



Systematic Literature Review: Research Ethics in Artificial Intelligence Development for Breast Cancer Histopathology Detection – Data Privacy, Informed Consent, and Accountability

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ABSTRACT

Breast cancer remains a leading cause of mortality in women worldwide. The development of Artificial Intelligence (AI) models, particularly Convolutional Neural Networks (CNN) and adaptive thresholding methods, has demonstrated significant potential in analyzing breast cancer histopathology images. However, developing these AI models requires large datasets containing sensitive patient data, thereby creating comprehensive research ethics challenges related to data privacy protection, informed consent implementation, and accountability clarity. This systematic literature review aims to identify current ethical practices, ethical challenges, and best recommendations regarding data privacy protection, informed consent implementation, and research accountability in AI model development for breast cancer histopathology detection. Study analysis encompassed identification, selection, eligibility assessment, and results synthesis stages using biomedical ethics frameworks (Belmont Principles and Four Principles Approach). The study identified three significant ethical gaps in current research practices: (1) data privacy protection remains suboptimal due to limited de-identification techniques and privacy-preserving methods; (2) informed consent implementation is still restricted in terms of comprehensiveness, comprehensibility, and voluntariness for AI-based research; and (3) institutional accountability remains unclear regarding responsibility allocation and oversight mechanisms. This systematic literature review concludes that a structured ethical framework and clear implementation guidelines are essential to ensure that AI research in breast cancer histopathology adheres to biomedical ethics principles while supporting sustainable and beneficial technological innovation for patients.

Keywords: Artificial Intelligence; Breast Cancer Histopathology; Research Ethics; Data Privacy; Informed Consent

1. Introduction

Breast cancer remains the leading cause of death among women worldwide, necessitating early detection strategies and accurate diagnosis to improve patient outcomes [1], [2]. Significant advances in Artificial Intelligence (AI), particularly through the application of deep learning and Convolutional Neural Networks (CNN), have demonstrated sensitivity rates exceeding 94.5% in detecting malignancy in histopathology images, thereby reducing analysis time and supporting pathologists' clinical decision-making [3], [4], [5], [9], [10], [11]. However, this technically sophisticated implementation must be

balanced with comprehensive ethical considerations encompassing data privacy protection, meaningful informed consent, and clear institutional accountability frameworks [6], [12], [13].

The development of AI models for breast cancer histopathology detection requires access to large datasets containing histopathology images linked to sensitive patient data, creating comprehensive research ethical challenges. Previous research has identified three primary categories of bias in medical AI—data bias, development bias, and interaction bias—which can result in diagnostic and treatment planning inequities [14], [15]. Specifically, this systematic literature review is designed to address three interrelated research questions in identifying ethical practices, ethical gaps, and best recommendations:

RQ1: *What are the current practices, standards, and implementations related to data privacy protection in AI research for breast cancer histopathology detection?*

RQ2: *How are informed consent processes designed, implemented, and evaluated in AI research for breast cancer histopathology, and what gaps exist in ensuring comprehensiveness, comprehensibility, and voluntariness within the context of AI-based research?*

RQ3: *Who is responsible, how is accountability structured, and what mechanisms exist to ensure that AI systems are well-managed in breast cancer histopathology research, and what are the deficiencies in institutional oversight and stakeholder accountability?*

The comprehensive examination of ethical dimensions, particularly data privacy protection, meaningful informed consent implementation, and clear accountability frameworks, remains limited in existing literature. Although previous research has examined the technical advances and clinical applications of AI in breast cancer diagnosis, existing literature systematically underrepresents technology-specific attributes and digital risks such as data reidentification and security breaches [16]. The integration of explicit ethical-by-design principles in the development of AI for histopathology remains an emerging concern, yet remains largely unaddressed systematically.

Significant implementation gaps persist between ethical principles and real-world practice: governance mechanisms for healthcare AI continue to evolve, interdisciplinary collaboration among developers, clinicians, ethicists, and patient advocates remains limited, and regulatory processes are largely post-hoc in nature [17], [18], [19]. Ethical frameworks such as SHIFT and Multi-Scale Ethics have been proposed to address these challenges, emphasizing the importance of transparency, fairness, inclusiveness, and human-centered design in healthcare AI implementation [20]. Understanding current ethical practices, identifying significant gaps, and synthesizing evidence-based recommendations constitute critical steps toward developing a comprehensive ethical framework that balances technological innovation with robust protection of patient rights and welfare. Therefore, this systematic literature review aims to synthesize evidence regarding research ethics in the development of AI for breast cancer histopathology detection, with specific focus on three critical ethical dimensions: data privacy protection, informed consent implementation, and institutional accountability. The findings will contribute to the development of a structured ethical framework and implementation guidelines that ensure breast cancer AI research adheres to established principles of biomedical ethics while supporting sustained technological innovation for patient benefit.

