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Original Article BASIC MEDICINE SCIENCES

LuminaConsent: AI-driven standardization and quality enhancement of urological informed consent documentation

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ABSTRACT

OBJECTIVE: Informed consent is the cornerstone of modern medical ethics, but current documentation systems negatively impact patient autonomy and clinical quality due to deficiencies in readability, comprehensibility, and standardization. These issues hinder patient participation and require innovative solutions. This study introduces the AI-powered LuminaConsent system to address standard deficiencies, comprehensibility issues, and efficiency constraints in urological informed consent documents.

METHODS: In a three-armed comparative study, LuminaConsent (artificial intelligence), Turkish Urological Surgery Association standard forms, and expert-developed documents were evaluated in 10 urological procedures. The system is based on the RAG architecture, which uses OpenAI's GPT-4o-mini model and a special knowledge base consisting of 12 clinical publications. Three independent urology specialists conducted a blind evaluation using a 100-point scale across five areas: scientific content accuracy, patient communication effectiveness, quality of risk-benefit information, perioperative guidance, and legal-ethical compliance.

RESULTS: LuminaConsent achieved higher performance with mean scores of 82.33 points (SD±4.2) versus 78.77 points (SD±6.1) for professional society standards and 57.43 points (SD±3.8) for specialist documentation, representing statistically significant improvements of 43.3% over specialist practices ($p<0.001$) and 4.5% over professional society standards ($p<0.05$). The system demonstrated consistent high-quality output across all procedures while generating comprehensive documentation within 96-180 seconds compared to traditional processes requiring multiple days.

CONCLUSION: LuminaConsent offers a pioneering model for systematic AI integration in clinical practice with its evidence-based content generation and bilingual processing capabilities. The findings support the potential to empower patient autonomy, reduce application variations, and improve ethical standards.

Keywords: Artificial intelligence; clinical decision support; informed consent; medical documentation; medical ethics; patient safety.

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Informed consent represents a cornerstone of contemporary medical ethics, functioning as the essential mechanism for preserving patient autonomy in clinical decision-making [1, 2]. Rather than mere administrative compliance, this process constitutes a sophisticated communication framework ensuring patients receive comprehensive information about proposed interventions, enabling autonomous decisions grounded in an understanding of risks, benefits, and alternatives [3]. As healthcare systems increasingly prioritize patient empowerment, the quality and effectiveness of informed consent processes have emerged as important determinants of both clinical outcomes and medico-legal integrity [2].

The ethical framework governing informed consent evolved from historical medical transgressions, with foundational documents—the Nuremberg Code (1947), Declaration of Helsinki, and Belmont Report—establishing principles that underpin contemporary physician-patient relationships [4, 5]. Valid consent processes necessitate four essential elements: patient competency, comprehensive disclosure of intervention purposes, risks, benefits, and alternatives, verification of comprehension, and adequate documentation [6, 7]. Nevertheless, contemporary healthcare systems encounter significant implementation challenges, particularly in high-volume environments where temporal constraints undermine the quality of patient-provider communication required for authentic informed consent [8].

The Turkish healthcare system exemplifies these implementation challenges through documented systemic deficiencies that compromise informed consent effectiveness. With 973,519,087 annual physician consultations and 5,992,338 surgical procedures—averaging 2.7 million examinations and 16,645 interventions daily—this substantial clinical burden generates critical impediments including inadequate time for patient education, institutional inconsistencies in information delivery, and degraded communication quality [9]. These constraints fundamentally impair practitioners' capacity to fulfill informed consent obligations, creating notable disparities between ethical imperatives and clinical reality.

Empirical research has identified four fundamental deficiencies in Turkish informed consent implementation that compromise both patient autonomy and clinical quality. Patient engagement remains inadequate, with 75.8% of surgical patients failing to read consent forms (CFs) and 62.4% of readers experiencing significant comprehension difficulties [10]. Institutional variations in documentation quality persist, evidenced by 74.2% of patients across nine surgical specialties characterizing explanations as insufficient despite formal information provision [11]. Preparation and delivery processes suffer from time constraints, preventing physicians from allocating adequate time for proper consent procedures [12, 13]. Additionally, existing consent documents demonstrate poor readability, creating fundamental barriers to meaningful patient participation in medical decision-making [14]. These interdependent deficiencies constitute systematic failures requiring innovative solutions beyond conventional approaches.

Highlight key points

- An AI-driven informed consent assistant (LuminaConsent) was evaluated across 10 urological procedures using expert- and society-based consent standards.
- LuminaConsent-generated consent forms achieved the highest overall quality scores compared with specialist and society forms.
- Mean ICF scores were 57.43 for specialists, 78.77 for society forms, and 82.33 for LuminaConsent.
- The RAG architecture utilizing curated clinical literature ensured consistent, standardized quality across all ten urological procedures evaluated.
- LuminaConsent has the potential to strengthen patient autonomy, equality, and ethical standards in consent processes.

Contemporary research demonstrates that artificial intelligence (AI) applications can effectively address these systematic deficiencies through enhanced standardization, improved patient comprehension, and streamlined clinical workflows. AI-assisted consent processes significantly enhance patients' risk comprehension while maintaining satisfaction levels equivalent to conventional methods, with AI-generated documentation demonstrating required completeness and accuracy, particularly in describing procedural benefits and alternatives [15, 16]. Digital platforms reduce documentation errors and enhance patient engagement in shared decision-making processes [17]. Nevertheless, existing AI applications remain limited in addressing multilingual healthcare contexts and specialized surgical domains, necessitating comprehensive clinical validation.

