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*The mission of the American College
of Cardiology and the American
College of Cardiology Foundation
is to transform cardiovascular care
and improve heart health.*

October 17, 2018

The Honorable Donald Rucker, M.D.
National Coordinator for Health Information Technology
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology,
Attention: EHR Reporting Program Request for Information,
Mary E. Switzer Building,
Mail Stop: 7033A, 330 C Street SW,
Washington, DC 20201.

RE: Request for Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program

Dear Dr. Rucker:

The American College of Cardiology (ACC) appreciates the opportunity to provide comments to the Office of the National Coordinator for Health Information Technology (ONC) on the Request for Information (RFI) Regarding the 21st Century Cures Act Electronic Health Record (EHR) Reporting Program.

The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned JACC Journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions. For more, visit acc.org.

Introduction

The promise of health information technology (IT) is an efficient, connected health care system that promotes innovation and improves patient outcomes by delivering efficient, high-quality patient care. To achieve this promise, ONC must take this opportunity to evaluate EHR certification standards and build upon efforts to refocus the program on interoperability, usability, and outcomes, rather than centering the program on the process of capturing and reporting data. By refocusing EHR certification standards on the promotion of interoperability and providing useful comparison tools and applications that allow clinicians and patients to access health data when and where they are needed, ONC can make substantial progress in achieving the promise of health IT.

Under the 21st Century Cures Act, Congress asked ONC to reevaluate the reporting criteria for the EHR reporting program, including certification standards and reporting criteria for several categories including interoperability and incorporation of user-reported data. The development of relevant health IT and EHR comparison tools would help clinicians make informed choices during the acquisition process, while incorporating user-reported criteria would allow EHR vendors and ONC to gather valuable input in real world settings and drive usability and workflow enhancements.

In this letter, the ACC will provide input to ONC on the EHR reporting program, on how a refocused certified electronic health record technology (CEHRT) program can provide clinicians with meaningful tools to compare health IT products, achieve true interoperability, and reduce administrative burdens associated with EHRs. Comments will focus on the following CEHRT criteria identified in the 21st Century Cures Act by Congress:

- Existing Data Sources
- Data Reported by Health IT Developers versus End Users
- User Reported Criteria
- Security
- Usability and User-centered design
- Interoperability
- Other Categories for Certification

Background

Administrative burden is one of the leading contributors to clinician burnout, and clinicians specifically highlight EHRs among the lengthy list of burdens. Clinicians report high click counts, note bloat because of documentation requirements, poor EHR usability, and a lack of interoperability as significant contributing factors to the burden increase. Additionally, patients have reported higher rates of dissatisfaction with clinicians resulting from decreased personal interaction between patients and clinicians and a lack of patient-centered communications with clinicians because of increased EHR utilization. In short, clinicians are now spending less time directly interacting with patients during visits because of the need to input data into EHRs.

Improving usability through the development, scoring, and reporting of user-centered designs and improved interoperability for all health IT systems, including EHRs, can significantly improve satisfaction among both patients and clinicians. Additionally, as cybersecurity threats continue to increase, threatening access to confidential patient health information and posing economic risks to practices and health systems, it is important for ONC to continue to mandate improved EHR security criteria and provide EHR purchasers with clear, understandable security capability comparisons. **The College encourages ONC to take the opportunity afforded by provisions in the 21st Century Cures Act to improve EHR usability, interoperability, design, and security. By doing so, ONC enable EHR systems to become trusted tools that assist with patient care and reverse clinician dissatisfaction.**

Existing Data Sources

When selecting an EHR system, the main determinants are often certification status, price (total cost of ownership (TCO) for the EHR system), and use by other providers in the geographic area. User-reported or comparative information is generally not a factor in the initial selection, leading to an often-ill-informed decision by health IT acquisition personnel and the purchase of a system that does not fit the needs of their practice. The difficulty of changing EHRs is so great that many are forced to retain that improperly selected EHR while making significant modifications to it to address concerns, rather than transitioning to another system that may be as a better fit at the outset. The addition of modifications only further increases the cost and resentment towards the EHR system.

To assist with this process, the ONC publishes a report comparing various EHR systems. Unfortunately, many clinicians are not aware that ONC publishes an EHR comparison report, nor are they aware of many of the other resources published by ONC or ONC contractors. To combat this problem, the ACC believes it is important that ONC make information contained in any future EHR comparison reports widely available and increase targeted marketing efforts to improve clinician awareness of these tools. **ONC should emphasize development of a marketing strategy and educational resources to increase awareness of and access to such important comparison tools.** Development of interactive online and application-based resources that allow for side-by-side comparisons and real-time user input and reviews would provide much-needed accessibility and context to the decision-making process.

