



**American Society for
Gastrointestinal Endoscopy**

3300 Woodcreek Drive
Downers Grove, Illinois 60515
630-573-0600 / 630-963-8607 fax
info@asge.org / www.asge.org

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May 6, 2024

The Honorable Ami Bera, MD
U.S. House of Representatives
172 Cannon House Office Building
Washington, DC 20515

Sent to: bera.ai@mail.house.gov

Re: RFI on the Current State of AI in the Health Care Industry

Dear Congressman Bera:

On behalf of the American Society for Gastrointestinal Endoscopy (ASGE), thank you for the opportunity to respond to your request for information on the use of artificial intelligence (AI) in health care. ASGE appreciates your leadership in this area, and I thank you for taking the time to meet with our President Elect and AI Task Force Chair, Prateek Sharma, MD, FASGE in Washington, D.C. on April 30.

With more than 16,000 members worldwide, ASGE is the global leader in advancing digestive care through education, advocacy and promotion of excellence and innovation in endoscopy. In 2019 ASGE formed an AI Task Force to establish and integrate the optimal use and application of AI technology in gastrointestinal (GI) patient care. This effort represents ASGE's long-standing commitment in applying new and advanced technology to deliver improved care for GI patients.

GI cancers, including colorectal, esophageal, gastric, pancreatic, and liver cancers, benefit from early detection and intervention. AI integrated into endoscopy procedures is improving the diagnosis and treatment of these cancers. AI algorithms can accurately analyze images and videos obtained during endoscopy, aid in the early detection of abnormalities, such as polyps and suspicious lesions in colorectal and gastric cancers. AI can also assist in identifying precancerous conditions like Barrett's esophagus and subtle changes in the pancreas during endoscopic ultrasound, allowing for timely intervention. In liver cancer, AI-enhanced imaging enhances lesion detection and tracking, ultimately improving diagnostic accuracy and patient outcomes.

AI in the field of health care is emerging rapidly, and it is estimated that in the next 10 years, a substantial investment will be made in health AI within health care. This investment reflects the growing recognition of AI as a permanent and integral component of modern medicine, one that is already influencing patient outcomes and workflow efficiencies. We look forward to a continued dialogue as you consider policy to ensure the responsible use of health AI to advance patient care and improve the efficiency of health care delivery.

Medical societies must play a critical role in facilitating the secure and ethical integration of AI technology into practice. Toward that end, this September, ASGE will host its 6th Annual Global AI Summit on AI and Gastroenterology where critical discussions on these topics will continue. The Summit brings together physicians, educators, regulators, innovators, industry, and payers to discuss the opportunities and implications of AI in GI. More immediately, ASGE will launch in May the Artificial Intelligence Institute for Gastroenterology, with the mission to seamlessly integrate AI into GI care, enhance patient outcomes, and drive innovation in gastroenterology through cutting-edge AI solutions.

The ASGE is pleased to offer the following feedback on the following aspects of health care AI as requested in your RFI: Implementation; Efficacy, Accuracy, and Transparency; and Ethical and Regulatory Considerations.

Implementation

How extensively is AI currently being implemented in health care institutions and other settings across the country?

AI adoption is growing, but its penetration varies significantly across different health care settings. Major urban centers and academic hospitals are at the forefront, leveraging AI primarily in patient care management, and slowly for diagnostic gastroenterology procedures. Currently in the field of gastroenterology, there are a few Food and Drug Administration (FDA)-approved commercial algorithms for detecting precursors for colon cancer during a colonoscopy. However, smaller, and rural health care facilities often face significant barriers to adoption due to budget constraints and limited IT infrastructure which can lead to disparities in access to AI-driven technology.

What areas of health care are benefiting the most from AI integration, and what are the primary challenges hindering further adoption?

The most profound impact of AI is observed in fields requiring extensive data analysis, such as diagnostic imaging and most recently tools to improve interaction with electronic health records (EHRs). In gastroenterology, AI is helping to improve diagnostic accuracy for conditions like colorectal cancer. The primary challenges to broader AI integration include the high cost of technology, concerns about patient data security, the need for extensive datasets for AI training, and resistance to change or lack of understanding among health care providers of how these algorithms work. Moreover, some of the technologies that have been developed for clinician burnout are not validated and the models seem to be drifting and no accountability currently exists for such tools.

What are the various applications of AI in clinical or operational contexts?

Clinically, currently AI is used in the enhancement of diagnostic precision through advanced imaging techniques. Predictive analytics, while in the pipeline, have not seen much generalizability and validity in clinical domain and, hence, have seen less adoption to date. Operationally, AI may help in optimizing scheduling, patient flow, and resource allocation, significantly enhancing administrative efficiency and patient satisfaction.

How does AI distinguish itself from other health care technologies? How does AI support existing health care technologies?