Despite technological progress, significant gaps persist in developing and validating AI-driven solutions for specialized surgical contexts within non-English healthcare systems. Previous research has predominantly examined general medical applications or isolated AI model capa-

Table 1. Most frequently performed urological surgical procedures in Turkish healthcare institutions

CF	Operative Intervention
CF1	Varicocelectomy for Varicocele Disease
CF2	Transurethral Resection (TUR) for Bladder Tumors
CF3	Circumcision Procedure for Ritualistic or Medical Purposes
CF4	Radical Prostatectomy for Prostate Cancer
CF5	Transurethral Resection of the Prostate (TURP) for Benign Prostatic Hyperplasia (BPH)
CF6	Orchiopexy for Cryptorchidism (Undescended Testis)
CF7	Hypospadias Repair Surgery for Hypospadias
CF8	Internal Urethrotomy for Urethral Stricture Disease
CF9	Penile Prosthesis Implantation for Erectile Dysfunction (ED)
CF10	Diagnostic Cystoscopy for Lower Urinary Tract Disorders

CF: Consent form.

bilities, lacking comprehensive frameworks that address the systematic challenges of standardization, comprehensibility, preparation efficiency, and institutional variation inherent to informed consent processes. Evidence regarding the clinical effectiveness of AI-driven systems in enhancing patient outcomes and workflow efficiency remains limited, particularly in urological practice where complex procedures necessitate detailed risk communication and comprehensive patient education.

This investigation addresses these critical gaps by evaluating LuminaConsent, an AI-driven informed consent system specifically engineered to resolve systematic deficiencies in urological practice. The primary objective involves assessing the system's performance in generating informed consent documentation against established standards through comprehensive clinical validation across diverse urological procedures. LuminaConsent employs retrieval-augmented generation (RAG) architecture, similar to approaches demonstrated in specialized medical applications [18], addressing standardization deficiencies through consistent content generation, comprehensibility challenges via natural language processing optimization, temporal constraints through automated documentation, and institutional variations through standardized quality protocols. Unlike previous investigations examining isolated AI capabilities, this study provides rigorous expert evaluation across multiple procedural categories, contributing empirical evidence for AI-driven solutions' potential in informed consent processes while establishing a foundation for evidence-based implementation of AI technologies in specialized medical domains.

MATERIALS AND METHODS

Study Design and Research Setting

This comparative effectiveness study systematically evaluated AI-generated informed consent documentation quality against conventional methodologies through expert assessment. We employed a three-arm comparative framework examining documentation generated through: (1) standardized forms from the Turkish Society of Urological Surgery, representing official institutional templates and regulatory compliance standards, (2) forms developed by individual urology specialists reflecting clinical practice patterns, and (3) forms produced by the AI-driven LuminaConsent system incorporating large language models (LLM) calibrated for Turkish healthcare contexts.

Three independent urological specialists (one professor and two associate professors) with expertise in urological practice conducted blinded evaluations of documentation quality across multiple procedural categories. Evaluators were selected based on clinical experience, academic standing, and recognized expertise in urological informed consent processes, enabling objective comparison while maintaining clinical relevance for healthcare delivery implementation.

Surgical Procedure Selection and Categorization Framework

The evaluation framework incorporated ten commonly performed urological procedures within contemporary Turkish clinical practice, systematically identified through consultation with senior urological

Table 2. Core medical information categories required for informed consent form generation

No.	Heading (Turkish)	Heading (English)
1	{hastalık} Hastalığının Tanımı Nedir ve {hastalık} Hastalığının Sebepleri Nelerdir?	What is the Definition of {disease} Disease and What are the Causes of {disease} Disease?
2	{hastalık} Hastalığının Belirtileri Nelerdir?	What are the Symptoms of {disease} Disease?
3	{hastalık} Hastalığının Tanısı Nasıl Konur?	How is {disease} Disease Diagnosed?
4	{hastalık} Hastalığının Tedavi Yöntemleri Nelerdir?	What are the Treatment Methods for {disease} Disease?
5	{ameliyat} Ameliyatının Şekli ve Aşamaları Nelerdir?	What are the Types and Stages of {surgery} Surgery?
6	{ameliyat} Ameliyatının Faydaları ve Başarı Oranı Nedir?	What are the Benefits and Success Rate of {surgery} Surgery?
7	{ameliyat} Ameliyatının Risk ve Komplikasyonları Nelerdir?	What are the Risks and Complications of {surgery} Surgery?
8	{ameliyat} Ameliyatının Yapılmaması Durumunda Neler Olabilir?	What are the Potential Consequences if {surgery} Surgery is Not Performed?
9	{ameliyat} Ameliyatı Sonrasında Takip Nasıl Olmalı?	How Should Post-operative Follow-up Care be Managed After {surgery} Surgery?
10	{ameliyat} Ameliyat Olduktan Sonra Hasta ve Hasta Yakını / Refakatçi Nelere Dikkat Etmelidir?	What Should the Patient and Their Family Member / Attendant Pay Attention to After {surgery} Surgery?
11	{ameliyat} Ameliyat Olmadan Önce Hasta Nelere Dikkat Etmelidir?	What Should the Patient Pay Attention to Before Undergoing {surgery} Surgery?
12	{ameliyat} Ameliyat Öncesi, Ameliyat Sırası ve Ameliyat Sonrasında Kullanılma İhtimali Olan İlaçlar Hakkında Genel Bilgilendirme Nasıl Olmalıdır?	How Should General Information be Provided Regarding Potential Medications That May be Used Before, During, and After {surgery} Surgery?

specialists (distinct from the three blinded evaluators) and analysis of procedural frequency data from major healthcare institutions (Table 1). This selection methodology prioritized clinical relevance, procedural frequency, and representative complexity distribution to ensure comprehensive evaluation across diverse surgical scenarios.

