



American Society for
Gastrointestinal Endoscopy

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The Honorable Bill Cassidy, MD

U.S. Senate Committee on Health, Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Via HELPGOP_AIComments@help.senate.gov

Re: Senate HELP Committee RFI on the Framework for the Future of AI

Dear Ranking Member Cassidy and Members of the U.S. Senate HELP Committee,

On behalf of the American Society for Gastrointestinal Endoscopy (ASGE), thank you for the opportunity to provide feedback on the “Framework for the Future of AI.”

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 Artificial Intelligence (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 of 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.

We appreciate your leadership in examining key policy issues related to health care and AI as the field is emerging rapidly. We look forward to a dialogue with you as you consider modification or creation of legal frameworks that support the use of AI but also consider the need for patient and consumer safeguards. We hope you will view ASGE as a resource on this topic.

In soliciting input from stakeholders regarding the Framework, you raise important questions specifically related to healthcare in the areas of supporting innovation, medical ethics and patient protection, and education. On September 9, ASGE hosted its 5th Annual Global AI Summit on AI and Gastroenterology in Washington, DC where critical discussions in this arena took place. This year's summit primarily focused on advancing education, regulation, and reimbursement in AI. The Summit brought together physicians, educators, regulators, innovators, industry, and payers to discuss the opportunities and implications of AI in GI.

In 2020, ASGE issued a position statement outlining its priorities for AI in endoscopy.¹ In February 2023, ASGE published a paper outlining a guiding framework for all stakeholders in the endoscopy AI ecosystem regarding standards, metrics, and evaluation methods needed for emerging and existing AI applications.² The Society is actively working to release two additional papers this year. The first paper explores the perceptions of the gastroenterology community regarding AI, shedding light on its reception and impact. The second paper is a consensus document that outlines crucial research areas within AI, aimed at providing a comprehensive understanding of AI's relevance and application in the field of endoscopy. These initiatives underline ASGE's commitment to fostering awareness, understanding, and responsible implementation of AI in endoscopy. The consensus document includes all relevant stakeholders in AI in GI.

Role of Medical Societies in AI Implementation

Medical societies can and should play a critical role in facilitating the secure and ethical integration of AI technology into practice. ASGE is committed to advancing AI through a set of strategic initiatives. As a convener, for five years ASGE has brought together physicians, AI experts, innovators, and regulators to develop consensus on AI's application in GI endoscopy. ASGE has sought to collaborate with regulatory bodies, including the FDA, offering our expertise to assist in the development of a framework for AI in gastroenterology to ensure adherence to safety and efficacy standards. ASGE continues to be at the forefront of developing education and training programs to provide GI endoscopists with the essential knowledge and skills for use of.

ASGE is taking a leadership role in shaping standards and quality metrics around AI in GI endoscopy. Additionally, we are dedicated to providing guidance and tools to healthcare facilities to seamlessly integrate AI into their clinical practices, streamlining processes and optimizing AI utilization. In our pursuit of responsible data procurement for AI applications in endoscopy, we collaborate closely with industry stakeholders to advocate for equitable data collection across all

¹ Berzin, Tyler M. et al. Position statement on priorities for artificial intelligence in GI endoscopy: a report by the ASGE Task Force. *Gastrointestinal Endoscopy*, Volume 92, Issue 4, 951 - 959

² Parasa, Sravanthi et al. Framework and metrics for the clinical use and implementation of artificial intelligence algorithms into endoscopy practice: recommendations from the American Society for Gastrointestinal Endoscopy Artificial Intelligence Task Force. *Gastrointestinal Endoscopy*, Volume 97, Issue 5, 815 - 824.e1

populations. To this end, ASGE has initiated an imaging collection database called Endonet to further this endeavor. Through these efforts, ASGE is actively shaping the ethical and effective incorporation of AI in GI endoscopy for the betterment of patient care and healthcare practices.

With standardization in priorities from Congress and regulators on AI in healthcare, we believe medical societies can assist in developing these types of initiatives in AI.

Transparency in Algorithm Development

Transparency in algorithms is essential to ensure accountability, mitigate biases, and build public trust in healthcare AI. Transparency of algorithms is needed at the point of care and in coverage decisions to allow for the identification potential biases and discriminatory outcomes, fostering fairness and ethical conduct.

