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# Health IT End-Users Alliance Artificial Intelligence Consensus Statement

## Summary

Artificial intelligence (AI) is rapidly transforming healthcare, with developments and innovations producing promising non-clinical and clinical benefits in various medical settings and specialties. Still, there are concerns about how AI models are developed, trained, used, and monitored, and the significant impact AI has on healthcare operations and health outcomes. The widespread adoption of AI in healthcare requires thoughtful oversight and governance frameworks to minimize risks and ensure the appropriate, safe, and ethical use of AI. Health information technology (IT) end-users are at the forefront of AI use in healthcare and are well-equipped to collaborate on common principles to ensure the proper balance between innovation and use of AI with appropriate guardrails and regulatory oversight.

## Issue

AI, often recognized as augmented intelligence, is proliferating in the healthcare industry, with tools and applications largely focused on methods to improve administrative efficiency and supplement the care delivery experience. With successful implementation and use of AI, clinicians can experience reduced administrative burden and spend more time with patients, while patients benefit from more personalized medicine, earlier disease detection, and improved treatment outcomes. While these benefits are encouraging, AI in healthcare currently exists in a largely unregulated environment, introducing concerns regarding the design, use, and impact of AI.

Government involvement has continued to develop as AI technology grows and is implemented in various settings. The Food and Drug Administration (FDA) regulates certain AI-enabled medical devices used in healthcare, as well as clinical decision support (CDS) software.[1] Other groups with influence in this area include the National Institute of Standards and Technology (NIST),[2] which conducts research and supports evaluations of standards for AI technologies, prepares AI guidelines, assists with measuring and evaluating AI, and informs policies on risk management and governance.[3] Additionally, the Assistant Secretary for Technology Policy (ASTP) regulates electronic health records (EHRs), which includes any AI and decision support interventions (DSI) embedded into EHRs.

Congress can enact legislation to regulate the use of AI in healthcare and provide authority for federal agencies to implement regulatory requirements in specific areas. Many existing efforts and initiatives of federal agencies that are broadly applicable to health IT are also applicable to AI, and with legislative authority, agencies have a unique role in identifying the opportunities and challenges with AI, including where guardrails may be necessary. These regulatory components to optimize health IT and AI include the need for appropriate and robust data to build and train models with, real-world testing of these models, protection of individuals' privacy, validation, end-user input, post-market surveillance, and the need for the model to be adjusted and corrected as appropriate. Agencies can leverage their capabilities and authorities within the rulemaking process and incorporate public feedback to ensure the appropriate balance between innovation and risk management.

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## Opportunities

AI has been impactful in streamlining and improving the efficiency of routine administrative tasks, freeing up time, and allowing clinicians and staff to focus more on optimizing the healthcare delivery experience for patients. Many of these processes impacted by advances in non-clinical AI involve coordinating with payers, government agencies, medical supply companies, and patients. Streamlining these tasks has the potential to improve working relationships and efficiency across all parties. Non-clinical applications of AI include technology that can improve scheduling to minimize wait times, support prior authorization processes, identify appropriate billing and service codes based on medical notes with provider review, track inventory and utilization patterns to forecast medical supply orders, and automate reporting of regulatory compliance measures.[4] Indeed, a survey of health information professionals indicated that 45 percent are using AI and ML technologies, with the top applications being for coding, patient matching algorithms, and administrative workflow assistance.[5] Physician surveys have also shown that 25 percent are using non-clinical AI in their practice, with 32 percent using clinical AI.[6]

AI can also enhance the care delivery experience by serving as a supplementary tool for clinicians to provide accurate, patient-centered, and quality care, leading to more positive experiences for patients. Common clinical applications of AI include real-time clinical transcription, answering routine patient questions using chatbots, drafting patient education materials, and predicting adverse clinical outcomes based on vital signs. AI assistants that support physicians with documentation, chart review, and visit preparation have also become common, with initial studies demonstrating significant reductions in documentation burden, thorough clinical review, improved patient notes, and saved time.[7, 8]

AI models have also been developed to address areas in different specialties and sub-specialties where processes can be quicker and more consistent.[9] For example, AI can detect arrhythmias and other heart abnormalities through electrocardiograms in cardiology, augment the triage of patients in emergency medicine, monitor blood pressure via connected devices and alert the patient's care team in family medicine, identify stroke risk through analysis of imaging data in neurology, and detect and classify features on imaging exams in radiology.

