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Artificial Intelligence in Diagnostic Pathology: A Comprehensive Review of Current Applications and Future Prospects

Belukurichi Sadasivam Sangeetha[1], Suriakumar J[2*], T. Murugalakshmi[3], Devi J[4], R. Akila[5]

[1]Professor, Department of Pathology, Chettinad Hospital and Research Institute, Chettinad, Academy of Research Education, Kelambakkam, Tamil Nadu, India
[2]Associate Professor, Department of Microbiology, Government Medical College, Dindigul, Tamil Nadu, India
[3]Assistant Professor, Department of Pharmacology, Government Medical College, Dindigul, Tamil Nadu, India
[4]Associate Professor, Department of Pathology, Government Vellore Medical College and Hospital, Vellore, Tamil Nadu, India
[5]Associate Professor, Department of Pathology, Government Medical College Nagapattinam, Tamil Nadu, India

*Corresponding Author: Dr. J. Suriakumar, M.D. Email: suryjay@gmail.com

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Abstract: Artificial intelligence (AI) is transforming diagnostic pathology by improving the accuracy, efficiency, and repeatability of histopathological examinations. AI systems can analyze high-resolution whole slide images (WSIs) using machine learning (ML) and deep learning (DL) algorithms to diagnose malignancies, classify tissue types, grade cancers, and quantify biomarkers with accuracy comparable to expert pathologists. These technologies are very useful in cancer diagnosis, such as breast, prostate, and lung malignancies, where they help identify tumor characteristics, mitotic activity, and lymph node metastases. Furthermore, AI is being utilized to predict prognosis, evaluate therapy response, and detect infectious pathogens in tissue samples.AI integration into digital pathology operations has numerous benefits, including faster diagnostic turnaround times, increased consistency, and support for remote consultation and telepathology. However, issues persist in terms of data quality, model generalization across populations and institutions, and the need for rigorous clinical validation. Regulatory permissions and ethical considerations such as data protection, algorithm transparency, and medico-legal accountability are also required for safe deployment. This review presents a comprehensive examination of existing AI applications in pathology, investigates the technology that enables this transition, and analyzes future possibilities. Understanding AI's function is critical for creating dependable, egalitarian, and successful diagnostic tools in contemporary pathology practice.
Keywords: Chronic Otitis Media, Pure Tone Audiometry, Ossicular Chain, Hearing Loss, Air-Bone Gap.

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1. INTRODUCTION

Diagnostic pathology is a core medical study that provides critical insights into disease diagnosis, prognosis, and therapeutic administration [1]. It entails microscopic inspection of tissue and cellular specimens to detect anomalies, diagnose illnesses, and inform clinical decisions [2]. Traditionally, this has been a highly laborious and subjective process, with experienced pathologists interpreting morphological patterns and traits [3]. However, in the current day, the sector is confronted with various obstacles, including increased caseloads, increasing pathological complexity, expanding demand for subspecialty competence, and a global training scarcity [4].One of the most significant advancements in solving these difficulties is the use of artificial intelligence (AI), namely machine learning (ML) and deep learning (DL) [5]. These technologies have the potential to improve diagnostic accuracy, standardize interpretations, increase efficiency, and minimize diagnostic errors [6]. AI systems, particularly those based on convolutional neural networks (CNNs), have shown the ability to recognize complex patterns in whole slide images (WSIs), detect malignancies, quantify biomarkers, and even predict patient outcomes based only on histological traits [7].Advances in processing power, cloud storage, and the digitalization of histopathology slides have allowed digital pathology and AI technologies to converge [8]. Whole Slide Imaging (WSI) has transformed traditional glass slides into high-resolution digital images that can be computationally evaluated [9]. This digitalization not only enables remote diagnosis and telepathology, but it also supplies large image datasets needed to train and verify AI models [10].The first AI applications in pathology focused mostly on oncologic illnesses, where tissue architecture and cellular morphology play an important role in diagnosis [11]. AI models have demonstrated exceptional ability in detecting breast, prostate, colorectal, and lung cancers, with diagnosis accuracy frequently matching or exceeding that of human pathologists in controlled environments [12]. Furthermore, AI tools have been created to help with tumor grading, mitotic counting, margin assessment, and lymph node metastasis detection [13]. Beyond cancer, AI has been used to detect infectious pathogens (such as *Helicobacter pylori* and *Mycobacterium tuberculosis*), assess inflammatory states, and quantify immunohistochemistry (IHC) markers [14 & 15].Despite the promise, there are still significant impediments to routine clinical implementation. These include issues about model generalizability across institutions, inter-laboratory variability in staining and scanning techniques, a lack of big annotated datasets, and the "black-box" nature of deep learning models [16 & 17]. Furthermore, ethical concerns such as data privacy, accountability, and transparency must be addressed in order to foster trust among pathologists and assure safe deployment [18].This review aims to provide a complete overview of AI's involvement in diagnostic pathology. We begin by looking at the technological foundations that allow AI to perform effectively in this domain. This contains a review of machine learning principles, digital slide acquisition, and data annotation methods. We then look at current AI applications for various diagnostic tasks and illness categories. We then discuss the crucial features of clinical validation, regulatory approval, and integration into existing procedures. Finally, we discuss the future prospects, current research trends, and problems that must be overcome in order to fully realize AI's potential in pathology.