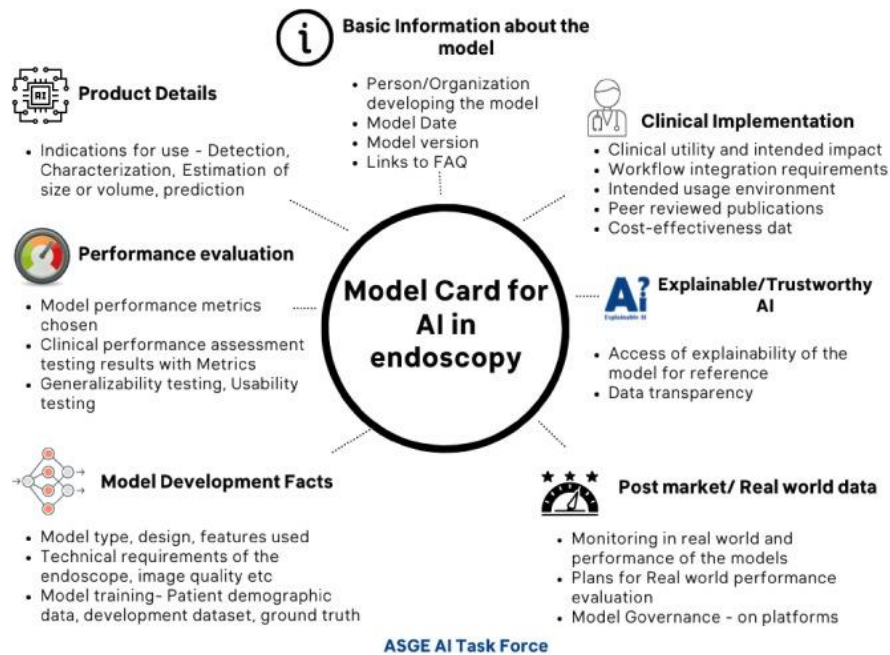
As noted in the Framework, an investigative story published in *ProPublica* alleged Cigna used a computer algorithm to review requests for authorization and then had physicians sign off on batches of denied claims without proper review. We appreciate that story led to an [inquiry](#) by House Energy and Commerce Committee Republicans into Cigna's prior authorization practices. We are also pleased that state insurance commissioners have [taken notice](#) and believe prior authorization practices that use AI warrant greater scrutiny. 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 policy](#), as referenced in the Framework, 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.

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.

Additionally, Congress should fund an awareness campaign to help the public understand how algorithms work to improve patient care. Congress can allocate resources for public education and training initiatives to help individuals understand algorithmic decision-making and how to protect their rights in algorithm-driven contexts.

In the context of endoscopy, we recommend a model card that is easier for the end user to use which highlights performance evaluation of the algorithms, explainability, data used for model building as shown in illustration below.



FDA Collaboration

Congress should allow the FDA flexibilities in its review of AI technologies used in healthcare. The FDA can enhance its ability to evaluate AI-based medical products effectively and in a timely manner by embracing collaboration and external expertise. Collaboration can also ensure that AI technologies meet the highest standards of safety, efficacy, and reliability before entering the healthcare market.

The FDA should seek external expertise from groups such as ASGE. Subject matter experts can provide insights and assessments of AI applications relevant to their expertise. We can also provide valuable perspective on the safety of the device for our patients. As mentioned previously, the FDA can also look to external experts such as ASGE to assist in the development guidelines and to provide external validation of studies.

The FDA should collaborate with external experts to establish standardized datasets and benchmarks for AI evaluation. We believe that ASGE's Endonet can be helpful in this effort. Lastly, as AI advances around the world, the FDA should consider incorporating diverse sources of data into the evaluation process including international data and data from organizations that have large data sources such as the Veterans Administration. Using data from large organizations provides access to large and diverse patient datasets for training and testing AI algorithms.