**Including end-users in all stages of AI development, implementation, use, and monitoring is crucial to ensure AI tools function as intended and do not add additional burden on clinicians and their staff.**

As healthcare organizations become more comfortable with AI and increase its use, developers and policymakers can work with end-users to address resource constraints and hesitancy in deploying AI tools. **By incorporating end-users in the design, testing, implementation, and monitoring of AI tools, AI can be developed and tailored to organizations in ways that fit their unique needs, integrate well with current workflows, promote trust and confidence in AI use, and equip end-users with a more focused, organization-specific governance framework and oversight.[10]**

## Challenges

Several challenges inhibit the operationalization and successful deployment of AI tools. While there is tremendous opportunity to include end-users in each stage of the AI lifecycle, there exists possibility of increased administrative burden if the technology is implemented inappropriately. If a tool is not designed to fit into existing activities and workflows, it may not function as intended. This may exacerbate burden as end-users must identify and compensate for those errors.[11]

Additional challenges related to the deployment of AI tools include determining the optimal methods for end-users to understand how these tools operate and make decisions, as well as the data used in the development and testing of each tool. Transparency information is helpful for end-users in developing trust, confidence, and understanding of AI tools. However, this is only the first step to ensuring these tools are accepted and implemented into existing workflows. Along with transparency, it can be challenging to establish clinical validity, safety, and a clear and consistent process for clinicians and other end-users to provide feedback on the performance, accuracy, and usefulness of AI tools. Relatedly, there is a need for clear and consistent AI standards to help ensure quality and build trust with end-users.

Challenges also lie in the performance of AI tools post-implementation. Because AI tools are developed and trained on human data, varying biases can exist in the data used to train the tool. This includes biases in the AI algorithm itself as well as the inability of the AI to incorporate feedback and change course. As a result, the training data is not representative of or applicable to the environment in which the tool is used, which may perpetuate harmful stereotypes and harm patient and community health.[12] Biases that go unaddressed can impact an organization's operations by affecting patients' access to safe and personalized medical care, straining administrative tasks and operations, and delaying patient care.

The issue of liability for use of AI-enabled technologies presents novel and complex legal questions and concerns. It remains unclear if liability for a tool's performance resides with the AI developer or the end-users and their use of the tool. If an AI tool functions inappropriately, it can result in patient harm as well as add administrative burden, impeding patient access to care. A lack of clarity on liability prevents patients and clinicians from trusting an AI tool and can make it difficult for clinicians to evaluate a tool's risk.

Data privacy and security are key challenges in the use of AI tools. Both non-clinical and clinical AI interact with large volumes of data, including patients' sensitive demographic and clinical information. Without appropriate protections for patient data used in AI in accordance with the Health Insurance Portability and Accountability Act (HIPAA) and related privacy regulations, organizations and patients risk the exposure and compromise of sensitive data.[13]

While the use of AI in payment and claims processes can also be an opportunity with many benefits, there is evidence that it has led to adverse consequences.[14] In some instances, using AI as part of payment processes has led to increased denial rates and adverse determinations while exacerbating prior authorization burdens.[15,16] In the absence of understanding how these models are being used, it is difficult for healthcare organizations to understand the decision-making criteria surrounding coverage and payment and be able to reconcile claims, which costs healthcare organizations financial and personnel resources as well as delays patient care.

## Principles

Appropriate guardrails on the federal level are needed to assist the industry in fostering innovation in AI while maintaining the protection of health data, lowering administrative burden, and improving health outcomes. The following principles should guide efforts for appropriate guardrails, regulation, and oversight of AI in healthcare.

