

May 6, 2024

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

Dear Representative Bera:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 130,000 family physicians and medical students across the country, I write to thank you for your leadership on issues impacting family physicians and their patients and to offer our response to your request for information (RFI) on the state of artificial intelligence (AI) in health care.

The family medicine experience is based on a deeply personal patient-physician interaction that requires support from technology, including artificial intelligence. In 2023, the AAFP developed an initial set of principles that we believe must be followed in Al/machine learning (ML) if they are to be applied to family medicine. The AAFP believes AI/ML should be evaluated with the same rigor as any other tool utilized in health care, and that it has the potential to support the four C's of primary care: first contact, comprehensiveness, continuity, and coordination of care.

The AAFP believes artificial intelligence and machine learning should:

- 1. Preserve and Enhance Primary Care
- 2. Maximize Transparency
- Address Implicit Bias
- 4. Maximize Training Data Diversity
- 5. Respect the Privacy of Patients and Users
- 6. Be Designed with a Whole-System Mindset
- 7. Be Designed for Accountability
- 8. Be Designed for Trustworthiness

Our principles were created to guide appropriate application of these emerging technologies and maximize their value for the health care system and family medicine. In response to some of the specific questions and broader categories presented in the RFI, the Academy offers the following responses:

<u>Implementation of Artificial Intelligence in Family Medicine</u>

- How extensively is AI currently being implemented in health care institutions and other settings across the country?
- 2. What areas of health care are benefiting the most from AI integration, and what are the primary challenges hindering further adoption?
- 3. What are the various applications of AI in clinical or operational contexts?

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AAFP Response:

Currently, the use of AI is not uniform across family physicians. One of the barriers reported by our members is that employers are not allowing physicians to implement AI tools in their practice even though the physician has expressed interest in using them. There is still some skepticism around AI, but there is also hope that it can relieve some of the administrative burden physicians face. AI is nowhere near being universally adopted, but practices are starting to trial certain technologies to see if they can be implemented. The most common AI uses we see amongst our members are notetaking, electronic medical record (EMR) management, and submission of prior authorization requests, which is showing great promise in helping physicians spend less time on seemingly neverending administrative requirements.

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

AAFP Response:

Al differs from other health care technologies for several reasons. First, Al is constantly learning, which means the technology is uniquely capable of getting better over time without much intervention. Because of this, some family physicians believe that Al is better poised to help alleviate administrative burden than other technologies. Al is well-suited to support existing technologies because it can be integrated into them. In fact, it is already being used in EMR systems such as EPIC. Al is designed to work in tandem with existing technologies to improve them, not to replace them. Second, unlike other commonly used technology, Al is intelligent rather than automated. Automation is where a computer system can perform tasks without human intervention, but those tasks must be defined with known paths forward and all necessary variables defined. Intelligent systems can perform the tasks when all the variables are unknown or not all the paths forward are known. Because of this, there seems to be a consensus that Al, unlike some other technological advances, has the ability to help physicians alleviate administrative burden rather than add to it. Al is a more hands-off tool than most other popular technologies and applications.

Efficacy, Accuracy, and Transparency of Artificial Intelligence in Family Medicine

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

AAFP Response:

Many <u>studies</u> are <u>showing</u> the efficacy of Al-driven health care solutions. However, the question remains: is there evidence of generalizability for Al-driven health care solutions? <u>Studies</u> have <u>shown success</u> with Al-driven solutions when designed and deployed within a hospital, practice, or health system only to find out that the efficacy and accuracy are very different when deployed at another organization. There are many reasons for this, including data issues, process variations, and differences in the patient populations. However, some Al-driven solutions have also shown efficacy across organizations, particularly the solutions aimed at combatting administrative burden such as documentation and chart review.

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

AAFP Response:

When it comes to best practices in AI to ensure sufficient availability, accuracy, and use of health data for AI-driven health care solutions, there are three key components: data privacy, interoperability, and informed consent.

While data privacy and informed consent go beyond AI, they are both critical to discuss within this context. Informed consent is critical for availability of high-quality data, so common, appropriate use definitions and clear language in data use policies would likely improve availability of patient data. Additionally, data privacy in health care is a key issue as policy continues to expand the interoperability of health care data, thereby increasing the exchange of protected health information outside of covered entities and their business associates. This moves the data outside the protections of the Health Insurance Portability and Accountability Act (HIPAA), which is traditionally where protections for health information lay. Given this trend and new issues due to AI in health care, health data privacy will likely be a key policy issue over the next several years. The AAFP recommends the federal government avoid AI-only privacy laws or regulations and instead work to implement an integrated, comprehensive health data policy that emphasizes informed consent.