2. Method

The diagram presented illustrates a comprehensive systematic literature review (SLR) framework specifically designed to assess research ethics dimensions in artificial intelligence development for breast cancer histopathology detection [21][22][23]. The framework employs a hierarchical, cascading structure that systematically narrows the scope from broad to specific ethical focus areas, beginning with a Systematic Literature Review as the overarching methodology, establishing the rigorous, evidence-based approach for synthesizing existing literature on the research topic. The review then focuses on AI Development for Breast Cancer Histopathology Detection, clearly demarcating the specific clinical application and technological context within which ethical concerns are examined. At this critical juncture, the framework branches into Research Ethics Assessment, which serves as the primary analytical lens to evaluate the ethical dimensions, principles, and considerations embedded

within AI development research for breast cancer detection [24][25]. Subsequently, the framework branches into three distinct but interrelated ethical pillars that represent the core dimensions of ethical assessment. Data Privacy addresses data protection mechanisms, de-identification strategies, secure data storage and sharing protocols, and compliance with privacy regulations (GDPR, HIPAA, etc.) in AI research involving sensitive patient histopathology images and associated clinical data [26][27][28]. Informed Consent examines consent processes, including design and implementation of meaningful informed consent frameworks [29], comprehensiveness of disclosed information, comprehensibility for research participants [30][31], and voluntariness in data contribution for AI model training and validation [32]. Accountability investigates institutional governance structures, responsibility attribution among stakeholders (researchers, institutions, funding agencies), oversight mechanisms, regulatory compliance, and institutional review processes ensuring responsible AI development and deployment.

This framework represents an integrated approach, recognizing that effective research ethics in AI healthcare applications cannot be achieved through isolated consideration of individual dimensions. Rather, data privacy protections must operate in conjunction with transparent informed consent processes, and both must function within robust accountability structures. The convergent nature of the three branches symbolizes their interdependence and the necessity of comprehensive, multidimensional ethical oversight in AI development for medical applications. The framework effectively operationalizes the research questions posed in the systematic literature review RQ1 (data privacy practices and protections), RQ2 (informed consent design and implementation), and RQ3 (accountability mechanisms and institutional responsibility) thereby providing a structured methodology for evidence synthesis on research ethics in AI-driven breast cancer histopathology detection. This hierarchical structure ensures that the review maintains methodological rigor while addressing the multifaceted ethical complexities inherent in AI healthcare research, ultimately contributing to the development of comprehensive ethical frameworks and implementation guidelines for responsible AI innovation in oncology and digital pathology. at a clearer stage can be seen in Figure 1.

SLR - Research Ethics in AI Development for Breast Cancer Histopathology Detection

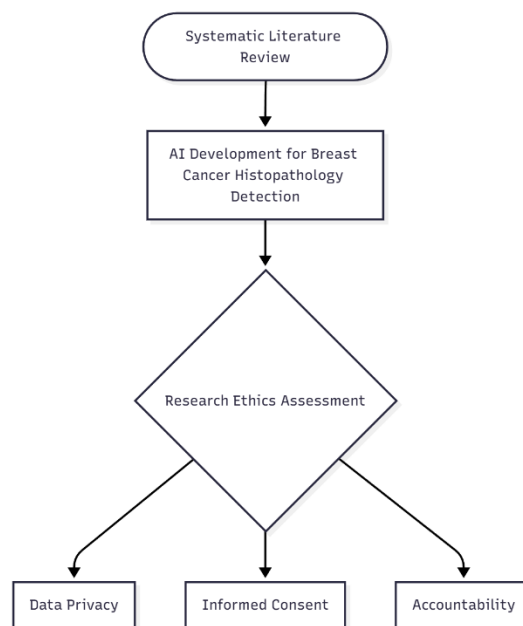


Fig .1. Research Ethics Framework for AI in Breast Cancer Histopathology Detection