The selected interventions demonstrated varying complexity, ranging from routine diagnostic procedures (diagnostic cystoscopy, circumcision) and intermediate complexity interventions (varicocelectomy, internal urethrotomy) to complex oncological procedures (radical prostatectomy). Each procedure represented established standard-of-care interventions with well-documented risk profiles and standardized consent documentation requirements, enabling systematic comparison across documentation methodologies while maintaining clinical authenticity. This approach facilitated targeted analysis of documentation quality across varying clinical scenarios and enabled comprehensive assessment of AI-generated content accuracy across the spectrum of contemporary urological practice.

Comparative Documentation Generation Methodology

The comparative assessment employed three distinct methodological approaches for informed consent form (ICF) generation across the selected urological procedures. The AI-driven approach utilized the LuminaConsent system, incorporating advanced natural language processing algorithms with retrieval-augmented generation (RAG) methodology specifically calibrated for clinical consent documentation within the Turkish healthcare context. The system's knowledge foundation comprised twelve carefully selected clinical publications (eight Turkish and four English authoritative sources), establishing a comprehensive bilingual framework for evidence-based consent documentation. AI-generated forms utilized a standardized structural framework incorporating twelve core medical information categories essential for comprehensive informed consent documentation (Table 2), ensuring systematic coverage of critical elements including disease definition, symptomatology, diagnostic procedures, treatment methodologies, surgical benefits and risks, post-operative care protocols, and medication guidance.

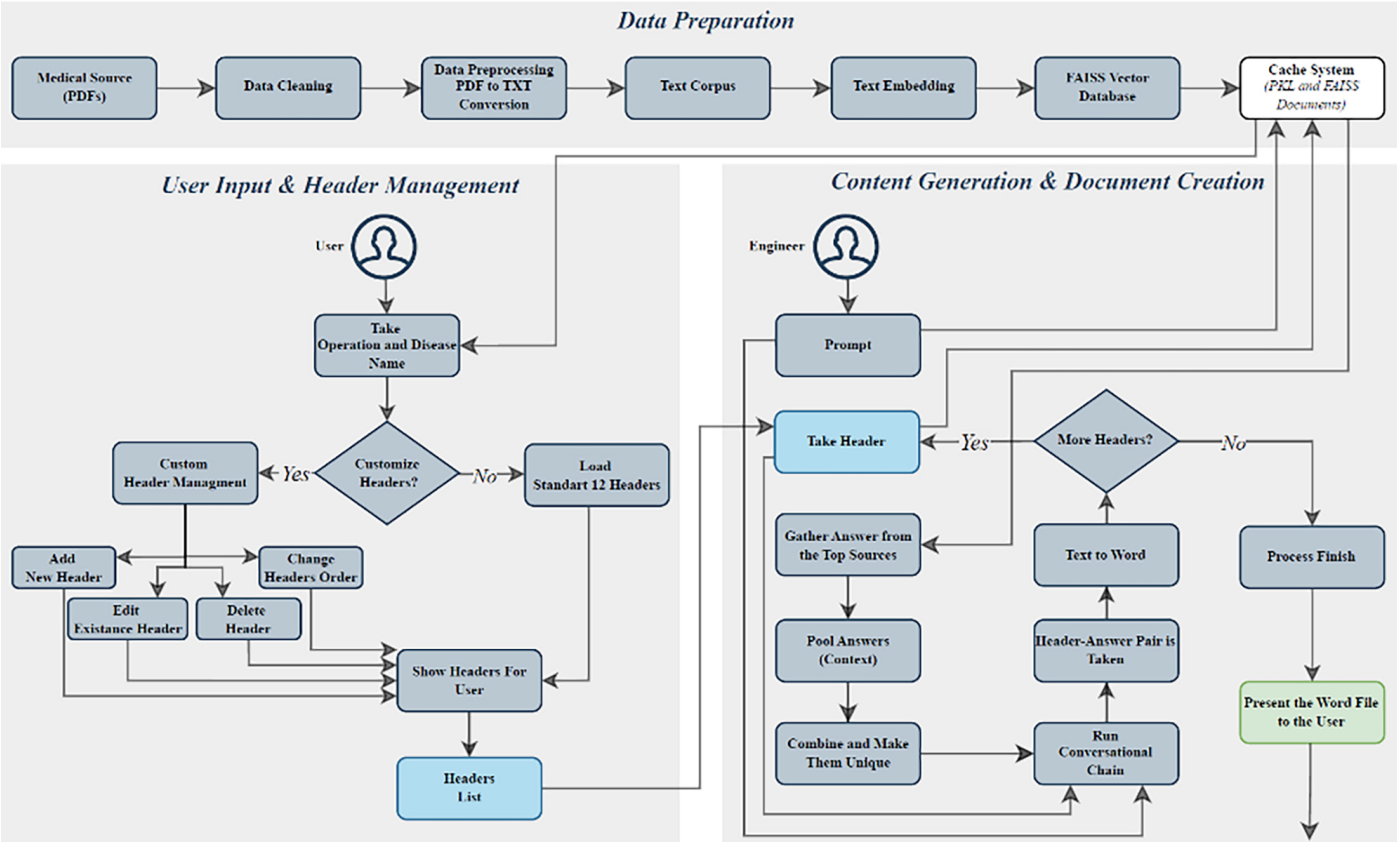

FIGURE 1. LuminaConsent: AI–Driven Informed Consent Assistant.

The professional society standardized approach employed officially endorsed informed consent templates provided by the Turkish Society of Urological Surgery, representing current institutional standards and regulatory compliance requirements. The individual specialist methodology incorporated ICFs developed by practicing urologists through conventional clinical documentation processes, reflecting clinical practice patterns and individualized institutional approaches.

This three-arm comparative design generated thirty distinct informed consent documents across the ten selected procedures, with each document evaluated against the comprehensive information categories outlined in Table 2, establishing a robust dataset for systematic quality assessment while ensuring representative coverage of contemporary documentation methodologies employed within Turkish urological practice.