Data Reported by Health IT Developers versus End Users

The ACC believes that data reported by health IT developers to ONC under the certification process must complement the needs of end users and serve the purpose of driving informed decision-making for health IT acquisition. It is important that developer-reported data to be easy to read, providing necessary technical specifications for IT personnel and plain language information useful for end users. Examples of developer-reported data that would be useful for end users include:

- Manufacturer's expected full-time equivalent (FTE) IT and end user installation and support staff
- Data standard and version adherence
- Availability of app stores to allow for customization and tool development

It is important that ONC report this data in a uniform and comparable format, allowing for the side-by-side comparison of different system capabilities. **Data reported by Health IT developers as part of the certification process should specifically work to advance improvements in usability, user-centered design, security, and interoperability.**

User-Reported Criteria

The inclusion of user-reported data into the EHR certification and maintenance process is essential for measuring progress in key metrics such as interoperability, usability, and user-centered design. Future action by ONC, such as defining data-blocking, implementing data-blocking enforcement provisions, and issuing additional application programming interface (API) guidance has the potential to improve interoperability and usability, but these actions are likely to be insufficient on their own. Additional publicly reported CEHRT criteria will force EHR vendors to make continued progress on interoperability, usability, and user-centered design.

Provisions in the EHR certification and maintenance process to require the submission of user-reported data and the public reporting of such metrics promise to provide additional pressure for continued progress in addressing the concerns of the clinical community. More importantly, ONC must incorporate user-reported data on usability, user-centered design and EHR system interoperability into the certification and maintenance decision-making process. ONC-mandated requirements and external market pressures from informed consumers will help to ensure that vendors address interoperability and usability concerns. ONC should ensure that public user reporting to ONC can occur throughout during the EHR procurement process, from purchasing systems to installation to the transition period following system integration. This will allow for real-time feedback from end-users in real world settings, leading to improved systems and installation processes. **Usability and interoperability will only improve when clinicians can provide feedback to ONC that will directly contribute to the certification and maintenance of an EHR system.**

Usability and User-Centered Design

Including user-reported data in the EHR certification and maintenance process will assist in shifting user-centered design to the focus of the EHR design and implementation process. **Rather than strictly being designed to address billing and data capture processes, vendors must account for different users, tasks, care settings, and other unique circumstances when designing EHR systems.** In addition to user-reported data and market forces, it is important that ONC account for usability and user-centered design criteria in the certification process. Incorporating usability and user-centered design criteria will ensure EHR vendors consider these elements during the design phase. Factoring these components into the initial design will assist in keeping the EHR TCO down, enabling practices and health systems to more accurately plan for the resources required for EHR system purchase, installation, training and maintenance.

There are several human-computer interface evaluation methods¹ that ONC can incorporate into the certification and maintenance process that would benefit clinicians and health IT decision makers. These include but are not limited to:

- Heuristic techniques to evaluate a user interface
- Keystroke level models that sum up the time taken for keystrokes, pointing, clicking, thinking, waiting, and deciding
- Comparative analysis between similarly commercially available systems

There are also several user-reported criteria that ONC should consider for inclusion in the EHR certification and maintenance process and published comparison reports:

- Work-after-work (WOW) time per provider (time spent on an EHR following conclusion of the work day)
- Measurements of time spent logged into an EHR versus the number of patients seen
- Ease of displaying user-defined report formats
- Total time extracting and manipulating health information transferred from external data source

These listed usability and user-centered design criteria are not an exhaustive list of criteria available for incorporation into the EHR certification, maintenance and reporting process. The College encourages ONC to

¹ C.M. Johnson et al. *Journal of Biomedical Informatics*, 38 (2005) pp. 75-87.

work with end users to include these and other criteria in the certification and maintenance process. Increasing the availability of this data, those measured by ONC and those reported by end users, to clinicians and health IT decision makers would greatly expand the number of variables to be factored into the EHR procurement process and enable group practices and healthcare systems to make better informed decisions. In turn, EHR vendors would be forced to consider the needs of the end-user when developing EHRs, leading to improved products, decreased frustration and burden for clinicians and patients, and increased time for discussions between clinicians and patient.

Security

EHRs promise the ability to access and transmit health data to clinicians and patients when and where it is needed. Increased connectivity to external health IT systems also presents unique cybersecurity threats and vulnerabilities for EHR systems. Increasingly, health systems and their IT infrastructure are targets of cyberattacks, threatening the security of patient health information and the wellbeing of patients. These attacks attempt to cripple systems, harvest valuable protected personal data, and hold hostage vital medical systems.

Recently, as part of the Medical Device Safety Action Plan, the Food and Drug Administration (FDA) announced its intention to evaluate requirements that manufacturers build cyber risk mitigation capabilities into product design. The College believes ONC should adopt a similar approach by integrating cyber risk mitigation capabilities directly into EHR design, certification and maintenance processes to protect patients and clinicians. In addition to embedding these capabilities into an EHR's design, the ACC also believes that ONC should continuously monitor EHR systems in real-world settings to ensure manufacturers are continuing to update EHR systems to protect against new cyber threats as they emerge. It is equally important that manufacturers incorporate methods for clinicians and their staff to quickly and easily update EHR systems and integrated applications and connected systems without special effort. The College urges ONC to work alongside manufacturers to ensure updates, patches and necessary security actions are effortlessly and rapidly developed and implemented.