The data collection stage was conducted by searching for scholarly articles published between 2022 and 2025 from international databases such as ScienceDirect, SpringerLink, IEEE Xplore, and Scopus. The search strategy focused on peer-reviewed articles that address artificial intelligence development, research ethics, and clinical applications in breast cancer histopathology. Boolean operators and controlled terminology were used to identify studies examining three ethical pillars: Data Privacy (de-identification, GDPR/HIPAA compliance, secure data sharing), Informed Consent (consent processes, comprehensibility, voluntariness), and Accountability (institutional governance, regulatory oversight). The inclusion criteria required studies to address research ethics in AI development for breast cancer medical imaging. The exclusion criteria eliminated studies lacking ethical analysis, those focusing solely on technical metrics, or those published before 2022.

Tabel 1. Search strings used in this study

Code used	Formula used in this study for search strings
SS-1	"Artificial Intelligence" OR "Machine Learning" OR "Deep Learning" OR "Neural Network" OR "AI Algorithm" "Research Ethics" OR "Ethical"
SS-2	Framework" OR "Ethical Consideration" OR "Ethics Assessment" OR "Ethical Principle"
SS-3	"Data Privacy" OR "Data Protection" OR "De-identification" OR "GDPR" OR "HIPAA" OR "Informed Consent" OR "Patient Consent" OR "Accountability" OR "Institutional Governance" OR "Regulatory Compliance"
SS-4	"Breast Cancer" OR "Histopathology" OR "Histopathological Image" OR "Digital Pathology" OR "Pathology Image Analysis"
SS-5	"Medical Imaging" OR "Clinical Application" OR "Healthcare System" OR "Medical Diagnosis" OR "AI in Medicine" OR "AI in Healthcare"
SS	SS-1 AND SS-2 AND SS-3 AND SS-4 AND SS-5

The search string formulation in this study was designed to encompass all major aspects of the research topic under investigation. **SS-1** focuses on Artificial Intelligence and Machine Learning as core techniques in histopathological medical image analysis, particularly those involving algorithms such as Deep Learning and Neural Networks for breast cancer classification and detection. **SS-2** is directed toward the dimensions of research ethics, including ethical frameworks, ethical principles, and ethical assessments that play a crucial role in responsible AI development. **SS-3** targets three fundamental pillars of research ethics: data privacy (de-identification, GDPR, HIPAA), informed consent (patient consent, comprehensibility), and accountability (institutional governance, regulatory compliance). **SS-4** targets the application domain of breast cancer with emphasis on digital histopathology as the primary source of tissue-based diagnostic data. Meanwhile, **SS-5** expands the scope of the search by considering aspects of clinical integration, medical implementation, and AI application in real-world medical diagnostic systems. These five search strings collectively ensure that the collected literature encompasses technical AI approaches, dimensions of research ethics, and practical implementation aspects in the medical field. The search for relevant articles in this study was limited to publications that have undergone a peer-review process, been published in reputable academic journals, and possess full-text availability in English. Articles that provided only English-language abstracts without complete full-text were excluded from the analysis. After extracting metadata from publication databases, the titles, abstracts, and full texts of articles were subsequently screened manually using two sets of assessment criteria in table 2.

Tabel 2. Screening criteria used to select papers

Title and abstract assessment criteria	Full text assessment criteria
- Only articles that have gone through a peer-review process and are published in reputable scientific journals. - Only articles written in English and available in full text form. - The aims, findings, and/or implications of the research relate to research ethics, data privacy, informed consent, accountability, or the application of artificial intelligence in breast cancer histopathology detection. - The research context is related to the fields of biomedicine, digital pathology, or histopathology tissue pattern recognition. - Articles that only touched on the topic of AI in general without histopathological context were not included.	- The focus of the article is the application of research ethics frameworks in AI development for breast cancer histopathology detection. - The article comprehensively explains the implementation of data privacy protocols, including de-identification, GDPR/HIPAA compliance, and secure data-sharing strategies. - The study addresses informed consent mechanisms, patient consent processes, comprehensibility of information disclosure, and voluntariness in research data contribution. - The article describes accountability structures, institutional governance, attribution of responsibility, and regulatory oversight in the development and implementation of medical AI. - Studies that did not provide comprehensive ethical analysis or descriptive evaluation results regarding privacy, consent, and accountability were excluded from the analysis.

