

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***

For

***National Science Foundation, National
Coordination Office (NCO) Networking
and Information Technology Research
and Development (NITRD)***



Submitted by Russ Johnson
Director, Government Business Unit,
NantHealth, Inc.



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March 15, 2019

National Coordination Office (NCO)
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Email: HITRD-RFI@NITRD.gov

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

Dear Alex Thai:

We are pleased to submit NantHealth's RFI Response to the NCO/NITRD for Action on Interoperability of Medical Devices, Data, and Platforms.

NantHealth, Inc. ("NantHealth") is offering this information to provide an industry perspective from a market leader in healthcare IT solutions that enable interoperability between medical devices and other clinical systems and platforms. NantHealth has been connecting devices and data repositories for over a decade now and does so with great skill and ease of use. The desired outcome of this project should be to increase the volume of near-real-time data fed into the electronic data repositories and provide the care team an enterprise approach to data collection. By scaling the medical device data that is captured you will be able save clinician's time to provide direct patient care. Any member of the care team will have access to patient data quickly and easily. This will allow all care teams to have the most accurate and timely data to ensure they can provide the highest level of care that clients are accustomed to. The ability to minimize disruptions to patient care and maximize efficiency with focused and highly skilled implementation teams will ensure project success but also client and patient satisfaction.

Please review our information and feel free to contact Russ Johnson, Director, NantHealth's Government Business Unit, at [REDACTED] to answer any questions you may have.

Lastly, please know that our team at NantHealth considers this collaboration an honor, and we look forward to building a strong relationship with the Networking and Information Technology Research and Development (NITRD), National Coordination Office (NCO), National Science Foundation.

Respectfully Submitted,
Russ Johnson
Russ Johnson

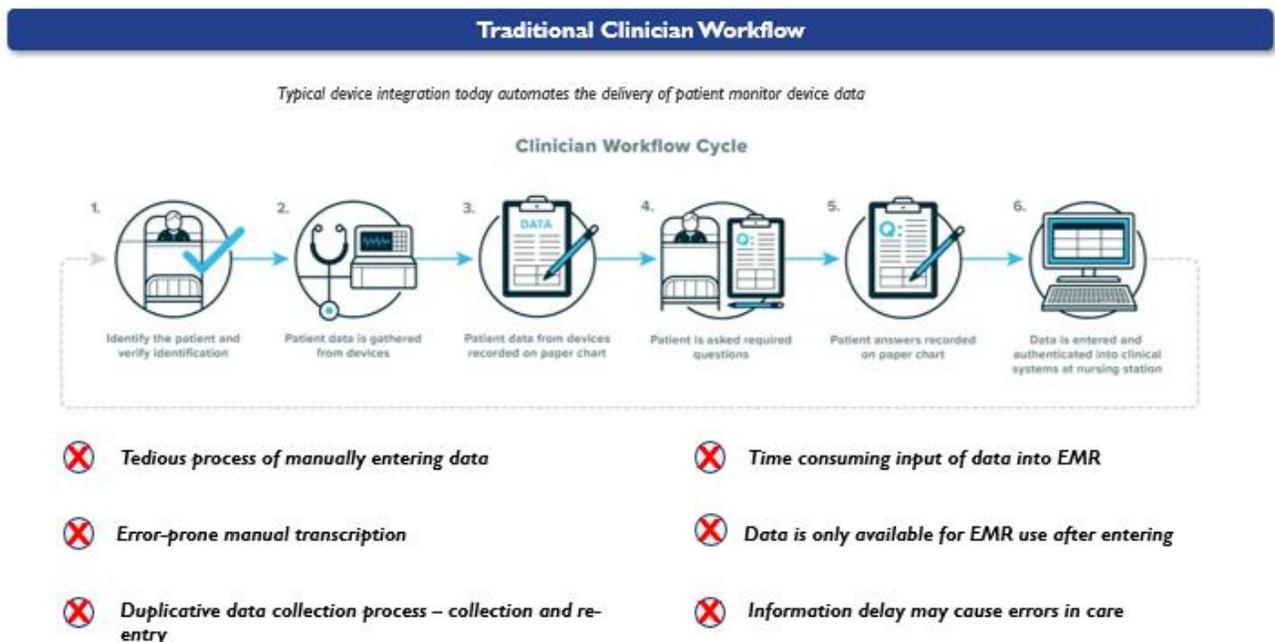
Section I Mission & Expertise

Mission

Optimize patient outcomes and enable value-based care through advancements in technology and precision medicine.