2. TECHNOLOGICAL FOUNDATIONS OF AI IN PATHOLOGY

The successful integration of Artificial Intelligence (AI) into diagnostic pathology is based on numerous interconnected technological pillars. These include breakthroughs in machine learning techniques, digital pathology infrastructure, and the availability of high-quality annotated datasets [19]. This section discusses the fundamental technologies that enable AI applications in pathology, such as Machine Learning (ML), Deep Learning (DL), Whole Slide Imaging (WSI), and the importance of data annotation and management. The table 1 summarizing the key technologies in AI-based diagnostic pathology, particularly focusing on Machine Learning (ML), Deep Learning (DL), Whole Slide Imaging (WSI), and Annotation and Data Management.

Table: Key Technological Foundations in AI for Diagnostic Pathology

Technology	Core Concept	Primary Uses in Pathology	Advantages	Challenges	Ref
Machine Learning (ML)	Involves algorithms that learn from data by detecting patterns and making predictions based on historical information.	Applied for tasks like cancer classification, prediction of disease progression, and clustering of tissue types based on histopathological features.	Capable of learning from small datasets, interpretable results, flexible in application across various pathology domains.	Requires manual feature extraction, can underperform on complex images compared to DL, and lacks robustness in certain clinical scenarios.	[20]
Deep Learning (DL)	A type of machine learning using neural networks with multiple layers (e.g., Convolutional Neural Networks or CNNs) to process complex patterns directly from raw data.	Used in automated image analysis, such as identifying patterns in tumor structures, segmentation, and detecting minute changes in tissue morphology.	High performance in complex tasks (e.g., tumor detection, grading), minimal feature engineering, powerful in large datasets.	Requires large datasets for training, computationally expensive, limited interpretability, and prone to overfitting without proper validation.	[21]
Whole Slide Imaging (WSI)	The process of scanning traditional glass pathology slides to create high-resolution digital images that preserve tissue details at multiple magnifications.	Provides the visual data necessary for AI systems to analyze tissue morphology, facilitating remote diagnosis, and enabling large-scale image storage.	Enables telepathology, scalable data for AI models, enhanced diagnostic collaboration, and archiving for research purposes.	Storage and processing requirements for large image files, integration challenges with current systems, and issues with data standardization.	[22]
Annotation and Data	The process of labeling image regions	Provides labeled data required for training	Ensures accurate training for AI	Requires substantial time from pathologists	[23]

Management	and organizing data for AI model training, including securing patient information and handling datasets effectively.	supervised learning models. Includes marking key features such as cancerous regions, tumor grading, or cell counts.	models, aids in model validation, and promotes consistency in diagnostic interpretations.	to annotate images, need for large-scale, high-quality annotated datasets, and privacy concerns around data usage.	

