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Clinical Implementation of Artificial Intelligence in Gastroenterology: Current Landscape, Regulatory Challenges, and Ethical Issues



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Artificial intelligence (AI) is set to rapidly transform gastroenterology, particularly in the field of endoscopy, where algorithms have demonstrated efficacy in addressing human operator variability. However, implementing AI in clinical practice presents significant challenges. The regulatory landscape for AI as a medical device continues to evolve with areas of uncertainty. More robust studies generating real-world evidence are required to ultimately demonstrate impacts on patient outcomes. Cost-effectiveness data and reimbursement models will be pivotal for widespread adoption. Novel challenges are posed by emerging technologies, such as generative AI. Ethical and medicolegal concerns exist relating to data governance, patient harm, liability, and bias. This review provides an overview for clinical implementation of AI in gastroenterology and offers potential solutions to current barriers.

Keywords: Endoscopy; Artificial Intelligence; Regulation; Implementation; Gastroenterology.

Artificial intelligence (AI) is set to transform health care, with gastroenterology emerging as a leading specialty prime for innovation. Gastrointestinal endoscopy has some of the most translationally mature AI applications in medicine, notably with AI algorithms achieving regulatory approval for AI-assisted colorectal polyp detection (computer-aided detection [CADe]) and characterization (computer-aided diagnosis [CADx]) in colonoscopy. Crucially, the clinical efficacy of CADe in colonoscopy is now supported by high-quality evidence from multiple randomized controlled trials (RCTs).[1]

However, the path to real-world clinical implementation of AI in gastroenterology is complex, presenting multiple challenges. These including navigating regulatory hurdles in an evolving landscape that is adapting to the unique characteristics of AI technologies, generating robust real-world clinical evidence, ensuring cost-effectiveness with associated reimbursement models and addressing ethical concerns.

As gastroenterology stands on the brink of this technological revolution, addressing these implementation challenges will be crucial for realizing the full potential of AI to improve patient outcomes in gastroenterology. This review provides a current overview and explores potential solutions for these key implementation challenges.

Methods

A literature search of English-language articles was conducted on several databases, including PubMed, Google Scholar, and Scopus. Search terms were broad and included "artificial intelligence," "endoscopy," "barriers," "implementation," "regulation," and "gastroenterology."

For regulatory status, these were confirmed on the websites of the major endoscopy companies and in press releases, as well as on the websites of the regulatory bodies; primarily the US Food and Drug Administration (FDA) and resources from the European Commission, including its library and the European Database on Medical Devices.

A narrative review was performed following this search strategy.

Abbreviations used in this paper: **AI, artificial intelligence; AIaMD, artificial intelligence as a medical device; CADe, computer-aided detection; CADx, computer-aided diagnosis; EU, European Union; FDA, US Food and Drug Administration; genAI, generative AI; MDR, Medical Device Regulation; ML, machine learning; RCT, randomized controlled trial; SMEs, small- and medium-sized enterprises.**

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Regulatory Approval Pathways

There is global variation in regulatory pathways for software as a medical device, although common principles apply to frameworks in major jurisdictions, such as the United States and European Union (EU). Fundamentally, processes are defined for demonstrating safety and clinical efficacy. These rely broadly on a clearly stated intended use for the device, associated risk classification, followed by outlining of necessary performance and safety requirements.

The FDA categorizes devices into the following 3 classes based on level of perceived risk: class I (low risk), class II (medium risk), and class III (highest risk).[2] The EU also divides class II into IIa (medium risk, devices installed in the body for a short period of time) and IIb (higher risk, installed within the body for 30 days or more).[3]

There are 3 main pathways for FDA approval and devices can be either "cleared" or "approved."[4] All 3 pathways share common requirements, including details about intended use, design, manufacturing processes, and evidence of safety and effectiveness. However, the depth and complexity of the required data differ considerably. The 510(k) clearance is granted to a device that is "substantially equivalent" to another device (the predicate) that has already received FDA clearance. The 510(k) pathway generally requires the least evidence, focusing on bench and performance data to demonstrate safety, effectiveness, and substantial equivalence to a predicate device. Although it is usually the fastest and least resource-intensive option, all endoscopy AI systems cleared so far under the 510(k) pathway have been evaluated in RCT settings.[5]

Premarket approval is for class III devices and, due to the higher risk they pose, these undergo much higher levels of regulatory scrutiny before approval.[6] As the most rigorous pathway, extensive clinical evidence is required, often including RCTs with US-representative populations. It entails considerable time and cost, with the FDA encouraging early collaboration during the process to mitigate approval challenges pathways.[4,7] Facility inspections are also typically conducted to verify data integrity and quality management systems. The De Novo pathway bridges the two, targeting novel devices without predicates. It typically relies on pivotal studies, but the FDA may consider feasibility studies, real-world data from other jurisdictions, or literature reviews for similar devices to assess safety and effectiveness.[8]

