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Navigating Clinical Implementation of AI in Gastroenterology: Regulatory, Economic, and Skills Development Challenges

Abstract: Artificial intelligence (AI) is rapidly transforming gastroenterology, with endoscopic and radiologic applications achieving regulatory approval, yet clinical implementation faces significant barriers requiring strategic solutions. This analysis examines current challenges in AI deployment across gastroenterological practice, with emphasis on emerging physician deskilling concerns and new competency requirements. A comprehensive review of regulatory pathways, approved AI devices, implementation barriers, and recent clinical evidence was conducted, incorporating practical insights from AI development coaching experience. Currently, over 20 AI devices have received FDA or EU approval for gastroenterological applications, including 10 radiologic tools primarily targeting liver assessment and 6 endoscopic systems for polyp detection. While endoscopic AI required randomized controlled trials for FDA approval, radiologic applications achieved clearance through less stringent 510(k) pathways. Major implementation barriers include evolving regulatory frameworks struggling with AI's adaptive nature, limited real-world evidence demonstrating patient outcomes, unclear cost-effectiveness and reimbursement models, ethical concerns regarding data governance and algorithmic bias, and critically, newly documented physician deskilling effects. A 2025 multicentre study demonstrated that adenoma detection rates in standard colonoscopy decreased significantly from 28.4% to 22.4% after endoscopists were exposed to routine AI use, representing the first evidence of AI-induced performance degradation. Successful AI implementation requires developing AI-specific regulatory pathways, generating robust real-world evidence, establishing transparent bias mitigation strategies, creating value-based reimbursement models, and implementing new competency frameworks to prevent deskilling while enhancing clinical capabilities through strategic human-AI collaboration.

Keywords: Artificial Intelligence, Medical Imaging, Implementation Science, Human-AI Interaction, Clinical Decision Support, Gastroenterology.

Biography: Dr. Kateryna Nechypurenko is a radiologist with over 15 years of clinical experience and Founder/Business Development Director at Radimeds LLC, specializing in general radiology, trauma, and multimodality imaging across X-ray, CT, CBCT, MRI, and sonography. Since 2017, she has been coaching AI developers internationally, providing expertise in data quality management, annotations, use case development, and clinical implementation strategies. Her educational background spans Gorky National Medical University (Ukraine), Vilnius University (Lithuania), and Stanford University School of Medicine. Dr. Kateryna focuses her research on AI implementation in healthcare and serves as a consultant for hospitals, clinics, and AI companies worldwide, bridging the gap between clinical practice and artificial intelligence innovation in medical imaging