

Responsibly Bringing AI to the Medicare System: Advancing Health Equities to Benefit Patients and Providers

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Being able to leverage a wide range of datasets, including patient-generated health data, with artificial intelligence (AI) tools holds incredible promise. For instance, artificial intelligence machine learning and deep learning have been adopted by a multitude of groups to develop automated diabetic retinopathy detection algorithms. A handful of these technologies are currently commercially available, and with the help of improved diagnostic performance informed by future research, many more screening technologies will enter the market with the ability to tackle global health issues such as diabetes ([Grzybowski, 2020](#)).

Similarly, AI systems are being harnessed to lessen instances of misinterpretation of mammogram results. Although breast cancer screening programs are in existence worldwide, high rates of false positives and false negatives are often associated with human error during the interpretation phase of the process. This is where AI tools become a valuable alternative; this is an example of how AI systems are capable of making better predictions than human experts ([McKinney et al., 2020](#)). When “incredible promise” equates to outcomes such as more efficient and more accurate diagnoses across a wide range of medical fields, it is imperative that such technology is brought forth responsibly.

Yet, equitably advancing value-based care in research, health administration and operations, population health, practice delivery improvement, and direct clinical care is not easily achieved.

When algorithms are deemed unsuccessful, their shortcomings are typically summarized as unintended consequences. Commercial prediction algorithms are relied on by health systems to help identify patients that have complex health needs, and while at first glance this seems to be an innovative way to address an issue using AI, one of these widely used algorithms that affects millions of patients was exhibiting racial bias. Due to the fact that the algorithm was meant to predict health care costs and not illness, unequal access to care became a contributing factor to the algorithm’s output. Thus, at a given risk score, Black patients were considerably sicker than White patients. If this disparity were to be corrected, the percentage of Black patients receiving additional help would increase from 17.7 to 46.5%. This is a prime example of how convenient and seemingly effective proxies for ground truth can prove to be a source of algorithmic bias ([Obermeyer et al., 2019](#)).

More recently, the Coronavirus Aid, Relief, and Economic Security (CARES) Act and Paycheck Protection Program designated \$175 billion for COVID-19 response efforts and reimbursement to health care entities for expenses or lost revenues. Yet, these funds were allocated based on past revenue, which is often lower in non-White and indigent communities because of underinsurance and undertreatment. Because of the way these funds were meant to be allocated, racial bias was able to insert itself into the equation resulting in a disparate impact on Black populations ([Kakani et al., 2020](#)). From algorithms that “correct” their outputs based on the patient’s race or ethnicity, even though race is not a reliable proxy for racial difference ([Vyas, et al., 2020](#)), to biased datasets used to train AI, there are many facets of algorithmic bias to address by relying on thoughtful and impactful strategies.

Certainly, realizing a truly accessible and equitable healthcare ecosystem will require proactivity and collaboration between and amongst the private sector, consumer and patient communities, and

government regulators (among others). Given the broad policy and legal areas implicated by the increased uptake of AI tools in supporting healthcare decisions, it can be difficult to target where the initial steps should be taken. Indeed, progress is already underway in areas such as assuring quality and patient safety and enhancing AI transparency and explainability (among others), undeniably, reimbursement incentives for the responsible use of such AI tools in bellwether government health beneficiary programs, namely the Medicare program, are already, and will very likely continue to be, a leading force in the transition to a broader healthcare system that enables the use of AI innovations efficaciously.

Recent developments in the coding and reimbursement context provide a strong foundation for that bellwether, the Medicare system, as well as other organizations, to build upon, and represent significant steps towards the wide leveraging of AI tools to assist in making clinical decisions. These developments include:

