to inform hospital management and

policymakers in designing standard operating procedures (SOPs), developing targeted digital training, and conducting continuous quality audits to improve the legal accountability and quality of informed consent documentation in caesarean section procedures through EMR systems, ultimately enhancing patient safety and care quality[17].

Materials and Methods

Study Design

This study employs a qualitative research approach aimed at gaining an in-depth understanding of the completeness of informed consent documentation in caesarean section procedures and the role of Electronic Medical Records (EMRs) in supporting this process. Qualitative methods are designed to explore meaning, personal experiences, and social contexts behind observed phenomena by collecting and interpreting non-numerical data[18]. In this study, data collection was conducted through direct observation, in-depth interviews, and relevant literature review. The analytical framework refers to indicators of healthcare service effectiveness previously discussed in studies such as that by Fadillah PR, Soelistijaningroem M, and Nuraeni YA (2023)[19]. The population of interest consisted of informed consent forms for caesarean section procedures collected from November 2024 to February 2025. The sample was drawn based on the number of patients undergoing caesarean sections within that period, ensuring data relevance and capturing the most recent documentation practices.

Sample

To obtain a representative sample from the selected population, the Slovin formula was applied. With a total population of 120 informed consent forms recorded in Hospital X during the specified period, the sample size was calculated as follows:

$n = N / (1 + Ne^2)$
$n = 120 / (1 + 120 * 0.1^2)$
$n = 120 / (1 + 1.2)$
$n = 120 / 2.2$
$n \approx 54.54$

Thus, the final sample consisted of 54 informed consent forms for caesarean section procedures. These forms were selected from the archives of the hospital's medical record unit covering the period from November 2024 to February 2025. The study analyzed 54 informed consent forms that met specific inclusion criteria: (1) the forms were specifically used for caesarean section procedures, (2) they were official patient documents archived in the medical record unit, and (3) the forms were intact and legible. Exclusion criteria included forms not associated with caesarean sections, damaged or illegible documents (e.g., torn, faded, or incomplete), and forms lacking clear patient identity or unit origin.

Data Collection Technique

Technique Observation Observation was conducted to capture actual conditions in the field regarding workflow and EMR system use. Yunengsih and Oktaviani (2024)[20], in their study on EMR readiness at Dr. Hasri Ainun Habibie Eye Clinic, emphasized the use of triangulation combining observation, in-depth interviews, and documentation analysis to obtain comprehensive and valid data from multiple sources. This triangulated approach was adopted in the present study to explore the interaction between technological readiness, human resource competency, and hospital policies in influencing the quality of medical documentation, including the informed consent process.

Interview In-depth interviews were conducted to explore the behaviors, operational challenges, and perceptions of healthcare

personnel regarding the digitalization of medical records through EMR implementation. As noted by Notoadmodjo (2020)[21], interviews allow researchers to gain nuanced insights into non-technical aspects of healthcare services. Informants were selected from the medical records staff of Hospital X, who are directly involved in managing informed consent documentation. The purpose of involving these informants was to obtain detailed, accurate, and relevant data to support the study's analytical framework.

Literature Review This study also included a literature review as part of its qualitative methodology. Various primary and secondary sources were collected and analyzed to strengthen the conceptual understanding of EMR implementation and documentation quality. According to Ilhami et al. (2024)[22], the case study method in qualitative research enables researchers to understand complex phenomena in a contextual and holistic manner. Scientific literature served as a key reference to evaluate the effectiveness of EMR implementation in Indonesian hospitals, particularly concerning the digital documentation of informed consent forms. The literature review also provided a theoretical foundation to reinforce the arguments and interpretations developed throughout the study.

Data Analysis Technique

The collected data were analyzed using a descriptive qualitative approach. The analysis process involved organizing the informed consent forms based on thematic categories aligned with the six quality indicators: content completeness, data accuracy, timeliness, legal compliance, information confidentiality, and system integration[23]. Data from observations and in-depth interviews were transcribed and coded thematically to identify patterns, discrepancies, and operational challenges in the completion of informed consent forms within the EMR system[24]. The findings were then triangulated with literature references and document reviews to enhance the validity and depth of interpretation. The calculation of form completeness was assisted by using the KLPCM formula (Kelengkapan Pengisian Consent Form Medis) to quantify the level of documentation quality based on the proportion of complete forms during the study period.

