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Via Email (HITRD-RFI@NITRD.gov)

March 15, 2019

National Science Foundation
National Coordination Office
Networking and Information Technology Research and Development (NITRD)
Attn: Alex Thai
2415 Eisenhower Avenue
Alexandria, VA 22314

RE: Request for Information: Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care

Dear Mr. Thai:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the Request for Information (RFI) from the NITRD Health Information Technology Research and Development Interagency Working Group (HITRD IWG) on approaches to solve the interoperability issues between medical devices, data and platforms, 84 *Fed. Reg*. 4544 issued by the National Science Foundation (NSF).

The AAMC 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. Together, these institutions and individuals are the American academic medicine community.

The AAMC supports the NSF's efforts to address interoperability of medical devices. Medical devices play an important role in transforming the future of health care delivery. These devices have the ability to capture essential medical data regarding patients. Many of the AAMC's member institutions were early adopters of electronic health record (EHR) technology and medical devices; they have helped to pioneer their development and use and are committed to providing quality care using these devices and technology. Providing safe and effective care is of utmost importance to the AAMC and our members**.**

While medical devices have great potential to improve care, they have a limited ability to interact with other devices and with EHR systems. Improving the ability of medical devices to exchange information safely, accurately, and securely with other medical devices and technology has the potential to improve patient care by decreasing medical errors and reducing provider burden.

Future Vision

In the RFI, NSF outlines a future vision where, when people with serious illness or injuries are hospitalized, medical device additions and changes are automatically recorded with no deficit in patient safety, or loss of data security as the patient transitions across the continuum of care. NSF also discusses a future where new equipment would replace existing equipment seamlessly. The automation of the seamless sharing of this information between devices and the EHR would allow clinicians to spend more of their time caring for the patient rather than data entry. Improved interconnectivity would also reduce redundant testing due to inaccessibility and shorten lengths of stay due to delays created by the manual transfer of information. Other tasks that would benefit from device interoperability would be the linkage of monitoring systems with equipment. For example, feedback from arterial blood gas measurements could be integrated real time into ventilator settings to allow optimization of gas exchange and avoid the repetitive manual blood draws, waiting for results, conveyance of the information to clinicians who then need to order changes in the respirator.

Also, in this vision connectivity between patient's remote devices (e.g., home glucometers, weight scales, heart rhythm or blood pressure monitors, and even pulse oximeters), if automatically integrated into the EHR, could be used to provide early warning systems to trigger clinical intervention and significantly improve the efficacy of telemedicine. There would also be great value where data flows seamlessly as equipment changes when the patient moves across the care continuum from the emergency room, to the operating room, to intensive care, to post-acute care, and eventually home. The AAMC supports this future vision so long as it can be achieved without jeopardizing patient safety and quality of care.

Clinicians and their patients desire technology that facilitates access to health information that leads to quality, person-centered care and reduces administrative burden. Medical devices should enable providers in clinical settings to seamlessly access relevant data for their patients.

Barriers to the Vision

In this RFI NSF solicits feedback on the challenges and impediments to making interoperability happen, how these issues could be addressed and by whom.

The need for further development and enhancing the use of existing standards, as well as a general lack of standards, inhibits the successful exchange of health information from these medical devices. To achieve exchange of accurate information, the transfer, storage, and display of underlying data must be standardized so that all systems are "speaking the same language." There need to be standards related to data format, transfer, and terminologies. Variability in use of and lack of standards creates a barrier to interoperability. Through its current rulemaking, the Office of the National Coordinator for Health Information Technology (ONC) is proposing standards[1] that would need to be met by health IT to achieve interoperability. A regulatory agency entity must play a role in achieving standardization to ensure that developers of medical devices meet the established requirements, and the AAMC encourages NSF to collaborate with ONC and other federal agencies that are currently engaged in developing interoperability standards.

[1] 84 Fed. Reg. 7424 (March 4, 2019)

In addition to meeting standards, there must be a requirement that the medical devices be tested in the setting(s) in which they are intended to be used in order to ensure that the device is effective, does not significantly increase clinician or patient burden, meets the expressed standards, and does not introduce safety concerns.

Patient matching is also a critically important component of interoperability as providers need to be able to accurately match a patient to his or her data from the medical device. Patient matching continues to be a barrier and often requires manual intervention due to incomplete or inconsistently formatted demographic information that is utilized to match patient records. Matching errors can lead to adverse events that seriously compromise a patient's safety. We recommend that NSF and other Federal agencies work with stakeholders to explore best practices for patient matching. We support the ongoing work of ONC and others on identifying patient matching solutions to promote interoperability.

Ensuring the privacy and security of the patient's information that is shared through medical devices is also of paramount importance. Devices would need to incorporate protections that are sufficient to comply with HIPAA privacy and security regulations and other laws (federal, state, local) that apply under the circumstances. In addition, it will be important to educate patients about interoperability of devices and how it may be used to improve care.

Health care providers, medical schools and teaching hospitals, academic societies, the Department of Veterans Affairs, Department of Defense, and other federal agencies play important roles in moving the NSF vision forward. The AAMC welcomes engagement on these issues and appreciates the opportunity to comment. We look forward to continuing work with NSF on these issues. If you have any questions, please contact Gayle Lee at (202) 741-6429 or galee@aamc.org and Alexander Ommaya (202) 741-5520 or akommaya@aamc.org.

Sincerely,

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