3. Results and Discussion

A systematic literature search was conducted across four major academic databases: ScienceDirect, IEEE Xplore, Springer, and Scopus. The automated search strategy employed relevant keywords and Boolean operators to identify studies related to ethical considerations in the development of AI for breast cancer histopathology detection. The automated search yielded a total of 1,042 articles across all databases. ScienceDirect produced the highest number of results with 420 articles, followed by IEEE Xplore with 320 articles, Scopus with 175 articles, and Springer with 127 articles. After removing duplicates and applying initial screening criteria, 152 articles from Q1 and Q2 journals were identified as potentially relevant to the research questions. Through title and abstract review conducted by two independent reviewers, 52 articles met the inclusion criteria and were selected for full-text analysis. The breakdown of selected articles by database source is as follows: ScienceDirect yielded 16 articles, IEEE Xplore yielded 14 articles, Springer yielded 10 articles, and Scopus yielded 12 articles. This distribution demonstrates that databases with the largest initial search results do not necessarily produce a proportionally higher number of high-quality articles meeting stringent inclusion criteria, thereby emphasizing the importance of systematic and meticulous screening procedures.

Tabel 3. Data on articles generated to follow up on SLR articles.

No.	Source	Automated Search	Jurnal Q1 and Q2	Related Abstract
1	ScienceDirect	420	35	16
2	IEEE Xplore	320	30	14
3	Springer	127	15	10
4	Scopus	175	72	12

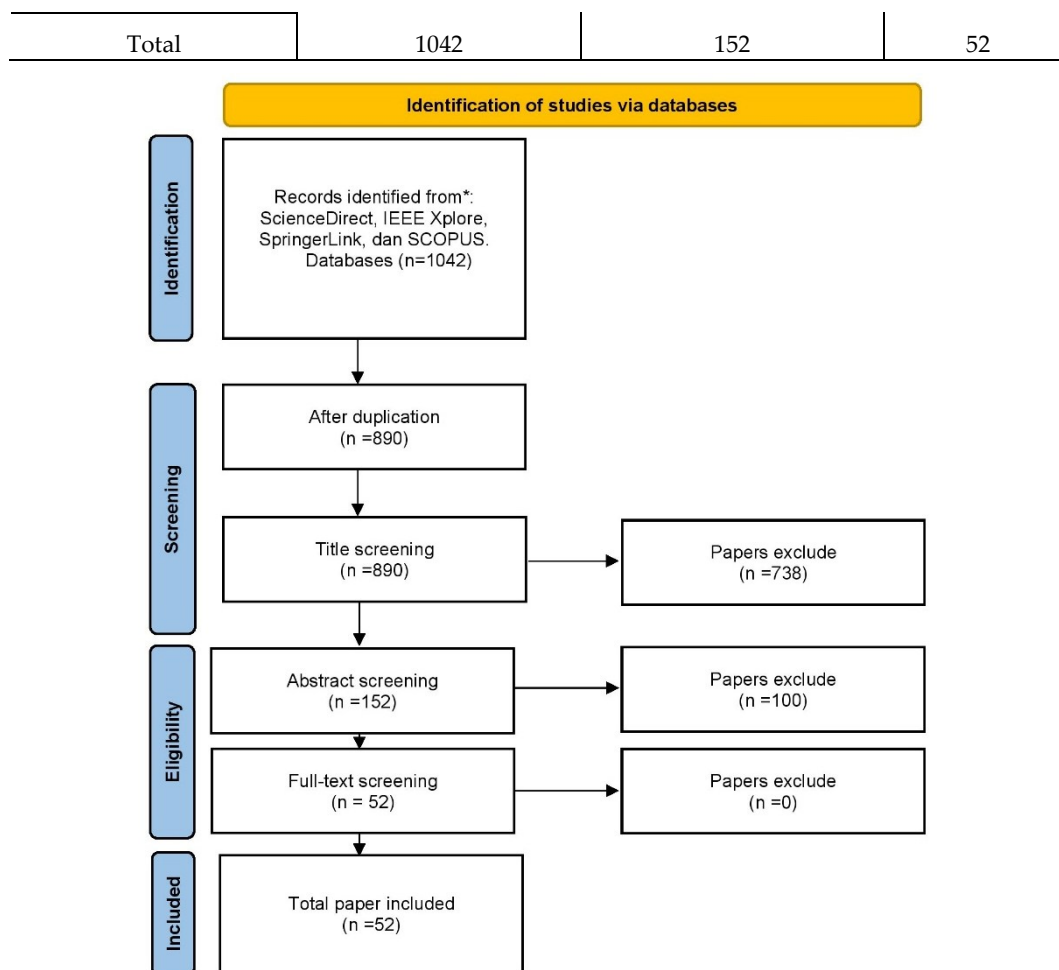


Fig. 2. Research Ethics Framework for AI in Breast Cancer Histopathology Detection