2.1 Machine Learning (ML) and Deep Learning (DL)

Machine Learning (ML) is a class of computing algorithms that can recognize patterns in data and generate predictions or judgments without being explicitly programmed with rule-based reasoning [24]. In pathology, ML approaches are commonly used for image classification, feature extraction, clustering of comparable tissue types, and outcome prediction [25]. Traditional machine learning techniques such as support vector machines (SVM), decision trees, k-nearest neighbors (KNN), and random forests rely on manual feature engineering to extract meaningful properties from tissue pictures [26]. Deep Learning (DL), a powerful area of ML, has transformed image analysis by allowing for end-to-end learning from raw image data. DL models, particularly Convolutional Neural Networks (CNNs), have proven particularly useful in pathology because to their capacity to automatically learn and extract hierarchical characteristics from histopathological pictures [27 & 28]. CNNs are made up of several layers that mimic the function of the human visual cortex, allowing them to recognize forms, patterns, textures, and spatial hierarchies within tissue slides [29].The use of CNNs in pathology has resulted in major advances in cancer diagnosis, tumor categorization, mitotic figure counting, and tissue segmentation (e.g., nuclei, glands, stroma) [30]. Advanced architectures such as ResNet, Inception, U-Net, and Vision Transformers (ViTs) continue to push the frontiers of what is possible with deep learning in digital pathology [31].One of DL's primary characteristics is its scalability: once trained on big datasets, these models may be deployed quickly and consistently across several cases, possibly lowering diagnostic variability and burden [32].

2.2 Whole Slide Imaging (WSI)

Whole Slide Imaging (WSI) is the process of scanning traditional glass pathology slides and producing high-resolution digital copies. These digitized slides serve as the foundation for AI-based pathological analysis [9]. WSI technology has advanced greatly in recent years, with scanners capable of collecting gigapixel images at magnifications comparable to those used in optical microscopy (usually 20x or 40x) [33].

WSIs have various advantages:

Data accessibility: Digital slides can be kept, shared, and studied remotely, allowing for telepathology and collaborative diagnosis [34].

Standardization: Digital formats allow for consistent pre-processing, color normalization, and quality control [35].

AI models can process WSIs by analyzing spatial, morphological, and cellular patterns to aid or automate diagnostic activities [36].

A typical WSI file can be several gigabytes in size, posing issues for storage, computing, and real-time processing. This has resulted in the creation of patch-based analysis approaches, in which the image is broken into smaller tiles or regions of interest (ROIs) to train and infer AI models [37]. WSI operations have been further streamlined using technologies such as pyramid tiling and slide streaming. Despite its benefits, WSI implementation varies across the globe due to infrastructure costs, regulatory barriers, and integration issues [38]. Nonetheless, as digital pathology becomes more widely used, WSI will continue to play an important role in allowing AI applications [39].

2.3 Annotation and Data Management

AI model effectiveness in pathology is directly proportional to the quality and quantity of annotated training data [40]. Models in supervised learning require labeled datasets with ground truth annotations from expert pathologists, such as the presence of malignancy, tissue type, or biomarker expression [41].

Annotation often includes:

- Bounding boxes or polygons to delimit regions of interest (e.g., tumor vs. non-tumor areas) [42].
- Pixel-level segmentation for tasks such as nuclear detection and tissue compartmentalization [43].
- Classification labels for diagnoses at the slide or tile level [44].
- Quantitative indicators, such as mitotic counts or % positive for IHC markers [45].

Given the time-consuming nature of annotation, numerous tactics are employed to speed up the process, including semi-automated labeling systems, active learning frameworks, and crowd sourcing with quality assurance. In some circumstances, weak supervision or unsupervised procedures are used to utilize partially labeled or unlabeled data [46].Effective data management is equally important. To meet with privacy rules like HIPAA and GDPR, pathology datasets must be managed, securely kept, and anonymized [47]. Metadata, such as patient demographics, clinical history, and staining techniques, can increase the contextual value of images and improve model performance [48].Furthermore, the utilization of public repositories (such as The Cancer Genome Atlas, CAMELYON, PANDA, and TUPAC) has sped up research by offering standardized, benchmark datasets for model construction and comparison [49]. The increased emphasis on federated learning, in which models are trained across decentralized data sources without revealing sensitive patient information, represents a viable approach to cross-institutional AI research [50].

3. CURRENT AI APPLICATIONS IN DIAGNOSTIC PATHOLOGY

Artificial intelligence (AI) has emerged as a useful tool in diagnostic pathology, improving diagnostic accuracy, efficiency, and reproducibility [51]. AI systems, particularly those that use deep learning techniques such as Convolutional Neural Networks (CNNs), have shown great promise in several major areas of disease [52]. These tools can analyze enormous datasets, find subtle trends, and assist pathologists with formerly labor-intensive or error-prone operations [53]. This section delves into the present use of AI in diagnostic pathology, with an emphasis on cancer diagnosis, tumor grading, biomarker prediction, microbe detection, lymph node metastasis identification, and immunohistochemistry (IHC) quantification.