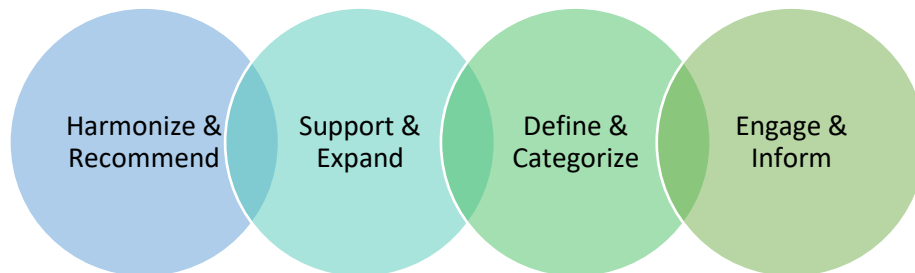
- **To date, CMS has taken a number of important steps to make AI's benefits available to more caregivers and patients.** Moving forward, CMS should aim to provide national payment rates for AI's responsible use in addressing specific use cases, such as in diabetic retinopathy; and integrating AI into value-based care, specifically in various Quality Payment Program Merit-based Incentive Payment System quality measures. Notably, in its proposed CY 2022 PFS rule, CMS asked a wide range of questions about the use of innovative technologies, including software algorithms and AI in health, to better understand the resource costs for services involving their use. We are encouraged by CMS' leadership in exploring medical AI definitions, present and future AI solutions, how AI is changing the practice of medicine, and the future of AI medical coding.
- **Even more recently, the CPT[©] Editorial Panel accepted the addition of a new Appendix S to provide guidance for classifying various AI applications. The Panel intended the Appendix to be consulted for code change applications to describe work associated with the use of AI-enabled medical services and or/procedures.**¹ This taxonomy provides guidance for classifying various AI applications (e.g., expert systems, machine learning, algorithm-based services) for medical services and procedures into one of three categories: assistive, augmentative or autonomous, and its adoption represents a significant step forward in the evolution of CPT[®] coding.

So, what steps should next be taken in the Medicare program? We suggest that, in order to adequately and ethically explore the costs associated with AI, the medical definitions of AI, present and future AI solutions, how AI is changing the practice of medicine, and the future of AI medical coding, that CMS continue to lead by taking the following steps:

1. As a baseline for payment policy decisions impacting AI's use in Medicare, rely on the CPT[®] Editorial Panel's new Appendix S to harmonize definitions and understanding of health AI and the CHI AI Task Force's released general health AI policy recommendations, recommended good machine learning practices for FDA-regulated AI, and recommendations addressing how to create and maintain the trust of both healthcare professionals and patients in health AI tools.
2. Continue to support and expand responsible payment (aligning, where possible, with valuation recommendations of the Relative Value Scale Update Committee) for AI tools that will drive greater access to innovative AI mechanisms for Medicare beneficiaries. CMS should also adopt national rates for the payment of AI services and shift away from contractor pricing that encourages disparate approaches among Medicare Administrative Contractors.

¹ <https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures>.

3. Recognize that AI (either standing alone or used in a system) is appropriately paid for as a direct practice expense (PE). AI software is not simple “off the shelf” software and cannot not be properly categorized as an indirect PE. Like medical equipment and medical supplies, software as a medical device (SaMD) is a device as defined by FDA regardless of whether it is loaded onto and used on general purpose platforms or used as dedicated ancillary medical devices.
4. Continue to engage in dialogue with the digital health community to inform new steps forward towards an expanded and nationally harmonized approach to AI’s use in Medicare



As demonstrated by the detailed steps above, the process of harnessing AI tools can seem complex and intimidating. By methodically approaching specific obstacles that are central to broader systemic changes, however, meaningful progress towards responsibly bringing AI to the Medicare system in a way that will advance health equities and benefit all patients and providers.

What is the Connected Health Initiative (CHI)?

The CHI is a not-for-profit multistakeholder policy and legal advocacy coalition driven by a consensus of stakeholders from across the connected health ecosystem which aims to realize an environment where Americans can improve their health using digital and connected health technologies to enhance health outcomes and reduce costs equitably.

What is the Health AI Task Force?

As a part of the CHI’s commitment to responsibly advancing AI in healthcare, this task force was assembled and consists of a comprehensive group of innovators and thought leaders. Additionally, this task force has developed a range of resources, including a position piece supporting AI’s role in healthcare, and a terminology document targeted at policymakers. More recently, the CHI’s AI Task Force has developed Good Machine Learning Practices, specifically for the AI development and risk management of AI meeting the Food and Drug Administration’s (FDA’s) definition of medical device, as well as recommendations on ways to improve transparency for caregivers, patients, and others necessary for the appropriate uptake of AI tools across the care continuum.