Figure 2. The study selection process followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) framework to ensure systematic and transparent identification of eligible studies. The identification phase retrieved 1,042 records from four academic databases, providing a comprehensive foundation for the review. During the screening phase, duplicate removal reduced the dataset to 890 unique records, followed by title-based screening that excluded 738 studies, resulting in 152 potentially relevant records. The eligibility phase involved two sequential steps: abstract screening eliminated 100 records lacking sufficient detail on the three targeted ethical dimensions (data privacy, informed consent, and institutional accountability), while full-text screening retained all remaining 52 articles without further exclusions. The progressive refinement from 1,042 initial records to 52 final articles demonstrates the PRISMA approach of applying increasingly stringent selection criteria at successive stages. The attrition pattern 14.6% at duplication removal, 82.9% at title screening, and 65.8% at abstract screening reflects the systematic application of predefined inclusion and exclusion criteria, with title screening serving as the primary filter for obvious irrelevance and abstract screening focused on substantive assessment of ethical content. The zero-exclusion rate at full-text review validates the effectiveness of earlier PRISMA screening stages in accurately identifying studies meeting inclusion standards, ensuring that the final 52 articles represent a high-quality, rigorously selected evidence base for addressing the research questions on ethical considerations in AI for breast cancer histopathology.

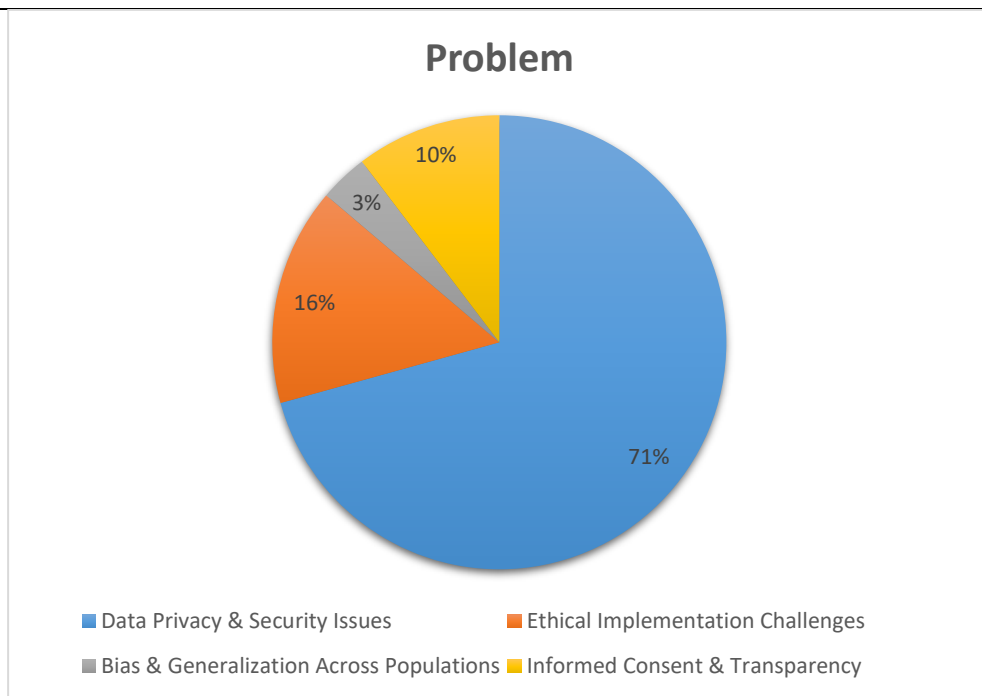


Fig. 3. Research Ethics in Artificial Intelligence Development for Breast Cancer Histopathology

Figure 3. illustrates the distribution of ethical challenges in the development of artificial intelligence for breast cancer histopathology detection. Data Privacy & Security Issues constitute the dominant concern, accounting for 71% of the identified problems, which reflects the primary focus on protecting patient data and ensuring the security of AI systems. Ethical Implementation Challenges represent the second largest category at 16%, highlighting the complexities involved in translating ethical principles into practical applications. Informed Consent & Transparency accounts for 10% of the issues, underscoring the critical importance of transparency in communicating AI utilization to stakeholders and patients. Conversely, Bias & Generalization Across Populations comprises the smallest proportion at 3%, although this dimension remains essential for ensuring the fairness and accuracy of AI systems across diverse patient populations. Overall, the chart demonstrates that data privacy and system security emerge as the paramount ethical concerns in the responsible implementation of AI within histopathology, followed by the necessity for ethical implementation practices and transparent communication with relevant stakeholders and end-users.