AI-Driven Content Generation System Architecture and Clinical Implementation

The LuminaConsent AI system employed a RAG architecture integrating OpenAI's GPT-4o-mini large language model with specialized clinical knowledge retrieval mechanisms designed for urological consent documentation (Fig. 1) [19]. Unlike conventional approaches that rely on direct queries to general-purpose language models, the system operates through a clinical knowledge framework utilizing exclusively pre-approved clinical documentation. The system incorporated vectorized representations of the twelve selected clinical publications, processed through advanced text embedding algorithms and indexed using Facebook AI Similarity Search technology for optimal retrieval performance, ensuring all generated content derives from verified medical literature rather than potentially unreliable general knowledge databases [20].

The clinical implementation process enabled urological specialists to generate ICFs through a web-based interface, where practitioners input specific procedural details and disease classifications to initiate automated content generation across twelve standardized medical information categories (Fig. 2). The system provided header management functionality, allowing healthcare professionals to customize section organization, add

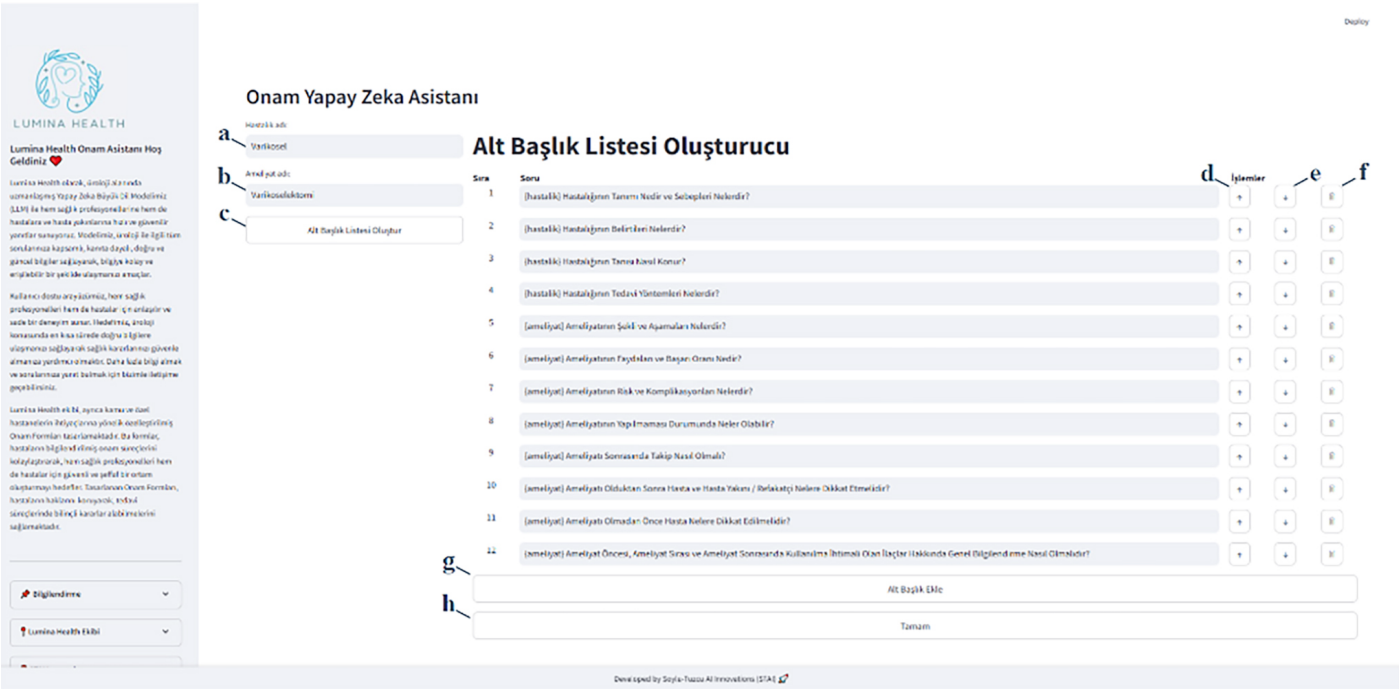

FIGURE 2. LuminaConsent's Interface for Medical Procedure Selection and Automated Informed Consent Form Section Generation.

