AMERICAN COLLEGE OF SURGEONS

September 22, 2023

The Honorable Bill Cassidy, M.D.
U.S. Senate
455 Dirksen Senate Office Building
Washington, DC 20510

Dear Ranking Member Cassidy:

On behalf of the more than 88,000 members of the American College of Surgeons (ACS), I appreciate the opportunity to respond to your request for information on the oversight and legislative role of Congress over the integration of Artificial Intelligence (AI) in health care and other industries. The ACS is dedicated to improving the care of the surgical patient and to safeguarding standards of care in an optimal and ethical practice environment. As such, we understand the critical role that technology plays in achieving this mission, as well as the need for thoughtful policymaking to ensure that tools such as AI are used with the utmost regard for patients' rights and safety. As we discuss below, it is essential that AI tools are trained and maintained with high quality, diverse, valid, and representative data; are regularly assessed for continued accuracy and reliability; that regulators engage clinical experts in the assessment of AI health tools; and that physicians' clinical judgement remains paramount.

The ACS appreciates the Senate Health, Education, Labor, and Pensions (HELP) Committee's attention to this critical issue and welcomes the opportunity to share our response to a few of the questions posed on the use of AI in health care.

Supporting Medical Innovation

How can FDA improve the use of AI in medical devices?

The ACS supports efforts to expand the use of real-world evidence (RWE) in the development and maintenance of medical technology. RWE is clinical evidence regarding the use and the potential benefits or risks of a medical product derived from analysis of real-world data (RWD), data related to a patient's health status or delivery of care that can be collected from a variety of sources such as mobile devices, wearables, and sensors; patient generated data used in home-use settings; product and disease registries; claims and billing activities; electronic health records, and more. Such data can complement data that are collected through traditional means and enhance clinical decision-making.

For the Food and Drug Administration (FDA) and other regulators, RWE is necessary for monitoring the safety of drugs, devices, and emerging technologies such as AI. As devices that use AI evolve, RWD will be reported back to the FDA regarding the product's safety, effectiveness, and potential risks. The true power of AI-based software lies in its ability to improve over time instead of remaining static. But this is problematic for regulation because the device that was approved or cleared may no longer be operating in a similar fashion as it learns. RWD is necessary to show that the AI-based device still functions appropriately and in the way that it was intended. RWD is also important for accurately

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training AI algorithms. These data should be high quality, diverse, valid, and representative of the uses for which it will be applied.

What updates to the regulatory frameworks for medical devices should Congress consider to facilitate innovation in AI applications while also ensuring that products are safe and effective for patients?

As mentioned above, the use of RWE will be necessary for regulators to ensure that AI products are safe and effective as they iterate over time. Any regulatory framework should require that AI applications are assessed, maintained, and updated over their lifetime to ensure continued clinical safety and effectiveness, but also technological integrity. AI tools must be reviewed to make sure they are still valid, reliable, and accurate as they learn.

How can FDA harness external expertise to support review of products that are developed using AI or that incorporate AI?

AI health tools must be both (1) clinically and (2) technologically sound. Validity, reliability, and accuracy are required on both levels. The ACS believes that clinical experts, such as physician informaticists, are best positioned to determine whether data used in AI applications are the best quality and the most appropriate from a clinical perspective, and to monitor the technology for clinical validity as it evolves over time. The FDA should engage advisory groups for clinical and technical excellence that are condition or programmatically defined with cross specialty expertise, in order to ensure an AI tool is reliable and valid on multiple levels.

In addition, physicians and specialty societies are well-equipped to assist the FDA as they consider what tools and/or information would be most useful in driving improvements and advancements in clinical care and the format in which the information should be expressed. Understanding where physicians see the benefits of AI in their practices is crucial to help build trust in the capabilities of the technology, leading to broader utilization. Likewise, understanding why physicians decide not to use or do not trust certain health technologies in their clinical practices would also be useful as regulators certify products for real-time use.

Medical Ethics and Protecting Patients

What existing standards are in place to demonstrate clinical validity when leveraging AI? What gaps exist in those standards?

Validation of digital health tools, including AI applications, is truly essential to physician trust, improving care delivery, and avoiding patient harm. There are many aspects to validation. Validation is necessary in terms of the technology/algorithm used, the patient population on which the device is trained, whether the outcomes are accurate and unbiased, and whether the tool is appropriate for the specific setting in which it is used. While the FDA is responsible for regulating many digital health tools, the FDA should work in collaboration with an appropriate specialty society, clinical expert, or physician informaticist to reinforce physician trust in the tool. Use and validation of digital health tools are two of the most critical areas for physicians to successfully realize the potential of these technologies.

