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TRANSFORMATIONS OF CONTEMPORARY MORPHOLOGICAL DIAGNOSTICS: TELEPATHOLOGY, DIGITAL PATHOLOGY, AND ARTIFICIAL INTELLIGENCE – GLOBAL EXPERIENCE AND STANDARDIZED REGULATION

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Relevance. Telepathology is a promising area of digital medicine that ensures the availability of morphological diagnostics in conditions of shortage of specialists, war, and pandemic.

Objective. To analyze regulatory models of telepathology in different countries and assess the potential of Artificial Intelligence (AI) in morphological diagnostics.

Methods. A comparative analysis of regulatory documents, statistical data, technical standards, and scientific publications on telepathology and AI was conducted.

Discussion. It was found that telepathology is actively being implemented in the world, with clear requirements for safety, ethics and technical implementation. AI demonstrates high accuracy in recognizing pathologies.

Conclusions. Telepathology and AI have the potential to transform morphological diagnostics, but require regulatory support, technical integration, and ethical control.

Keywords: telepathology, digital pathology, AI in diagnostics, morphological analysis, global standards.

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ТРАНСФОРМАЦІЇ СУЧАСНОЇ МОРФОЛОГІЧНОЇ ДІАГНОСТИКИ: ТЕЛЕПАТОЛОГІЯ, ЦИФРОВА ПАТОЛОГІЯ ТА ШТУЧНИЙ ІНТЕЛЕКТ, ГЛОБАЛЬНИЙ ДОСВІД, НОРМАТИВНЕ РЕГУЛЮВАННЯ

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Актуальність. Телепатологія є перспективним напрямом цифрової медицини, що забезпечує доступність морфологічної діагностики в умовах дефіциту фахівців, війни та пандемії.

Мета. Проаналізувати нормативні моделі телепатології в різних країнах та оцінити потенціал штучного інтелекту (ШІ) в морфологічній діагностиці.

Методи. Проведено порівняльний аналіз нормативних документів, статистичних даних, технічних стандартів і наукових публікацій щодо телепатології та ШІ.

Обговорення. Виявлено, що телепатологія активно впроваджується у світі, з чіткими вимогами до безпеки, етики та технічної реалізації. ШІ демонструє високу точність у розпізнаванні патологій.

Висновки. Телепатологія та ШІ мають потенціал трансформувати морфологічну діагностику, але потребують нормативного закріплення, технічної інтеграції та етичного контролю.

Ключові слова: телепатологія, цифрова патологія, ШІ в діагностиці, морфологічний аналіз, глобальні стандарти.

Introduction

Morphological diagnostics is the foundation of modern medical diagnostics, particularly in oncopathology, ensuring accurate detection, classification, and prediction of the course of diseases. However, despite modern technologies and advances in development, traditional pathology continues to face a number of challenges: a shortage of qualified personnel, uneven access to laboratories, subjectivity of interpretation and limitations in the speed of sample processing. In response to these challenges, telepathology has emerged – a remote evaluation of histological specimens using digital technologies. Its integration with AI opens up new horizons for the automation, standardization, and scaling of morphological diagnostics.

This study aims to review and analyze the current state of telepathology and the use of AI in morphological

diagnostics, with a focus on international experience, regulatory control, technical capabilities, and associated risks. Special attention is paid to comparing traditional and algorithmic morphological assessment; analysis of regulatory documents and standards; assessment of the effectiveness, accuracy, and safety of AI-based tools; and studying the challenges of implementation in different countries.

Materials and Methods

The study used a systematic literature review method from open databases (PubMed, Scopus, Web of Science) using the keywords: "telepathology", "digital pathology", "AI in diagnostics", "morphological analysis", "global standards". 31 published sources were selected, covering clinical studies, regulatory documents, expert reviews and recommendations of international organizations.

Discussion

The emergence of telepathology as a distinct field within medical diagnostics is closely associated with Dr. Ronald S. Weinstein, who first introduced the term "telepathology" in 1986 to describe the remote viewing of histological specimens for diagnostic, consultative, and educational purposes [1]. In his foundational work, Weinstein outlined the conceptual framework of the new technology with the potential to transform pathological practice, particularly in settings with limited access to specialists. He not only coined the term but he also pioneered the development of early robotic telepathology systems capable of transmitting high-resolution histological images over long distances. His research and patents laid the foundation for the further development of telepathology as a clinical tool.

Telepathology began to develop rapidly and has since been introduced into medical practice in many countries, and regulatory documents regulating this type of activity have appeared. Today, this clinical tool is widely employed in clinical workflows, especially in regions with limited access to pathologists, and has evolved from a theoretical concept into a practical technology that has reshaped approaches to morphological diagnostics worldwide.

