AMERICAN COLLEGE of CARDIOLOGY

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March 15, 2025

Networking and Information Technology Research and Development (NITRD)
National Coordination Office (NCO),
National Science Foundation
AI Action Plan
Attn: Faisal D'Souza,
2415 Eisenhower Avenue,
Alexandria, VA 22314, USA

Comments Submitted Electronically

RE: Request for Information on the Development of an Artificial Intelligence (AI) Action Plan

Dear Mr. D'Souza,

The American College of Cardiology (ACC) appreciates the opportunity to provide feedback in response to the Request for Information on the Development of an Artificial Intelligence (AI) Action Plan. The American College of Cardiology (ACC) is the global leader in transforming cardiovascular care and improving heart health for all. As the preeminent source of professional medical education for the entire cardiovascular care team since 1949, ACC credentials cardiovascular professionals in over 140 countries who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. Through its world-renowned family of *JACC* Journals, NCDR registries, ACC Accreditation Services, global network of Member Sections, CardioSmart patient resources and more, the College is committed to ensuring a world where science, knowledge and innovation optimize patient care and outcomes. Learn more at www.ACC.org or follow @ACCinTouch.

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Introduction

The Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO) is requesting input from interested parties on the Development of an Artificial Intelligence (AI) Action Plan to help define the priority policy regarding AI and to ensure that AI innovation is not hampered. The College appreciates the opportunity to engage with the White House Office of Science and Technology Policy (OSTP) and is pleased to provide comments to help shape actions that should be included in the plan.

AI has the potential to transform U.S. health care by analyzing large data sets to drive innovation, reduce clinicians' administrative burdens, and accelerate the development of new therapeutics and personalized medicine. However, despite the promise of AI, it is essential that government agencies and stakeholders appropriately monitor and balance the potential risks AI presents. These include but are not limited to usurping clinicians' autonomy when treating patients, deploying unproven technologies that can harm patients with incorrect outputs guiding decision-making, and burdening health systems and clinicians with increasingly expensive systems without adequate reimbursement.

Building on input submitted in response to documents and regulations across multiple administrations, the College is pleased to submit comments for the AI Action Plan. The ACC's comments in response to this request for information focuses on three primary areas: Ensuring Clinician Autonomy, Establishing Public Trust in AI, and Unified Agency Approach to Governance.

Ensuring Clinician Autonomy

AI-enabled systems provide well-established benefits by leveraging computing power to enhance patient care. However, the deployment of new tools also comes with great risks that could just as easily put patients in harm's way and threaten the clinician-patient relationship that has been the central tenet of medicine.

Currently the US healthcare system does not have the infrastructure to support autonomous AI. Therefore, the systems established for implementation in the near future are best based in assistive AI or collaborative intelligence, with the clinician as the responsible entity, using AI as a tool. Diagnostic tests or genetic underpinnings where an AI application contributes and enhances patient care are best utilized in coordination with and under the clinical acumen and reasoning of trained clinicians. **While the College is acutely aware AI capabilities will continue to evolve, it is essential that the AI Action Plan must reaffirm that clinicians—not algorithms—remain at the center of patient care.**

The ACC strongly believes that clinical decision making should still lay in the hands of the clinician and the patient, deciding together the best course of action based on what is best for the patient and the evidence available at the time. While AI is a powerful tool, it serves to support clinical decision-making—not replace it. AI's role is to enhance care while preventing unnecessary treatment. The starting point for such decisions must always be the individual patient. The College believes AI can play an active role in helping clinicians explore options available to a patient by presenting information and serving as a tool adjunctive to clinician decision making, but it is important to ensure that clinician autonomy is not overridden, and software does not supplant the clinician-patient relationship.

Equally as important, any AI Action Plans should work to ensure that AI/ML-driven solutions are not considered or presumed the new "standard of care" in any way. There is great uncertainty on the potential risks and liability a clinician faces should they deviate from recommended AI-enabled software outputs, whether autonomous or augmentative. While many government agencies may not establish liability criteria, reiterating that these are simply tools that are used to inform the decision-making process, rather than dictate it, will help ensure that clinicians remain in charge of a patient's care.

Establishing Public Trust in AI

When developing an AI Action Plan, it is important that all interested parties, including developers, agencies, private sector organizations, and other interested parties work together to ensure that the public can trust that AI will be used in a safe, transparent, and accurate way. One of the prevailing ways to address this is through the reduction of AI bias in outputs. IBM refers to AI-bias, also called machine learning bias or algorithm bias, as the occurrence of biased results due to human biases that skew the original training data or AI algorithm—leading to distorted outputs and potentially harmful outcomes. In medicine, these biases can lead to inaccurate diagnosis and result in patient harm or death.

Due to the nature of health care, it is essential that any AI Action Plan work to ensure that any potential biases in data inputs, AI-enabled outputs, and passive and automated systems are minimized as much as possible or adjusted for accordingly to ensure that outputs do not lead to biased or incorrect outputs. Many of the top AI developers are actively working on methods to address and reduce bias, ensuring that systems produce accurate results, and the College believes that any AI Action Plan should consider this important work and reflect the importance of this issue.

To that end, it is important that an AI Action Plan also works to instill trust by the public through the development of policies that promote transparent, clinically validated AI systems in health care. This includes providing patients, clinicians, and

other stakeholders with a firm understanding of and information about data sets used to train AI models. Successful AI-enabled technologies require early engagement from clinicians and organizations like the ACC that stand at the nexus of this innovation. **The ACC strongly recommends any AI Action Plan should promote policies that encourage AI system developers to integrate clinicians' perspectives into the design, development, validation, implementation, and monitoring of AI in health care.**

This engagement includes utilization of validated sources of data, such as those captured by clinical data registries like the National Cardiovascular Data Registry (NCDR), to train AI applications. The College is engaging with both regulatory agencies and industry to ensure the clinician's voice is incorporated into the development of these AI systems and stands ready to work with OSTP, the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the Assistant Secretary for Technology Policy (ASTP)/ Office of the National Coordinator for Health IT (ONC) and other government agencies to create an AI framework and policies that protect patients while still delivering innovative approaches to solving our health care system's biggest problems.

Unified Agency Approach to Governance

Finally, as OSTP considers the development of an AI Action Plan, it is important that the White House coordinates with government agencies to promote a unified AI governance strategy**. A unified AI governance framework should establish clear standards on transparency, model card development, risk stratification to prevent overregulation, funding for comparative effectiveness research, harmonized definitions across federal agencies, and real-world case studies to guide clinicians and patients.**

Many of these concepts already exist and are defined either through regulations or sub-regulatory guidance in other components of the US health care system and are accepted by developers, researchers, and experts from across the ideological spectrum. **Borrowing from and building on existing concepts and developing a unified, whole of government approach can remove subjectivity from the decision-making process, boost adoption, and promote the development of innovative AI systems that are cutting edge, transparent, and accurate.**

Conclusion

The ACC appreciates the opportunity to provide input on the Request for Information on the Development of an Artificial Intelligence (AI) Action Plan. The development of a unified, coherent AI Action Plan is essential to maintain the current pace of innovation while appropriately balancing the potential risks AI places on patient health. If you have any questions or follow up, please contact Joseph Cody, Associate Director of Health IT and Digital Heath Policy at jcody@acc.org or (202) 375-6251.

Sincerely,

Cathleen Biga, MSN, FACC
President, American College of Cardiology

The Mission of the American College of Cardiology and the American College of Cardiology Foundation is to transform cardiovascular care and improve heart health for all.