Ref	Title (Author, Year)	Model/Approach	Strengths	Limitations
33	Emerging research trends in artificial intelligence for cancer diagnostic systems (Abbas et al., 2024)	Machine Learning, Deep Learning, Federated Learning, Explainable AI	Comprehensive overview of XAI techniques (LIME, GRAD-CAM, SHAP); integration of multi-data types (imaging, genomics, clinical data); accuracy up to 99.98% (CNN models)	Model interpretability remains challenging; dataset imbalance issues; ethical considerations insufficiently addressed
34	Recent Applications of Explainable AI (XAI): A Systematic	XAI techniques (LIME, SHAP, Grad-CAM, Saliency Maps)	Strong focus on health applications; improved cancer diagnosis clarity; enhanced model transparency	Trade-off between interpretability and accuracy; XAI methods lack

	Review (Saarela et al., 2024)			standardization; limited domain-specific evaluation
35	Ethical and Bias Considerations in AI-ML within pathology and medical domain (Hanna et al., 2025)	Ethical framework, bias mitigation strategies	Comprehensive ethical analysis; identifies three bias categories (data, development, interaction); domain-specific focus	Implementation gap between principles and practice; absence of concrete deployment guidelines
36	The Role of AI in Hospitals and Clinics: Transforming Clinical Decision-Making (Varnosfaderani et al., 2024)	AI clinical integration, operational optimization	Holistic view of AI applications; excellence in medical image analysis; personalized medicine approach	Adoption barriers insufficiently addressed; privacy concerns mentioned but not thoroughly analyzed
37	Bridging ethical gaps in digital health research: An analysis of informed consent forms in technology-driven studies (Researchers et al., 2025)	Informed Consent Framework with 63 attributes and 93 subattributes	NIH-aligned framework; comprehensive digital health consent model; identifies missing technology-specific elements	Only 63% of attributes present in institutional ICFs; post-guideline compliance remains limited; significant institutional variation
38	FUTURE-AI: International Consensus Guideline for Trustworthy AI in Healthcare (Lekadir et al., 2025)	Trustworthy AI framework (transparency, accountability, privacy, fairness)	Evidence-based guideline; international consensus achieved; multi-stakeholder approach; extensively cited (276 times)	High implementation complexity; regulatory alignment challenges; resource-intensive requirements
39	Artificial intelligence for breast cancer: Implications for disease screening and diagnosis (AlSamhori et al., 2024)	AI-based breast cancer detection and diagnosis systems	Excellent pattern recognition; accurate risk assessment; enables personalized treatment approaches	Remains a clinical support tool rather than a replacement for expert judgment; clinician expertise remains essential
40	Artificial intelligence for cancer screening and surveillance (Gentile et al., 2024)	Risk prediction models for breast cancer screening	Integration of multiple AI model types; comprehensive screening approach	Limited real-world deployment data; generalization issues across different populations

