HITRD RFI Responses, March 15, 2019

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

DISCLAIMER: The RFI public responses received and posted do not represent the views and/or opinions of the U.S. Government, NSTC Subcommittee on Networking and Information Technology Research and Development (NITRD), NITRD National Coordination Office, and/or any other Federal agencies and/or government entities. We bear no responsibility for the accuracy, legality or content of all external links included in this document.

RESPONSE to National Science Foundation Request for Information (RFI)

Federal Register Document 2019-02519

REGARDING Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care

RFI Response By:

Sandra H. Mitchell, RPh, MSIS, FASHP

VHIE Contractor, JP Systems, Inc., Data Quality Analyst, SME

CCNC, Pharmacy Interoperability Manager, NC Medicaid, SureScripts, ACO files

RFI Dates

Comments must be received by 11:59 p.m. (ET) on March 15, 2019.

RFI Addresses

Comments submitted in response to this notice may be sent by any of the following methods:

Email: HITRD-RFI@NITRD.gov. Email submissions should be machine-readable and not be copy-protected. Submission should include "RFI Response: Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care" in the subject line of the message.

Fax: (202) 459-9673, Attn: Alex Thai; or

Mail: Attn: Alex Thai, NCO, 2415 Eisenhower Avenue, Alexandria, VA 22314 USA.

RFI Supplementary Information

Purpose: There is ongoing recognition that medical device interoperability is an issue and has a documented impact on patient care and safety. These issues persist despite previous government efforts by the Food and Drug Administration, the Department of Defense, the Veterans Administration, the National Institute of Standards and Technology, the National Institutes of Health, and the National Science Foundation. The goal of this effort is to determine whether a vision of sustained interoperability in the hospital and into the community is feasible and, if so, what it will take to realize it. In addition, this RFI looks to examine how users might leverage the existing tools and processes for implementing this shared future vision.

RFI Background Information

Overview: Medical devices, electronic health records, and the data generated and stored in these systems are essential to the practice and advancement of modern medicine and healthcare. While healthcare systems are rife with medical devices and the data they produce, to date, these devices are not interoperable and cannot effectively interact with each other and the broader healthcare ecosystem. With interoperability between medical devices and systems enabled, new models for monitoring, device interaction, and control—including the development of closed loop, autonomous and semiautonomous systems—can be realized. These new models will provide greater support for patient safety, decrease medical errors, reduce provider burden, reduce practice variability across healthcare facilities/geographic areas and, ultimately, will enhance medical care quality and outcomes.

Future Vision: When people with serious injuries or illness are hospitalized medical device additions and changes are automatically recorded with no deficit in patient safety, loss in data fidelity, or data security as the patient transitions across the continuum of care. Additional medical devices can be added or

removed as the patient's status changes and details of these changes, calibration of the instruments, and each equipment's unique device identifier [UDI] and configuration settings are recorded and synchronized. If a piece of equipment breaks, it can be switched seamlessly with a device from another vendor. Data and settings from patient medical devices, such as insulin pumps, are identified, integrated, and time synchronized, and select data are included in the electronic health record. As autonomous capabilities are added, real-time care is logged, and supervisory control established to ensure the provision of real-time patient monitoring and support. When providers are not available, or have competing demands, medical devices will function in a closed loop, autonomous manner with appropriate safety and control measures to stabilize the patient. Data will flow through changes in equipment that occur in moves from the emergency room, to the operating room, to the intensive care unit, to a rehabilitation facility, and finally to the home. This will allow for data and metadata to flow even as changes in equipment are mapped to individual patient needs and environment. Each change in equipment configuration will be noted in the supervisory system/medical record and in the metadata (e.g., the UDI) generated by the device. The resulting patient record from these systems will include device data, metadata, and care documentation. These patient records can be stored and analyzed using medical black box recorder-equivalents to assess adverse events or examine unexpected positive outcomes. This will also improve the consistency and quality of care; create real-time automated care systems; create a learning health system.