Ethical Consideration

This study did not require formal ethical approval, as it did not involve direct interaction with patients or the collection of personal or sensitive human data. The data analyzed consisted solely of archival documents (informed consent forms) and interviews with healthcare professionals in non-intervention settings[25]. Nonetheless, the study adhered strictly to ethical principles and institutional procedures, including the protection of confidentiality, secure data handling, and obtaining verbal consent from informants prior to interviews. All collected documents were anonymized, and no identifiable information was disclosed, ensuring full compliance with professional and institutional research ethics standards.

Results

This section presents the main findings of the study, aligned with the objectives of assessing the completeness, accuracy, legal compliance, and information system integration of informed consent forms for caesarean section procedures at Hospital X during the period from November 2024 to February 2025. A total of 54 informed consent forms were analyzed.

Descriptive Analysis of Research

Variables The analysis began with a review of patient identification data. As shown in Table 1, components such as medical record number, patient name, gender, and date of birth were fully documented in 100% of the forms (54

forms). However, the patient address field was incomplete in 5 forms, resulting in a 91% completion rate for that component. Overall, the average completeness of patient identification data reached 98%.

Table 1. Review of Patient Identification Completeness

Variable	Category	Frequency (n)	Percentage (%)
Medical Record Number	Complete	54	100%
	Incomplete	0	0%
Patient Name	Complete	54	100%
	Incomplete	0	0%
Gender	Complete	54	100%
	Incomplete	0	0%
Date of Birth	Complete	54	100%
	Incomplete	0	0%
Patient Address	Complete	49	91%
	Incomplete	5	9%

Source: Processed by the author, 2025

The second component assessed was the documentation of essential medical content. As shown in Table 2, all 54 informed consent forms were fully completed across all evaluated elements, resulting in a 100% completion rate. This indicates that medical content documentation was in line with established standards.

Table 2. Review of Key Medical Information Completion

Variable	Category	Frequency (n)	Percentage (%)
Diagnosis	Complete	54	100%
	Incomplete	0	0%
Procedure	Complete	54	100%
	Incomplete	0	0%
Indication	Complete	54	100%
	Incomplete	0	0%
Objective	Complete	54	100%
	Incomplete	0	0%

Source: Processed by the author, 2025

In terms of documentation integrity, Table 3 shows that all forms (100%) were completed without erasures, strikethroughs, or use of correction fluid (tip-ex), suggesting strong procedural adherence in form handling.

Table 3. Review of Proper Documentation Practices

Variable	Category	Frequency (n)	Percentage (%)
Erasures/ Corrections	No	54	100%
	Yes	0	0%

Source: Processed by the author, 2025

However, issues were identified in the area of authentication, as outlined in Table 4. While doctor and patient signatures were present on all 54 forms (100%), witness signatures were less consistently included. Only 46 forms (85%) had a signature from witness 1, and just 37 forms (68%) had witness 2's signature. Thus, the overall average completion rate for authentication was 89%.

Table 4. Review of Authentication Elements

Variable	Category	Frequency (n)	Percentage (%)
Doctor's Signature	Complete	54	100%
	Incomplete	0	0%
Patient's Signature	Complete	54	100%
	Incomplete	0	0%
Witness 1 Signature	Complete	46	85%
	Incomplete	8	15%
Witness 2 Signature	Complete	37	68%
	Incomplete	17	32%

Source: Processed by the author, 2025

To further evaluate completeness, the research applied the KLPCM (Kelengkapan Pengisian Consent Form Medis) formula: KLPCM = (Number of complete items / Total number of items) x 100% This formula revealed persistent gaps in several critical sections, including patient address (9% incomplete), witness 1 signature (15% incomplete), and witness 2 signature (32% incomplete), as visualized in the figure below.

The synthesis of findings is summarized in Table 5, which evaluates the completeness of informed consent documentation across six quality indicators. The first indicator, content completeness, showed that only 52 of the 54 forms (96%) were fully completed, indicating that the forms cannot yet be classified as high-quality

medical records under Ministry of Health standards, which require 100% completion[5]. Missing information weakens both communication clarity and legal validity.