In the EU, the new Medical Device Regulation (MDR) became effective in 2021, replacing the Medical Device Directive. The MDR defines medical devices into classes based on risk, similar to the FDA but with the additional subcategories of class IIa and IIb within the medium-risk category. The class determines the subsequent conformity

Table 1. Approved Gastroenterology Artificial Intelligence Devices in the United States

Product	Manufacturer	Function
Video capsule endoscopy		
Navicam Proscan[9]	AnX Robotics Corporation	Automate reading of small bowel capsule endoscopy
Lower gastrointestinal endoscopy		
CADDIE[10]	Odin Medical Ltd	CADe
CAD-EYE (EW10-EC02)[11]	Fujifilm Holdings Corporation	CADe
EndoScreener[12]	Wision AI	CADe
GI GENIUS[13]	Medtronic Plc	CADe
MAGENTIQ-COLO[14]	Magnetiq Eye Ltd	CADe
SKOUT[15]	Iterative Health	CADe
Radiology		
FerriSmart[16]	Resonance Health Analysis Service Ltd	Assessment of liver iron concentration on MRI
FlightPlan for Liver[17]	GE Healthcare Technologies Inc	Assess liver vasculature in hepatocellular carcinoma
HealthFLD[18]	NANO-x Imaging LTD	Qualitative and quantitative assessment of liver attenuation on CT, for assessment of fatty liver
Hepatic VCAR[19]	GE Healthcare Technologies Inc	Automatic CT liver segmentation
HepaFatSmart[16]	Resonance Health Analysis Service Ltd	Assessment of degree of fatty infiltration of liver on MRI
iCAS-LV[20]	HighRAD Ltd	Assess liver lesions on CT
LiverSmart[16]	Resonance Health Analysis Service Ltd	Combines FerriSmart and HepaFatSmart
LiverMultiScan[21]	Perspectum Ltd	Diagnose and monitor patients with chronic liver diseases
MRCP+[22]	Perspectum Ltd	Visualization of the biliary tree
Velacur[23]	Sonic Incytes Medical Corp	AI-guided ultrasound elastography measurements of fatty liver
VisAble.IO[24]	TechsoMed Medical Technologies Ltd	Plan liver ablation procedure

CT, computed tomography; MRI, magnetic resonance imaging.

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Table 2. Approved Gastroenterology Artificial Intelligence Devices in the European Union

Product	Manufacturer	Function
Upper gastrointestinal endoscopy		
CADU[25]	Odin Medical Ltd	Analyzing dysplasia in Barrett's esophagus
WISE VISION (Be20)[26]	NEC Corporation	Analyzing neoplasia in Barrett's esophagus
Video capsule endoscopy		
Navicam Proscan[27]	AnX Robotics Corporation	Automate reading of small bowel capsule endoscopy
Lower GI endoscopy		
CADDIE[25]	Odin Medical Ltd	CADe + CADx + percentage mucosal surface seen + cecal detection
CAD-EYE (EW10-EC02)[28]	Fujifilm Holdings Corporation	CADe + CADx
DISCOVERY[29]	Pentax Medical	CADe
ENDO-AID[30]	Olympus Corporation	CADe
EndoScreener[31]	Wision AI	CADe
GI GENIUS[32]	Medtronic Plc	CADe + CADx
MAGENTIQ-COLO[33]	Magnetiq Eye Ltd	CADe
SMARTIBD[25]	Odin Medical Ltd	Ulcerative colitis assessment
SKOUT[34]	Iterative Health	CADe
WISE VISION Endoscopy (Ce20/ Cx20)[35]	NEC Corporation	CADe + CADx
Radiology		
Ferrismart[16]	Resonance Health Analysis Service Ltd	Assessment of liver iron concentration on MRI
FlightPlan for Liver[36]	GE Healthcare Technologies Inc	Assess liver vasculature in hepatocellular carcinoma
Hepatic VCAR[36]	GE Healthcare Technologies Inc	Automatic CT liver segmentation
LiverMultiScan[37]	Perspectum Ltd	Diagnose and monitor patients with chronic liver diseases
MRCP+[38]	Perspectum Ltd	Visualization of the biliary tree

CT, computed tomography; MRI, magnetic resonance imaging.

assessment route, requiring the involvement of an independent notified body in most cases. Notified bodies are private entities with technical expertise in assessment of device testing and clinical trials, which are designated by EU member states.

Current Status of Regulatory Approved Artificial Intelligence/Machine Learning–Based Software as a Medical Device in Gastroenterology

Tables 1 and 2 summarize the current AI devices in gastroenterology that have received regulatory approval from the FDA and Conformité Européenne Marking from the EU. Most approved devices relate to gastrointestinal endoscopy.