3.1 Cancer Diagnosis and Classification

AI has been widely used in the identification and categorization of malignancies, with results that are often comparable to or better than those obtained by humans [54]. Some of the most popular applications are breast, prostate, and lung cancer.

Breast Cancer: AI algorithms are trained to recognize essential aspects of breast cancer pathology, such as mitotic figures, tumor size, and invasion patterns [55]. These algorithms can also identify tumor forms, such as invasive ductal carcinoma and lobular carcinoma, and forecast receptor status (ER, PR, and HER2) [56]. AI systems, such as PathAI and IBM Watson, have shown the ability to forecast recurrence and aid in tailored treatment planning by linking histological markers with receptor status and genetic expression patterns [57 & 58].

Prostate Cancer: AI models, such as Paige Prostate, help locate malignant foci and grade tumors using the Gleason score [59]. The Gleason score method, which classifies prostate cancer based on cellular architecture, is fundamentally subjective and differs between pathologists [60]. AI has been found to standardize the scoring process, minimizing inter-observer variability and providing a more consistent and accurate grading system [61]. Furthermore, AI may estimate the possibility of tumor progression, assisting in treatment options.

Lung Cancer: AI has also showed great promise in lung cancer diagnosis, particularly in distinguishing between histological subtypes like adenocarcinoma and squamous cell carcinoma [62]. This difference is critical for identifying optimal therapy because the molecular profiles and treatment responses vary greatly between different subtypes. AI models can assess histopathological characteristics and tissue architecture to provide more precise categorization, thereby speeding up diagnostics and improving treatment precision [63].

3.2 Grading and Staging Tumors

Tumor grading and staging are crucial for predicting a patient's prognosis and directing therapy decisions. However, these tasks are frequently subjective and rely on pathologist knowledge, resulting in inter-observer variability. AI has the ability to increase the uniformity and reproducibility of tumor grading and staging [17 & 64].

Grading: Artificial intelligence aids in the semi-quantitative grading of tumors by assessing variables such as nuclear pleomorphism (change in nuclei size and form), mitotic rate (number of cell divisions), and tissue architecture [65 & 66]. AI systems can automatically identify these qualities, quantify their presence, and deliver an accurate grade. This decreases the variability associated with manual assessments while increasing the objectivity of grading systems like the Gleason score in prostate cancer and the Nottingham grade in breast cancer [63 & 67].

Staging: Tumor staging, which entails estimating the degree of cancer spread, is another application where AI is proven useful [68]. By evaluating histopathology slides, AI can determine if cancers have invaded surrounding tissues or expanded to neighboring lymph nodes, offering an objective estimate of tumor stage [69]. The use of AI in staging methods such as the TNM (Tumor, Node, Metastasis) classification can assist ensure that patients are correctly staged, resulting in more effective treatment planning [70].

3.3 Prognostic biomarker prediction

AI can predict patient outcomes by studying histological traits associated with prognosis. AI models are trained to detect tiny traits in tissue samples that correlate with survival rates, recurrence risk, and treatment responsiveness [71].AI can predict patient survival in breast cancer by analyzing histomorphological parameters such as tumor grade, mitotic rate, and lymphovascular invasion. AI techniques have been integrated into clinical processes to predict the probability of recurrence in early-stage breast cancer, allowing physicians to adapt treatment plans and follow-up strategies as needed [72].In colorectal cancer, AI has been used to analyze tumor budding (small clusters of tumor cells at the invasive front of the tumor) and other histological markers associated with a bad prognosis [73]. By assessing these characteristics, AI can assist identify high-risk patients who may benefit from more aggressive therapy.AI-powered prognostic models give more tailored treatment approaches, enhance survival prediction, and help clinicians manage patients based on their specific risk profiles [74].

3.4 Detection of Microbes

AI techniques have broadened the scope of diagnostic pathology by aiding in the detection of infections in tissue samples [75]. Detecting infectious organisms such as bacteria, viruses, and fungi in histopathology has traditionally been a manual and time-consuming process [76].

Helicobacter pylori: Artificial intelligence algorithms have been trained to detect the presence of *Helicobacter pylori* bacteria in gastric biopsy samples, which is a critical diagnostic marker for illnesses such as gastritis and ulcer disease. AI systems can improve diagnostics by autonomously recognizing germs within stomach tissue [77].

Mycobacterium tuberculosis: AI can also be used to detect *Mycobacterium tuberculosis*, the bacterium that causes tuberculosis, in tissue sections stained with Ziehl-Neelsen or immunohistochemistry [78]. AI's capacity to examine these samples faster than traditional approaches may reduce diagnostic delays, particularly in resource-constrained environments [79].