In terms of interoperability, the AAFP has long supported federal and industry efforts to advance interoperability of health information technology (IT). Interoperability is essential for ensuring family physicians have access to meaningful, actionable data at the point of care, which in turn enables them to provide high-quality, patient centered care across the lifespan. Truly interoperable health records will also reduce administrative tasks for physicians and facilitate patients' access to their health data. All is often integrated into existing technologies such as EMR systems, which notoriously struggle with interoperability because they cannot communicate with each other. Therefore, the AAFP strongly supports the Office of the National Coordinator for Health Information Technology's (ONC) ongoing work to advance interoperability in the health care ecosystem. We have also long called for effective data segmentation standards that enable physicians to prevent sharing select patient data to protect patient privacy and security. The AAFP urges ONC to continue its work on advancing effective, real-world tested data segmentation standards, which will support the responsible availability and use of health data in Al-driven health care solutions.

8. What quardrails or accountability mechanisms could be set to ensure end-to-end transparency?

AAFP Response:

Al/ML solutions must provide transparency to the physician and other users to evaluate a solution's efficacy and safety. The AAFP believes companies should strive for the highest safety, reliability, and correctness levels in their Al/ML solutions. The AAFP recommends that companies provide transparency around the training data used to train the models and provide clear, understandable information describing how the Al/ML solution makes predictions. The more transparency exists around Al and its use in health care, the more trust patients, physicians, clinicians, and health care organizations will have to use this technology.

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

AAFP Response:

Addressing bias in AI has been a big focus since it started to become more common in health care. There have been a number of <u>studies</u> on the implication of bias in the use of AI in health care and what steps can be taken to address the issue. The AAFP believes companies providing AI/ML solutions must address implicit bias in their design. While implicit bias cannot always be eliminated, companies should have standard processes to identify and mitigate the AI/ML models from learning

those same biases. In addition, when applicable, companies should have processes for monitoring for differential outcomes, particularly those that affect vulnerable patient populations. As part of their authorization application for an AI/ML solution, HHS could require companies to submit documentation detailing their implemented processes to recognize bias and prevent AI/ML from learning based on identified biases. In 2020, the Government Accountability Office published a report about AI in health care and offered a number of recommendations on how to address concerns of bias including ensuring data is representative, transparent and equitable. Like the AAFP, GAO recommends stakeholders and experts develop best practices for development, implementation and use of AI technologies.

10. What are accountability mechanisms that can be put in place to ensure that there is an accurate spread of information?

AAFP Response:

The AAFP believes AI systems must be developed and used in a transparent and accountable manner, with clear guidelines and standards for their design, development, and deployment. Any entity that creates, stores, organizes, manages, or transfers health data should be accountable for maintaining patient privacy and confidentiality. If an AI/ML solution is going to take a prominent role in health care, the company must take accountability for ensuring the solution is safe. A rigorous evaluation must be undertaken for AI solutions designed for direct patient care, like any other medical intervention. The AAFP believes companies should take on liability where appropriate. The appropriateness should be based on a risk-based model that accounts for the role played by AI/ML and the situation in which it is being applied. In addition, it should be easy for end-users and others to find transparency data such as through a central repository or standard reporting process.

11. Are there specific examples of AI applications that have significantly improved patient outcomes or streamlined health care processes?

AAFP Response:

One example of an AI application that has streamlined health care processes is AI assistants. In one study, the AAFP saw an over 70% reduction in documentation time when using an AI assistant to help with documentation. This reduction occurred before assistants included ambient listening with generative AI, sometimes known as an AI scribe. We have also seen a decrease in the burden of chart review with AI assistants that summarize the medical record into a problem-oriented summary. More evidence will likely be added to the literature around AI assistants' impact on inbox burden, which has dramatically increased with and since the COVID-19 pandemic.

Ethical and Regulatory Considerations about Artificial Intelligence in Family Medicine

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

AAFP Response:

As mentioned previously, the AAFP published a <u>set of principles</u> we believe are critical to ensuring responsible application of AI/ML in family medicine. First and foremost, AI should preserve and enhance the components of the health care system that drive up quality and reduce cost, such as primary care. In addition, training data used for AI should be diverse to help mitigate biases. AI should also be transparent to help drive responsible practices and establish trust by patients, physicians, and others. These AI models and applications should be considered as tools in a larger system, and we must ensure they are integrated into workflows and have a system's view in their design. Finally,

there must be a method to establish accountability and liability when a physician makes a medical decision in combination with AI.