The first commercially approved AI-powered endoscopy device was GI Genius (Medtronic), receiving Conformité Européenne Marking in 2019[39] and cleared by the FDA under the De Novo Pathway in 2021.[13] It consists of CADe software designed to detect polyps during colonoscopy. The clearance paperwork made public by the FDA shows the burden of evidence required. The landmark clinical trial, with clinical end points used for approval in both the EU and United states, was a multicenter RCT.[40]

Since then, there has been a proliferation of other endoscopy AI systems that have received regulatory approval, mostly in colonoscopy. All of the approved devices for colonoscopy in the United States so far are only approved for CADe. These include EndoScreener (Wision AI), cleared via the 510(k) Pathway using data from a US-based multicenter trial[41] and SKOUT (Iterative Health), also cleared via the 510(k) Pathway[15] using trial data from a US RCT.[42] Both used GI Genius as the predicate device. There have also been new technologies, including Navicam Proscan (AnX Robotics), an algorithm cleared under the De Novo Pathway to automate reading of video capsule endoscopy.[9]

Multiple devices are approved for radiologic use in gastroenterology and hepatology, almost all focus on the liver. Uses include assessing for degree of fatty infiltration on magnetic resonance imaging,[16] assessing liver lesions on computed tomography,[20] and planning ablation procedures in hepatocellular carcinoma.[24]

For the EU, many of the same devices are authorized for use in colonoscopy, although some AI systems have also received Conformité Européenne Marking for other endoscopic applications, such as CADx for colorectal polyps, endoscopic scoring of ulcerative colitis activity, and CADe of Barrett's neoplasia. Unlike the FDA, the EU does not make the evidence used to reach their decision publicly available.

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This lack of transparency complicates direct comparisons of regulatory requirements across the jurisdictions. Notably however, CADe and CADx AI systems approved in the EU were authorized without evidence from RCTs. This is in stark contrast to the more rigorous evidence typically required by the FDA for premarket approval or De Novo clearance.

Regulatory Challenges and Future Directions for Artificial Intelligence as a Medical Device

Regulatory pathways for artificial intelligence as a medical device (AIaMD) are evolving and the associated uncertainty around requirements may delay technological innovation. The traditional pathways for medical device regulation are not well designed for the dynamic pace of AI innovation. Moreover, novel AIaMD use cases are often developed by small- and medium-sized enterprises (SMEs) or startups, frequently in collaboration with academia. These collaborations might be disproportionately affected by the regulatory burden involved with AIaMD because SMEs must prioritize limited resources and cannot invest in the regulatory expertise required to navigate complex processes.[43]

The new EU MDR legislation poses challenges for device manufacturers by extending requirements, including the reclassification devices to a higher-risk, more rigorous testing with clinically relevant end points, increasing responsibility of notified bodies, introduction of expert panels, and extending clinical testing and surveillance to the entire life cycle of medical devices.[44] AIaMD providing information for clinical decision making will be classified as at least class IIa under the MDR. The European Commission extended the deadline for recertification of devices under the previous Medical Device Directive after concerns were raised by physician organizations and industry about risks of shortages of critical devices. A 2022 survey of medical technology providers across Europe showed that MDR certificates had, at the time, not been issued for >85% of the more than 500,000 devices previously certified.[45] Indeed, up to 30% of SMEs had still been unable to access an MDR-designated notified body, a particularly striking fact when 90% of the medical technology market in Europe are SMEs.[46] Larger companies are generally more likely to receive approval in both the United States and EU.[47] Due to the regulatory burden, approximately one-half of respondents to the survey were planning a portfolio reduction within Europe, and approximately one-half again planned to deprioritize Europe as the market to achieve their first regulatory approval.[45]

In addition, the EU recently introduced the AI Act, the world's first comprehensive legal framework on AI.[48] The EU AI Act created strict rules for high-risk AI systems with specific compliance requirements on developers covering key areas such as data governance, transparency, traceability, cybersecurity, and robustness throughout the lifecycle. The AI Act requires comprehensive AI-specific technical documentation (ISO/IEC 420001 AI Quality Management System), although developers already have obligations to create a Quality Management System to satisfy requirements of EU MDR (ISO/IEC 13485 Medical Device Quality Management System), it is likely that manufacturers will extend this to incorporate the additional requirements under the EU AI Act.

In the United States, there is currently no AI-specific clearance or approval pathway for AIaMD. Most AI algorithms so far have been cleared under the 510(k) Pathway.[47] This can lead to so-called "predicate creep," when a lenient interpretation of substantial equivalence facilitates clearance of generations of devices that claim substantial equivalence to each other with iterative design changes, resulting in devices dissimilar from original predicates. In an analysis of FDA-cleared AI/machine learning (ML) algorithms using the 510(k) Pathway, almost one-third were cleared on the basis of on a non-AI/ML–based initial predicate, which itself may be many generations removed from the AI/ML system.[49] This could pose safety risks and has led to questions regarding the robustness of this pathway for AIaMD.