These types of records and the real-time systems interactions they enable are widely used or are being actively developed in other industries, such as the industrial controls and autonomous systems in the automotive, aviation, and energy sectors. That is not the case for healthcare. While there are many factors that may inhibit real-time interaction in a medical setting, interoperability solutions that are relevant for healthcare and patient safety need to be developed. Seamlessly flowing, interoperable data from medical devices and systems, when utilized effectively, could significantly enhance patient outcomes, identify and reduce errors, enhance the efficiency of care delivery, reduce development times and costs, improve standardization/consistency of care delivery, and decrease healthcare provider burnout.

Next Steps: The Government anticipates hosting a conference in June/July 2019 to allow for additional engagement. The results of the conference discussion, in addition to the written responses to this RFI, will be used to determine next steps in addressing federal efforts in interoperability of data, platforms, and medical devices. This RFI is solely issued to engage with interested parties to inform the Government on developing a strategy for medical device, data, and platform interoperability. The Government will not reimburse costs associated with participating in the conference. The Government may contact respondents regarding their submissions, such as to ask questions, to learn more, or to notify them of further developments related to the effort.

RESPONSE to National Science Foundation Request for Information (RFI)

Federal Register Document 2019-02519

REGARDING Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care

General Information

Question (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?

Response (1):

Vision: Total Re-design on the Clinical Data Onboarding End-to-End Process with the focus on "Clinical Data Nutrition". Same as the Food Pyramid defines nutrition that humans need to ingest to support optimal health, the "Data Nutrition Pyramid" defines the clinical data that healthcare information systems need to ingest for optimal health.

The critical missing piece in Healthcare Interoperability is that nobody is looking at the clinical quality of the data content being exchanged for relevance, robustness and repercussions. From a completeness and content perspective, the results of any analysis, where they even exist, is shocking. The entire industry is moving away from display-only of the external clinical data to ingesting the clinical data into native systems and clinical workflows. Well-balanced "clinical data nutrition" can address the Relevance, Robustness and Repercussions of this data ingestion.

Relevance: Clinical Interoperability is relevant because the clinical data needs to be shared throughout the healthcare continuum and across the multiple healthcare enterprises and clinicians that treat each patient. The concept of poor "clinical data nutrition" alludes to the inadequate quality, completeness and clinical data sharing. This leads to each clinician knowing only a "slice of the data content pie" and not having a holistic data record of the patient. Each healthcare system optimally needs to ingest the shared clinical data, clinical results and more. And without quality data, upstream initiatives such as Artificial Intelligence (AI) cannot perform to expectations.

Robustness: Robustness refers to the clinical data content being complete, coded right, and a high-quality enterprise data resource. Nutritional deficiencies in clinical data can lead to missing key patient clinical issues. Primary causes of poor "data nutrition" include:

- Lack of conformance validation of HL7 standards specification on data exchanged
- Lack of a robust and clinically focused Interoperability Content Implementation Guide nationally
- Business models that focus on "checking the boxes" for data exchange instead challenging and complex exchanges that more fully support the clinician during the patient engagement
- Extensive use of local value sets where national codes exists

Repercussions: Data is a resource and the repercussions of poor clinical data nutrition are significant including patient safety issues, duplicate testing, and many other aspects of healthcare delivery. The yearly cost of poor data in healthcare can be estimated around $500 billion[1].

Clinicians distrust data from external sources, having experienced incomplete data, incorrect codes, and missing clinical data. This erosion of trust in the data exchange results in clinicians spending more time with technology than the patient.