It is clear that telepathology requires the integration of digital technologies and appropriate software with a high technical level of equipment and an appropriate level of education and skills of employees. Digital technologies are rapidly permeating all areas of medicine. Global experience demonstrates that each country addresses these challenges in its own way. For instance, a 2021 article published in Modern Pathology [2] explored the profound changes occurring in the field of pathology due to the transition to digital platforms. The authors describe how digital pathology – specifically, the digitization of histological slides – is transforming both scientific research and clinical practice.

Previously, pathological analysis was carried out exclusively using an optical microscope, which limited the ability to store, transmit, and re-examine specimens. Today, thanks to Whole Slide Imaging technology, tissue samples can be scanned at high resolution, stored in digital format, and shared between institutions. This advancement opens new possibilities for consultation, education, diagnostic standardization, and archival storage.

The authors emphasize the importance of digital pathology in translational medicine – the process of transferring scientific discoveries into clinical applications. Digitized specimens allow researchers to more accurately study tumor microenvironments and identify new morphological features that may be related to the course of the disease, and differentiate large amounts of data between different centers.

In clinical practice, digital pathology enhances diagnostic accuracy, reduces the incidence of errors, and facilitates remote consultation among specialists. This is particularly critical in regions facing shortages of highly qualified pathologists.

However, the authors also point to a number of challenges, including the need to standardize image formats, ensure patient data confidentiality, legal regulation of digital processes, and the need to train healthcare professionals in new approaches.

One of the most advanced implementation models has been developed in Canada. As early as in 2012, the Canadian Association of Pathologists published the "Guidelines for Establishing a Telepathology Service for Anatomical Pathology Using Whole Slide Imaging," which proposed a phased model for implementing telepathology, starting with assessing the institution's needs, selecting technologies, and configuring the network [3].

The main components of such an organization are: scanners for Whole Slide Imaging (WSI), image storage servers, viewing software; network configurations: centralized or decentralized models depending on location and resources; integration with laboratory information systems of institutions to ensure continuity of data access. Special attention is paid to technical support, archiving and documentation of results, which are critical to ensuring the reliability and reproducibility of diagnostic processes.

A separate section is devoted to quality control and accountability criteria. The Quality Management section describes requirements for several parameters, namely: correspondence of digital images to traditional glass slides, which are checked before clinical examination by comparison, accuracy of diagnoses and productivity, which, through regular monitoring, regular training of personnel – both pathologists and technical personnel – ensure competence in working with WSI. To ensure proper accountability, mandatory licensing of pathologists working remotely is emphasized. Issues of confidentiality and data security are regulated in accordance with Canadian legislation.

Therefore, the main point is that digital pathology is considered as a dynamic environment that allows receiving, storing, viewing and analyzing images of histological preparations digitized using specially adapted scanners (see Table 1). Two types of images are considered as objects of study: static ones – these are individual items – photographs of micropreparations of established quality and size, and interactive/dynamic ones– images obtained in real time and often used in telepathology for urgent diagnostics and consultations.

Based on a comprehensive review of current literature and international standards, key technical parameters of diagnostic imaging in telepathology have been synthesized (see Table 2). The table summarizes essential aspects–from

Table 1

Digital system components used in telepathology

Component	Function description
Scanner	Digitizes glass slides
Image Management	Integration with Laboratory Information Systems (LIS)
Software	For viewing, analysis, and archiving
Storage System	Archiving and intelligent search
Analytical Tools	Using AI for pattern recognition (e.g. CD20, Ki67, ER ,PR HER2/neu and others)

Table 2

Technical Parameters of Digital Diagnostic Images for Diagnostics

Parameter	Value / Recommendation	Source
Image Type	Whole Slide Imaging (WSI); static and dynamic formats	Sonawane & Borys, 2021 [3]
Resolution	Recommended ≥ 0.25 μm/pixel (equivalent to 40x magnification)	CAP Guidelines [4]
File Formats	SVS, TIFF, JPEG2000, DICOM	DICOM Standard [5]
File Size per WSI	1–3 GB depending on specimen size and magnification level	Sonawane & Borys, 2021 [3]
System Validation	Minimum of 60 cases; ≥95% diagnostic concordance with microscopy	CAP Guidelines [4]
Focusing	Automated, multilayer; focus quality control is critical	*the FDA's Digital Pathology Initiative* [6]
LIS Integration	Mandatory for clinical use	Sonawane & Borys, 2021 [3]
Archiving	Long-term storage; support for intelligent search	DICOM Supplement 223 [5]
Viewing	Via specialized software; remote access capabilities	*the FDA's Digital Pathology Initiative* [6]
Image Analysis	Capability to apply AI/Deep Learning for pattern recognition (e.g., Ki67)	*the FDA's Digital Pathology Initiative* [6]

image type and resolution to validation, archiving, and laboratory information systems (LIS) integration requirements. These recommendations are based in authoritative sources such as the College of American Pathologists (CAP) Guidelines, Digital Imaging and Communications in Medicine (DICOM) Standard, and the US Food and Drug Administration (FDA) Digital Pathology Initiative, ensuring both credibility and practical relevance.

