ConnectedHealth

April 15, 2020

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RE: *Connected Health Initiative Request for FDA Steps to Enable Artificial Intelligence Tools for the Diagnosis and Treatment of COVID-19*

The Connected Health Initiative (CHI) writes to request action by the Food and Drug Administration (FDA) to enable the use of artificial intelligence (AI) models for imaging technologies to accurately detect COVID-19, and to distinguish COVID-19 from other lung diseases including pneumonia and assess disease progression through its Breakthrough Devices Program framework and/or under other public health emergency authority. CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their health through digital health technologies. We seek policy changes that enable all Americans to realize the benefits of an information and communications technology-enabled American healthcare system. For more information, see www.connectedhi.com.

The COVID-19 pandemic poses an unprecedented threat throughout the United States. With an increasingly strained healthcare workforce during this time of crisis, all levels of government must take extraordinary steps to enable access to care for those in need. Early diagnosis of COVID-19, assessment of disease progression, and determining

patient prognosis are vital for treatment and the isolation of infected patients to prevent the spread of this virus is critical. Further, the COVID-19 emergency makes it essential to automate tasks, which enhances workflow speeds and streamlines redundant processes to improve efficiency. We support the FDA's measures taken to address this public health emergency to date and stand ready to assist the FDA in accomplishing its important mission during this crucial time.

Particularly during public health emergencies, AI--powered by streams of data and advanced algorithms--has incredible potential to improve healthcare, prevent hospitalizations, reduce complications, and improve patient engagement. Not surprisingly, public health experts are leveraging AI in a variety of ways to combat COVID-19 and its spread. Specifically, AI is being used to analyze large data sets to identify infection clusters, spread patterns, and high-risk patients. Additionally, scientists are using AI for natural language-processing in a White House-supported effort to mine research papers related to COVID-19 to assist with the development of a vaccine. Providers are also using AI-driven decision support and triaging tools to manage their services and patients. Notably, new studies indicate that imaging AI models can accurately detect COVID-19, and distinguish COVID-19 from other lung diseases including pneumonia.[1] Making such determinations during the COVID-19 public health emergency (PHE) would provide an enormous benefit for all Americans. Symptoms of COVID-19 can be identified at an earlier detection stage through rapid and reliable analysis and post-processing of lung images, enabling a more efficient method of diagnosis and prognosis for allocation of scarce hospital resources. Further, with healthcare facilities needing to carefully manage resources and space for patients already diagnosed with COVID-19, such tools will enable them to admit to hospital those patients at the most risk, while sending home patients at less risk for self-isolation.

CHI believes that the FDA can take steps now to enable the benefits of AI imaging analysis for patients at all stages of detection and treatment during the COVID-19 PHE by immediately providing a streamlined pathway to the market for this AI use case. We support the FDA establishing this pathway through its Breakthrough Devices Program framework and/or public health emergency authority as soon as possible. As the FDA has established device pathways in AI to automate diagnostic radiology, including workflow and AI used to guide/assess image acquisition, analysis, and reporting, we believe that the FDA should leverage its experience with these pathways and support rapid re-training and re-approval for deep learning models analogous to the existing diagnostic radiology/workflows permitted to date.[2]

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[1] *E.g.*, *Artificial Intelligence Distinguishes COVID-19 from Community Acquired Pneumonia on Chest CT* (Mar 2020), https://doi.org/10.1148/radiol.2020200905.

[2] In the context of its recent workshop on AI's use in radiological imaging, the FDA has emphasized the need for rapid re-training and re-approval in noting that "[w]hile historically the information provided by [AI] algorithms has augmented the tasks performed by radiologists, software developments now can enable the devices to perform certain tasks autonomously. The potential for independent action by these devices

Finally, we note that CHI has long recognized that AI healthcare applications have also given rise to a variety of potential opportunities and challenges for U.S. policymakers to consider, including notice/consent, bias, inclusion, transparency and digital due process, and law enforcement access to data, among others. Representing the leading developers of healthcare AI, we recognize that the design of healthcare AI systems must be informed by real-world workflow, human-centered design and usability principles, and end-user needs, facilitating the "Quadruple Aim."[3] CHI's AI Task Force has developed a set of healthcare AI policy principles that address the range of opportunities and challenges associated with AI in healthcare and propose the appropriate role of government regulation[4] that we urge the FDA to act consistently with both during and after the current public health emergency. We believe that the FDA action requested above would be consistent with these principles.

to bypass human clinical review is an important factor in their benefit-risk profile, and it heightens expectations for the safety and effectiveness of these devices." https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-evolving-role-artificial-intelligence-radiological-imaging-02252020-02262020#event-information.

[3] *See* https://www.ama-assn.org/system/files/2018-11/playbook-resources-step-3-quadruple-aim-value.pdf.

[4] https://actonline.org/wp-content/uploads/Policy-Principles-for-AI.pdf.

We appreciate FDA's consideration of our request and stand ready to work with the FDA both during and after the COVID-19 public health emergency to advance the FDA's mission.

Sincerely,

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The Connected Health Initiative (CHI), an initiative of ACT | The App Association, is the leading multistakeholder spanning the connected health ecosystem seeking to effect policy changes that encourage the responsible use of digital health innovations throughout the continuum of care, supporting an environment in which patients and consumers can see improvements in their health. CHI is driven by the its Steering Committee, which consists of the American Medical Association, Apple, Bose Corporation, Boston Children's Hospital, Cambia Health Solutions, Dogtown Media, George Washington University Hospital, Intel Corporation, Kaia Health, Microsoft, Novo Nordisk, The Omega Concern, Otsuka Pharmaceutical, Podimetrics, Proteus Digital Health, Rimidi, Roche, Spekt, United Health Group, the University of California-Davis, the University of Mississippi Medical Center (UMMC) Center for Telehealth, the University of New Orleans, and the University of Virginia Center for Telehealth.

For more information, visit www.connectedhi.com.