HITRD RFI Responses, March 15, 2019

ACTION ON INTEROPERABILITY OF MEDICAL DEVICES, DATA, AND PLATFORMS TO ENHANCE PATIENT CARE

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

March 14, 2019

Open mHealth

http://www.openmhealth.org/

Founded in 2011, Open mHealth is an independent non-profit organization whose mission is to make mobile health data more accessible. We do this by enabling a community of developers and clinical users to use our open data standard and mobile health tools for ingestion, storage and analysis. For our purposes, mHealth data encompasses personal health data collected from sensors and mobile applications, including patient-reported outcomes. The main contributions of Open mHealth include open data and metadata standards for mHealth, a suite of open source tools for mHealth data aggregation, and a growing global community of developers, product managers, health IT decision makers and clinical researchers working to promote standards-based semantic interoperability in mobile health. Indeed, a 2018 report on connectivity in digital and mobile health lists Open mHealth with 20% market share of data aggregation services, the third highest market share after Apple Health Kit and Google Fit.[1]

To further promote adoption of Open mHealth standards, Open mHealth has entered into partnership with two dominant standards organizations. First, in 2017, the IEEE Standards Association approved the creation of the IEEE P1752 *Open Mobile Health Working Group* to define specifications for standardized representations for mobile health data and metadata, based on Open mHealth. This working group, which has representatives from industry, academia, and government from around the world, is producing and vetting open data schemas for submission to the IEEE balloting process, anticipated in late 2019. Secondly, Open mHealth has developed the OmH-to-FHIR Implementation Guide[2] that maps Open mHealth schemas to HL7 FHIR resources to facilitate interoperation with electronic health record (EHR) systems.

Most recently, we have been working with Office of the National Coordinator for Health IT on developing and piloting Open mHealth standards for use in precision medicine initiatives, including NIH's All of Us project. Non-proprietary public-private partnership work within the past three years with Federal, State, or local governments include:

- Mobile Data to Knowledge (MD2K) NIH Big Data to Knowledge Center of Excellence in Mobile Health (Grant #U54EB020404)
- Open mHealth: Community-based Data and Metadata Standards for Mobile Health (Grant #R24EB025845-01)
- mProv: Provenance-based Data Analytics Cyberinfrastructure for High-frequency Mobile Sensor Data (NSF Award #1640813)

[1] https://research2guidance.com/product/connectivity-in-digital-health/
[2] https://healthedata1.github.io/mFHIR/index.html

- Office of the National Coordinator for Health IT: ONC Health IT Standards Development and Testing for Precision Medicine (subcontract)
- Personal Mobile and Contextual Precision Health (California Institute to Advance Precision Medicine, 2017-2018)

In sum, Open mHealth reflects the needs and perspectives of a wide range of stakeholders and is the foremost open-source organization working to promote mobile health data interoperability across academia, industry clinical care, and clinical research.

Comment

(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?

Over half of Americans have at least one chronic condition. Over a third have two or more chronic conditions, which by definition occur 24/7 outside of the hospital or clinic setting. Multiple chronic conditions (MCC) account for over 70% of US healthcare spending. We argue strenuously that medical device interoperability must consider mobile, wearable, and Internet of Things (IoT) devices as being as least as if not more important than hospital- or clinic-based devices. We support the FDA's expanded and more nuanced notion of devices to include Software as a Medical Device (SaMD), which are increasingly going to be combinations of hardware sensors with software algorithms for monitoring (e.g., mobility data as indicator of post-surgery recovery for orthopedic patients) and intervening on health states (e.g., stress reduction intervention triggered by stress detection) in everyday settings.

Open mHealth is focused on data sharing in mobile health. From our perspective, interoperability consists of physical connectivity (that which enables two systems to transfer data), syntactic interoperability (that which enables recognition of data as valid in terms of format) and semantic interoperability (that which enables recognition of the meaning of the data and therefore its appropriate processing for interpretation and decision support). It is only through semantic interoperability that we know we are comparing or combining apples to apples across disparate data sources.

Semantic interoperability requires a model of the data of interest that clearly establishes definition, datatype, unit of measure and value set as applicable, references to a standard vocabulary (e.g., SNOMED, LOINC) and relevant context (e.g., temporal relationship to eating for blood glucose measurements, body position for blood pressure measurements). It also requires a model of the metadata that establishes provenance and characteristics of the measuring device, the measurements, any data processing and more. Some of the metadata is dynamic and should travel with the data (e.g., version of the device and of its software, data schema to which the data complies syntactically and semantically). Other metadata is static and can be accessible on demand (e.g., validation protocol applied to the device and validation results). **Standardizing mobile health data and metadata is a foundation of medical device interoperability.** It will make data aggregation across multiple mobile health sources easier and

more accurate and will reduce the costs of using mobile health data to make biomedical discoveries and to improve health and manage disease.