Gaps in Clinical Validity when Leveraging AI

ASGE believes that gaps in clinical validity when leveraging AI in healthcare encompass the following key areas. A major concern is off-label use of AI, as it can be applied in unintended

ways, raising questions about its clinical validity and safety. Additionally, the quality and representativeness of training data can affect AI models, potentially introducing biases or inaccuracies. The transparency of AI algorithms also plays a key role and lack thereof can hinder the understanding needed to assess their clinical validity and decision-making processes. The absence of standardized evaluation criteria for AI systems and limited knowledge about AI among healthcare professionals further compound these challenges. Global collaboration and data-sharing are crucial for validating AI models in diverse healthcare settings. We believe the FDA needs to better collaborate on obtaining datasets. Lastly, the availability of open-source AI models underscores the importance of rigorous validation and testing to ensure their clinical validity. Addressing these gaps is essential to harnessing AI's potential while maintaining clinical reliability and patient safety.

AI Reimbursement in Healthcare

AI's future contributions to healthcare will need to be appropriately recognized and compensated. The Committee notes that, “Defining AI is challenging since AI experts have not arrived at a static definition of the rapidly developing general purpose technology.” ASGE agrees with the assessment in the RFI that we currently lack a clear and universal definition for AI within the context of healthcare. The term “AI” alone is insufficient to define a specific healthcare service, which poses challenges when attempting to differentiate AI from other computer and software-based technologies in the healthcare 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*³, in February 2020, the Consumer Technology Association (CTA) released standards for AI⁴ 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.⁵ 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 healthcare.

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 healthcare industries. We strongly encourage Congress to take a leading role in defining AI within the healthcare domain. Establishing clear and standardized definitions will provide a crucial framework for innovators to align their work.

³ (Pub. L. 116–283, div. E, §5002, Jan. 1, 2021, 134 Stat. 4523.)

⁴ Consumer Technology Association, “ANSI/CTI Definitions/Characteristics of Artificial Intelligence in Health Care: ANSI/CTA-2089.1” (February 2020) available at <https://www.cta.tech/Resources/Newsroom/Media-Releases/2020/February/CTA-Launches-First-Ever-Industry-Led-Standard>.

⁵ American Medical Association, <https://www.ama-assn.org/system/files/cpt-appendix-s.pdf>

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.

Physician Education and AI

ASGE is fully aligned with the imperative of building trust among physicians when it comes to the adoption of AI tools in healthcare. In a recent survey conducted among our members, AI emerged as the top area in which members wanted additional education and resources.

Recognizing this, ASGE is committed to providing comprehensive education and resources on various areas related to AI, with the goal of fostering mass adoption within the GI practice community.

ASGE has developed educational offerings and resources to ensure that our members have access to the basic knowledge required to comprehend AI concepts and principles. ASGE is also educating its member about the diverse applications of AI in GI from clinical to operational. Understanding how to evaluate AI algorithms in the GI literature and clinical trials is important for gastroenterologists, trainees, and researchers. ASGE understands the significance of transparency, interpretability, and explainability of AI algorithms and believes it is necessary to the advancement of this technology in medicine. ASGE holds hands-on AI workshops during our annual scientific conference with AI experts and leaders to educate on the underpinnings of AI technology and how it is being used in healthcare.

Congress can emphasize the importance of ongoing education and professional development in the rapidly evolving field of AI. It can support initiatives through setting educational criteria on training and funding to keep healthcare professionals updated on the latest AI advancements and best practices.

Physician Training

Standardization of training in AI across medicine will be important. Those who design education curriculum needs to pay immediate attention on how to incorporate it into training. Congress can play a key role in ensuring the standardization of training in AI in healthcare through legislation, funding, and oversight. Standardization of this training will not only be important for future physicians but will be critical for those training the next generation. At our most recent Summit, a majority of participants stated that curriculum in AI and GI endoscopy needs to be developed within the next two years. Areas of consideration in training included critical appraisal of AI studies, providing hands-on training of AI applications and data interpretation, ensuring that

educators are equipped to teach the topic and seamlessly integration of AI education into existing medical school and fellowship training and continuing education.

Congress could assist in this effort by mandating the development of standardized training requirements for AI in healthcare and allocating funds to educational institutions and healthcare organizations to support the creation and expansion of standardized training programs in AI. Congress can also play a role in ensuring that standardized frameworks are in place that provide guidance on minimum qualifications, certification, ongoing education, and assessment of training for healthcare professionals involved in AI implementation and utilization.

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 enhance patient care and clinical outcomes while upholding the highest ethical and safety standards. We welcome the opportunity to assist in any way as you develop this framework for AI in healthcare. 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 long horizontal flourish extending to the right.

Jennifer A. Christie, MD, FASGE
ASGE President