Table 5. Analysis Summary of Informed Consent Form Completion for Caesarean Section Procedures at Hospital X

Quality Indicator	Assessment	Percentage	Notes
Content Completeness	52/54 forms fully complete	96%	Missing addresses and witness signatures.
Data Accuracy	Generally high, but some discrepancies noted.	-	Requires more thorough verification.
Timeliness	Delays in returning forms to medical records.	-	Exacerbated by incomplete entries.
Legal Compliance	Doctor/patient signatures 100%; witness signatures low.	89% average	Undermines legal robustness.
Information Security	Dependent on EMR system protocols.	-	Potential risk if data protection is weak.
System Integration	Limited interoperability between units.	-	Hinders tracking and validation.

Source: Processed by the author, 2025

Discussion

The findings of this study reveal that the completeness of patient identity components on caesarean section informed consent forms reached an average of 98%, with key components such as medical record number, patient name, gender, and birthdate recorded at 100%. This suggests that the auto-fill feature of the Electronic Medical Record (EMR) system supports high consistency in critical identity fields[26]. However, the patient address was often incomplete (91%), indicating either system-level limitations in mandatory field configuration or human factors such as haste or lack of awareness during data entry[27]. These results emphasize that while EMR can support documentation accuracy, consistent quality control and routine staff training are still required to ensure that non-automated fields are not overlooked.

The analysis also showed that 100% of essential medical content such as diagnosis, procedure, indication, and objectives were completed across all forms. This indicates that medical staff are generally compliant with documentation standards, likely due to clear clinical Standard Operating Procedures (SOPs) and the legal implications associated with informed consent documentation[28]. The absence of erasures or correction fluid in all forms (Table 3) further reflects a culture of proper documentation and legal awareness among health professionals. However, completeness in documentation does not always equate to quality. Future evaluations should examine the clarity of medical explanations and the extent to which patients truly understand the consent content, which is crucial for procedures like C-sections that may impact post-operative recovery and pain management[29].

The 89% average in authentication completeness, particularly the lower rates of witness signatures (85% for witness 1 and 68% for witness 2), reflects a continuing gap in legal compliance. This finding aligns with research by Fitriani & Ulfah (2023)[10], who reported incomplete digitization and inconsistencies in legal documentation processes, and Puspitasari (2023)[9], who highlighted deficiencies in authentication fields. While Adham et al. (2024)[8] documented informed consent completeness of 85.75%, our study shows a slightly higher figure, especially in medically driven content fields. However, the gap in legal validation through witness signatures remains concerning and suggests a lack of

understanding regarding the legal function of witness involvement, which is critical for high-risk procedures like caesarean sections[30].

These findings reinforce the need for strengthening EMR-based documentation standards, particularly regarding the integration of digital features such as auto-validation, signature alerts, and mandatory fields[31]. Incomplete informed consent forms, especially those lacking essential legal elements, can undermine the hospital's legal protection and the patient's rights, and may pose risks in the event of disputes. As Hossain et al. (2025)[12] noted, EMR effectiveness depends not only on infrastructure but also on the digital literacy and behavioral compliance of healthcare providers. This study supports that assertion and highlights the importance of continuous digital training and organizational support to close those gaps.

The results of this study are consistent with previous research that has identified persistent challenges in medical documentation quality, even after EMR implementation. For instance, a study by Kruse et al. (2022) in the United States found that while EMRs improved documentation availability, they did not automatically solve issues related to data completeness and accuracy, which were often dependent on user behavior and system design[32]. Similarly, a multi-country study by Aqil et al. (2023) highlighted that in low- and middle-income countries, the benefits of EMRs are often constrained by inadequate training, poor internet connectivity, and a lack of alignment between system design and local clinical workflows[33]. Our findings align with these international studies, suggesting that the challenges faced at Hospital X are part of a broader global issue in health informatics implementation.