The FDA recently published a special communication acknowledging that AI-enabled products will require an adaptive, science-based regulatory scheme to prevent harm, while also supporting innovation that optimizes their benefits.[50] The FDA has already proposed a total product lifecycle regulatory approach to overcome the limitations of traditional medical device regulation that was not designed for adaptive AI technologies, which have the potential to adapt and optimize device performance in real time to continuously improve. This highlights the commonly neglected issue that AI-based software can function on a spectrum from being locked to continuously learning. The following 3 categories of modification have been identified after initial approval of the software as a medical device: changes in performance, inputs, and intended use. This later aligned with the FDA draft guidance on predetermined change control plans issued in 2023, which provided a Q7 pathway for device manufacturers to respond to AI's continuous modification without necessitating additional marketing submissions to the FDA for each modification. By including a predetermined change control plan in the original FDA submission, manufacturers can proactively prespecify and seek premarket authorization for intended modifications. The FDA also previously piloted a software precertification program, as highlighted in the Digital Q8 Innovation Action Plan, which was designed to provide a more streamlined and efficient pathway for software as a medical device. This novel pathway placed an emphasis on the technology developer rather than the focusing on the product, appraising for organizational excellence. However, the implementation of such a pathway would fundamentally require the FDA to be granted new statutory duties.

The FDA's medical product centers recently described global collaboration as a key area of focus to promote international cooperation on standards, guidelines, and best practices to encourage consistence and convergence in the use and evaluation of AI. The FDA has previously

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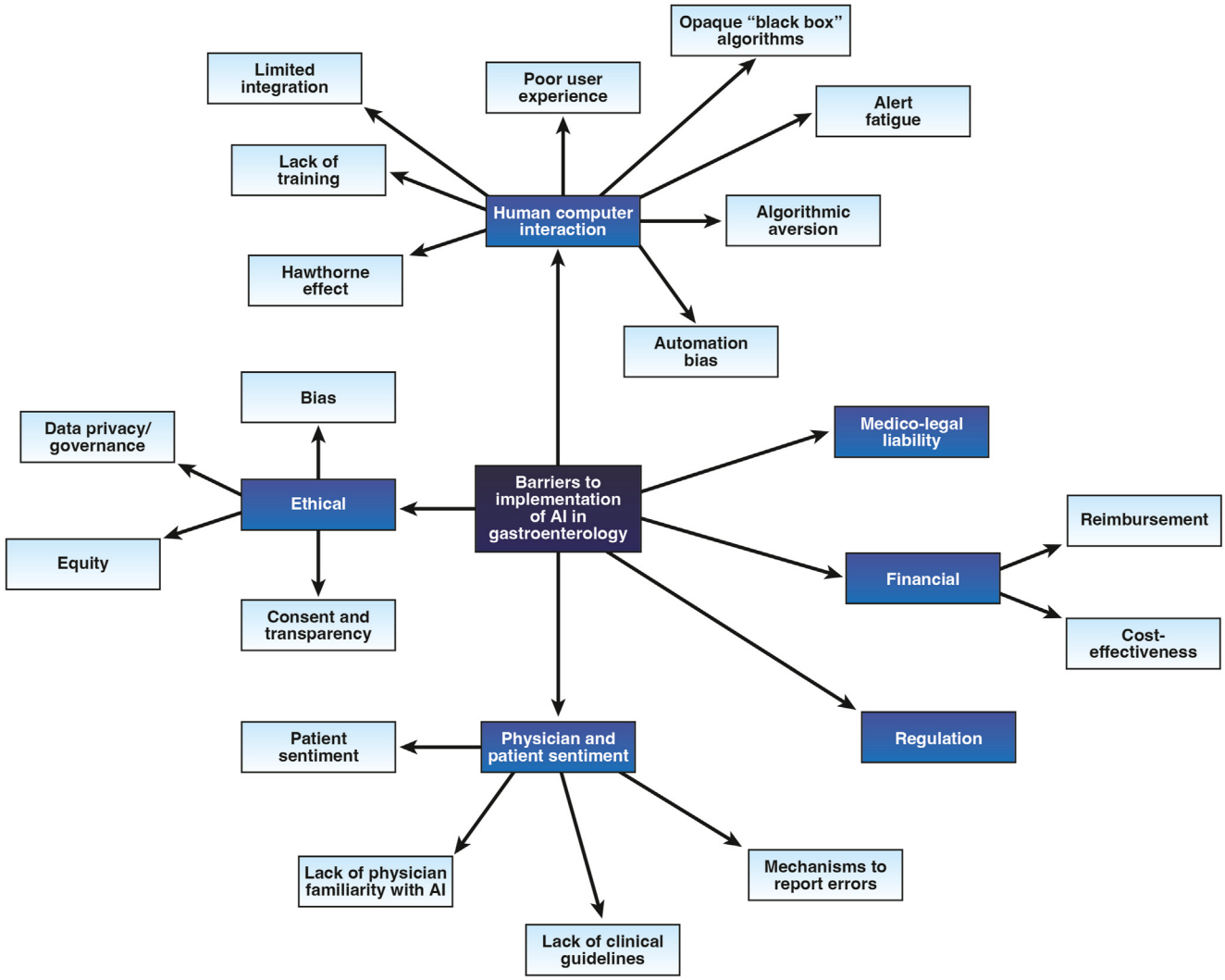