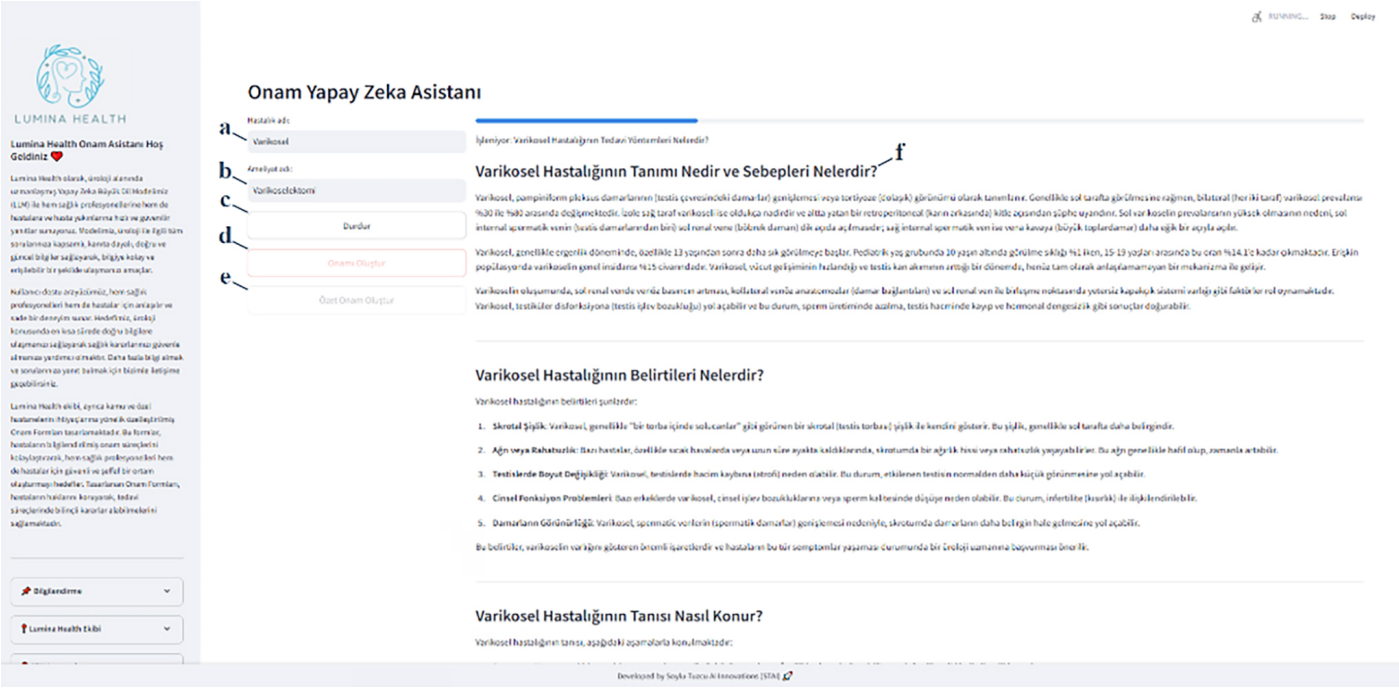

FIGURE 3. LuminaConsent's Automated Medical Informed Consent Form Generation Interface and Document Export Process.

or remove content categories, and reorder documentation structure according to institutional requirements. The platform employed bilingual processing capabilities, automatically translating Turkish clinical queries to English for knowledge base searches, subsequently generating contextually appropriate Turkish consent documentation through specialized prompt engineering strategies.

Table 3. Comprehensive evaluation framework for informed consent documentation quality assessment

No.	Assessment domain / evaluation criteria	Score
1	Scientific Content and Accuracy	20
	Alignment with contemporary urological guidelines	5
	Completeness of diagnostic and treatment processes	5
	Comprehensive explanation of disease definition, etiology, and symptomatology	5
	Accuracy of statistical data and success rates	5
2	Patient Communication and Comprehensibility	20
	Effective translation of medical terminology into patient-accessible language	5
	Logical sequence and organization of information presentation	5
	Strategic emphasis of critical clinical points	5
	Overall text readability and linguistic fluency	5
3	Risk, Benefit, and Treatment Information	20
	Realistic presentation of complications and procedural risks	4
	Clear articulation of expected therapeutic benefits	4
	Detailed explanation of surgical procedure stages and techniques	4
	Unbiased presentation of alternative treatment modalities	4
	Discussion of consequences of non-treatment	4
4	Pre- and Post-operative Process Information	20
	Comprehensive perioperative medical follow-up protocols	7
	Clear guidance for patient and family member responsibilities	7
	General information regarding potential medications and management	6
5	Structural Organization and Legal-Ethical Compliance	20
	Effective organization and readability of information	5
	Consistent and systematic use of headings and structure	5
	Adherence to patient rights and informed consent standards	5
	Protection of patient privacy and clinical autonomy	5
Total score		100

Upon content generation completion, the system presented a visualization of generated sections with immediate editing capabilities, enabling urologists to review, modify, and customize each component according to specific clinical considerations and institutional protocols (Fig. 3). The finalized documentation underwent automated conversion to standardized Word format, providing healthcare professionals with ICFs ready for clinical implementation and patient consultation processes.

Expert Evaluation Framework and Quality Assessment Methodology

Documentation quality assessment employed a comprehensive 100-point scoring framework administered by three independent urological specialists (one professor and two associate professors) with expertise in urological practice, who conducted blinded evaluations of documentation quality across multiple procedural categories. These evaluators were entirely distinct from those involved in initial document development processes, ensuring methodological rigor and evaluation objectivity. The assessment utilized a standardized evaluation instrument specifically designed for urological informed consent documentation, prioritizing patient-centered communication effectiveness and clinical accuracy.

The evaluation framework comprised five equally weighted assessment domains of twenty points each, systematically addressing important dimensions of informed consent documentation quality based on estab-

lished literature and legal-ethical standards (Table 3). The Scientific Content and Accuracy domain assessed alignment with contemporary urological guidelines, diagnostic and treatment process completeness, comprehensive disease definition encompassing etiology and symptomatology, and statistical data accuracy. The Patient Communication and Comprehensibility domain evaluated medical terminology translation effectiveness into patient-accessible language, logical information sequencing, emphasis of critical clinical elements, and overall readability with linguistic fluency.

The Risk, Benefit, and Treatment Information domain analyzed realistic complication and procedural risk presentation, therapeutic benefit articulation, comprehensive surgical procedure explanation, unbiased alternative treatment presentation, and non-treatment consequence discussion. The Pre- and Post-operative Process Information domain examined perioperative care protocol thoroughness, patient and family instruction clarity, and medication guidance with follow-up requirements. The Structural Organization and Legal-Ethical Compliance domain assessed information organization effectiveness, documentation structure consistency, adherence to patient rights and informed consent standards, and patient privacy protection with clinical autonomy preservation.

These evaluation criteria were established through literature review encompassing informed consent best practices, international bioethics guidelines, and Turkish legal requirements for medical documentation, ensuring alignment with evidence-based standards and regulatory compliance expectations.