Viral Inclusions: AI algorithms can detect distinctive viral inclusions or cytopathological alterations in tissue sections, allowing for faster and more accurate detection of viral infections such as cytomegalovirus (CMV) and Epstein-Barr virus (EBV) [80 & 81].

3.5 Lymph Node Metastasis Detection

Identifying lymph node metastases is critical for staging and prognosis in many malignancies, including breast, prostate, and colorectal cancer. Micro metastases in lymph nodes can be difficult to detect since they are typically tiny and not visible to the naked eye [13 & 82].AI models, notably CNNs, have demonstrated great sensitivity and specificity in detecting micro metastases in lymph nodes [83]. The CAMELYON challenge series revealed AI's capacity to identify metastases in breast cancer lymph nodes with the same degree of accuracy as pathologists [84]. By automating this process, AI can cut the time pathologists spend reviewing slides and increase diagnostic confidence.

3.6 Immunohistochemistry (IHC) Quantification

Immunohistochemistry (IHC) is frequently used to detect specific biomarkers that provide information about tumor behavior and help guide targeted therapy [85]. AI systems can help quantify IHC indicators like Ki-67, HER2, and PD-L1, which are important for predicting prognosis and therapy options [86].Ki-67 is a measure of cellular proliferation, and AI can automatically count positive cells across complete tissue slices, ensuring reliable and reproducible results [87]. Similarly, HER2 overexpression in breast cancer is a strong predictor of response to targeted therapy, and AI can evaluate HER2 IHC slides with high accuracy, reducing the subjectivity that typically comes with hand scoring [88].The table 2 summarizing the additional applications of AI in diagnostic pathology, detailing how AI is used in different areas and its advantages:

Table: 2 Additional Applications of AI in Diagnostic Pathology

Application Area	Description	AI's Role	Advantages	Ref
Image Segmentation	AI helps segment histological images into distinct regions to focus on relevant areas, such as tumor regions, blood vessels, or lymphatics.	Uses Convolutional Neural Networks (CNNs) and other deep learning algorithms to separate tissues, aiding in accurate and efficient image analysis.	Automates time-consuming tasks, reduces human error, and improves the accuracy of feature identification.	[89]
Automated Quality Control	AI ensures the quality of diagnostic slides by checking for issues like artifacts, improper staining, or focus problems.	AI tools evaluate slide quality and flag poor-quality images or errors, alerting pathologists to recheck or retake the slide.	Reduces diagnostic errors caused by poor-quality slides, enhancing the accuracy of subsequent analysis.	[90]
Pattern Recognition	AI identifies unique patterns within histopathological images, such as tissue architecture, which are difficult for humans to detect.	Detects patterns that might indicate disease presence or progression, including subtle features that are not easily visible to the naked eye.	Increases diagnostic sensitivity and reduces the chances of missing rare or subtle pathologies.	[91]
Digital Pathology Workflow Optimization	AI helps streamline workflow in pathology labs, improving efficiency from slide scanning to diagnosis reporting.	Optimizes the handling of digital slides, assists in prioritizing urgent cases, and integrates results from multiple	Increases throughput, reduces delays in diagnosis, and supports better resource	[92]

		sources to improve workflow efficiency.	management in labs.	
Radiology-Pathology Integration	AI facilitates the integration of pathology data with radiology images (e.g., CT, MRI), enabling comprehensive, multimodal diagnosis.	Analyzes radiological images and correlates them with pathology slides to provide a unified diagnosis, often used in cancers like breast, lung, and prostate cancer.	Enhances diagnostic accuracy by integrating different types of medical data, enabling more holistic treatment decisions.	[93]
Personalized Medicine	AI aids in tailoring treatments based on individual patients' genetic and histopathological profiles, optimizing outcomes.	Analyzes both genomic data and histopathology images to recommend personalized treatment plans, considering molecular biomarkers, mutations, and tissue characteristics.	Improves treatment effectiveness, reduces adverse effects, and enables a more individualized approach to patient care.	[94]
Patient Monitoring and Follow-Up	AI monitors patients over time to predict outcomes and detect recurrences early by analyzing follow-up tissue samples.	Compares initial and follow-up tissue slides, using AI to detect subtle changes that may indicate recurrence or progression of disease.	Enhances early detection of disease recurrence, leading to timely intervention and potentially improved survival rates.	[95]

