November 22, 2019

Belinda Seto, PhD
Office of Data Science Strategy
National Institutes of Health

Via Email (FHIRRFI@nih.gov)
Via Electronic Submission (https://datascience.nih.gov/fhir-rfi-submission)

RE: Request for Information (RFI): Use of the Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) for Capturing and Sharing Clinical Data for Research Purposes (NOT-OD-19-150)

Dear Dr. Seto:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide comments to the National Institutes of Health (NIH) about how the Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard could be used to exchange clinical data for research purposes.

The Association of American Medical Colleges is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 154 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC supports the NIH in its efforts to identify ways to enhance the use of clinical data for research. We also appreciate the NIH and other federal health agencies' attention to improving interoperability and the flow of data across health information systems. We are pleased to provide the following comments in response to this request for information (RFI).

The AAMC shares the NIH's interest in identifying ways to accelerate the use of clinical data in research. We also praise the NIH for issuing this RFI to seek input directly from the medical research community. Users of health IT systems, such as clinicians and researchers, are best suited to comment on the FHIR standard's potential use in research.

Many of the AAMC's member institutions were early adopters of health information technology (IT). They have helped to pioneer its development and are knowledgeable about both the potential and limitations for using clinical data generated through electronic health records (EHRs) in research. The following information was drawn from leading clinicians and researchers at our member institutions who are most familiar with the FHIR standard.

Current experiences of researchers either using or not using FHIR.

Currently, the FHIR standard is used primarily for clinical care purposes. In terms of adoption, using FHIR for research is still relatively new. The nature of clinical data requires that it be transformed for research. FHIR can be used alongside another system, such a REDCap, to pull data out of EHRs, but additional work is required to make the data available for research purposes.

Even across the research community, there isn't a broad level of understanding about FHIR's capabilities and limitations related to its application in research. Many are interested in its potential and are aware of FHIR's use as a solution to interoperability challenges, but additional education and training are needed around what is possible for research. Educational opportunities exist to inform the community about best practices, and the AAMC recommends that more training and information be made available to researchers and clinicians about FHIR's capabilities. The AAMC is happy to assist the NIH and others with these efforts.

The application of the FHIR standard to research data, considering anticipated challenges and anticipated opportunities.

While there are benefits in establishing a standard structure for capturing and sharing research data, currently there are limitations to how FHIR can be used in research, including:

Challenges related to EHR vendor-level differences in how FHIR is implemented. We agree that FHIR is a highly regarded standard in the health IT field; however, more infrastructure is needed before the standard can be uniformly used for research. EHR vendors implement FHIR differently, so there are potential issues when trying to combine data from different sources. Regardless of what standard is developed and recommended, our members have found that it is often up to what the EHR developers agree to adopt and implement. To support the use of FHIR for research, we recommend that the NIH—along with other federal agencies overseeing interoperability initiatives—work with the medical, research, and health IT communities to determine what common set of data must be made available through EHRs, and vendors should adopt these standards.

Challenges related to FHIR's design and the capabilities it offers from a research perspective. FHIR is a framework for accessing data. It is designed to be an open interface, and data must be pulled into other systems for analysis. Therefore, using FHIR to collect clinical data for research requires an additional step of transforming the clinical data after it is pulled.

There is much promise and opportunity to use patient and population-level data for research purposes. It is important to note that currently the way FHIR is most commonly implemented enables data pulls only from an EHR for an individual patient and not for a population, which is a limitation for research.

Usability challenges. Researchers and clinicians at our member institutions who are working with FHIR acknowledge that using FHIR for research can be challenging. We recommend that the NIH convene a group of clinicians, researchers, and EHR vendors to discuss improving the implementation of FHIR so that it can be used to advance research in ways the RFI identified.

Additional routes by which NIH can encourage the development and use of FHIR for research purposes.

It is important to distinguish the capabilities of FHIR from the research challenges that will still exist after it is implemented. FHIR enhances interoperability across systems and is used to exchange health information electronically. If data structures in the health information vary, or if the measurements or models for collecting data differ, simply adopting FHIR won't help advance research. It is critical that the research community develop common data models and standards for using clinical data for research, and that the EHRs capture clinical data according to established standards. We encourage the NIH to help advance efforts to ensure that clinical data is collected in a standard format that can be used for research.

Ethical, privacy, and security considerations when using FHIR to share research data.

The AAMC supports the FHIR standard so long as protections are in place to promote the privacy and security of patient health information. FHIR resources allow accessing patient information to happen more quickly and easily, so safeguards must be adopted to restrict access to certain data. The AAMC recommends that the NIH address this security concern by collaborating with other federal health agencies to closely study FHIR's ability to grant access to only certain specified data, not all data available for the patient.

Tools that would assist NIH funded researchers in advancing identified opportunities using FHIR.

As FHIR is more widely adopted, we recommend that the NIH create a mechanism for researchers to submit feedback about where improvements are needed. When researchers identify challenges, they can report issues to their institutions, but from a wider implementation perspective, this approach doesn't directly improve the overall function. By creating a single source for submitting recommendations for research enhancements, the NIH can gather input necessary to support FHIR adoption.

Training and education are necessary to support and advance FHIR's use in research. We recommend that implementation guides be developed in consultation with researchers and clinicians. The users of FHIR should be directly involved during testing to identify any issues that occur when data is pulled.

Ways NIH can stimulate research into FHIR-related standards development.

We support the need for more studies to examine FHIR's potential in research and encourage the identification of best practices for using FHIR to collect and share research data. We also recommend additional studies be conducted around FHIR's existing privacy and security specifications to identify what security enhancements must be made when FHIR is used to collect clinical data for research.
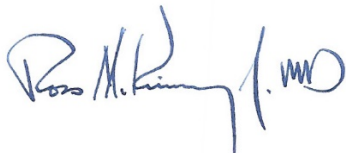
Any other topic which may be relevant for NIH to consider in encouraging the use of the FHIR standard for research and to facilitate the interoperability of research data.

The AAMC appreciates the NIH's efforts to ensure that health IT is interoperable, and that data can move across systems. The AAMC strongly encourages the NIH to include clinicians and researchers in discussions about data needs and data gaps in EHR design. These individuals are working directly within the health IT systems, and understand the potential, limitations, and shortcomings of what these systems offer, particularly when the information is pulled for research. We recommend that the NIH not only work collaboratively with other federal health agencies as it moves forward with standards setting, but that it also convenes a specific group of leading researchers and clinicians who can identify gaps in the data's application in research.

The AAMC supports ongoing efforts of the NIH and other federal health agencies to promote interoperability. We recommend interagency collaboration across health IT-related initiatives so that efforts can be coordinated and aligned.

We encourage the NIH to continue to engage the scientific community on the topic of exploring how FHIR can be used to advance research. Please let us know how the AAMC and our members can assist the NIH with these efforts. The AAMC appreciates the opportunity to comment on this issue and would be happy to provide any additional information moving forward. Please contact me or my colleague, Anne Berry, MPP, Lead Specialist, Implementation Research and Policy, at aberry@aamc.org or 202-739-2987 with any questions.

Sincerely,

Ross McKinney, Jr., MD
Chief Scientific Officer