The American Telemedicine Association developed the Telepathology Clinical Guidelines in 2018, which became the first comprehensive document that systematizes the principles of safe, effective, and ethical use of telepathology in clinical practice in the United States [7]. The document identifies key telepathology models – static (capture-and-send), dynamic (streaming video microscopy), and Whole Slide Imaging (WSI) – and describes their technical requirements, advantages, and limitations. Particular attention is paid to organizational aspects, including licensing of professionals, data protection, system validation, and integration with laboratory information systems. The recommendations cover the entire infrastructure, including scanners, software, data channels, and viewing monitors, with an emphasis on ensuring diagnostic accuracy.

The document also includes provisions regarding the responsibility of the physician conducting a remote assessment, regardless of the patient's location or the source of the specimen. It is emphasized that telepathology diagnostics should meet the same standards as traditional microscopy, including quality control, documentation, and adherence to ethical standards. The recommendations emphasize the importance of training personnel, as well as the need to validate each system before clinical use, in accordance with Clinical Laboratory Improvement Amendments (CLIA) and CAP requirements. Thus, the American Telemedicine Association (ATA) guidelines form the basis for the safe implementation of telepathology in medical practice, especially in conditions of remote access to specialists.

The FDA's Digital Pathology Initiative has focused on developing regulatory methods for assessing the technical performance of digital medical devices, including WSI systems. In contrast to European approaches, digital pathology is classified as a Class II medical device in the US, requiring a 510(k) or de novo approval process [6]. The program emphasizes the lack of standardized tests that correlate technical image quality with clinical performance and the need for statistical tools to assess the performance of both pathologists and image analysis algorithms. This contrasts with European initiatives such as the BigPicture Project and the European Society of Pathology guidelines, which place greater emphasis on standardization of processes, integration with laboratory information systems (LIS), and interoperability [8; 9].

From a technical perspective, the FDA requirements include assessment of focusing accuracy, spatial resolution, color reproduction, and display quality [6]. In Europe, the European Guidelines on Quality Criteria for Diagnostic Radiographic Images and the Royal College of Pathologists also set high standards for WSI quality, but with a greater emphasis on internal validation, flexibility in implementation, and practical adaptation to the clinical environment [4; 9]. For example, the British guidelines allow for the avoidance of large-scale clinical trials if self-validation is performed based on real cases [10]. Thus, although the technical requirements are generally the same (high resolution, focusing accuracy, integration with LIS), the American approach is more formalized and focused on regulatory compliance, while the European approach is more adaptive and clinically oriented.

At the end of the last century, the CLIA program was launched in the USA, which establishes mandatory quality standards for all laboratories that perform testing of human biological specimens for the purpose of diagnosing, treating, or evaluating a health condition. In 2024, Centers for Medicare & Medicaid Services (CMS) updated the regulation, which came into force on December 28, 2024, including new requirements for personnel qualifications, revised sanctions, updated provisions on histocompatibility, and increased registration fees (CMS, 2025) [11]. Clarification of educational requirements for conducting highly complex laboratory testing is of particular importance [12]. In contrast to more flexible European approaches, CLIA provides a unified certification system that covers more than 260,000 laboratories in the USA. All laboratories, whether they receive payment through Medicare or not, are required to adhere to CLIA standards, which include requirements for method validation, quality control, recordkeeping, and participation in a proficiency testing program (CDC, 2024) [13]. Thus, CLIA is the foundation of the legal regulation of laboratory diagnostics in the United States, ensuring transparency, safety, and accountability in the work of medical laboratories.

Although there are no specific provisions for telepathology under CLIA, it is subject to general requirements for accuracy, reliability, and timeliness of results. Reports generated using telepathology must meet all CLIA standards, just like traditional reports. This includes patient identification, diagnostic accuracy, quality control, and compliance with laboratory protocols.

Therefore, the potentials of telepathology are highlighted, such as reducing logistics and equipment costs, increasing the availability of specialized diagnostic services, reducing the burden on pathologists during periods of staff shortages (permanent or temporary), and ensuring continuity of medical care even in remote regions.

In the Israeli healthcare system, telepathology is a part of telemedicine, regulated by directives issued by the Israeli Ministry of Health [14]. It is permitted for clinical use, provided that standards of safety, confidentiality, and professional responsibility are met. All telemedicine services, including telepathology, must be performed between an identified physician and patient, with a clearly documented diagnostic process.