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

AAFP Response:

While data privacy is an important issue in AI, it is also an issue that is larger than AI. The AAFP strongly supports patients' right to privacy and the need to provide differential confidentiality to support patients' privacy. We have long called for effective data segmentation standards that enable physicians to prevent sharing select patient data to protect patient privacy and security. The need for these functionalities has become even more pressing as certain types of evidence-based medical care are criminalized in some states. The AAFP has urged ONC to use its authority to provide physicians and patients with more tools to protect patients' data, and we appreciate ONC's efforts to do so. However, existing technology does not meet current data segmentation needs, could lead to unintended consequences, and will instead add to physicians' administrative burdens. We urge ONC to continue its work on advancing effective, real-world tested data segmentation standards. The AAFP recommends the federal government avoid AI-only privacy laws or regulations and instead work to implement an integrated comprehensive health data policy.

Al/ML requires large volumes of data for training, and patients and physicians must trust companies will maintain the confidentiality of that data. Companies must provide clear policies around collecting, storing, using and sharing data from patients and end-users. Companies must get consent for collecting any identifiable data and the consent should clearly state how the data will be used or shared. Informed consent is critical for availability of high-quality data, so common, appropriate use definitions and clear language in data use policies would likely improve availability of patient data. To maximize the generalizability of Al/ML solutions, training data must be diverse and representative of the populations cared for by family medicine. Companies must provide clear documentation on the diversity of their training data and should work to increase the diversity of their training data. Companies should also have standard processes to identify implicit bias, mitigate the Al/ML models from learning those same biases, and monitor for differential outcomes, particularly those that could impact vulnerable patient populations.

Efforts to increase training data diversity, mitigate implicit bias in AI system designs, increase patient trust, and maximize transparency will improve the patient experience and the quality of the information physicians are working with, improving the care patients receive.

Other Considerations

14. What emerging trends do you foresee in the intersection of AI and health care?

AAFP Response:

The AAFP asked our members about trends they foresee, given their experience using AI in their practices. The feedback focused largely on AI's role in simplifying administrative processes and reducing physician burden through EMR management and chart and documentation review.

According to one physician, the biggest trend they foresee is using AI in clinical documentation, which has long been a source of burnout, reimbursement inaccuracies, and error. Integrating AI into clinical documentation can help significantly reduce these issues. Another member said they believe AI will help them navigate a patient's EMR and aid in developing a differential and plan of care.

Finally, one of our members noted that there is more to the therapeutic relationship than facts and knowledge; therefore, AI can never fully replace a physician. However, they stated that AI is a great tool that can help physicians gather past information and help guide them through the workflow more efficiently.

Overall, there seems to be consensus among many AAFP members that AI is a useful tool for documentation and EMR management. It can help physicians alleviate burden, reduce errors, and prioritize time with patients.

15. Are there any promising innovations or potential disruptions on the horizon that warrant attention from policymakers?

AAFP Response:

In the midst of the ongoing discussions about the dangers of AI, it is important that federal lawmakers also keep in mind the potential benefits. As we have discussed in response to previous questions, AI can help physicians alleviate administrative burden and reduce charting errors, providing an enhanced patient experience and improved patient outcomes. AI is already being utilized in both clinical and administrative ways in health care, such as interpreting radiology scans and eye exams, taking notes during appointments, and monitoring EMR inboxes. Policymakers must be aware this technology is already being used and consider that when legislating. In addition, policymakers should consider the successes and failures of other technological rollouts, such as the federal government's push for widespread EMR adoption in the late 2000s, as they legislate artificial intelligence.

16. Are there legislative measures that Congress can take to ensure access to safe, reliable Al healthcare services?

AAFP Response:

The AAFP believes ensuring health data privacy long-term will require a federal citizen data privacy law and regulatory framework, and we urge Congress to pass such a law. Other legislative measures Congress could consider to ensure access to safe, reliable AI health care services include:

- Requiring any entity that receives patient data from a HIPAA-covered entity to comply with the
 requirements of the HIPAA Privacy and Security rules. This is currently enforced through
 Business Associate Agreements (BAAs), but if a patient extracts their health information from
 a covered entity, the BAA does not apply to the entity to which the patient gives their health
 data. Congress could mandate this loophole be closed;
- Establishing safeguards to ensure responsible application of AI in primary care (and medicine at large). This would include investing resources to ensure the application of AI is equitable across health care, so as to not perpetuate a divide between large urban health systems and rural and small clinics; and
- Providing funds to health care entities or federal agencies to research how AI can be safely
 used to improve outcomes in health care. To this point, Congress should consider passing the
 Healthcare Enhancement and Learning Through Harnessing Artificial Intelligence (HEALTH
 AI) Act (H.R. 7381) which would award NIH grants to universities, nonprofits and government
 agencies to explore how generative AI can improve patient care.

Thank you for the opportunity to share the family physician perspective and offer this feedback on the state of AI in health care. Should you have any questions, please contact Anna Waldman, Associate of Legislative Affairs at awaldman@aafp.org.

Sincerely,

Tochi Iroku-Malize, MD, MPH, MBA, FAAFP American Academy of Family Physicians, Board Chair