4. INTEGRATION WITH PATHOLOGY WORKFLOW

The incorporation of Artificial Intelligence (AI) into the pathology process is a key step toward a more digital, standardized, and efficient diagnostic ecosystem. Rather than replacing pathologists, AI is an assistive tool that improves the accuracy, speed, and consistency of pathological examinations [96]. Integration extends throughout the workflow, from pre-analytical operations like slide preparation to analytical duties like diagnosis and even reporting and data exchange [97]. This section discusses how AI aids pre-analytical quality control, improves workflow efficiency, and enables telepathology and remote consultation. The table 3 summarizes the integration of AI into the pathology workflow, outlining each phase, the AI functionalities applied, and the benefits gained.

Table: 3 Integration of AI into Diagnostic Pathology Workflow

Workflow Phase	AI Functionality	Benefits	Ref
Slide Preparation	- Artifact detection - Staining quality check - Tissue adequacy assessment	Reduces pre-analytical errors, ensures usable specimens before digitization	[98]
Pre-Analytical QC	- Focus assessment - Color normalization - Slide orientation correction	Enhances image clarity and consistency, ensures quality for AI and human analysis	[99]
Digitization (WSI)	- Optimized scanning guidance - Region-of-interest detection	Prioritizes diagnostically relevant areas, enables efficient digitization	[100]
Analytical Phase	-Tumor detection and classification - Grading and staging - IHC quantification	Improves diagnostic accuracy, reduces inter-observer variability, speeds up analysis	[63]
Workflow Optimization	- Case triaging by urgency/complexity - Discrepancy alerts - Routine task automation	Streamlines workload, reduces turnaround time, ensures priority case handling	[101]
Telepathology Support	- Real-time diagnostic suggestions - Image compression - Decision support	Expands access in remote areas, facilitates expert consultation, reduces bandwidth dependency	[102]

4.1 Pre-analytical and Analytical Support

Pre-analytical errors are responsible for a considerable share of diagnostic inaccuracy in pathology. These include issues with tissue processing, staining, slide preparation, and digitization. During these early stages, artificial intelligence can play an important role in quality control [103].

Slide Preparation Quality: AI systems may evaluate the quality of prepared slides by examining typical concerns such as tissue folding, poor fixation, staining artifacts, and sectioning errors. Early discovery of such conditions avoids misdiagnosis and the need for additional preparation [104].

Focus Quality Assessment: During slide digitalization, focus mistakes might degrade image quality. AI can automatically assess the sharpness and focus of a complete slide image (WSI), identifying out-of-focus areas for rescanning or correction before analysis [38].

Stain Normalization: Differences in staining techniques between institutions and even within labs might have an impact on the consistency of picture interpretation [105]. AI-based stain normalization techniques normalize color and intensity across slides, allowing AI models and human pathologists to interpret pictures consistently. This is especially crucial for training deep learning models, which are sensitive to color variation [106].

Tissue Detection and ROI Selection: AI can detect regions of interest (ROIs) in WSIs, such as those with high cell density or possible tumor foci. This automated pre-screening allows pathologists to concentrate their efforts on diagnostically relevant regions, hence increasing productivity [21].

4.2 Workflow Optimization

Pathology departments, particularly in high-volume facilities, are dealing with increased workloads, which can put a strain on resources and cause diagnostic delays. AI provides a spectrum of technologies that can greatly improve pathological workflows and operational efficiency [107].

Case Triaging: Artificial intelligence systems can automatically evaluate incoming digital presentations and classify them depending on urgency or complexity. For example, a slide with worrisome malignant signs may be prioritized for immediate assessment, but benign cases may be deferred. This sort of triage guarantees that essential cases are addressed in a timely manner, thereby improving patient outcomes [108].

Flagging Diagnostic Discrepancies: AI systems can compare current instances to past diagnostic data to identify inconsistencies that may indicate an error [109]. For example, if an AI system detects a high risk of malignancy in a case previously identified as benign, it can flag the case for a second review, acting as a safety net for human intervention [110].

Automating Repetitive jobs: Some pathology jobs, such as counting mitotic figures, analyzing resection margins, and identifying specific cell types, are repetitive and time-consuming. AI can automate these processes, allowing pathologists to focus on more sophisticated interpretative duties [111].