AI is unique in its ability to analyze large datasets rapidly and learn from them, offering insights that are not feasible with traditional computational methods. As we move toward petabytes of health care data, carefully delineating wisdom out of that massive information would be possible only by using AI

technologies. Traditional statistical methods and their underlying mathematical concepts might not support this kind of analysis. Moreover, in comparison to other health care technologies, the strength of AI machine learning is that they learn iteratively in a very active way as it considers every new data point and learns optimizes the algorithm as opposed to versions of medical hardware.

What measures can be employed to guarantee proper reimbursement and coverage for AI technologies in health care?

The term "AI" alone is insufficient to define a specific health care service, which poses challenges when attempting to differentiate AI from other computer and software-based technologies in the health care sector. Currently, there are definitions across multiple stakeholders and government agencies. For example, Congress defined the term "artificial intelligence" in the *National Artificial Intelligence Initiative Act of 2020*¹, in February 2020, the Consumer Technology Association (CTA) released standards for AI² in which it defined "assistive intelligence" and "automated / autonomous" intelligence" and American Medical Association (AMA) Current Procedural Terminology (CPT®) Editorial Panel accepted a new Appendix S: AI Taxonomy for medical services & procedures that defines healthcare AI services for purposes of medical coding.³ The AMA has generally categorized AI as part of practice expense in physician payments, which include practice overheads and equipment such as computers. We believe that this classification does not accurately reflect the unique nature and potential impact of AI in health care.

Our concern is that the absence of a precise definition that is universally accepted and an appropriate placement of AI in payment structures has the potential to hinder patient care and appropriate access to AI technology and innovation in both AI and health care industries. Policymakers must take a leading role in defining AI within the health care domain. Establishing clear and standardized definitions will provide a crucial framework for innovators to align their work.

ASGE supports the AMA definition and taxonomy for physician services involving AI. This taxonomy encompasses work conducted by algorithms, including machine learning and expert systems, and categorizes AI into three distinct types: Assistive, Augmentative, and Autonomous.

We believe that by embracing and implementing these definitions, the healthcare industry can move toward a more equitable and standardized approach to AI reimbursement. This, in turn, will facilitate innovation, enhance patient care, and ensure that AI's unique contributions to healthcare are appropriately recognized and compensated.

Reimbursement structures must also not disadvantage physicians who have not integrated/adopted AI technology and addressing liability concerns must be addressed for AI technology for physicians to use it to the fullest potential. For example, any efficiencies from the use of AI would not be realized if, for example, a physician feels he or she must review all images from a test, even those discarded by AI technology, if there is concern about risk of liability that is not spread evenly across all parties, including AI developers.

¹ Pub. L. 116–283, div. E, §5002, Jan. 1, 2021, 134 Stat. 4523

² Consumer Technology Association, "ANSI/CTA Definitions/Characteristics of Artificial Intelligence in Health Care: ANSI/CTA-2089.1" (February 2020). <https://www.cta.tech/Resources/Newsroom/Media-Releases/2020/February/CTA-Launches-First-Ever-Industry-Led-Standard>. Accessed May 2, 2024.

³ American Medical Association, <https://www.ama-assn.org/system/files/cpt-appendix-s.pdf> Accessed May 2, 2024.

Efficacy, Accuracy, and Transparency

What clinical evidence exists regarding the efficacy and accuracy of AI-driven health care solutions?

There is a growing body of clinical evidence demonstrating the efficacy and accuracy of AI applications in health care. Studies published in reputable medical journals have consistently shown that AI could improve diagnostic efficacy of clinicians. For instance, AI has been proven to be augmenting performance of the endoscopist in detecting and diagnosing digestive diseases from endoscopic images and precancerous lesions. However, it must be noted that not all clinical evidence is rated the same. Very few randomized control trials exist for evaluating the efficacy of AI in clinical practice. Fortunately, as shown in a recent study published in *Lancet*, gastroenterology is leading the space as 43% of all AI RCTs in medicine were done in gastroenterology. We urge the congress and FDA to develop standard guidelines in clinical research design for AI tools. Medical societies with their domain expertise can aid in the process.⁴

What best practices are recommended to ensure sufficient availability and use of health data for AI-driven health care solutions?

Ensuring the availability and ethical use of health data for AI involves adhering to strict data protection standards and ethical guidelines. Best practices include anonymizing patient data to protect privacy, creating large and diverse data sets to train AI systems effectively, and ensuring the continuous updating of data sets to reflect new medical insights and demographic changes.

What guardrails or accountability mechanisms could be set to ensure end-to-end transparency?

To achieve end-to-end transparency, it is essential to implement clear documentation standards for AI development processes and decision-making pathways. This includes recording and reporting the data sources used, the AI training methods, the versioning of AI systems, and the rationale for clinical recommendations provided by AI. Clear guidance for these processes were recommended by the ASGE AI task force as shown in the picture below.