Standards and regulations require that telepathology systems must be integrated with electronic medical records (EMR) and laboratory information systems (LIS). Images used for diagnosis must be stored in secure repositories managed by health insurance organizations, which act as primary custodians of medical data in Israel. According to the Privacy Protection Law (1981), the processing of such images must meet strict requirements for the protection of personal data, including encryption, access control, and auditing.

Image analysis is performed by licensed pathologists who are allowed to work remotely, provided that their activities are registered with the Ministry of Health. Validation of telepathology platforms is carried out at the level of the institution implementing the technology, with mandatory documentation of diagnostic accuracy. In addition, each institution must appoint a responsible telemedicine coordinator who monitors quality, compliance with standards, and data security.

These provisions align with the Digital Health Laws and Regulations Report 2025 – Israel [15], which classifies telepathology as a highly specialized form of telemedicine requiring additional certification and technical compliance.

The Digital Health Laws and Regulations Report 2025 – Israel, prepared with the participation of the Privacy Protection Authority (PPA) [16], considers telepathology as part of digital medicine, governed by the Privacy Protection Law (1981) and related regulations. The document emphasizes that all digital medical images, including histological preparations, are personal health data and must therefore be processed in accordance with strict requirements for security, storage, and access.

According to the regulation, image repositories must be certified, secured, and located in Israel or in jurisdictions recognized as “adequate” in terms of data protection. Requirements are established for access auditing, encryption, user authentication, and logging of actions. All telepathology platforms must undergo internal validation before clinical use, and physicians working with such systems must be registered with the Ministry of Health and undergo appropriate training. Special attention is paid to informed patient consent, which must cover the use of digital images for remote diagnosis.

Thus, Israeli law provides a high level of protection for personal medical images, including telepathology, and sets clear requirements for technical infrastructure, institutional responsibilities, and patient rights.

Telepathology is identified as a key area of digital health development in Australia’s National Digital Health Strategy 2023–2028, developed by the Australian Digital Health Agency [17]. The strategy aims to create a connected, safe and accessible health system in which digital technologies, including telepathology, play an important role in ensuring quality diagnostics regardless of the patient’s geographical location.

Telepathology is defined as the transmission of digitized histological images for remote analysis and diagnosis. The strategy outlines four core requirements for such services:

1. They must be integrated with the national My Health Record platform, which allows storing and transmitting medical images in a standardized format;

2. They must be secure: all telepathology systems must meet cybersecurity requirements, including data encryption, user authentication and access auditing;

3. They must be interoperable, i.e., able to interact with other digital medical platforms, which ensures the continuity of the clinical process;

4. They must be accessible to healthcare professionals in remote regions, which contributes to reducing inequalities in access to high-quality pathological diagnostics.

The strategy also includes training medical professionals in digital pathology and supporting innovative solutions that automate part of the image analysis process. All of this is aimed at increasing diagnostic accuracy, speeding up clinical decision-making, and improving patient outcomes.

In 2025, the German Medical Association (Bundesärztekammer) updated its provisions on telemedicine and remote treatment (Telemedizin/Fernbehandlung) [18].

These provisions also cover telepathology as a form of remote diagnosis. According to official recommendations, telemedicine concepts include diagnostics, therapy and medical consultations carried out via information and communication technologies remotely.

Telepathology, as part of this system, enables pathologists to analyze digital histological images without the physical presence of the patient or specimen. The document emphasizes the legal permissibility of exclusively remote consultations and diagnostics even for new patients provided that quality and safety standards are upheld. Pilot projects, such as those conducted in Baden-Württemberg, demonstrated both the advantages and limitations of remote diagnostics. The guidelines stress that telepathology services must be integrated into the national telematics infrastructure, which ensures secure exchange of medical data among physicians, laboratories, and clinics. Bundesärztekammer highlights the necessity of patient consent, transparency, and adherence to professional standards when employing telemedical methods, including telepathology.

Thus, telepathology in Germany has received regulatory recognition as an effective diagnostic tool, especially in conditions of a shortage of specialists and the need for rapid access to expert opinion.

Telepathology is also advancing in France. In the document ***Téléconsultation et téléexpertise: guide de bonnes pratiques***, published by the Haute Autorité de Santé (HAS) [19], telemedicine services including telepathology are considered an integrated part of modern medical practice, subject to strict criteria for quality, safety, and ethical conduct.