Statistical Analysis and Performance Assessment Protocol

The evaluation data underwent statistical analysis employing descriptive and comparative methodologies to assess documentation quality differences across the three generation approaches. Mean scores and standard deviations were calculated for each documentation approach within individual evaluation categories and overall composite scores, enabling systematic comparison of performance metrics across methodological approaches. Statistical significance testing employed independent samples t-tests to identify differences between documentation approaches, with significance levels established at $p<0.05$.

Inter-evaluator consistency was assessed through calculation of variation coefficients, providing insight into evaluator consensus across different documentation approaches. The analysis incorporated assessment based on procedural complexity levels, categorizing interventions into routine procedures with standardized protocols and complex procedures requiring comprehensive risk-benefit discussions, facilitating targeted evaluation of documentation quality across varying clinical scenarios. The analytical framework prioritized clinical significance alongside statistical significance, incorporating effect size calculations through percentage improvements to determine the practical relevance of observed quality differences for clinical implementation and patient care optimization.

Data Management and Quality Assurance Protocols

All evaluation data underwent quality control measures to ensure methodological integrity and reproducibility. Independent verification was conducted through duplicate assessment of randomly selected documents (30% of total documentation) by two additional urological specialists with comparable academic credentials to the primary evaluation panel. Significant scoring variations (>10 points difference) required consensus discussion to establish final scores. The research protocol maintained audit trails documenting all procedural steps, evaluation criteria applications, and decision-making processes to facilitate methodological transparency and enable future replication studies.

RESULTS

Comparative Performance Analysis of Informed Consent Documentation Systems

Three-arm evaluation revealed major performance differentials across documentation methodologies. LuminaConsent achieved superior quality metrics with a mean score of 82.33 points (SD±4.2) versus 78.77 points (SD±6.1) for professional society standards and 57.43 points (SD±3.8) for specialist documentation (Table 4). These findings demonstrate statistically significant improvements of 43.3% over current specialist practices ($p<0.001$) and 4.5% over established professional society standards ($p<0.05$).

The system exhibited superior consistency across procedural categories, achieving scores from 76.67 to 90.00 points for nine procedures, with internal urethrotomy representing the sole outlier at 66.67 points. This standardization distinguished the system from conventional approaches, where quality variability correlated directly with procedural complexity and individual practitioner expertise.

TABLE 4. Evaluation and comparison of informed consent forms

Consent forms	Informed Consent Form of Urology Specialists				Informed Consent Form of the Society of Urological Surgery				Informed Consent Form of LuminaConsent			
	U_1	U_2	U_3	Form Avg.	U_1	U_2	U_3	Form Avg.	U_1	U_2	U_3	Form Avg.
Consent Form 1	75	50	65	63.33	90	70	80	80.00	92	80	70	80.67
Consent Form 2	70	55	60	61.67	85	60	70	71.67	90	70	70	76.67
Consent Form 3	60	55	65	60.00	92	80	90	87.33	95	80	80	85.00
Consent Form 4	65	40	50	51.67	90	80	85	85.00	93	85	80	86.00
Consent Form 5	78	50	60	62.67	88	70	70	76.00	90	75	85	83.33
Consent Form 6	55	50	60	55.00	85	70	75	76.67	92	80	70	80.67
Consent Form 7	55	55	60	56.67	88	75	75	79.33	90	80	85	85.00
Consent Form 8	60	45	50	51.67	91	50	55	65.33	95	50	55	66.67
Consent Form 9	45	50	70	55.00	82	80	85	82.33	88	85	95	89.33
Consent Form 10	55	55	60	56.67	92	80	80	84.00	95	85	90	90.00
Total Avg.				57.43	Total Avg.			78.77	Total Avg.			82.33

Procedural Complexity Stratification and Performance Metrics

Complexity-based analysis revealed systematic performance advantages for the system across all procedural categories (Table 4). For routine procedures (CF1-3), the system achieved 80.78 points versus 79.67 for professional society forms and 61.67 for specialist documentation, representing a 31.0% improvement over specialist practices. Complex interventions (CF4-7) demonstrated the most pronounced differentials, with the system scoring 83.75 points compared to 79.25 for professional society and 54.00 for specialist forms, yielding a 55.1% improvement over current specialist practices. Specialized procedures (CF8-10) achieved 81.33 points versus 77.22 for professional society and 54.44 for specialist documentation.

LuminaConsent demonstrated optimal efficacy in complex interventions, where performance differences reached maximum values, suggesting enhanced utility for procedures requiring comprehensive risk stratification and detailed technical explanation.

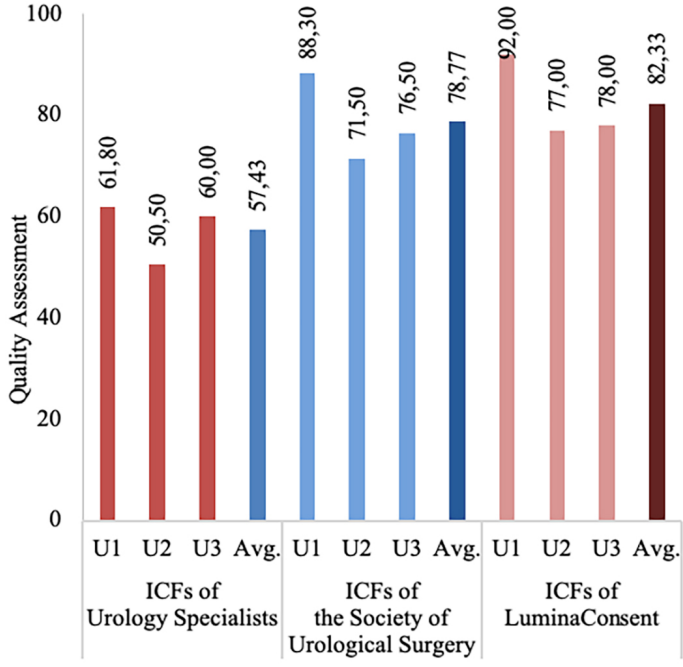

FIGURE 4. Evaluation Scores Comparison of Informed Consent Forms.