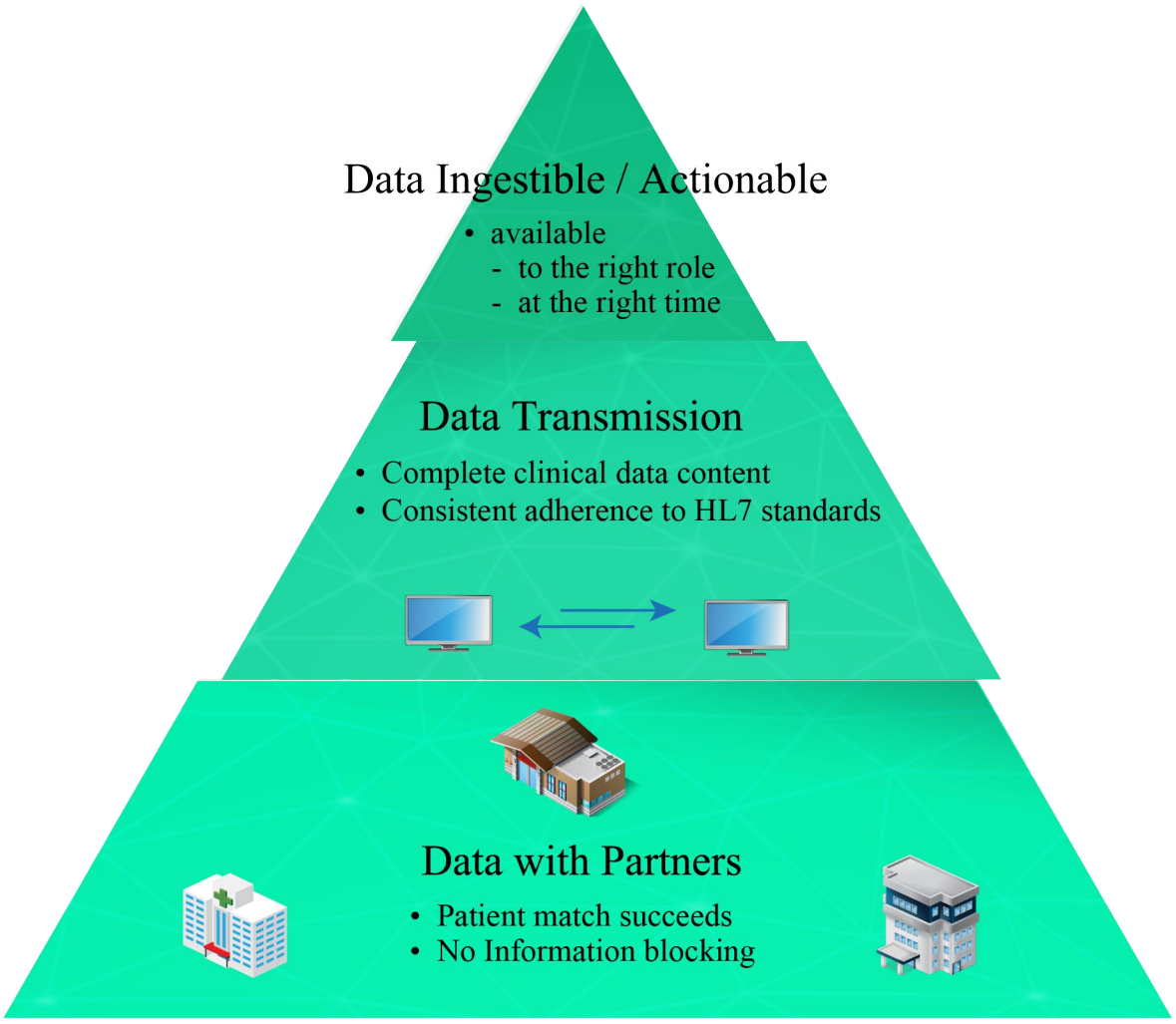

Figure 1: Data Nutrition Pyramid

KEY USE CASES

- Incomplete data

  ED Clinician has acute situation with a suicide attempt that is a repeat of the same event two weeks previously at an external healthcare enterprise. He requests data through the appropriate exchange process. The data returned is minimal: Name, Location, Date, Diagnosis of suicide attempt. Poor clinical data of little value to the clinician in this acute situation.

  Next day the clinician reviews the original EHR (unavailable during the acute session) and views comprehensive clinical data elements and clinical notes that were not shared.

  Multiple places in the dataflow impacted the technology success of an HL7 message shared and the clinical failure with no data of clinical value shared. The situation might have been caused by the loose adherence to the HL7 standard, the EHR configuration, the HL7 standards message construction, the HIE process and business rules for sharing and other Standard Operating Policies and Procedures and more.

