



March 15, 2019

Alex Thai  
2415 Eisenhower Avenue, Alexandria, VA 22314  
NITRD HITRD IWG  
Via email: [HITRD-RFI@NITRD.gov](mailto:HITRD-RFI@NITRD.gov)

**Re: RFI Response: Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care**

The American College of Radiology (ACR)—a professional organization representing more than 38,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to provide feedback to the Networking and Information Technology Research and Development (NITRD) Health Information Technology Research and Development Interagency Working Group (HITRD IWG) regarding interoperability of medical devices, data, and platforms to enhance patient care.

**(1) What is your vision for addressing interoperability issues between medical devices, data, and platforms? How would this plan to create interoperable systems address your key use cases and pain points?**

Addressing the interoperability issues between medical devices, data, and platforms requires a technical standard that includes both protocols for communication and a common semantic framework that ensures data can be correctly interpreted. Decades ago, the ACR worked with NEMA to create DICOM specifically for the purpose of enabling the integration of medical imaging devices such as scanners, servers, workstations, printers, network hardware, and picture archiving and communication systems (PACS) from multiple manufacturers. The standard has been widely adopted by healthcare facilities across the country, so that images can now be exchanged from one facility to another, regardless of the originating or destination device.

As we seek to promote precision medicine and facilitate advanced information processing, integration across domains has become increasingly important. The introduction of artificial intelligence (AI) to the healthcare setting, for example, brings new needs for standards of interoperability. Similar to DICOM for the transferring of images, a standard nomenclature for describing imaging procedures such as that found in ACR Common, and a standard description of imaging findings such as the ACR/RSNA RadElement effort is required. Standard profiles for

defining clinical scenarios such as the ACR DefineAI Use Cases allow vendors to understand both the data elements and the clinical context necessary for AI applications to be integrated effectively. Protocols for transmitting findings in DICOM, HL7 and FHIR need to be promoted, and standard APIs for hosting and invoking analytic models will be needed to ensure AI models can be applied consistently throughout the healthcare setting. The ACR Data Science Institute is actively working with the vendor community to develop standards in these areas.

As thin-client web applications and RESTful APIs have become increasingly prevalent, there is an improving ability to access data in real-time within EMRs and other systems that house patient data. Allowing the data to stay at a facility and bringing the consumer to the data is another strategy that allows for seamless flow of information while limiting movement of data. FHIR and other emerging standards can help pave the way for this type of real-time access as can thin-client radiology imaging viewers and other advanced applications.

## **(2) Who are the relevant parties and their contributions to your interoperability solution?**

Both healthcare providers and the vendor community must be involved in the solution. Parties would include:

- **Hospitals and other health care providers** to enable interfaces and connectivity between EHR technology and imaging IT for exchange of electronic orders, reports, and images.
- **RIS/PACS and other imaging IT vendors** to work closely with EHR technology vendors on mutually agreeable, standardized, and secure connectivity solutions.
- **EHR technology/EMR software vendors** who have historically considered imaging to be firmly outside their domain.
- **AI vendors** will increasingly be involved.
- **Regulatory and research agencies** to establish new incentives and regulatory obligations to encourage the relevant industries to address imaging exchange issues. There is especially an opportunity for the Office of the National Coordinator for Health IT (ONC) to work specifically with the imaging community to identify areas of need to facilitate better integration and interoperability of imaging IT and EHRs.
- **Standards development organizations**, including HL7, DICOM standards committee, IHE, etc.
- **Professional associations and patient groups** to represent the interests of end-users and consumers and work with vendors to encourage pathways that are desirable to their customers.
- **Health information exchanges/networks** that have typically considered images and imaging data (including orders and reports) to be outside their purview.

**(3) What are the challenges and impediments to making interoperability happen? How might these issues be addressed and by whom?**

Some of the biggest challenges to interoperability include a clear roadmap with sufficient clinical context and standards along with incentives that make it advantageous to provide and adopt interoperable solutions. In the AI domain, it is becoming clear to vendors that a proprietary solution to hosting or invoking AI is inferior to standards that have the potential to promote a viable AI ecosystem. At the ACR Data Science Institute, we have promoted such an ecosystem and have found that vendors, in general, are very supportive.

