HEALTHCARE
LEADERSHIP COUNCIL

May 06, 2024

The Honorable Ami Bera
U.S. House of Representatives
Washington, D.C. 20515

Re: Response to Request for Information on Use of Artificial Intelligence in the Healthcare Industry

Dear Representative Bera:

The Healthcare Leadership Council (HLC) appreciates the opportunity to submit comments regarding the rapidly advancing application and use of Artificial Intelligence (AI) in the healthcare industry.[1] Our membership is dedicated to thoughtful integration of this technology to leverage opportunities to improve patient outcomes, advance quality, and reduce inefficiencies while ensuring patient safety, privacy, and equity.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, homecare providers, group purchasing organizations, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

HLC and our members share your enthusiasm regarding the potential for AI to transform the efficiency of patient care, bolster health outcomes, lower costs, and make other advances in the field. Beyond advancing these continuous improvement goals, AI also can alleviate persistent challenges facing the healthcare industry such as workforce shortages and access barriers. In assessing the impact and guardrails for responsible use, distrust and trepidation persist as implementation efforts continue. As with other transformative technologies, these tools need to be regulated; protections are essential to safeguard privacy and to best serve patients given the risks that emerge particularly when technology interfaces with personal health data. Therefore, it is imperative that stakeholders collaborate to strike the right balance between protecting individual liberties and allowing this evolving innovation to flourish. Our comments here are in response to four categorical aspects of your request dated March 20, 2024, as Congress develops policies regarding AI in healthcare that promote innovation while safeguarding patients. In each of these categories (Implementation; Efficacy, Accuracy, and Transparency; Ethical and Regulatory Considerations as well as other considerations), HLC is sharing examples from member companies harnessing and incorporating the power of AI in healthcare to serve patients.

[1] https://www.hlc.org/download.php?file=/wp-content/uploads/2024/04/Bera-RFI-The-State-of-Artificial-Intelligence-in-Health-Care65

Implementation

AI is already an invaluable tool within the healthcare sector, but its implementation in the healthcare sector generally and in treating patients specifically is not singularly or independently transformative. Instead, AI is a tool to augment the human elements of delivering healthcare. Developing a new therapy still requires scientists at both discovery and clinical phases; performing a treatment or prescribing a test still requires the assessment from medical staff. Reviewing certain health records and diagnostics still requires an actual clinician. The role of AI in each of these tasks is to better evaluate the information available, identify potential actions to consider, and empower the human elements of healthcare sector to act with more information. Specific examples to highlight the innovative uses of AI include:

- In the real-time evaluation of data sets, AI facilitates expeditious responses within a hospital by alerting physicians to conditions and enabling a near immediate respond with necessary treatments and/or tests. Epic Systems developed the Epic Deterioration Index capable of identifying patients at higher risk for sudden deterioration that was shown to reduce emergency outcomes by 10.4%. New York-Presbyterian has partnered with the Cardiovascular and Radiologic Deep Learning Environment Lab to develop an algorithm to identify patients at high risk of structural heart disease during an electrocardiogram.[2,3] Similar capabilities are also being integrated directly into medical devices, as seen in Johnson and Johnson's Monarch Platform for bronchoscopy that assists physicians in examining areas of the lung more difficult to access with conventional bronchoscopes.[4]

- In patient engagement and experience, AI helps streamline processes to improve both patient interactions while also lowering avoidable costs. A study out of UC San Diego leveraged AI to draft responses inside Epic Systems' electronic health record (EHR), for example to produce instructions that are easier for patients to understand, and helped ensure a greater adherence and compliance to follow-up care instructions as demonstrated.[5] Assisting in these communications alleviates the burden placed upon physicians and nurses, allowing more time spent meeting patients' needs.

- In the drug discovery process, labs utilize AI to conduct computational modeling and simulation to streamline the identification of drug targets and potential therapeutic candidates that can slow or stop progression of a disease. Pfizer used this process in developing PAXLOVID, screening millions of protease inhibitors and planning modifications to arrive at an effective oral therapy in four months.[6] Additionally Merck & Co. Inc. has utilized Amazon Web Services to build its own platform, Hawk AVI, that combines descriptive analytics, artificial intelligence, and machine learning to generate insights regarding rejected drug product images and recommend corrective actions to the manufacturing team.[7]