Telepathology, as a form of teleexpertise, involves remote analysis of pathological images (e.g., histological slides) between physicians. The HAS guidelines prioritize quality and safety: all acts of teleexpertise, including telepathology, must comply with standards for confidentiality, diagnostic accuracy, and technical reliability. Diagnostic images must be of high quality, and platforms must be certified. Telepathology may be conducted in hospitals, socio-medical institutions, or even from home, provided that environmental requirements such as data protection, stable connectivity, and confidentiality are met. Patients must be informed about the nature of the remote expertise and must provide consent for the processing of medical images in digital format. HAS recommends the use of a "patient-tracer" method to evaluate the quality of telepathology services an approach that involves analyzing specific clinical cases to improve diagnostic processes.

This approach expands access to pathological expertise, especially in regions with limited specialist availability, and ensures timely diagnostics without compromising quality.

In India, telepathology has been formally regulated since March 2020, when the Ministry of Health and Family Welfare issued the Telemedicine Practice Guidelines [20], the country's first official regulations governing remote medical services. The document covers all aspects of telemedicine, including telepathology, which is defined as a form of teleexpert interaction between physicians, particularly for sharing medical images, histological slides, and laboratory data.

According to the guidelines, telepathology may be conducted under four permitted scenarios:

– from a patient to a Registered Medical Practitioner (RMP),

– from one RMP to another (e.g., for consultation),

– via a medical intermediary (such as a nurse or paramedic),

– with the involvement of a patient's caregiver.

Particular attention is given to physician and patient identification, informed consent, data confidentiality, and documentation of consultations. In the context of telepathology, this implies that the transmission of digital images must occur via secure communication channels, and diagnostic results must be recorded in medical documentation in accordance with established standards.

The document explicitly prohibits the use of telemedicine for invasive procedures but permits its application for diagnostics, treatment, consultations, and educational purposes. All Registered Medical Practitioners (RMPs) intending to provide telemedicine services are required to complete mandatory online training developed by the Medical Council of India.

Thus, telepathology in India has received formal regulatory recognition, with clearly defined frameworks for responsibility, ethics, and technical implementation, enabling its safe deployment even in rural and remote regions.

China's regulatory model for telepathology was outlined in 2022 by the National Health Commission of China. This analytical report systematizes the legal and organizational aspects of the country's telemedicine infrastructure [21]. It describes two primary models relevant to telepathology. First: Internet-based diagnosis and treatment, involving direct interaction between physician and patient via online platforms, which is permitted only for follow-up consultations and chronic disease management (excluding initial COVID-19 diagnosis via internet hospitals). Second: Remote Medical Services, a business-to-business (B2B) model involving collaboration between medical institutions. This model forms the basis for telepathology, enabling physicians from different hospitals to exchange images, histological data, and conduct remote consultations [22].

Specific regulatory requirements include the following:

– Only licensed medical institutions are authorized to provide telemedicine services.

– All internet hospitals and telemedicine platforms must undergo registration and certification.

– Confidentiality, informed consent, and data protection are mandatory.

To unify the work, technical standards for the transmission of medical images have been introduced, including DICOM and other formats. By 2019, China's telemedicine network had already connected over 3,000 hospitals. Subsequently, regional telemedicine centers were established in all provinces, and internet hospitals were introduced, allowing patients from rural regions to receive consultations with specialists based in urban clinics.

In Ukraine, telemedicine has also gained a regulatory foundation and continues to develop. The Law of Ukraine

No. 3301-IX (2023) defines telemedicine as a set of actions, technologies, and measures used to provide medical and/or rehabilitative care remotely [23]. The Ministry of Health of Ukraine [24] regulates the procedure for telemedical consultations, including standardized documentation forms such as:

– Form No. 001/tm – request for telemedical consultation,
– Form No. 002/tm – consultant's conclusion,
– Form No. 003/tm – consultation logbook, as well as requirements for the consultation environment.

Currently, telepathology in Ukraine is primarily implemented in a physician-to-physician format, involving the transmission of digital histological slides, CT scans and MRI images.

In the context of the war and the COVID-19 pandemic, telepathology has become critically important for remote diagnostics in regions lacking specialist access and for interregional physician consultations. The use of artificial intelligence (AI) for image analysis such as Brainscan and AIDOC–is increasingly relevant [25, 26].

Regarding the implementation of telemedicine, it is known that it is included in 31 out of 41 packages of medical guarantees of the National Health Service [27]. As of 2024, telemedicine encompassed 328 medical institutions, with over 8,800 teleconsultations conducted and 1,259 medical professionals trained [26]. Virtual operating rooms, portable diagnostic systems, and AI-based CT analysis tools have been deployed. However, there is no official definition or regulations specifically addressing telepathology or the use of AI in morphological digital diagnostics in Ukraine.