Under the umbrella of transparency, an investigative story published by *ProPublica* in March 2023 alleged Cigna used a computer algorithm to review requests for authorization and then had physicians sign off on batches of denied claims without proper review.⁵ We appreciate that story led to an inquiry⁶ by House Energy and Commerce Committee Republicans into Cigna's prior authorization practices.

We are also pleased that state insurance commissioners took notice, suggesting that prior authorization practices that use AI warrant greater scrutiny.⁷ We agree.

AI makes it more economical for payers to require prior authorization for a greater number of services, even services that are considered low-volume or are low-cost. This is why ASGE led the adoption of new

⁴ [https://doi.org/10.1016/S2589-7500\(24\)00047-5](https://doi.org/10.1016/S2589-7500(24)00047-5)

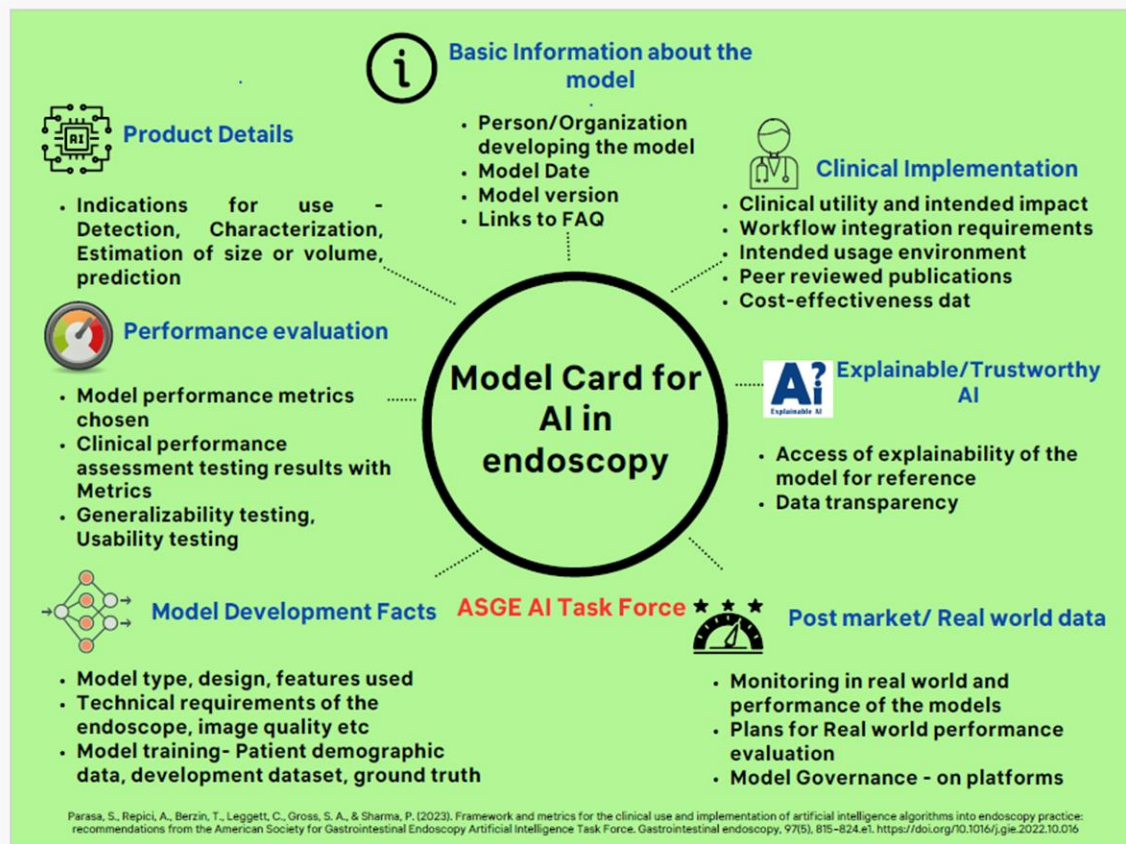
⁵ How Cigna Saves Millions by Having Its Doctors Reject Claims Without Reading Them. *ProPublica*. March 25, 2023. <https://www.propublica.org/article/cigna-pxdx-medical-health-insurance-rejection-claims> Accessed May 2, 2024.

⁶ <https://energycommerce.house.gov/posts/e-and-c-republicans-press-cigna-for-clarification-after-investigative-report-accuses-insurance-company-of-denying-claims-without-reading-them>

⁷ <https://www.beckerspayer.com/payer/insurance-commissioners-eye-cigna-following-report-of-physicians-denying-claims-without-reading-them.html>

policy, at the June 2023 American Medical Association's (AMA) House of Delegates meeting which calls for greater regulatory oversight of the use of AI for review of patient claims and prior authorization requests.⁸

Congress can play a significant role in setting standards for transparency in algorithmic systems and ensuring accountability. Congress should consider legislation that mandates oversight and accountability in the transparency requirements for algorithmic systems including how it makes decisions, data usage, and potential biases. Further, because insurers are putting an increasing number of services through prior authorization and may be using AI to process large volumes of coverage requests, we believe strongly that more transparency must be required of insurers regarding the rationale for subjecting new services to prior authorization, include release of internal data that may show geographic variation in utilization or proof of inappropriate utilization.