Interoperability

A lack of true interoperability is one of the main drivers for clinician discontent with EHR systems. The ACC believes interoperability requires more than the ability of two or more health information systems or components to exchange clinical and other information; it also requires that information be exchanged using common data standards to facilitate coordinated care and improved outcomes. Many systems can open and share different documents and files, such as a PDF, with relative ease. However, it is often difficult for clinicians to extract any information from the resulting document. Under current systems, a patient's care team receiving a transition of care summary and accompanying test results and images often must sort through hundreds of pages to find relevant medical information. This results in the risk that important health information will be inadvertently overlooked, as well significant cognitive overload that directly leads to clinician burnout. The burden is placed on clinicians and staff to compile the necessary information through manual transcription or other methods such as third-party software. Solely having the ability to transfer medically necessary information to another facility does not constitute true interoperability.

Instead, interoperability must include the seamless transmission and receipt of data using consensus methods and standards that allow for effortless extraction, interpretation, and manipulation of data. Common data standards must exist to address challenges clinicians continually face when exchanging the simplest elements of data

between EHRs. As ONC indicated in its recent report regarding the adoption of the Fast Healthcare Interoperability Resources (FHIR) standard, increased adoption of consensus standards by multiple vendors across the care spectrum can help to improve interoperability.

As ONC seeks input on a means of assessing, comparing and reporting on interoperability across certified health IT products, it is important for ONC to provide useful information to clinicians and those empowered to make decisions involving the acquisition of health IT products. Examples of useful metrics and reports that could be included in future certification criteria and reports are:

- Adhering to data standards and version
- Quantifying the ease of accessibility for clinical concepts and data elements during the health information exchange
- Measuring the number of Integrating Healthcare Enterprise (IHE) interoperability profiles used by an EHR to accomplish data interchange tasks
- Reporting by users on the ease of data transfer, manipulation, and extraction processes
- Recording any data-blocking violations by the vendor
- Reporting on an EHR's ability to display imported test reports alongside locally generated test reports
- Providing information on the accessibility and preponderance of third party applications

Finally, any information required for the certification process and included in comparison reports and tools must be easily accessible and available in plain text to allow individuals without IT backgrounds and training to understand and compare capabilities. It is important for ONC to cater to all individuals, not only IT personnel. Many small and rural practices lack the ability to hire dedicated IT staff, forcing them to rely on potentially biased information provided by EHR vendors or larger health systems. Providing clinicians and health IT decision makers with sufficient information at an appropriate level is paramount to empowering them to make informed decisions regarding the most appropriate EHR system for their practice.

Other Categories for Certification

The 21st Century Cures Act provides numerous examples of “other possible categories for the EHR Reporting Program related to certified health IT product performance.” While the College understands statutory requirements define these “other categories for certification,” it is important that ONC ensure that these examples are not minimized in any way. Instead, the College believes that they are essential components of previously listed categories, such as interoperability and usability, and thus must be successfully integrated into the certification, maintenance and reporting process. Providing clinicians and patients with the ability to retrieve information from medical devices is a high priority for the ACC, and the College believes that ONC should ensure that EHR certification requires retrieval capabilities, along with consensus standards to assist with this process. For example, providing the ability to access data from implantable cardioverter defibrillator (ICD) systems allows for access to information essential for proper patient management. **The extraction and importation of vital health information from these and other medical devices into the EHR system in a usable, standardized format is a prime example of how a fully interoperable system will benefit patients and clinicians and is the standard ONC needs to set.**

The 21st Century Cures Act also includes provisions supporting the use of real-world evidence to bolster regulatory decision-making processes. Real-world evidence can include data collected through a clinical data registry or patient-generated data. Clinical data registries such as the ACC's National Cardiovascular Registry®

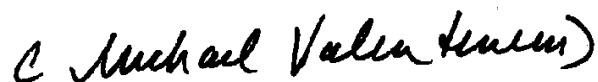
(NCDR®) provide clinicians and regulatory agencies with standardized terminology and access to data that can supplement traditional sources. It is important for ONC to harness the power of real-world data collection through the implementation of policies that promote seamless data transfer processes between clinical data registries such as NCDR®, patient-generated data sources, and EHR systems.

The ACC also believes that several of the “other categories” examples are already included in the Promoting Interoperability program, such as “accessing and exchanging information from other health care providers or applicable users” and “accessing and exchanging patient generated information reporting requirements.” ONC should require that EHR systems are able to perform these vital functions, not solely because of their importance to care delivery, but also to ensure clinicians are able to successfully report the information required by the Promoting Interoperability quality reporting program and other such programs.

Conclusion

The ACC thanks ONC for the opportunity to provide comments on this Request for Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program and looks forward to continuing to work together to address issues surrounding interoperability, usability, user-centered design, security and other important EHR program components. To address these comments or additional questions, please contact Joseph Cody, Associate Director, Research and Innovation Policy, at jcody@acc.org.

Sincerely,

A handwritten signature in black ink that reads "C. Michael Valentine". The signature is written in a cursive style with a large initial "C".

C. Michael Valentine
President