Figure 1. Barriers to implementation of AI Q17

collaborated with the UK's Medicines and Healthcare Products Regulatory Agency and Health Canada to develop guiding principles for Good Machine Learning Practices and predetermined change control plans. The FDA also recently took a significant step in global harmonization efforts by implementing ISO 13485, an international consensus standard to medical device quality management systems.[51] Q9

The advent of generative AI (genAI) highlights the challenges and complexities that rapidly evolving technologies bring to existing regulatory frameworks. genAI refers to a class of AI models that mimic the structure and characteristics of input data to generate derived synthetic content, and can include images, videos, audio, text, and digital content. genAI models are generally meant to create new data that resemble the data they learned from, rather than primarily identify pattens to make accurate predictions. genAI models are often developed on vast datasets, which are frequently intentionally broad and not initially tailored to specific tasks. genAI models designed for broad applications across multiple tasks are commonly known as "foundation models."

The FDA acknowledged the potential new regulatory challenges across the total product lifecycle posed by genAI-enabled devices by recently convening a Digital Health Advisory Committee meeting. The published executive summary identifies unique challenges, mainly relating to applying a traditional risk-based approach to classification of devices and determination of types of valid scientific evidence for the safety and effectiveness across the total product lifecycle. For instance, products using genAI or foundation models may have broad capabilities, making it challenging to identify a clearly constrained intended use. Furthermore, genAI models can be prone to "hallucinations," that is, the generation of erroneous or false content, which can be difficult to identify or explain. This can be further exacerbated by the lack of transparency relating to model development for genAI or large foundation models, especially when using off-the-shelf software, where the device manufacturer has very limited control of the foundation model incorporated into the product. This lack of transparency and potential for emergent or unanticipated behavior may be especially challenging to evaluate Q10

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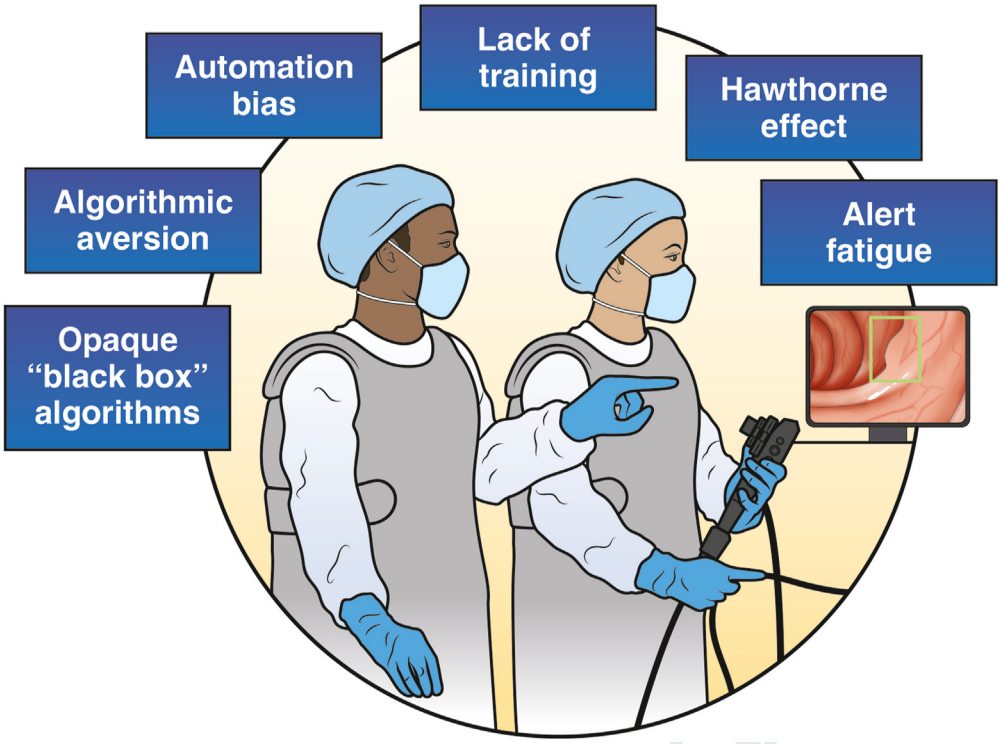

Figure 2. Aspects of human–AI interaction.

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premarket, requiring complementary effective ongoing postmarket monitoring strategies.