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## Role of Artificial Intelligence

- AI tools should augment, not replace, end-users' expertise—policy must ensure they supplement cognitive and administrative tasks while preserving human judgment.

## Regulation and Oversight of AI

- Healthcare AI requires a risk-based approach to oversight where the level of scrutiny and validation should be proportionally accounted for in policymaking to minimize the disparate harm and consequences the AI tool might introduce.
- Policies should be aligned across federal agencies to avoid competing and confusing standards that could lead to non-compliance and increased burden.
- Regulation should ensure that AI is developed in an ethical and responsible manner, safeguarding patient safety, quality, and continued access to care.

## Safety and Transparency

- Policymakers, developers, payers, and healthcare organizations have a shared responsibility to prioritize transparency and promote end-user trust and confidence that AI tools are safe and effective to use over time and will not result in unintended bias.
- Transparency on the development of AI tools, what data are used, in decision-making and governance, and ongoing testing and maintenance plans is critical.
- Transparency requirements should be tailored in a way to best suit the needs of the end-users.
- Policymakers should consult with patient groups, end-users, healthcare organizations, clinicians, medical specialties, ethicists, and bioethicists on the best approaches to inform patients on how AI is used in care.
- When deploying AI tools and technologies in the context of patient interactions, end-users should consider their disclosure and consent processes and adopt a risk-based disclosure approach.

## Liability

- Transparency can serve as a mechanism to clarify liability so that potential issues related to use of AI-enabled technologies can be isolated and accountability apportioned appropriately.
- Policymakers should consider the role of developers in the creation, maintenance, and use of clinical and non-clinical AI tools that result in patient harm.
- Policymakers should consider the responsibility of end-users in the use of clinical and non-clinical AI tools that result in patient harm, including ensuring providers are not held liable for an AI tool's performance if they have completed good faith evaluations and taken steps to mitigate quality or safety concerns.

## Privacy

- Confidentiality of patient and physician data must remain a priority throughout the development, implementation, and maintenance of AI tools.
- Developers should not compromise patient privacy, including going beyond minimum necessary, secondary use of data without consent, or data reidentification.

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## Security

- AI must not compromise the security of end-user IT systems and be strengthened against cyberattacks.

## Administrative Burden and Workflow Incorporation

- AI must be designed to be an integrated component within existing workflows in various settings and should avoid exacerbating administrative burden by incorporating end-user experiences and feedback into implementation plans.

## End-User Education, Participation, and Leadership

- End-users of healthcare AI tools will need considerable education specific to their needs to use the tools appropriately and effectively.
- The end-user community must be engaged throughout the design, development, implementation, and post-market surveillance of AI tools. This includes establishing appropriate feedback mechanisms.

## Accessibility and Usability

- Policymakers and AI developers should consider the accessibility and availability of AI tools for all end-users to ensure the benefits of deploying AI tools can be realized by all patients and clinicians, regardless of size or resource capability. This may include fostering positive incentives to encourage access to and adoption of AI across all care settings in ways that create efficiencies and avoid burden while not exacerbating digital divides.

## Mitigating Bias

- The design, development, implementation, and ongoing surveillance of AI tools must include efforts to identify and address biases that surface.
- Data used in the development of any specific AI tool should be reflective of the population(s) for which that tool will be used.

## AI Use in Payment and Coverage Activities

- AI used for coverage and payment decisions should maintain transparency and accountability, ensuring patients and providers can understand how those decisions are made.
- AI used for coverage and payment decisions must be reviewed by an appropriate expert in the applicable specialty to ensure the use of AI decisions do not increase inappropriate denials, unnecessarily delay care, or restrict access to care.
- AI used for coverage and payment decisions must be regularly evaluated for accuracy, fairness, and clinical validity, providing clear avenues for patients and clinicians to challenge or appeal decisions.

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