In the case of AI tools, it is especially important to emphasize that the data used to train algorithms is critical to their validity and reliability. The data should be high quality, diverse, valid, and representative of the uses for which it will be applied. While the data used to train the AI-based tool is important, it is equally important that up-to-date data are used to retrain such tools so that the algorithms themselves remain current, reliable, and valid. Additionally, Congress could take steps to create a government-sponsored relationship with a synthetic patient environment, a free, open source test bed that could be used to test the clinical and technical aspects of any AI application.

At the facility level, institutions should have their own governance and structure for AI-based tools, including pathways for user feedback and timely responses to feedback as physicians have concerns or encounter issues. Liability risks and uncertainty about who is responsible for issues with certain algorithms, outputs, or user errors can hinder implementation of these tools. Before leveraging AI technology, institutions should be confident in the quality of the tool and its capabilities.

Ultimately, digital health tools should reduce, not add to, a physician's cognitive burden. AI technology can enhance a physician's ability to gather, process, and exchange knowledge and ultimately improve patient care when the tool is developed using semantic data exchange standards in alignment with validated clinical workflows. This enables these tools to provide the right information at the right time and seamless incorporation into the clinical workflow.

What practices are in place to mitigate bias in AI decision-making?

It is critical to consider bias when designing, training, and using AI health tools. Various forms of bias based on race, ethnicity, gender, sexual orientation, socioeconomic status, and more can be perpetuated through the use of certain advanced digital health tools, especially those using AI. Bias can manifest in digital tools in various ways. For instance, if an AI algorithm is trained with data that fails to include all patient populations for which the tool is used, this would introduce inherent bias. Bias could also be unintentionally written into algorithms, leading to outputs that could have a biased impact on certain populations. The context in which the tool is used should also be considered when trying to avoid bias. If the tool were trained on a certain population for a specific purpose and is applied in a different setting with a different patient population with varying risk factors, this could also result in bias.

While we will be unable to eliminate bias completely, steps can be taken to validate the quality of the data and reduce bias in AI algorithms. As discussed above, the need for trusted and complete data sources for AI tools is critically important, and ensuring the algorithms and data are properly validated is crucial. If the tool is not developed and trained with data that are representative of the patient population the physicians serve, the data outputs could be inaccurate or biased. To lower the risk of bias, the use of trusted and complete data sources in development and testing stages is extremely important. The data sources, methods of data collection, data quality, data completeness, whether the data are fit for purpose, and how the data are analyzed, must all be considered.

In addition, building a framework through collaboration with stakeholders possessing clinical and technical expertise that guides the development and validation of algorithms can assist in reducing bias if done with a high level of rigor. The framework could include a checklist with certain steps that developers would have to complete to ensure algorithms have gone through rigorous testing and validation. By following the processes and validation criteria set forth by the framework, developers can ensure that the algorithms are free of significant bias and will output accurate predictions. This type of framework coupled with external validation that utilizes data across various practice settings and demographics, can also be applied periodically following the implementation of the tool, to ensure that as the algorithms take in real-time data, they are still achieving a high-level of accuracy.

Who should be responsible for determining safe and appropriate applications of AI algorithms?

The FDA holds an important role in ensuring the safe and appropriate application of AI technology. Physicians can place greater trust in devices using digital technology if these devices have received FDA clearance or approval. FDA approval is also important for patient trust. Patients should know when they are receiving AI-informed care, and that it comes from validated instruments.

However, the ACS believes strongly that AI tools should never replace a physician's clinical judgment; rather, the goal of these and other digital health tools is to enhance physicians' knowledge and augment their cognitive efforts. Medical care relies not only on science, but on the capabilities of the care team, the local resources, and the goals of the patient. Care is highly personalized and requires a physician-patient interface where the medical knowledge is contextualized and personalized in a trusted manner for each patient and physicians are empowered to make clinical decisions. As we assess AI applications, part of the assessment must evaluate the insertion of AI knowledge artifacts into a human workflow. It is the AI application's utility in the workflow that makes a difference in the informed nature of care, in the diagnosis, and in the treatment.

Concluding Remarks

The ACS thanks the HELP Committee for its thoughtful attention to the oversight of AI technology in health care and looks forward to continuing to work with lawmakers on these important issues. For questions or additional information, please contact Carrie Zlatos with the ACS Division of Advocacy and Health Policy at czlatos@facs.org.

Sincerely,

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Executive Director & CEO