41	Algorithmic bias in public health AI: A silent threat to equity (Joseph et al., 2025)	Bias recognition framework for public health applications	Identifies bias in low-resource contexts; equity-focused analysis; practical implications for underserved populations	Gap between bias identification and mitigation strategies; scalability of implementation remains uncertain
42	Bias recognition and mitigation strategies in artificial intelligence (Hasanzadeh et al., 2025)	Comprehensive bias mitigation review and framework	Stakeholder responsibility framework clearly defined; detailed mitigation strategies; extensively cited (98 times)	Bias in training data persists; fairness metrics lack universality
43	Fairness in AI for healthcare (Carey et al., 2024)	Fairness frameworks and bias solutions	Ongoing research synthesis with future-oriented perspective; solution-focused approach	Practical implementation barriers; significant resource constraints
44	Emerging algorithmic bias: Fairness drift as the next dimension (Davis et al., 2025)	Fairness drift monitoring framework (11-year longitudinal study)	Longitudinal tracking of fairness; real-world population data; highlights importance of model maintenance	Model maintenance complexity; sustainability challenges identified; long-term monitoring infrastructure required
45	Bias in artificial intelligence for medical imaging (Koçak et al., 2025)	AI bias mitigation in medical imaging applications	Comprehensive bias review (158 citations); demonstrates that AI can mitigate human cognitive bias but creates new algorithmic biases	Ongoing AI bias tendency; detection mechanisms remain limited
46	Deep learning approaches for breast cancer detection in histopathology images (CV Priya et al., 2024)	Convolutional Neural Networks, transfer learning for breast cancer detection	Accuracy of 93–94%; effective automated classification; histopathology-specific application; DenseNet transfer learning performs well	Low interpretability; dataset scarcity issues; limited clinical validation
47	Breast Cancer Detection Based on Simplified Deep Learning Technique with Histopathological Images (Toma et al., 2023)	Simplified deep learning model applied to BreKHis database	Simplified model facilitates implementation; achieves 97% accuracy; computationally efficient	Limited generalizability; reliance on single dataset; unclear real-world application potential
48	Histopathological image-based breast cancer diagnosis	Advanced deep learning techniques for	Enables early detection capability; reliable automated diagnostic	Still under development phase; clinical

	using automated deep learning (Thatha et al., 2025)	cancer subtype classification	system; accurate cancer subtype classification	adoption timeline remains unclear
49	histopathology-based breast cancer prediction using deep learning methods (Ramamoorthy et al., 2024)	Deep learning for healthcare applications in breast cancer prediction	Patient-centered approach; improved diagnostic accuracy; demonstrated clinical utility	Healthcare system integration challenges; high resource requirements
50	Attention-Based Deep Learning Approach for Breast Cancer Detection (Aldakhil et al., 2024)	Attention mechanism combined with deep learning architecture	Improved accuracy and computational efficiency; better interpretability through attention mechanisms; demonstrated diagnostic potential	Attention mechanism adds implementation complexity; remains an emerging approach
51	Transfer learning with self-learning algorithm for breast cancer classification (Abdulaal et al., 2024)	Transfer learning combined with novel self-learning algorithm	Transfer learning effectiveness confirmed; innovative self-learning approach; high classification accuracy achieved	Novel algorithm requires further validation; generalization capabilities uncertain
52	Deep Learning for Early Detection of Invasive Ductal Carcinoma (Chilumukuru et al., 2025)	DenseNet-based transfer learning applied to histopathology images	Achieves >94% accuracy; improved diagnostic performance; transfer learning demonstrates effectiveness	Limited to invasive ductal carcinoma; sample size considerations; clinical trials needed for validation
53	Health Equity and Ethical Considerations in Using Artificial Intelligence in Public Health and Medicine (Dankwa-Mullan I., 2024)	Ethical integration framework addressing bias mitigation, data governance, informed consent, and community engagement	• Concrete strategies for five categories of bias mitigation	Health Equity and Ethical Considerations in Using Artificial Intelligence in Public Health and Medicine (Dankwa-Mullan I., 2024)
54	The Role of Artificial Intelligence in Clinical Practice (S. A. Alowais et al., 2023)	Empirical study of AI in clinical decision-making emphasizing patient autonomy and informed consent	• Evidence-based findings across multiple clinical domains	The Role of Artificial Intelligence in Clinical Practice (S. A. Alowais et al., 2023)

4. Conclusion

Although artificial intelligence technology demonstrates remarkable diagnostic potential for breast cancer histopathology detection with accuracy exceeding 94%, this study identifies three critical ethical gaps: suboptimal data privacy protection, incomplete informed consent implementation, and unclear institutional accountability. To address these gaps, a structured ethical framework is required that encompasses the implementation of privacy-preserving techniques, development of standardized informed consent procedures, establishment of transparent accountability mechanisms, and continuous monitoring for algorithmic bias. Future research should prioritize longitudinal ethical compliance studies, investigation of implementation science, patient and community engagement research, validation of algorithmic fairness across diverse populations, and development of harmonized international regulatory guidelines. Through this comprehensive strategy, artificial intelligence innovation in breast cancer histopathology detection can proceed ethically, equitably, and sustainably while delivering optimal benefits to patients.

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