Other Barriers to Clinical Implementation of Artificial Intelligence

Clinical Trials and Real-World Evidence

AI health technologies require evidence generation to support clinical implementation. The vast majority of evidence generation for AI in health care consists of preclinical studies and small-scale prospective studies.[52] AI technologies are complex interventions with unpredictable impacts on health care pathways, especially due to variable generalizability of algorithms to different populations and deployment environments. Furthermore, the impact of human–AI interaction must not be overlooked. Therefore, early-phase studies offer limited estimation of real-world clinical effectiveness. A recent systematic review of prospective RCTs for AI health technologies identified only 65 eligible publications, with gastroenterology being the largest contributor.[53] In this regard, the use case of AI in endoscopy, especially CADe, represents the most robustly evaluated AI technology in health care, when considering the hierarchy of levels of evidence.

Although the RCTs and associated meta-analyses for CADe in colonoscopy have overwhelmingly demonstrated an improvement in adenoma dectection rate with AI-assisted colonoscopy, several nonrandomized or so-called "pragmatic" observational studies found CADe provided less or no efficacy.[54] RCTs can induce a Hawthorne effect, where clinicians modify their behavior simply from an awareness of participating in a trial, often favoring the intervention. Meanwhile, nonrandomized observational studies may reflect real-world scenarios but lack adequately controlled groups, and are prone to selection bias. A particular issue for AI systems is that clinical efficacy is also dependent on the human–AI interaction. For instance, detection gains from CADe require the endoscopist to perform high-quality mucosal exposure, and to not overlook true positives flagged by the AI, which could be inadvertently disregarded as false positives in the case of subtle lesions.[55] There is also concern about possible overreliance and modification of behavior with AI, for example, CADe could lead to simultaneous unconscious degradation in the quality of mucosal exposure. Eye-tracking studies have demonstrated that CADe led to an alteration in gaze patterns, with less time spent at the peripheries.[56] Similarly, CADx studies have demonstrated human endoscopist interaction was detrimental to performance, with the highest accuracy achieved for standalone AI.[57] More broadly, physician sentiment regarding AI could impact clinical outcomes considerably. Automation bias is a phenomenon whereby physicians may favor the algorithmic output over their own decision, even when it could be incorrect, due to strong trust in technology. Conversely, some physicians may experience "algorithmic aversion," linked with a general mistrust of AI technology, leading to overcriticism and rapid loss of confidence in the setting of errors, even when the overall standalone performance of the algorithm is superior.[58]

CADe trials have highlighted the importance of optimal trial design and associated relevant end points.[59] Adenoma detection rate is an established end point in screening colonoscopy studies, inversely correlating with risk of interval

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colorectal cancers.[60] CADe has been shown to increase detection of mainly diminutive polyps (<5 mm) in RCTs.[61] The impact of the additional detection of such lesions on long-term colorectal cancer incidence is uncertain. Moreover, there is a potential risk of overdiagnosis leading to more intensive surveillance and follow-up that may not be clinically beneficial. A large scale, prospective study is ongoing with an aim to establish an association between CADe use and long-term patient outcomes, including CRC incidence and mortality.[62] In addition to long-term outcome studies, others have proposed more pragmatic randomized implementation studies, where new interventions, such as CADe, are integrated into existing health care systems, such as cancer screening programs, making the study participants less biased to the intervention.[54]

It is critical that the anticipated exponential growth in AI applications for gastroenterology clinical practice is matched by robust evidence generation. The associated hype and technological sophistication surrounding AI can lead to unfamiliarity for end users and decision makers in health care. However, the evaluation of AI largely builds on well-established existing methodologies. International collaborations have already led to the extension of AI-specific guidelines, such as with the EQUATOR Network, for the reporting of trials as different stages of the AI translational pathway.[52] This needs to be supported by generation of more real-world evidence, especially accounting for human–AI interaction and deployment environments, to ultimately demonstrate the impact of AI technologies on patient outcomes in the intended clinical pathway and on wider health systems. The infrastructure and frameworks to generate ongoing evidence to monitor the clinical impact of AI systems post implementation will also need to be established.

Cost-Effectiveness

Establishing cost-effectiveness and associated reimbursement for AI in gastroenterology represent major current barriers for implementation.[63] Cost-effectiveness estimates are informed by an economic evaluation, usually conducted alongside a clinical study or using a decision model.[64] Economic evaluations are used by health care decision makers, reimbursement authorities, and health technology assessment agencies. AI creates new challenges for traditional health technology assessments and economic evaluation. A recent systematic review of economic evaluations of AI-based interventions identified only 21 published studies with significant methodological limitations.[65]