ICF: Informed consent form, Avg: Average.

Individual Procedure Analysis and Quality Optimization

Procedure-specific analysis revealed the system's superiority across nine of ten evaluated interventions (Fig. 4, Table 4), with better performance in procedures requiring comprehensive technical explanation and risk stratification. Oncological procedures demonstrated the most substantial improvements, where precise patient communication directly influences therapeutic outcomes.

Radical prostatectomy exemplified this advantage, with the system achieving 86.00 points versus 51.67 points for specialist documentation, representing a 67.0% improvement in this technically complex intervention. Penile prosthesis implantation (89.33 points) and diagnostic cystoscopy (90.00 points) demonstrated strong performance, indicating effective system performance for procedures with well-established technical protocols. Conversely, internal urethrotomy presented unique challenges, achieving 66.67 points and representing the lowest score across all LuminaConsent-generated documentation. This variation indicates that specific procedural characteristics may present distinct requirements for AI-generated documentation, potentially reflecting inherent technical complexity or specialized patient communication needs.

Inter-Evaluator Consistency and Validation Metrics

Inter-evaluator consistency analysis revealed considerable differences in documentation standardization across methodologies. LuminaConsent achieved superior evaluator consensus with assessments ranging from 77.00 to 92.00 points and a variation coefficient of 0.082, indicating quality characteristics that consistently satisfy clinical expectations across diverse professional perspectives.

Professional society documentation demonstrated intermediate consistency (71.50 to 88.30 points, variation coefficient 0.097), while specialist documentation exhibited the greatest variability (variation coefficient 0.143) despite compressed scoring ranges. These findings establish the platform's capacity to generate standardized, quality documentation that consistently achieves professional recognition across diverse urological specialists.

Clinical Effectiveness and Implementation Efficiency

Beyond quantitative performance improvements, LuminaConsent demonstrated significant clinical effectiveness through standardized documentation quality across procedural categories, effectively eliminating the variability inherent in specialist practice patterns. The system achieved consistent quality output independent of procedural complexity, addressing critical limitations in contemporary consent workflows where quality directly correlates with practitioner expertise and time constraints.

Implementation efficiency represented a notable advantage, with LuminaConsent generating comprehensive documentation within 96–180 seconds per form compared to traditional processes requiring multiple days for specialist review of extensive legal documentation and clinical literature. Professional society consensus development necessitates coordinated multi-specialist committee processes spanning several months.

Expert evaluator feedback validated LuminaConsent's clinical utility while identifying optimization opportunities. Evaluators recognized system strengths in material organization and standardization, noting areas for refinement including content filtering precision for procedure-specific approaches and technical detail balance for routine applications. These findings establish that AI-assisted documentation systems can simultaneously enhance quality metrics and delivery efficiency essential for clinical implementation, supporting systematic integration into urological practice workflows while maintaining thoroughness and legal compliance.

DISCUSSION

This investigation establishes AI-driven systems' capacity to achieve superior standardization and quality in urological informed consent documentation. LuminaConsent demonstrated exceptional performance with mean scores of 82.33 points, representing statistically significant improvements of 43.3% over specialist-generated documentation (57.43 points, $p<0.001$) and 4.5% over professional society standards (78.77 points, $p<0.05$). These findings align with emerging evidence demonstrating AI performance advantages in clinical documentation, with Shi et al. [21] showing superior outcomes in accuracy, completeness, and comprehensibility for clinical trial consent generation, while Vaira et al. [22] established ChatGPT-4's significant performance advantages ($p<0.001$) in oral surgery consent documentation. The results demonstrate clinically meaningful advances in patient communication effectiveness, legal compliance, and ethical standards through consistent quality output across procedural complexity categories.

The notable variability in specialist documentation (quality scores ranging from 51.67 to 63.33 points) reveals critical deficiencies in contemporary urological practice that compromise patient safety and clinical standardization. These findings corroborate Decker et al. [23], who demonstrated improved completeness and accuracy in AI-generated surgical documentation compared to surgeon-generated content (2.2 vs 1.6, $p<0.001$). However, this investigation advances beyond conventional AI applications by implementing a specialized retrieval-augmented generation (RAG)

framework operating exclusively through curated clinical knowledge bases rather than general-purpose language models. Unlike studies utilizing direct queries to ChatGPT or similar platforms, LuminaConsent ensures clinical accuracy through vectorized pre-approved medical literature, eliminating inaccuracies inherent in general AI knowledge databases. This systematic standardization eliminates practitioner-dependent variations while achieving remarkable temporal efficiency—generating comprehensive documentation within 96–180 seconds versus multiple days required for traditional specialist review.

This specialized approach aligns with recent domain-specific RAG implementations in clinical practice, exemplified by Ge et al. [18], who developed LiVersa, a liver disease-specific LLM using RAG methodology with AASLD clinical guidelines for hepatology question answering. While both systems employ vectorized clinical document embeddings and retrieval mechanisms for specialized medical knowledge, LuminaConsent advances beyond clinical question answering to address the specific workflow challenge of informed consent documentation generation. The demonstrated bilingual processing capabilities represent significant advancement beyond predominantly English-language AI healthcare applications, addressing healthcare equity gaps for diverse patient populations. LuminaConsent achieved the most significant improvements in clinical domains where current practice demonstrated the greatest deficiencies, with the 67.0% improvement over specialist documentation for radical prostatectomy procedures demonstrating particular value in high-stakes scenarios where comprehensive patient understanding critically determines therapeutic outcomes.