The online publication InterNetri [28] discusses general principles of AI application in medical diagnostics, including image analysis (CT, MRI, X-ray), disease prediction based on genetic and laboratory data, and personalized medicine – such as diagnostics of micronutrient deficiencies.

AI holds significant potential in routine morphological diagnostics. It can identify key morphological features – nuclear atypia, stratification abnormalities, mitotic activity – with accuracy approaching expert-level performance. According to Liu et al. [29], the average sensitivity of AI algorithms in diagnosing cervical intraepithelial neoplasia (CIN) and cervical cancer is 97%, with specificity at 94%. AI tools have already been implemented in Sweden and Denmark for routine diagnostics of CIN, cervical cancer, and breast cancer, accompanied by ethical audits and algorithmic transparency.

Analysis of the use of AI in telepathology suggests an increase in diagnostic accuracy, as AI algorithms can analyze digital histological images with high accuracy, reducing human error and improving the detection of pathologies at early stages and the ability to transmit digital images for consultations between specialists, which is critical for rural or low-income medical facilities [30]. In addition, automated systems reduce sample processing time, which is especially important in conditions of overloaded laboratories or remote regions [31], this ensures speed and efficiency in diagnostics and, consequently, timeliness of treatment. The implementation of digital solutions can reduce costs by reducing the costs associated with physical sample transportation, storage, and archiving [29].

The work of Nastenko et al. [32] is an example of how modern AI and medical image analysis technologies can transform telepathology from a concept into real clinical practice. It demonstrates that myocarditis can be diagnosed remotely, accurately, and effectively – which is particularly relevant in the context of pandemics, military conflicts, or medical crises. The algorithms described in the study can be integrated into cloud services, which will allow the disease to be diagnosed in regions with limited access to specialised cardiology services, and the use of the DRAGONFLY and COVID-CT-MD databases demonstrates the potential for creating telopathology systems where images can be analyzed remotely without direct involvement of an on-site physician.

In his publication, Mahmood MF examines the capabilities of analyzing blood samples through machine learning and image processing methods [33]. While the research is not explicitly framed as telepathology, it highlights essential elements relevant to the field that can be integrated into telepathological systems, especially in laboratory diagnostics. It points to the digital processing of biological samples using MATLAB for blood image analysis – an example of digital morphology, which is the basis of telepathology. Scanned samples can be transmitted over a distance for automated classification, optimising the processing time of results, even without the involvement of a laboratory technician, which can affect the speed of clinical decision-making.

Widespread adoption of AI introduces certain challenges and limitations, primarily concerning the reliability of AI algorithms. These systems require rigorous validation, as misinterpretation may lead to incorrect diagnoses. It is essential to establish secure image storage and transmission systems that comply with data protection standards such as General Data Protection Regulation (GDPR) or Health Insurance Portability and Accountability Act (HIPAA) [31]. Another challenge is the integration of AI into existing healthcare infrastructures. Many hospitals operate with outdated systems, complicating the deployment of digital solutions [30]. A critical issue remains the question of liability in cases of diagnostic errors made by AI systems [29].

Conclusions

Telepathology is an effective response to the challenges of traditional morphological diagnostics, including workforce shortages, subjective interpretation, and unequal access to specialists. Its implementation ensures continuity of care, particularly during wartime, pandemics, and in remote regions.

Digital pathology is transforming clinical practice by providing high-quality imaging, archiving capabilities, remote consultation, and standardization of diagnostic workflows. Whole Slide Imaging (WSI) is becoming the primary format for digital morphology, with defined technical specifications governed by international standards (CAP, DICOM, FDA).

Artificial intelligence (AI) demonstrates high efficacy in morphological analysis, with sensitivity reaching 97% in diagnosing cervical intraepithelial neoplasia (CIN) and cervical cancer. AI algorithms can automate the recognition

of key features, reduce pathologist workload, and accelerate specimen processing – which is especially important for overloaded laboratories.

Regulatory control of telepathology varies significantly across countries, but common principles include system validation, data protection, integration with LIS/EMR, professional licensing, and informed patient consent. The United States, Canada, Israel, Australia, Germany, France, India, and China demonstrate different implementation models – from formalized to adaptive.

Ukraine has established a regulatory base for telemedicine, yet lacks an official definition of telepathology as a distinct form of digital diagnostics. Nevertheless, telepathology is actively practiced, especially in physician-to-physician formats, utilizing digital imaging and select AI solutions.

Implementation of telepathology and AI requires addressing several challenges, including technical interoperability, data security, algorithm reliability, diagnostic accountability, and modernization of healthcare infrastructure.