Cost-effectiveness studies for AI in gastroenterology are limited to CADe and CADx in colonoscopy, as these are the most translationally mature applications to date. Microsimulation studies have suggested that short-term health care costs may increase with CADe by increasing the number of detected polyps, polypectomies, and histopathologic examinations.[66] Furthermore, there would be an increased burden of surveillance colonoscopies. However, longer-term reduction in CRC incidence may lead to overall cost reductions, with the same microsimulation study estimating an approximate yearly saving of $290 million in the United States. Similar simulation studies have demonstrated cost savings with CADe use in screening populations in Japan and Canada.[67,68] Meanwhile, a post-hoc analysis of a large prospective study suggested that a CADx-enabled optical diagnosis strategy for diminutive rectosigmoid polyps could lead to a 11% reduction of average colonoscopy costs, potentially saving $85.2 million in the United States annually.[69] However, the assumptions and limitations of simulation-based modeling should be acknowledged, with the requirement of longer-term clinical studies with outcomes to inform more robust health economic evaluations.[70]

Health care systems and providers will carefully consider financial incentives before considering adoption of AIaMD. In the United States, for example, this will be influenced by reimbursement, the dollar amount paid for an AI service, as well as coverage, the likelihood of payment for a medically indicated AI service.[71] Only a small number of AI devices have achieved reimbursement via the Centers for Medicare and Medicaid Services through AI-specific Common Procedural Terminology codes and New Technology Add-On Payments. Currently, there is no reimbursement specifically for CADe in colonoscopy in the United States. The Japanese public health insurance body announced reimbursement in the form of an add-on payment for a CADe tool in February 2024.[72] Current reimbursement policies may need to be adapted for AI technologies, especially accounting for rapid scalability and automation. There is a concern that pay per-use models may lead to overuse of medical AI. Alternative reimbursement models have been proposed, which include value-based models that incentivize outcomes rather than volume, time-limited reimbursements for novel AI use cases, and advance market commitments.[73]

It is vital that gastroenterologists, AIaMD developers, and other key stakeholders collaborate to ensure high-quality, cost-effectiveness research is performed for emerging AI use cases. The Consolidated Health Economic Evaluation Reporting Standards for Interventions That Use Artificial Intelligence is a welcome AI-specific extension to reporting guidelines that should be used to ensure that AI-based health care interventions can be evaluated in a transparent and reproducible manner.[64]

Ethical and Medicolegal Issues

There are major ethical and medicolegal concerns related to the implementation of AI in gastroenterology.[74] These include issues relating to data governance, patient harm, accountability, and bias in decision making.

Data governance is a critical issue central to AI development in gastroenterology. AI algorithm development requires vast quantities of data not only for training, but ongoing validation and calibration, often across diverse geographical locations, which creates complex ethical and practical considerations. Organizations are facing increasing challenges dealing with privacy concerns, especially with the unprecedented creation of digital data. Patients are more aware of data privacy and the importance of

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transparency regarding data use. Health care providers and organization have an obligation to manage data according to relevant legislation, such as Health Insurance Portability and Accountability Act or General Data Protection Regulation. However, it should be acknowledged that current legislation alone does not address some concerns related to AI development. For instance, in some jurisdictions, fully anonymized data are not considered to be personal data and, therefore, explicit consent is not required for data sharing and secondary use. There are concerns, however, that it is not possible to achieve full anonymization, with risks of reidentification, especially for more rare diseases. Furthermore, traditional models of consent may need to be reimagined. Initial patient consent often restricts data use to specific, narrowly defined projects. This constraint creates uncertainty for future secondary AI-related research, which may provide novel insights or applications beyond the initial research proposal. For example, large-scale video endoscopy datasets initially collected for the purposes of CADe development could be valuable for multiple future use cases, such as automated endoscopy report generation and computer vision–driven quality assurance metrics. Furthermore, obtaining individual patient consent on the scale required for the development of gastroenterology-specific genAI or foundation models is almost impossible, particularly when the models have broad capabilities. In addition, data sharing with commercial organizations can lead to uncertainty regarding data ownership and perceived commoditization. Perhaps broader consent strategies could be effective, whereby patients provide consent for secondary uses of health care data without explicit knowledge of all future AI-related research. Such policies would need to be complemented by transparent and robust data governance mechanisms, including dedicated data custodians or research committees that ensure secondary use is only for projects that benefit patients. Health care organizations could mandate unrestricted use of novel AI technology that is co-developed or ensure any profits are reinvested directly to patient care.

As AI is deployed at scale, the likelihood of patient harm becomes more likely. Accountability and associated medicolegal liability are complex and evolving issues. There are numerous parties that could be accountable when harm occurs with AI use: the clinician, health care organization, algorithm developer, platform vendor, or even the individual who provided or labeled training data. A key consideration is the distinction between improper use of the AI device and errors resulting from flawed algorithmic outputs. Furthermore, the degree of AI automation is likely going to be critical in any judgment. Although most AI systems approved for use in gastroenterology currently offer decision support and no autonomy, it has been suggested that increasing levels of AI autonomy may shift the burden of responsibility toward algorithm developers.[75] For example, this could occur in a hypothetical scenario in which an erroneous AI-enabled autonomous read of a video capsule endoscopy procedure led to missed pathology and associated patient harm. In fully autonomous scenarios, the American Medical Association's AI policy states that the developer must accept liability in misdiagnosis or system failure scenarios, with a requirement to hold medical liability insurance.[76] A notable example is Digital Diagnostics, which carries medical malpractice insurance for its autonomous AI system IDx-Dr (now LumineticsCore), designed to screen for diabetic retinopathy.[77]