The Open mHealth vision of medical device semantic interoperability is as follows:

- Datapoints of derived data (as opposed to streaming data) should be represented in an appropriate standard schema such as Open mHealth schemas. These schemas should be open, community-based and should reference standard clinical terminologies to facilitate reference to EHR data and systems.
- Datapoints should include minimum metadata necessary for users of the data to know what the data is about (e.g., the units, when the data was true, etc.). Open mHealth, as part of the IEEE WG and the NSF mProv project, has defined a proposed minimum metadata set.
- Additional static (changes over months) and dynamic (changes over microseconds to days or weeks) metadata are needed for full interpretation and the capability for any black-box replay. Open mHealth, as part of the IEEE WG and the NSF mProv project, is in the process of identifying needed classes and types of dynamic and static metadata.
    - Static metadata include descriptions of computational models that generated a datapoint, the datasets that the model was trained on, the accuracy of the model, general and personal privacy policies, etc. It would be ideal if this static metadata have a standard format (like a “package insert” for drugs) and be available in a neutral persistent repository. This repository can be managed by a federal agency or a public-private partnership.
    - Dynamic metadata include metadata on missingness, runtime privacy, runtime data quality, etc.
- Transparent, trustworthy, openly accessible repositories are needed for both static and dynamic metadata. There may be multiple of these repositories serving different constituencies and use cases, but there should be common standards around the metadata of devices, algorithms, and data to ensure that a distributed metadata infrastructure still results in efficient and effective semantic interoperability.

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

As mentioned in the previous section, an expanded definition of medical device that reaches beyond the hospital or clinic setting is needed. Coupled with a consideration of the various levels of interoperability as discussed above, the list of stakeholders and their contributions to semantic interoperability include:

- Producers of mHealth data and metadata standards: medical device makers, wearable device makers, mobile health app developers
- Consumers of standardized mHealth data: health information technology systems, health information infrastructure providers, electronic health record companies, mobile health app developers, biomedical researchers, clinicians, data scientists

- Developers of mHealth data and metadata standards: medical device makers, wearable device makers, mobile health app developers, biomedical researchers, data scientists, computer scientists, informaticists
- Promoters of mHealth data and metadata standards: device and pharmaceutical regulatory agencies, research funding agencies, and health and non-health IT standards organizations
- Providers of metadata repository services: FDA, additional new public, public-private or private entities

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

This RFI response focuses on the challenges and impediments to medical device/wearable/IoT semantic interoperability. First and foremost, stakeholders need to acknowledge the importance of semantic standardization: it is insufficient for data to be transported seamlessly between devices and systems if the parties involved are not sure what the data represents (e.g., is the blood glucose value fasting or random?). Too often, device interoperability focuses on hardware interoperability or syntactic interchange standards without explicitly addressing semantic interoperability. Federal agencies (e.g., FDA, NIST), standards bodies (e.g., HL7, IEEE), industry groups (e.g., Consumer Technology Association) and federal research funders (e.g., NSF, NIH) need to keep the focus on full syntactic and semantic interoperability.

Secondly, we argue that federal device interoperability initiatives should encompass not only the hospital but also the free-living community setting. In this case, the distinction between health and non-health data is vanishing. The music you listen to, your purchases, where you drive to -- all are relevant to aspects of health and disease. As such, it becomes very challenging to draw a line between health interoperability and interoperability in general. Interoperability leaders should choose driving use cases that reflect the 80/20 rule of current needs, but architect the overall interoperability approach to allow for the broadest reach beyond traditional health care scenarios.

Thirdly, interoperability must support clinical research as well as clinical care. In the learning health system model, the goal is to learn from every patient (i.e., every patient participates in “research”) and to have every patient receive care based on the best research. Interoperability for clinical care cannot be divorced from interoperability for clinical research (e.g., clinical trial recruitment, data capture). While CDISC addresses some aspects of clinical research interoperability in the context of a learning health system, they are too focused on pharmaceutical industry research. The NIH could play a larger role in this space.

Finally, for standards to be adopted, stakeholders must have a clear sense of the direct benefit they will derive (e.g., for clinical care, business, or clinical research). Standards developers and promoters must be sure to begin with and continually work from compelling, real-life use cases reflecting the needs, fears, and constraints of potential standards adopters. Where the needs, fears, and constraints conflict, neutral conveners (e.g., government, non-profits, neutral industry

groups) need to collaboratively broker a solution and then to promote standards adoption through regulation and peer pressure that build off of clear demonstrable value.

(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 proposed federal vision is aspirational and is theoretically viable. For it to be practically viable, the federal government needs to play a more active role in bringing together public and private partners around the vision and brokering which groups will deliver which pieces and how, and under what overall governance structures. A firm commitment to the public good as the main objective will allow public health to benefit, while also building a robust shared infrastructure for commercial entities to innovate and profit.

Recommendations

1. Promote adoption of Open mHealth data and metadata standards for mobile/wearable devices.
2. Define and implement a minimum metadata dataset to accompany datapoints
3. Define and implement metadata standards beyond the minimum, and foster the establishment of a network of metadata repositories that can collectively serve all parts of the healthcare and health system
4. Convene stakeholders to define and promote the value propositions of standards to all necessary parties

Open mHealth thanks the NITRD Health Information Technology Research and Development Interagency Working Group for the “Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care.” We appreciate the opportunity to provide comments for your further consideration. We hope the agency finds these comments helpful in preparation for the proposed interoperability conference in June/July 2019.

Respectfully submitted,

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On behalf of Open mHealth