- Wide Variety of adherence to HL7 standards

  EHR construction and generation of the HL7 standards message span a wide adherence to the HL7 standards. The lack of detailed Interoperability Content Implementation Guides adds to the challenge. The notion of "just enough to check the boxes" and meet regulatory and exchange requirements is widespread. The resulting clinically data-deficient exchanges increase clinician frustration with the interoperability concept.

- Education and Transparency

  Education of these clinical data challenges to the clinician, the public, and the vendors is minimal. Most of these use cases do not see the light of day. The clinicians hope that someday the way the patient thinks interoperability works will actually be the reality.

- Data Overload

  Evolving interoperability environment, by definition, will increase the data overload from medical devices. And the update of the VA policy (Mission Act) on data sharing that defaults the Veteran to "Sharing" versus the historic model of the default being "Not Sharing". The general milieu of younger generations willing to share everything on social media and other platforms adds to the congestion.

- Upstream applications that use the clinical data have poor performance

Many projects and applications plan to use Artificial Intelligence routines, but without data completeness, what happens to the partial records that do not fit well within these algorithms?

CLINICIAN PAIN POINTS

- Clinician pain points with lack of data
    - Data sharing can produce many historic records without the recent relevant events.
- Clinician pain points with overload of data
    - Automated devices will produce large data files and the receiving system must determine the appropriate display within the native systems (e.g. Is it the average heart rate over 24 hours? Is it the median? Does it include the outliers?).
- Clinician pain points with poorly displayed data
    - Data sharing can include many files displayed as a list of file names that the clinician must guess as to what file to select.
    - Separation of the native data and the external data in displays does not support the clinician during the few minutes shared with the patient.
- Clinician pain points with data not being timely or appropriate
- Clinician pain point with incomplete/mis-coded data
    - Opportunities to match to a clinical protocol may be missed by the patient with poor data quality.
    - Data that uses local coding instead of the HL7 Standards message cannot be incorporated into the native Clinical Decision Support (CDS) or Artificial Intelligence (AI) projects.
    - Lack of Interoperability Content Guides detailing at the data element level leads to a wide variety in the messages. “Allergies” needs to have minimally the text, the code, and the code system in order to be ingested by the receiving system and not just displayed.

Question (1.1). How would this plan to create interoperable systems address your key use cases and pain points?

Response (1.1):

Clinician driven definition of clinically usable datasets for each specialty can lead to successful external ingestion of these recognized datasets.

Onboarding clinical data through exchanges that provide continuous end-to-end data-quality processes and monitoring on clinical content as part of their process.

- Initial onboarding process that includes more than the technology handshake.
- By requiring the clinical content certification process, the process begins to provide better content. But without continuous monitoring surveillance, the value of a single review of a single test messages proves little value.
- Defining data-quality thresholds for data elements will mean that until the sender provides enough data to be useful, clinically actionable and reasonable – it is not shared through the network.
- Including a "quarantine" phase where the new data remains unshared until the data-quality threshold is met. This prevents the sharing of low-quality and incomplete data. It also protects the receiver from the potential high cost of transaction fees on poor data.

Interoperability Content Implementation Guide

- A well-defined Veterans Health Information Exchange (VHIE) Content Implementation Guide will result in higher quality data exchange.
  The Carequality/CommonWell implementation guides provide a solid foundation to build a VHIE Content Implementation Guide.
  - Query-Based Document Exchange Implementation Guide
  - Concise Consolidated CDA: Deploying Encounter Summary CDA Documents with Clinical Notes

These guides provide technical specifications, content standards specifications, and practical guidance to assist with best practice implementations.

Although the guides do provide domain-level guidance, they fail at the data element constraint definition level. This more granular level is required for successful ingestion of data exchanged and supports healthy "Clinical data nutrition".