Digital Reporting and Integration: AI can help generate structured diagnostic reports based on picture analysis and integrate them smoothly with Laboratory Information Systems. This lowers documentation time and allows for standardized transmission of findings [112].

4.3 Telepathology & Remote Consultation

Telepathology the process of transferring digital pathology pictures for remote diagnosis and consultation has grown in importance, particularly in light of global health and pandemic-related constraints. AI has the potential to change telepathology services by making them more efficient and scalable [10].

Decision Support for Remote Pathologists: In areas with limited access to professional pathologists, AI can serve as an intelligent assistant by pre-analyzing slides and identifying suspicious spots or providing differential diagnoses. This not only benefits local clinicians, but it also boosts diagnostic confidence and accuracy [113].

Real-Time Assistance: AI algorithms connected with telepathology platforms can provide real-time input during consultations, such as a second opinion or confirmation of findings. This is especially beneficial in time-critical situations like intraoperative consults (frozen section analysis) [114].

Global Collaboration: AI-powered systems enhance worldwide collaboration by allowing experts to assess complex situations from across boundaries. AI can help match cases to specialists, organize second opinions, and share annotated photos for instructional purposes [115].

Infrastructure Efficiency: In remote or resource-constrained environments, bandwidth and technology limitations can impede digital pathology adoption. AI can aid by compressing images, identifying critical parts for transmission, or summarizing slides into metadata, decreasing data burden and speeding up diagnosis [116].

5. VALIDATION AND REGULATORY LANDSCAPE

AI deployment in diagnostic pathology, particularly in clinical settings, necessitates extensive validation and regulatory oversight to ensure patient safety, data integrity, and diagnostic reliability. While AI technologies have enormous potential, their real-world application is dependent on strong evidence of efficacy, legal compliance, and ethical use [117]. This section delves into the key pillars of validation, regulatory frameworks across geographies, and the ethical-legal implications of AI in clinical pathology.

5.2 Regulatory Approval

Before being used in clinical settings, AI-based pathology tools must be approved by regulators to ensure their safety and usefulness. In the United States, the FDA classifies AI as Software as a Medical Device (SaMD), which necessitates extensive clinical evidence [118]. In Europe, CE certification under the Medical Device Regulation (MDR) verifies adherence to safety and performance specifications [119]. Similar frameworks exist on a worldwide scale. Several AI technologies, like Paige Prostate and Ibex Galen, have received regulatory approval, clearing the path for clinical integration [120].

5.3 Ethical and legal considerations

The use of AI in pathology also raises serious ethical and legal concerns. Protecting patient data privacy and obtaining informed consent for data usage is critical, particularly under legislation such as HIPAA and GDPR [121]. Furthermore, algorithmic bias often resulting from non-representative training data can jeopardize diagnostic fairness. There is also an increasing demand for transparency in AI decision-making processes and precise definitions of medico-legal responsibility in cases of diagnostic errors employing AI-assisted instruments [122].

6. CHALLENGES AND LIMITATIONS

Despite its transformational promise, incorporating AI into diagnostic pathology presents numerous key hurdles. One of the most pressing concerns is a scarcity of high-quality, annotated datasets, which are required for training and verifying effective AI models [123]. Manual annotation is time-consuming and requires expert input, which limits scalability. Another difficulty is generalizability, as models trained on data from a single institution may underperform when applied to slides from other demographics, scanners, or staining methods [124]. Furthermore, many deep learning models lack explain ability, functioning as "black boxes" with decisions that physicians struggle to interpret or trust, particularly in key diagnostic circumstances [125].Finally, integration constraints such as pathologists' opposition, limited IT infrastructure, high implementation costs, and workflow interruption continue to impede widespread clinical usage [126]. Addressing these limitations is critical to maximizing the benefits of AI in pathology. This table 4 highlights the key challenges AI faces in diagnostic pathology and the impact each issue has on the broader adoption and integration of AI tools in clinical practice.