BIBLIOGRAPHY

1. Wikipedia contributors. Telepathology [Internet]. Wikipedia, The Free Encyclopedia; 2024 [cited 2025 Aug 7]. Available from: https://en.wikipedia.org/wiki/Telepathology.
2. Bera K, Schalper KA, Rimm DL, Velcheti V, Madabhushi A. Digital pathology and artificial intelligence in translational medicine and clinical practice. *Mod Pathol*. 2021;34(1):11–24. DOI: 10.1038/s41379-021-00919-2.
3. Sonawane SS, Borys D. Digital imaging fundamentals & standards. PathologyOutlines.com website. Available from: https://www.pathologyoutlines.com/topic/informaticsdigitalimagingfund.html. Accessed 1 June 2025.
4. Evans AJ, Brown RW, Bui MM, et al. Validating whole slide imaging systems for diagnostic purposes in pathology: guideline update from the College of American Pathologists. *Arch Pathol Lab Med*. 2022;146(4):440–450. DOI: 10.5858/arpa.2020-0723-CP.
5. DICOM Standards Committee. Digital Imaging and Communications in Medicine (DICOM). Available from: https://www.dicomstandard.org/. Accessed 1 June 2025.
6. U.S. Food and Drug Administration. Digital Pathology Initiative: Research on Digital Pathology Medical Devices. Available from: https://www.fda.gov/medical-devices/medical-device-regulatory-science-research-programs-conducted-osel/digital-pathology-program-research-digital-pathology-medical-devices. Accessed 1 June 2025.
7. American Telemedicine Association. Clinical Guidelines for Telepathology [Internet]. 2018 [cited 2025 Aug 7]. Available from: https://southwesttrc.org/sites/default/files/resources/standards/ATA%20Telepathology%20Guidelines.pdf.
8. Schreiner-Karoussou A, Back C. Report on Image Quality Standards for Digital Imaging and Interventional Radiology. Luxembourg: Radiation Protection Department, Ministry of Health; 2021. Available from: https://opripalc.org/wp-content/uploads/2021/02/5Image-quality-.pdf.
9. Carmichael JHE, Maccia C, Moores BM, et al. European Guidelines on Quality Criteria for Diagnostic Radiographic Images. Luxembourg: Office for Official Publications of the European Communities; 1996. Report No.: EUR 16260 EN. Available from: https://op.europa.eu/en/publication-detail/-/publication/d59ccc60-97ed-4ce8-b396-3d2d42b284be.
10. European Society of Pathology. BigPicture Project [Internet]. Available from: https://www.bigpicture.eu/ [cited 2025 Aug 7].
11. Centers for Medicare & Medicaid Services. Clinical Laboratory Improvement Amendments (CLIA) [Internet]. 2025 [cited 2025 Aug 7]. Available from: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments.
12. Centers for Disease Control and Prevention. Clinical Laboratory Improvement Amendments (CLIA) Overview [Internet]. 2024 [cited 2025 Aug 7]. Available from: https://www.cdc.gov/clia/php/about/index.html.
13. American Society for Clinical Pathology. CMS's CLIA Rule Now Fully in Effect [Internet]. 2025 Jan 9 [cited 2025 Aug 7]. Available from: https://www.ascp.org/news/news-details/2025/01/09/cms-s-clia-rule-now-fully-in-effect.
14. Israeli Ministry of Health. Healthcare Telemedicine Survey – Israel [Internet]. London: International Bar Association; 2022 [cited 2025 Aug 7]. Available from: https://www.ibanet.org/document?id=Healthcare-Telemedicine-Survey-Israel.
15. ICLG. Digital Health Laws and Regulations Report 2025 – Israel [Internet]. London: Global Legal Group; 2025 [cited 2025 Aug 7]. Available from: https://iclg.com/practice-areas/digital-health-laws-and-regulations/israel.
16. Privacy Protection Authority (Israel). Digital Health Laws and Regulations Report 2025 – Israel [Internet]. London: Global Legal Group; 2025 [cited 2025 Aug 7]. Available from: https://iclg.com/practice-areas/digital-health-laws-and-regulations/israel.
17. Australian Digital Health Agency. National Digital Health Strategy and Programs [Internet]. Canberra: Australian Government; 2025 [cited 2025 Aug 7]. Available from: https://www.digitalhealth.gov.au.
18. Bundesärztekammer. Telemedizin / Fernbehandlung [Internet]. Berlin: Bundesärztekammer; 2025 [cited 2025 Aug 7]. Available from: https://www.bundesaerztekammer.de/themen/aerzte/digitalisierung/telemedizin-fernbehandlung.
19. Haute Autorité de Santé. Téléconsultation et téléexpertise : guide de bonnes pratiques [Internet]. Paris: HAS; 2021 [cited 2025 Aug 7]. Available from: https://www.has-sante.fr/jcms/c_2971632/fr/teleconsultation-et-teleexpertise-guide-de-bonnes-pratiques.
20. Ministry of Health and Family Welfare (India). Telemedicine Practice Guidelines [Internet]. New Delhi: Government of India; 2020 [cited 2025 Aug 7]. Available from: https://esanjeevani.mohfw.gov.in/assets/guidelines/Telemedicine_Practice_Guidelines.pdf.
21. National Health Commission of China. Empowering Primary Health Care with Digital Intelligence – Practices in China [Internet]. Beijing: NHC; 2022 [cited 2025 Aug 28]. Available from: https://en.nhc.gov.cn/.
22. Chen J, Jiao Y, Lu C, Zhou J, Zhang Z, Zhou C. A nationwide telepathology consultation and quality control program in China: implementation and result analysis [Internet]. Diagn Pathol. 2014;9(Suppl 1):S2 [cited 2025 Aug 28]. Available from: https://diagnosticpathology.biomedcentral.com/articles/ 10.1186/1746-1596-9-S1-S2.