Nevertheless, methodological limitations constrain the interpretation and generalizability of these findings. The evaluation framework relied primarily on expert clinical assessment rather than incorporating patient-reported outcomes or comprehension measures, potentially limiting the capture of the fundamental objective—ensuring authentic patient understanding and autonomous decision-making capacity. Contemporary evidence demonstrates that AI systems require integration with human clinical expertise rather than autonomous implementation. Brock et al. [24] established that although ChatGPT-generated information demonstrated quality compared to patient information leaflets ($p=0.014$), effective approaches involve collaborative utilization of AI-generated and human-developed materials. Similarly, Cosma et al. [25] confirmed that AI-supported CFs enhance healthcare communication effectiveness when combined with human knowledge and clinical experience. Building upon Smith et al. [26], who reduced consent interview duration from 76 to 44 minutes while maintaining 96% comprehension rates, specialty-specific adaptations could systematically extend standardized AI-assisted documentation benefits across healthcare systems.

The RAG architecture, while ensuring clinical accuracy through vectorized pre-approved medical literature, remains constrained by document corpus scope and currency limitations. This approach may inadvertently restrict the system's capacity to incorporate emerging clinical evidence or address novel procedural variations beyond its training dataset. The singular instance of lower performance (internal urethrotomy, scoring 66.67 points) exemplifies system limitations when addressing highly specialized procedures requiring nuanced clinical judgment beyond standardized protocols. Furthermore, multilingual processing requirements and cultural adaptation complexities may compromise system performance across diverse patient populations and institutional settings, necessitating extensive validation across geographic regions and medical specialties before establishing universal applicability.

The empirical evidence supports the systematic integration of AI-assisted informed consent systems into routine clinical practice, particularly within surgical specialties requiring effective communication of complex procedural information. However, successful implementation necessitates recognizing AI systems as augmentation tools rather than replacements for human clinical judgment and patient communication skills. Healthcare organizations must establish robust protocols ensuring AI-generated content undergoes systematic clinical review, incorporates institutional considerations, and maintains flexibility for individualized modifications based on patient-specific circumstances and procedural complexity.

Future research must prioritize patient-centered outcome measures and multi-specialty validation studies to provide comprehensive stakeholder assessment. Longitudinal investigations examining patient comprehension rates, satisfaction metrics, and clinical outcome correlations will establish evidence regarding practical benefits and risks associated with AI-driven documentation systems across diverse healthcare contexts.

The standardization achieved through AI-assisted documentation demonstrates significant potential for reducing practice variations, improving patient outcomes, and enhancing healthcare quality. This advancement facilitates evolution toward more consistent, evidence-based, and patient-centered care delivery models, provided implementation frameworks maintain appropriate emphasis on human oversight, clinical judgment, and individualized patient care considerations. Unlike LiVersa's focus on clinical vignette responses, LuminaConsent provides comprehensive documentation standardization with quantified workflow efficiency improvements and systematic quality enhancement across procedural complexity categories, establishing precedents for evidence-based AI integration in specialized medical domains.

Conclusion

This investigation demonstrates that AI can substantially enhance urological informed consent documentation quality while establishing a methodological framework adaptable to other surgical specialties. LuminaConsent represents both a technological advancement in medical documentation and a meaningful response to fundamental ethical challenges in contemporary informed consent processes. Through consistent, comprehensive, and patient-centered documentation generation, AI-driven systems contribute to enhanced patient autonomy and improved ethical standards in healthcare delivery.

The successful deployment of RAG architecture establishes important precedents for evidence-based AI integration in healthcare informatics, demonstrating that specialized clinical knowledge bases effectively address reliability concerns while maintaining rigorous quality standards. The bilingual processing capabilities and culturally adapted content generation represent significant advancement beyond predominantly English-language AI healthcare applications, extending quality standardization benefits to diverse patient populations and addressing critical healthcare equity gaps in multilingual healthcare environments.

Although this investigation provides evidence for AI-assisted informed consent systems, future research should incorporate patient-reported outcomes and multi-specialty validation studies to provide comprehensive stakeholder assessment. Subsequent investigations should focus on expanding system capabilities to address documentation needs across diverse surgical specialties while refining language processing capabilities to accommodate specialized terminology and procedural requirements within various medical disciplines.

The broader implementation of AI-driven systems presents substantial potential for systematically addressing ethical challenges in informed consent processes across healthcare institutions. For healthcare decision-makers considering implementation, AI-assisted documentation contributes to reducing practice variations, improving patient outcomes, and enhancing healthcare quality while facilitating the transition toward more consistent, evidence-based, and patient-centered care delivery models.

Ethics Committee Approval: This study does not require ethics committee approval as it does not involve any procedures on human or animal subjects.

Informed Consent: Written informed consents were obtained from patients who participated in this study.

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Appendix 1. Supplementary materials

All informed consent forms (n=30) evaluated in this study can be accessed from the following sources:

1. Urology Specialists Ten consent forms by independent urologists:

https://drive.google.com/file/d/10SYyrKLs5aECd7mTrLD6AF3_VTY93_ea/view?usp=drive_link

2. Society of Urological Surgery Ten standardized forms used in Turkish healthcare:

https://drive.google.com/file/d/10RGD55njcoVSdUkILWhFWWOawq2cCOSQ/view?usp=drive_link

3. LuminaConsent Ten AI-generated consent forms:

https://drive.google.com/file/d/10OVNgU7ZxOVSdhu8DAhbsOuYTyCuaJtC/view?usp=drive_link

All repositories contain identical urological procedures for direct comparison. Contact the corresponding author for access inquiries. These materials support the study's validation and comparative analysis models.