However, our study adds a specific qualitative focus on the legal documentation of informed consent for a high-risk surgical procedure. The high completion rate for clinical content (100%) but lower rate for legal authentication (89%) is a unique finding that underscores a potential disconnect between clinical priorities and legal/administrative requirements among healthcare staff. This is a critical insight that quantitative studies alone might miss. Furthermore, our focus on a C-section population is relevant given the rising rates of this procedure globally and its associated documentation needs, which can impact maternal and infant health outcomes, such as the gut microbiota of newborns[15] and the management of post-operative pain[29].

The findings of this study have significant implications for clinical practice and hospital management. Clinically, incomplete or legally invalid informed consent forms can jeopardize patient safety and autonomy. If patients are not fully informed or if the documentation is not legally sound, it undermines the ethical foundation of surgical practice. For hospital management, these findings highlight the need for a multi-faceted approach to improve documentation quality. This includes technical solutions, such as optimizing the EMR to make critical fields mandatory and implementing digital signature systems, as well as process-oriented solutions, like regular audits and feedback mechanisms[31].

From a public health perspective, this study contributes to the broader goal of improving the quality and safety of healthcare services. Accurate and complete medical records are essential for quality improvement initiatives, research, and public health surveillance. In the context of caesarean sections, proper documentation is crucial for monitoring maternal and infant outcomes, understanding factors that may lead to adverse events like low birth weight[11], and evaluating the effectiveness of interventions, such as post-operative pain management protocols[29]. Therefore, investing in improving EMR

systems and the competencies of healthcare workers who use them is an investment in the overall quality of the healthcare system.

Advantages and Limitations of the Research A major strength of this study lies in its use of triangulation, combining document review, direct observation, and interviews to ensure data validity[20]. This mixed-methods approach allowed for a comprehensive understanding of the issue from multiple perspectives. Additionally, the use of KLPCM as a quantitative metric offers a structured way to assess form completeness. The focus on a high-risk, high-volume procedure like caesarean section makes the findings particularly relevant for many hospitals.

However, the study is limited by its focus on a single institution, which may not fully represent practices in other hospitals with different EMR systems or SOPs. The findings are context-specific and may not be generalizable. Furthermore, while the data show statistical completeness, this study did not include a patient-centered evaluation of comprehension, which is essential for ensuring true informed consent. The study also did not investigate the reasons behind the missing witness signatures in depth, which could be an area for future qualitative exploration.

Future research should consider expanding the sample to multiple institutions with varying EMR platforms to evaluate systemic factors affecting documentation quality. A mixed-methods approach combining quantitative document analysis with qualitative patient interviews could provide a more holistic view of how informed consent is understood and processed. Additionally, the development of a digital audit tool integrated into EMR systems may help automatically flag incomplete or incorrect entries, thereby improving real-time data quality and legal compliance. Finally, intervention studies are needed to test the effectiveness of specific strategies, such as mandatory field implementation, targeted training programs, or automated alerts, in improving the completeness and legal validity of informed consent documentation.

Conclusion

The implementation of the Electronic Medical Record (EMR) system at Hospital X has positively contributed to the documentation process of informed consent forms for caesarean section procedures, particularly in facilitating document tracking and improving documentation speed. However, the system has not yet ensured optimal quality standards, as technical and non-technical gaps remain. The study found that while the overall completeness of form entries reached 96%, certain fields—particularly patient address and witness signatures were frequently incomplete. These deficiencies have implications for the clarity of information and may weaken the hospital's legal position during audits or disputes. In addition, inaccuracies in patient identification and inconsistent entries across forms highlight the need for more thorough verification and a stronger understanding among healthcare staff regarding the legal and professional responsibilities tied to proper documentation.

Furthermore, delays in the completion and submission of consent forms suggest procedural inefficiencies, often exacerbated by high workloads and the absence of fully integrated digital workflows. The underutilization of advanced EMR features such as auto-fill, real-time validation, and automated reminders reveals a broader issue of system integration and digital literacy. Legal components of the consent forms, including witness authentication, were often lacking, reflecting insufficient awareness of their legal significance. To address these challenges, a multifaceted approach is necessary: this includes developing smart EMR features, implementing digital SOPs, providing

continuous training on ethical and legal aspects of informed consent, conducting regular audits, and educating patients and their families about their rights. These efforts are essential to ensure that informed consent documentation is complete, accurate, timely, and legally sound, thereby strengthening the overall quality of healthcare services.

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