The health care industry can draw lessons from the adoption of autonomous AI in other sectors, particularly the automotive industry. SAE International's 6-level classification for driving automation, ranging from level 0 (no automation) to level 5 (full autonomy), has been adapted for health care.[78] No level 5 autonomous cars are on the market yet. Public trust, a critical factor in health care, is equally crucial for autonomous vehicles, and hinges on transparency and safety. Survey results show widespread reluctance to use autonomous vehicles,[79] and regulators have penalized misleading claims by manufacturers to try to build trust.[80] Similarly, post-market monitoring, an essential part of a total product lifecycle, is crucial. Following several collisions, Waymo, an Alphabet subsidiary, recalled cars to address software flaws in detecting poles, highlighting the need for vigilance and ongoing data collection post rollout of AI systems.[81]

Liability is another shared challenge. The first pedestrian fatality involving an autonomous car led to legal action against the backup driver, not the ridesharing company Uber.[82] Such precedents may create concern among physicians using autonomous AI systems in the future. However, some automakers, like Mercedes, now accept responsibility for accidents in automated systems and it is likely that as cars become more autonomous, the burden of liability will shift increasingly toward corporations.[83]

Other sectors can also offer valuable insights. Some jurisdictions are moving toward principles-based regulation rather than ex-ante approaches in financial AI systems, encouraging innovation.[84] AI systems have been developed to assess the regulatory compliance of new technologies.[85,86] These approaches could serve as a model for health care, easing the burden on regulatory bodies. They may even enable more decentralized and agile regulatory frameworks, especially for low-risk class 1 systems.

The manufacturing industry offers a valuable example with collaborative robots, or "cobots," which enhance precision and efficiency by working alongside humans.[87] In health care, similar systems could assist gastroenterologists with complex procedures like endoscopic submucosal dissection or even perform some endoscopy procedures autonomously in the future, expanding access to high-quality care.[88]

AI algorithms may also introduce bias and exacerbate health inequalities. This has been demonstrated, at least in preclinical studies, using AI systems for medical imaging diagnoses. The lack of transparency in AI models, both in terms of the data used for algorithm development and interpretability of decision making, can make bias more challenging to identify and mitigate. AI could contribute to health inequities through multiple proposed mechanisms.[89] This includes disparities in the clinical research problem selection; bias in data collection; variable selection, which are proxies for or confounded by biases against underrepresented groups; and introduction of bias in the

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algorithm development stage and in the post-deployment stage due to poor generalizability to minority subgroups or because of bias in human–AI interaction. International regulatory bodies have jointly published guiding principles for good machine learning practice, which specifically recommended that data should be representative of the intended population in order to manage any bias, promote appropriate and generalizable performance across the intended patient population, assess usability, and identify circumstances when the model may underperform. Unfortunately, despite this recommendation, algorithm developers are not always transparent about the characteristics and patient demographic characteristics for model training datasets, for example, this information is not in the public domain for most CADe colonoscopy software. The STANDING Together (Standard for Data Diversity, Inclusivity and Generalizability) initiative is a much needed international, consensus-based exercise that aims to develop recommendations for the composition and reporting of datasets that underpin medical AI systems.[90] This will be complemented by ongoing research to address bias identification and mitigation in AI systems across the total product lifecycle.[91]

Conclusions

The rapid development of AI in gastroenterology, specifically in the field of endoscopy, represents a significant advancement in medical technology. However, the path to real-world clinical implementation involves overcoming and carefully navigating numerous challenges. Key hurdles include regulatory compliance across different jurisdictions, while regulatory landscapes for AIaMD continue to evolve. Frameworks aimed at traditional medical devices must adjust to the adaptive and iterative nature of AI-based technologies, pathways must be streamlined for efficiency to promote innovation while maintaining patient safety. There is also a critical need to invest in high-quality clinical research aimed at generating real-world evidence, especially to evaluate human–AI interaction in the intended clinical pathway, with reporting of patient outcomes. This should be complemented by robust economic evaluations and creation of reimbursement models that acknowledge the potential scalability and automation that AI can bring to health care systems. Mechanisms that facilitate machine interpretability alongside legal guidance on accountability will facilitate implementation. Meanwhile, patient-centered information governance policies can promote innovation alongside investment in data ecosystems that safeguard confidentiality. Potential bias and exacerbation of existing health care inequalities must be avoided, with transparent reporting of datasets and mitigation across the total product lifecycle. Technological advances, such as genAI will likely introduce new challenges. The route toward full clinical implementation of AI in gastroenterology will require ongoing proactive collaboration between stakeholders to ensure that the field ultimately harnesses the transformative potential of AI to improve patient care.

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