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

Response (2):

Relevant parties and their contributions to the proposed solutions include:

- HL7 Standards enhancement
  - National Clinical Specialty Organizations – for the clinically usable datasets within their specialty that are the minimum data requirements at the data-element level

  - Standards based organizations (e.g. HL7, IHI, AHRQ, CMS, ONC) to support more granular requirements since applications are moving to holistic view of patient and ingesting the data elements, not just displaying it.
  - Subject Matter Experts (SMEs)
  - Carequality Interoperability Implementation Guide resources
  - Vendors
- Business models supporting robust onboarding processes
  - New business models for the evolving exchange models (e.g. QHINs, ACOs, HIEs)
- Upstream users of high-quality data
  - Clinical Decision Support (CDS)
  - Artificial Intelligence applications (AI)
- Educate the industry and the patient organizations
  - Healthcare enterprises at all levels

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

Response (3):

The critical missing piece in Healthcare Interoperability is that nobody is looking at the clinical quality of the data content being exchanged for relevance, robustness and repercussions. From a completeness and content perspective, the results of any analysis, where they even exist, is shocking.

The industry needs to recognize the issue and the magnitude of the issue and be willing to create cost centers and throw resources toward the issues. Currently when vendors or individual healthcare enterprises are faced with gentle observations about the data, uniformly the response is that they are overwhelmed with the data challenges. Even when the data challenges are throughout an application or a healthcare enterprise, the first push back is that there is no cost center for a clinical data quality content initiative. And the second push back is that there are no resources dedicated to the data quality of the clinical content. If there are no existing resources, who were the proactive resources in place during development to prevent any issues from happening in the first place.

National organizations need to develop Webinars and educational conferences dedicated to Clinical data quality content. Currently the focus is on data quality content is within finance data elements because resources follow the money trail, not on the clinical content.

Standards organizations need to work with the data ingestion and clinical usability concept and draw in resources who use the clinical data and the clinical data displays daily, not the theorists. Clinical Specialty organizations have worked to develop datasets specific to their needs and those need to be closely incorporated into the exchange definitions by the Standards organizations.

Root cause analysis clinical teams need to review real world use cases and track down the causes and dataflow that resulted in the failure of having high quality clinical content in the right format/display and at the right time and on the right patient and including both the internal and external data on the topic. That can define true clinical usability in a data exchange.

Question (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.

Response (4):

The viability depends on:

- Assurance of "Clinical Data Quality Content" throughout the manual and automated processes within a healthcare enterprise
- Original design and implementation to require complete and high-quality clinical data
- Failure Mode and Effects Analysis is key – and it must be continuous,
- Monitoring of devices, clinical data quality content, resource training on both
- Robust hand offs during transitions of care including manual devices, medications and automated devices (e.g. does the patient home unit work the same way and provide the same data as the device used within the healthcare enterprise?)

Challenges:

- When an existing automation device model is not available and has to be swapped for new equipment
- When there is a system upgrade and the code value sets need to be updated on both the master and the child systems
- When there is facility work and the room numbers are changed
- When transitions of care exist and when patient flows to ambulatory facilities associated with the enterprise, but staffed with different levels of resource expertise
- When new CDS and AI upgrades to software happen – is there truly a backout plan available for a patient active on an automated device? Just tracking the change in metadata does not mean unexpected production problems with individual units.

- Just because a device can track the metadata – there is always a connection between the clinical data and the metadata – and that can be broken. (e.g. Will every automated device have a UPS?) What if the electricity goes out in part of the facility as the patient is wheeled around?
- Consistency of a bad clinical practice does not make it a good clinical practice.
- Will there be continuous surveillance monitoring with sample sizes across all automated devices?
- How to deal with patient owned devices and healthcare enterprise owned devices?

It's time for our reality to be as good as our patients think it is. Even with the new implementations of HL7 FHIR based exchanges, health data interoperability is still an issue that is in the headlines constantly.

Without the basic premise of complete and high-quality clinical data content being actively and aggressively managed, then the rest is just wasted energy. Without solid clinical data, how can any of the advanced data concepts and data algorithms expect to perform well?

It is time to have a frank and open discussion about the "nutritional deficiencies" in healthcare data quality content, how it impacts patients and clinicians, and the overall magnitude and cost of the problem.

References

1. Hollis, Tibbetts. $3 Trillion Problem: Three Best Practices for Today's Dirty Data Pandemic. Microservices Expo Journal. [Internet]. Available from: http://soa.sys-con.com/node/1975126