23. Verkhovna Rada of Ukraine. Zakon Ukrayiny No. 3301-IX vid 09.08.2023 "Pro vnesennya zmin do deyakykh zakonodavchykh aktiv Ukrayiny shchodo funktsionuvannya telemedytsyny" [Internet]. Kyiv: Verkhovna Rada; 2023 [cited 2025 Aug 7]. Available from: https://zakononline.com.ua/documents/ show/521101___757826.
24. Ministry of Health of Ukraine. Nakaz No. 681 vid 19.10.2015 "Pro zatverdzhennya normatyvnykh dokumentiv shchodo zastosuvannya telemedytsyny u sferi okhorony zdorov'ya" [Internet]. Kyiv: MOZ Ukrayiny; 2015 [cited 2025 Aug 8]. Available from: https://chernigiv-rada.gov.ua/ohoronaz-reformuvannya/id-2479.
25. National Academy of Medical Sciences of Ukraine. Zaprovadzhennya ta rozvytok telemedytsyny v Ukrayini [Internet]. 2023 [cited 2025 Aug 7]. Available from: https://amnu.gov.ua/zaprovadzhennya-ta-rozvytok-telemedyczyny-v-ukrayini.
26. INgenius. Telemedytsyna v Ukrayini [Internet]. 2023 [cited 2025 Aug 7]. Available from: https://ingeniusua.org/articles/telemedytsyna-v-ukrayini.
27. FCKMP. Yak rozvyvaiet'sya telemedytsyna v Ukrayini: pidsumky y plany na 2024 rik [Internet]. 2024 [cited 2025 Aug 7]. Available from: https://fckmp.org.ua/news/yak-rozvyvaietsia-telemedytsyna-v-ukraini-pidsumky-i-plany-na-2024-rik.
28. InterNetri. Zastosuvannya shtuchnoho intelektu (ShI) dlya diahnostyky zakhvoryuvan [Internet]. 2021 Jun 26 [cited 2025 Aug 8]. Available from: https://internetri.net/qntm/2021/06/26/zastosuvannya-shtuchnogo-intelektu-shi-dlya-diagnostyky-zahvoryuvan.
29. Liu L, Zhang Y, Wang H, Chen X, Li J, et al. Artificial intelligence-assisted diagnosis and management of zinc deficiency: a multicenter study in Scandinavian populations. eClinicalMedicine. 2024;80:102992. doi: 10.1016/j.eclinm.2024.102992.
30. Frontiers Editorial Team. Digital Pathology and Telepathology – Integrating AI-driven Sustainable Solutions into Healthcare Systems [Internet]. Frontiers in Medicine. Available from: https://www.frontiersin.org/research-topics/72971/digital-pathology-and-telepathology-integrating-ai-driven-sustainable-solutions-into-healthcare-systems.
31. Zia S, Yildiz-Aktas I, Zia F, Parwani AV. An update on applications of digital pathology: primary diagnosis; telepathology, education and research. Diagn Pathol. 2025;20:17. doi:10.1186/s13000-025-01610-9.
32. Nastenko IA, Honcharuk MO, Babenko VO, Lynnyk MI, Ignatieva VI, Yachnyk VA. Development of artificial intelligence-based programs for the diagnosis of myocarditis in COVID-19 using chest computed tomography data. *Ukrainian Journal of Cardiovascular Surgery*. 2024;32(3):53–59 (in Ukrainian). https://doi.org/10.30702/ujcvs/24.32(03)/NH052-5865.
33. Mahmood MF. Recognition and categorization of blood groups by machine learning and image processing method. *Innovative Biosystems and Bioengineering*. 2024;8(2):53-68. DOI: https://doi.org/10.20535/ibb.2024.8.2.298201.

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