CENTER *for* MEDICAL INTEROPERABILITY

April 28, 2016

Jeffrey Shuren, MD, JD
Director, Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
WO66-5429
Silver Spring, MD 20993

Re: Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices (Draft Guidance)

Dear Dr. Shuren:

The Center for Medical Interoperability (Center) appreciates FDA's efforts to advance the ability of medical devices to exchange and use information safely and effectively with other medical devices, as well as other technologies used in patient care. We welcome the opportunity to comment on this draft guidance and to work together to advance medical device interoperability.

About the Center

The Center for Medical Interoperability is a nonprofit organization led by health systems to change how medical technologies work together. The Center focuses on Infrastructure, Innovation and Transformation. We are working to repair health care's underlying infrastructure such that we have a solid foundation upon which to innovate and develop solutions that will transform health care for the benefit of our nation. As a cooperative R&D arm for health systems, the Center provides a vendor-neutral focal point for solutions providers to engage their customers. Our work is technical in nature and our engineers are collaborating with industry stakeholders to develop a reference architecture for a vendor-neutral platform that will make it easier and less expensive for devices to talk to each other and for devices to talk to electronic health records (EHRs) and other systems that support clinical decision-making, research, analytics, consumer engagement, etc. This will enable health systems to have real-time patient records that are complete and consistent, and gain greater control over the data needed to deliver safe, efficient and effective care. The Center is also establishing a centralized lab to test and certify that devices and enterprise applications meet members' technical requirements, thereby giving health systems confidence that the solutions purchased for patient care will work as expected, safely and securely.

Impact on Patients and Care Teams

The current lack of medical device interoperability contributes to many adverse drug events, medication ordering errors, transcription errors, redundant testing, inadequate monitoring and miscommunication, all of which factor in to preventable medical errors that adversely impact patients and caregivers. Missing symptom, test and relevant diagnostic data result in diagnostic errors and diminished patient outcomes. Medical device interoperability would mitigate much of the risk of preventable harm, thereby saving patients from preventable medical errors, which are reported to be the third leading cause of death in the U.S.[1] Furthermore, healthcare professionals are too often forced to waste time manually entering data or trouble-shooting technology instead of taking care of patients. An analysis conducted by the Gary and Mary West Health Institute suggests medical device interoperability could result in more than $30 billion a year in savings to the healthcare system[2].

Opportunity for Collaboration

The Electronic Data Interface-centric design considerations outlined with dimensions including user focus, security, risk analysis, standards, and ultimately verification and validation criteria, are the key elements of a Medical Interoperability Architecture Framework that we are developing with a broad-based industry coalition. Our goal is to ensure trusted interoperable solutions within our members' clinical environments and the medical domain as a whole. As noted above, the Center's role is to provide architecture guidance and reference interface specifications to the medical device and application community, then ensure the *testability* of those specifications by providing Test & Certification services. We would welcome FDA's input in reviewing and detailing these design recommendations, synthesizing them within a general Medical Interoperability Architecture Framework, incorporating them into our architecture guidance and interface specifications, and then generating verification and validation criteria for trusted interoperability.

General Comments

We agree with the need for standardized architectures and communication protocols. As noted, this is important to ensuring system level safety. We encourage FDA to work with healthcare organizations and other industry stakeholders to recognize reference architectures that could be used in the regulatory process.

FDA's guidance should aim to enable innovative solutions that meet key tenets of seamless interoperability. Health systems would benefit from a reference architecture for a vendor-neutral platform that meets the following requirements:

- Plug-and-play
    - When two independent pieces are connected, they self-configure and can talk to each other without (or with minimal) human intervention.

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[1] James JT. A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care. Journal of Patient Safety. 2013; 9: 122–128.

[2] Gary and Mary West Health Institute. The Value of Medical Device Interoperability. March 2013. Available at: http://www.westhealth.org/institute/interoperability.

- One-to-many communication
    - Once certified as being conformant with a Reference Specification or set of Standards, the device or system can be used with similarly certified devices and systems without additional testing. This is sometimes referred to as component-wise testing.
- Two-way data exchange
    - Information flows in both directions, enabling feedback loops and automation.
- Standards-based
    - Using open, as opposed to proprietary, solutions in reference architectures, interface specifications and testing.
- Trusted
    - Confidence that interoperable systems will be safe, secure and reliable.