---

[2] Effectiveness of an Artificial Intelligence–Enabled Intervention for Detecting Clinical Deterioration | Artificial Intelligence | JAMA Internal Medicine | JAMA Network
[3] https://www.dbmi.columbia.edu/cradle-lab-seeks-novel-ways-to-detect-cardiac-diseases-earlier/
[4] https://www.jnjmedtech.com/en-US/product-family/monarch
[5] https://www.sciencedaily.com/releases/2024/04/240415163745.htm
[6] https://insights.pfizer.com/pfizer-is-using-ai-to-discover-breakthrough-medicines/
[7] MSD Builds HawkAVI Platform on AWS to Reduce Product Reject Rates | AWS for Industries (amazon.com)

- IQVIA has leveraged decades of general AI-based tools to create a natural language processing platform used by 19 of the top 20 pharmaceutical companies, as well as leading healthcare organizations and government bodies. This technology enables access to previously hard-to-reach information and reduces manual abstraction while ensuring the platform remains user-friendly and facilitates human validation.[8] Utilities include: identifying consumer use of drugs to derive real-world evidence on outcomes; extracting clinical trial data to calculate ranking statistics for treatment-indication association, and; predicting success or failure of a target-indication pair based upon previous approved or failed cancer therapeutics.

Efficacy, Accuracy, and Transparency

Healthcare organizations that utilize AI should establish a risk-based approach and provide calibrated recommendations – ideally to align with or extend beyond, existing consensus-based risk management frameworks such as those produced by the National Institute for Standards and Technologies' (NIST's) AI Safety Institute and Consortium. While less restrictions are necessary for lower risk tasks, clarifying the role of clinicians and healthcare workers as both interpreters of information or findings produced by AI as well as the final decisionmaker with regards to high risk determinations will ensure that health organizations are deploying the technology in a manner that continues to put the patient at the center of care.

Clear communication, timely disclosure, and accurate reporting are essential not only for responsible use of AI but also for building trust in AI technology. Where appropriate and in alignment with a risk-based approach, organizations should be clear when using AI tools, especially as AI communication systems (such as chatbots) become more "lifelike." Entities are best served by making it explicitly clear when a patient is receiving communications from a computer rather than a person. Revealing the inner workings of AI systems to the public or regulatory agencies should not be required, nor would it be beneficial. Such detailed disclosure of either data inputs or algorithmic processes would not be meaningful to patients, providers, or payers. This unnecessary disclosure would force AI developers to reveal intellectual property or proprietary technology, create AI vulnerability risks, and limit innovators willingness to work with the already highly regulated healthcare industry on meaningful AI applications.

While requiring the disclosure of proprietary information is harmful to both innovation and the security of models, there is value in advancing standards for model information transparency. For example, developers communicating core elements useful for the deployers will assist in model/product/technology use, such information regarding the intended population for use. All stakeholders should be able to gauge the context in which an algorithm operates and understand the implications of the outcomes. Additional discussions are needed to determine and clarify the responsibilities of AI developers and deployers. Further, it is beneficial to develop standards for model explainability for individuals impacted by high-risk AI-assisted decisions. Meaningful and useful explanations should be tailored to the audience and calibrated to reflect the level of risk.

Ethical and Regulatory Considerations

[8] navigating-new-large-language-models-in-healthcare-nlp.pdf (iqvia.com)

HLC believes AI will improve equity in many aspects of healthcare. By leveraging high quality data that is as complete as possible and evaluating performance across a model's lifecycle, AI has the potential to improve not only accuracy, but also equity within healthcare systems. Extrapolating from highly detailed data can aid in assuring diversity in clinical trials by improving recruitment strategies.[9]

Additional regulatory considerations of particular importance for entities utilizing AI in healthcare center on existing industry laws and regulations around data privacy and security protections, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Affordable Care Act Section 1557 nondiscrimination, and regulatory guidance considerations related to the delivery of care and consumer protections. The challenge involves the current application of HIPAA for protected health information, and HIPAA-covered entities versus appropriate protections for non-HIPAA covered entities and non-HIPAA health data. In general, privacy principles should be integrated into AI tools. Sound data governance, including privacy and security, in alignment with all existing healthcare laws and regulations should be a cornerstone of any AI health policy.

Other Considerations

HLC believes it is necessary for any regulatory framework(s) governing AI applications to be risk-based, and developed and applied at the federal level as a single national standard that preempts state laws to avoid conflicting requirements and facilitate compliance without unduly restricting innovation. We are eager to engage to advance the development of thoughtful policy as our members continue utilizing this technology to improve patient safety and care. If you have any questions, please do not hesitate to contact Katie Mahoney at (202) 449-3452 or kmahoney@hlc.org.

Sincerely,

Maria Ghazal
President & CEO

[9] Artificial Intelligence Applied to clinical trials: opportunities and challenges | Health and Technology (springer.com)