Table: 4 Challenges and Limitations of AI in Diagnostic Pathology

Challenge	Description	Impact	Ref
Data Limitations	- Scarcity of high-quality, annotated datasets - Time-consuming manual annotation - Limited diversity in datasets	- Hinders training and validation of AI models - Affects model accuracy and generalizability	[127]
Generalizability	- Models trained on one dataset may not work well with others due to differences in staining, scanning, and patient demographics	- Decreases performance reliability across different institutions and populations	[128]
Explainability	- Many deep learning models operate as "black boxes" - Lack of transparency in decision-making processes	- Reduces trust in AI models - Limits clinical adoption due to inability to explain AI decisions	[129]
Integration Barriers	- Resistance from pathologists - Insufficient IT infrastructure - High upfront costs - Workflow disruption	- Slows down clinical adoption - Increases implementation cost and complexity	[130]

7. Future Prospects

As artificial intelligence advances, its potential to change diagnostic pathology grows even more attractive. Future AI breakthroughs are predicted to transform the integration of morphological data with other types of clinical information, resulting in more tailored and precise treatment options [130]. Furthermore, new machine learning approaches will provide more dynamic, flexible, and secure solutions to improve diagnostic accuracy, workflow efficiency, and cross-institutional collaboration [131].

7.1 Precision and Predictive Pathology

One of the most important future uses of AI in pathology is precision medicine [63]. AI will make it easier to integrate different sorts of data, such as morphological traits, genetic data, proteomic data, and clinical results, in order to provide personalized treatment plans tailored to each patient's specific needs. By merging these data sources, AI algorithms will improve their ability to forecast disease development, find biomarkers for targeted therapy, and optimise treatment plans based on an individual's genetic profile [132]. This data-driven strategy promises to transform healthcare from a "one-size-fits-all" model to highly individualized care, resulting in improved patient outcomes and fewer adverse responses to medicines [133].

7.2 Self-Learning and Adaptive Models

Future AI models are anticipated to include self-learning and adaptive learning capabilities, allowing them to continuously improve as they process new data. Most AI systems are now static and require manual retraining with new datasets [134]. Continuous learning algorithms, which can adjust to new data in real time, are expected to produce more resilient and up-to-date diagnostic tools. These models will adapt in response to new clinical data, allowing them to recognize emerging illness patterns and increase diagnostic accuracy over time [135]. This adaptive technique reduces the need for periodic retraining, making AI solutions more adaptable and better suited to the fast-paced nature of medical developments [136].

7.3 Federated Learning

Federated learning is an important advancement in AI training, especially in healthcare. This technique enables AI models to be trained across various institutions and datasets without sharing sensitive patient data, hence protecting patient privacy. In federated learning, data is kept secure in its original location, while only model changes are shared with a central server, which aggregates these updates to improve the global model [137]. This strategy not only protects data privacy and ensures compliance with standards such as GDPR and HIPAA, but it also improves the model's generalizability by incorporating data from a variety of patient groups and healthcare systems [138]. Federated learning will speed AI adoption in healthcare facilities, particularly those concerned about data privacy and security.

7.4 Augmented Pathology

In the future, AI will serve as a co-pilot to pathologists rather than replacing them. AI will help and improve decision-making by providing pathologists with enhanced tools for analyzing massive amounts of data and detecting subtle patterns that the human eye may miss [126]. AI can assist pathologists with tasks such as recognizing anomalies, measuring biomarkers, and evaluating tumor features [71]. However, human specialists will always have the last say, ensuring that critical thought and knowledge remain central to clinical decision-making [139]. This augmented pathology technique promises to improve diagnostic accuracy, reduce effort, and increase efficiency, while pathologists continue to play an important role in diagnosis and treatment planning [140].

8. CONCLUSION

Artificial intelligence (AI) is poised to alter diagnostic pathology by greatly boosting pathologists' diagnostic powers, increasing workflow efficiency, and allowing for precision medicine. AI systems, particularly those based on machine learning and deep learning, have the ability to automate mundane processes, discover subtle patterns, and give useful decision assistance, thereby enhancing diagnostic accuracy and patient outcomes. By combining clinical, genetic, and histological data, AI can create personalized therapy strategies for specific patients. However, significant obstacles exist to the mainstream adoption of AI in pathology, including data restrictions, difficulties in model generalization across varied datasets, and a lack of transparency in some AI models. Furthermore, ethical problems, data privacy, and medico-legal duties for AI-assisted diagnosis must be addressed. Despite these challenges, the future of AI in diagnostic pathology looks promising. As AI models grow and regulatory frameworks mature, human-AI collaboration is likely to become the norm in pathology, with AI acting as a co-pilot rather than a replacement for pathologists. Multidisciplinary efforts combining pathologists, data scientists, regulatory authorities, and healthcare institutions are critical to ensuring the responsible and effective integration of AI into clinical practice, thereby realizing its full potential to improve patient care.

Conflicts of interest

There are no conflicts of interest.

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