FDA recognizes the need for two-way data exchange in noting that interoperability is not limited to unidirectional patient data but includes more complex interactions, such as exerting command and control over another device. We are also pleased that the draft guidance references one-to-many communication and the importance of related verification and validation considerations, which will only increase as systems of connected devices grow. This guidance paves the way for a transition from the current approach of 1:1 integrator (sometimes called pair-wise) based testing and acceptance to 1:many (sometimes called component-wise) testing and acceptance. This will enable the creation of new solutions and ease the barriers of entry for small medical device vendors into system of system solutions. In order to enable this transition, trusted assessment and/or certification programs will need to be established in coordination and collaboration with FDA.

More pressure is needed to drive the industry toward standards-based solutions. Medical devices are especially challenging to integrate into system of systems solutions due to the wide use of proprietary communication protocols and a variety of physical layers such as Ethernet, Wi-Fi, Bluetooth, USB and RS-232. Unfortunately, this is not only a legacy issue; new medical devices continue to be placed into the market with proprietary data interfaces. The industry must converge from hundreds of proprietary communications interfaces to a small number of accepted open standards with traceable, verifiable requirements and the appropriate test tooling. As the private sector creates the pull for standards-based, interoperable solutions, we encourage FDA to support the push.

A model is needed to assess interoperability. To that end, FDA recognizes that interoperability is a complex topic and references different models. Interoperability, like security, is not a specific state, but a continuum of levels of achievement. It ranges from complete inability to exchange even a single data point to ubiquitous data liquidity. Unfortunately, achieving interoperability falls victim to the least common denominator, which sets a very low bar. Simple exchanges of information such as email or fax meet the definition of interoperability, but these do not reflect where the healthcare system needs to be in five years in order to reduce the cost of connecting systems and enable solutions that can take advantage of data interoperability.

It is necessary to make coordinated progress along a set of dimensions to increase the degree of interoperability from basic to advanced levels. These dimensions include:

- Infrastructure
  - Transport level connectivity including security; technology independent of systems and applications.
- Syntactic
  - Use of recognized formats to communicate and exchange information.
- Terminology/Semantic
  - Use of recognized vocabularies, nomenclatures, and ontologies, as well as information models.
- Conversational Complexity
  - Extent and sophistication of information exchange including orchestration.
- Contextual/Dynamic
  - Ability of devices and applications to share data based on the patient and clinical workflow.

Security Design Considerations

The Center is developing a security framework for medical interoperability with the goal of being able to verify the following:

- Data Encryption (specifically, in transit) – maintain confidentiality and data integrity
- Device Identification – trusted identification of device type, model, approved use
- Authentication – specifically, Machine-to-Machine (M2M) based authentication, certificate-based
- Authorization – authorizing specific access during Plug-n-Play "handshake"
- Audit – aspects of data auditability, including metadata/tagging by source, timestamp, system path, non-repudiation, interface versioning

Verification and Validation

The Center is targeting Automated-Testing as a means to increase agility in testing and provide rapid turnaround certification for our members. Our goal is to achieve 80% or more of our testing via automation, with the remainder expected to be specialized or custom manual/interactive testing to validate expected end-use behavior and usability criteria. Below are the basic categories of testing we are integrating into our Test & Certification services:

- Automated tests against the Interface-Under-Test (IUT) to verify expected security and behavior.
- Automated "red-teaming" tests and tools to attempt to break secure connections and corrupt data of the IUT.
- Manual/Interactive "red-teaming" with specialized tools, expertise where applicable.
- Manual/Interactive Validation testing to incorporate final end-user security and interoperability concerns.

As a key part of our Test and Certification services, the Center is developing a *Certification Lifecycle Model* to ensure that interface interoperability is maintained during the product lifecycle. As software or firmware upgrades are applied to medical devices in production, our members must be able to trust that the interoperability attributes originally tested and certified are maintained. In order to do this, our certification model includes 1) initial V&V and member certification based on results from rigorous testing to ensure secure, trusted interoperability; and, 2) product deployment with Center interoperability certificates/co-signing/etc. that can be managed and verified via third-party database to ensure the deployed module(s) were indeed certified.

Labeling

We support the need to specify the functional, performance and interface characteristics in labeling. FDA requires that manufacturers include considerable information in the device labeling, which is typically contained in the Instructions for Use. We suggest that, in the proposed world of interoperable devices, this information also be available electronically such that the capabilities of a data source can be discovered electronically. This would allow the data consumer to decide whether the data source has the appropriate capabilities to meet the Intended Use of the system of systems. This provides an automated layer of safety monitoring.

The Center appreciates FDA's commitment to promoting the development and availability of safe and effective interoperable medical devices. We look forward to working with you to achieve this shared goal and welcome discussion at your convenience.

Sincerely,

Kerry McDermott, MPH
Vice President, Public Policy and Communications
Center for Medical Interoperability
kerry@center4mi.org
202.617.6009