July 22, 2016

Attn: Terah Lyons
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Ave. NW,
Washington, DC 20504

Subject: (2016-15082; 81 FR 41610) Request for Information on Artificial Intelligence; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional organization representing more than 35,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to respond to the White House Office of Science and Technology Policy's (OSTP) Request for Information (RFI) on "Artificial Intelligence" (AI) published in the *Federal Register* on June 27, 2016 (document number 2016-15082; 81 FR 41610). The ACR supports the federal government's efforts to leverage AI and machine learning to improve government services in general, and we urge additional federal support for, and collaboration with, professional associations and other stakeholders within specific fields of interest to ensure a safe and efficacious use of this technology.

The following comments on the questions enumerated in the RFI were compiled by members of the ACR Clinical Data Science Committee, ACR Commission on Informatics, and ACR Research. Individual contributing members are listed at the end of this submission.

ACR Responses to RFI Topics

1. The legal and governance implications of AI:

Health care institutions, radiology groups, and vendors planning to develop algorithms using source data such as electronic health record technology and/or patient diagnostic imaging data need guidance from agencies on issues of patient

consent and appropriate methods/best practices. Moreover, AI incorporation into clinical radiology practice can introduce new medico-legal risks and uncertainties. Related concerns could potentially discourage acceptance and proliferation of AI by providers.

2. The use of AI for public good:

AI could offer various benefits to medical imaging in the future, including augmenting the capabilities of radiologists to enhance their efficiency and accuracy, as well as reducing costs by improving the appropriateness and cost-effectiveness of medical imaging utilization.

The use of AI and machine learning in health care in general could be best applied to the areas of precision medicine, predictive analytics, and outcomes assessments. AI can streamline healthcare workflow and improve triage of patients (especially in acute care settings), reduce clinician fatigue, and increase the efficiency and efficacy of training. Moreover, shortages of medical experts to meet the needs of vulnerable and underserved populations in domestic and international settings could potentially be relieved, in part, by AI.

3. The safety and control issues for AI:

Safety standards should be identified to facilitate the proper development and monitoring of AI-driven technologies in medical imaging. This could be addressed through a combination of regulatory oversight and professional association validation or certification of algorithms. Federal agencies could also partner with professional and trade associations to develop standardized datasets for algorithm training and testing.

In addition to oversight over the technology, safety issues need to be addressed via training and best practices for practitioners on appropriate incorporation of AI into clinical radiology.

5. The most pressing, fundamental questions in AI research, common to most or all scientific fields:

The most universal AI research question is how to measure the effectiveness of the technology; however, the specific definitions/measures of effectiveness and testing methodologies would likely vary from field to field. In medicine, research into effectiveness should focus on areas such as diagnostic error reduction, improved accuracy, workflow enhancement, and efficiency gains. Moreover, research should explore how AI tools can be seamlessly integrated into clinical workflow and to what degree there is impact, both positive and negative, on clinical decision making and patient care outcomes.

6. The most important research gaps in AI that must be addressed to advance this field and benefit the public:

In terms of the application of AI to medical imaging, there is a need to define standards by which images and corresponding data should be structured to facilitate AI research. As mentioned above, research needs to also explore impact measurement of AI tools on image/data interpretation, diagnostic accuracy, and workflow efficiency.

8. ***The specific steps that could be taken by the federal government, research institutes, universities, and philanthropies to encourage multi-disciplinary AI research:***

The Departments of Health and Human Services, Veterans Affairs, and Defense should increase grant opportunities to study and develop AI technologies in medical imaging. Federal agencies partnered with professional associations, academic institutions, patient advocates, and other organizations could develop and/or disseminate policy, ethical, scientific, and industry standards, including those related to interoperability and generalizability of AI-driven technologies. Standards around security, privacy, data-sharing, and the use of common datasets for researchers would facilitate the improved generalizability of algorithms. Importantly, added expertise in domains outside of traditional computer science and health information technology (e.g., image perception, human factors, and safety) should be consulted.

9. The specific training data sets that can accelerate the development of AI and its application:

The class of AI technologies that utilize machine learning techniques (neural networks, deep learning, etc.) require large data sets to learn relationships between inputs and outputs of information processing chains, or to discover and categorize patterns. The feasibility of acquiring and utilizing such large datasets varies tremendously across application domains. There are several significant impediments to acquiring such data for healthcare applications of AI, including the need to protect patient privacy, collect data across distributed sites and across multiple modalities (genomics, radiomics, pathology, etc.).

However, these problems have long been solved for clinical research initiatives, e.g., clinical trials and registries. The informatics platforms and processes developed to collect and create such repositories could be readily adapted for the healthcare AI domain. In addition, data from closed initiatives can be repurposed for AI research. The ACR has already begun to support the AI research of its members and partners in academia and industry, utilizing our TRIAD and DART platforms used for clinical imaging research.

De-identified training sets of various healthcare data types—including medical imaging data (MRI, CT, X-Ray, Ultrasound, PET)—covering the whole spectrum of pathologies need to be accessible in the public domain and validated to ensure that these sets meet government, academic, and industry standards. The creation and curation of labeled data sets is a time consuming yet critical process in the development of AI technologies in health care and medical imaging.

11) Any additional information related to AI research or policymaking, not requested above, that you believe OSTP should consider:

The ACR believes AI has the potential to alleviate administrative burden and inappropriate utilization, and it could someday increase the precision and efficiency of certain medical services, including diagnostic imaging. This technology has the potential, with appropriate testing/validation and safeguards, to improve the value, safety, and appropriate utilization of medical imaging. AI also has the potential to shift more mundane tasks from radiologists and other physicians to machines, freeing radiologists to focus on patient care, including interpreting images and providing clinical consultations to other specialists.

The American College of Radiology appreciates this opportunity to provide input to OSTP staff and members of the National Science and Technology Council Subcommittee on Machine Learning and Artificial Intelligence. We welcome further communications on this and related topics. Please contact Gloria Romanelli, JD, Senior Director, Legislative and Regulatory Relations (gromanelli@acr.org), or Michael Peters, Director of Legislative and Regulatory Affairs (mpeters@acr.org), if interested in reaching out to the ACR.

Sincerely,

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