In the image transfer domain, the ACR has initiated an effort to promote the exchange of imaging studies without the need for CDs (#DitchTheDisk). Sharing imaging studies via physical discs are inherently challenging. Patients that have multiple providers may experience limited access to their imaging study, there are often issues viewing such studies once the CD is received, and there is always the threat of losing a disc containing all of the patient's examinations<sup>1</sup>. The ACR believes it is critical to resolve this issue and is committed to pathways that will allow the imaging community to exchange imaging studies between facilities and with patients without needing CDs or other physical media.

**(4) Is the federal vision for a medical device, data, and platform interoperability end state outlined in this RFI viable? Please explain why you have reached the conclusion that you have.**

The end state outlined in the RFI is definitely viable as is evidenced by the success achieved in other industries; however, it will require significant work and cooperation by healthcare providers, healthcare vendors, and standards and professional organizations. The ACR's previous success in creating DICOM which has been adopted as an international standard for medical image exchange demonstrates that it can be done. Our current efforts to create an interoperable AI ecosystem has been strongly supported by the vendor community. In addition, ACR is in the process of initiating a "#DitchTheDisk" pledge campaign to encourage radiology providers to move away from sharing diagnostic images on physical media and to implement electronic exchange where feasible. We would welcome the opportunity to collaborate with the HITRD IWG so that we can coordinate the voluntary efforts of the imaging community with the activities of federal agencies that have jurisdiction over solutions that do not meet the "medical device" definition, particularly certified health IT/EHR technology under ONC's authority.

The ONC's March 4, 2019 proposed rule to modify the health IT certification criteria to incorporate imaging narrative information within "clinical notes" as part of the U.S. Core Data for Interoperability (USCDI), as well as the long-anticipated "information blocking" provision, could help facilitate additional exchange of certain imaging data between the EHR technology

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<sup>1</sup> David S. Mendelson, MD, Bradley J. Erickson, MD, PhD, Garry Choy, MD, MBA. Image Sharing: Evolving Solutions in the Age of Interoperability. Accessed 2019 March 6. [https://www.jacr.org/article/S1546-1440\(14\)00548-1/fulltext](https://www.jacr.org/article/S1546-1440(14)00548-1/fulltext)

and medical imaging IT domains. Certainly, there is a new recognition within CMS and ONC that, at a minimum, EHR-accessible imaging narrative data (i.e., sharing results) is of interest to everyone. We hope that in the future EHR and PHR technology would increasingly facilitate seamless provider and patient access to images.

We also recommend that ONC work with the radiology community to develop and implement health IT certification criteria for medical imaging record solutions that could be used by imaging specialists participating in CMS' Quality Payment Program to satisfy Promoting Interoperability requirements. The ONC's Interoperability Standards Advisory explores some basic interoperability needs related to imaging data exchange; however, this compendium of voluntary standards and implementation specifications is currently the only place in ONC's portfolio where image exchange, and not just sharing of imaging narrative information, is referenced. Moreover, ONC has historically lacked radiology expertise on its federal advisory committees, including the current iteration of the Health Information Technology Advisory Committee (HITAC). To address radiology device and EHR interoperability, proactive work needs to be done by ONC to unite the two disparate domains of health IT expertise.

Thank you in advance for your time and consideration. Should you have any questions on the points addressed herein, or if we can otherwise be of assistance, please do not hesitate to contact Michael Peters or Tina Getachew in ACR's Government Relations office at 202-223-1670.

Sincerely,

A handwritten signature in black ink, appearing to read "G. McGinty". The signature is fluid and cursive, written in a professional style.

Geraldine B. McGinty, MD, MBA, FACR  
Chair, Board of Chancellors  
American College of Radiology