How can we ensure guardrails are put in place to mitigate risks such as disparate impact from racial, ethnic, and other biases?

Addressing biases in AI, particularly those that could cause disparate impacts on different racial or ethnic groups, requires a multifaceted approach. This includes training AI models on diverse datasets that are representative of all patient demographics, conducting routine audits for bias and fairness, and implementing oversight by multidisciplinary teams will be important.

What are accountability mechanisms that can be put in place to ensure that there is an

⁸ [https://policysearch.ama-assn.org/policyfinder/detail/augmented intelligence?uri=/AMADoc/directives.xml-D-480.956.xml](https://policysearch.ama-assn.org/policyfinder/detail/augmented%20intelligence?uri=/AMADoc/directives.xml-D-480.956.xml)

accurate spread of information?

Ensuring the accuracy of information spread by AI systems can be safeguarded by establishing rigorous validation and certification processes for these technologies before they are deployed. Regular performance reviews, post-implementation monitoring, and mandatory reporting of errors or discrepancies should be instituted. Additionally, creating a transparent feedback mechanism where clinicians and patients can report issues or inaccuracies is crucial for ongoing improvement.

Ethical and Regulatory Considerations

With the increasing reliance on AI in health care decision-making, what ethical and regulatory considerations need to be addressed to ensure patient safety, privacy, and equity?

The ethical use of AI in health care requires a robust framework that addresses patient safety, privacy, and equity. Model governance frameworks should be developed with the help of clinicians and domain experts. Regulatory oversight must evolve with the technology, ensuring that AI systems are validated for safety and efficacy before and after deployment. Consent from the patient should be strongly encouraged when AI tools are used in clinical practice.

How can the use of AI in health care provide benefits while safeguarding patient privacy in clinical settings?

Protecting patient privacy while leveraging AI can be managed by employing advanced data encryption, using de-identified data whenever possible, and implementing strict access controls. Technology such as differential privacy and federated learning can be utilized to enhance AI systems without compromising individual privacy, ensuring that the AI applications learn from patient data patterns without accessing or revealing any personal information.

What regulations, policies, frameworks, and standards should entities utilizing AI adhere to, and what mechanisms are in place or should be in place to supervise and enforce them?

Entities using AI in healthcare should adhere to the Health Insurance Portability and Accountability Act (HIPAA) for data protection, alongside FDA guidelines for medical devices when applicable. Emerging frameworks, like those proposed by the EU's General Data Protection Regulation (GDPR), offer guidance on algorithmic transparency and data handling that could be adapted for the U.S. context. Oversight mechanisms should include regular audits, mandatory reporting of AI performance, and compliance checks by independent bodies.

Other Considerations

Emerging Trends at the Intersection of AI and Healthcare:

Claims regarding the use of AI tools in medicine and health care are currently being made. A balance between the hype and actual function by ensuring clinical validity should be strongly encouraged. This is critically important as consumers currently have direct access to these tools and misinformation arising from these “unvetted solutions” can lead to unwarranted panic and harm to the public.

Innovations and Disruptions on the Horizon:

Promising innovations include AI-driven predictive analytics for chronic disease management and help in understanding disease processes better. As an extension of the current technological evolution foundational models such as small language models aid solutions to be deployed in edge devices such as the mobile phone. Hence policy attention is needed to ensure these innovations align with health goals while limiting misinformation and are accessible to all segments of the population.

Legislative Measures to Ensure Access to AI Healthcare Services:

Congress can facilitate access to reliable and safe AI health care services by promoting legislation that supports transparency in AI development, funding for AI research, and incentives for developing AI solutions that address unmet medical needs, and advancement of medicine to improve our understanding of the pathophysiology, management. We ask that clinicians and clinical domain experts be part of the policy making process.

Conclusion

Thank you for the opportunity to provide input on this critical issue. ASGE is committed to advancing the responsible and beneficial use of AI in GI endoscopy that enhances patient care and clinical outcomes while upholding the highest ethical and safety standards. We welcome the opportunity to be a resource to you. Should you have questions or need additional information, please contact Lakitia Mayo at lmayo@asge.org or (630)570-5641 or Camille Bonta at cbonta@summithealthconsulting.com or (202) 320-3658.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Christie', with a stylized flourish at the end.

Jennifer A. Christie, MD, FASGE
President