Expertise

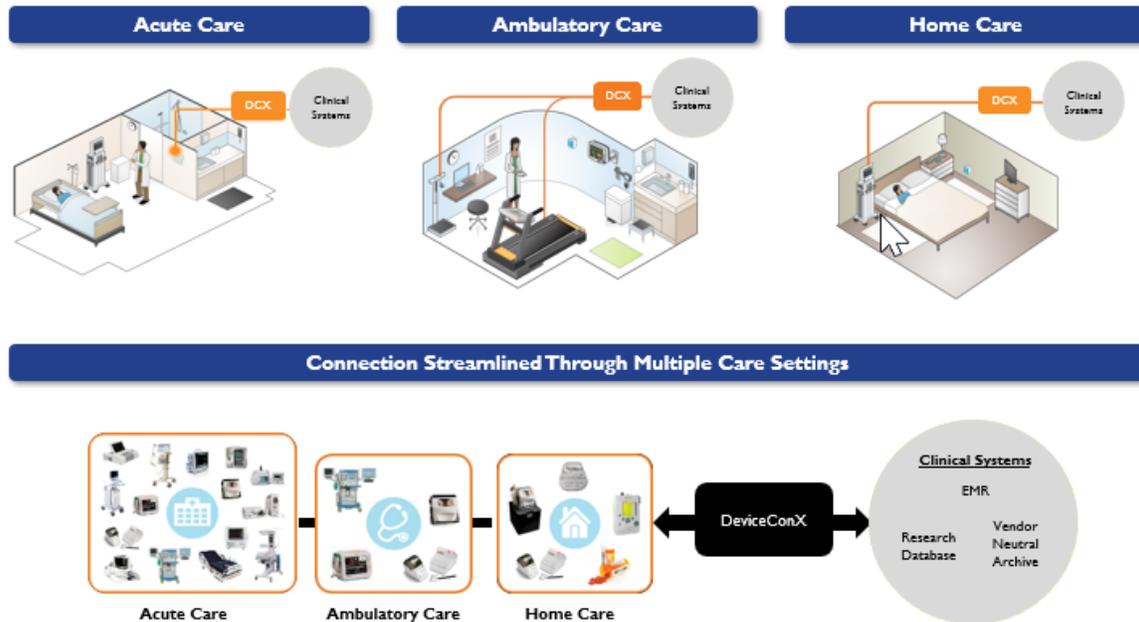
NantHealth's expertise is in our ability to connect medical devices regardless of vendor to a wide variety of electronic medical record (EMR) platforms without vendor lock-in that would restrict future technology investment. Our focus is to improve patient care through automated collection and bedside authentication of patient medical device data that dramatically reduces the likelihood of errors inherent in manual vitals transcription. Our flexible data collection methods coupled with configurable user interface are capable of relaying medical device data as well as observations, assessments, and manually-entered parameters to endpoint clinical systems. This interoperability results in increased clinician productivity and satisfaction while allowing the care team to focus on patient care delivery instead of performing manual administrative tasks and error-prone data entry as depicted below.



Section 2 Solution Overview

Solution Overview

NantHealth's medical device integration (MDI) platform is called DeviceConX™, commonly referred to as "DCX". DeviceConX can integrate wired, wireless, and networked medical device data from any setting across the continuum of care. See below.



DeviceConX is a software-based system, typically installed on-premises at hospitals and health systems with significant advantages over competing solutions:

1. DeviceConX is vendor-neutral. The device manufacturer and destination/endpoint system is inconsequential. It supports proprietary messaging as well as standards such as HL7 and FHIR to accommodate integrations regardless of vendor.
2. DeviceConX is software based. There is little required in terms of hardware investment for implementation. Hospitals can use their existing computer hardware to act as nodes or servers to host DeviceConX and they can use their existing network infrastructure to route the data.
3. DeviceConX has an easy-to-use interface for configuration changes, unit-of-measure (UoM) conversions, etc., to allow for a normalized data stream to be sent to one or many endpoint clinical systems.
4. Through the use of nominally-priced proprietary adapters, DeviceConX is capable of network-enabling older medical devices or devices without native network communication support. This maximizes the number of devices a healthcare organization can connect and leverages existing medical device investments without requiring new device purchases to enable network communication as illustrated below.

Connecting Non-Networked Medical Devices



- Provides a software solution for connecting stand-alone devices that can be deployed on industry standard computing platforms such as clinical workstations and PC's in the patient room
- For device connectivity, non-networked devices require a Shuttle Cable if using PCs / HBox
- Customers can use either a PC or HBox for maximum flexibility
- Networked devices communicate with Connected Care's server through a gateway or central station
- Legacy devices with serial output

Connecting Networked Medical Devices

- Wired or wireless configurations
- Newer devices with network connectivity

In addition to the underlying software platform, DeviceConX supports optional hardware including HBox and Shuttle to streamline implementations and offer the ultimate in flexibility for supporting the widest variety of medical devices and environmental scenarios. Overview of HBox and Shuttle Cable below.

HBox Overview

HBox is a hardware hub that provides wired or wireless integration to multiple patient care devices and transmits data via a DCX server to third-party clinical systems



60601 Compliant with Multiple Integration Options



Communications with DeviceConX Servers



Secure and Reliable

Shuttle Cable Overview

Provides end to end security with both hardware and software authentication between the cable and the HBox layering security from the medical device through the HBox to the EMR on premise data warehouse



60601 Compliant with RS232 to USB A Connection



Water / Fluid Resistant



Designed for hospital rooms and the ER / OR

HBox Equipment

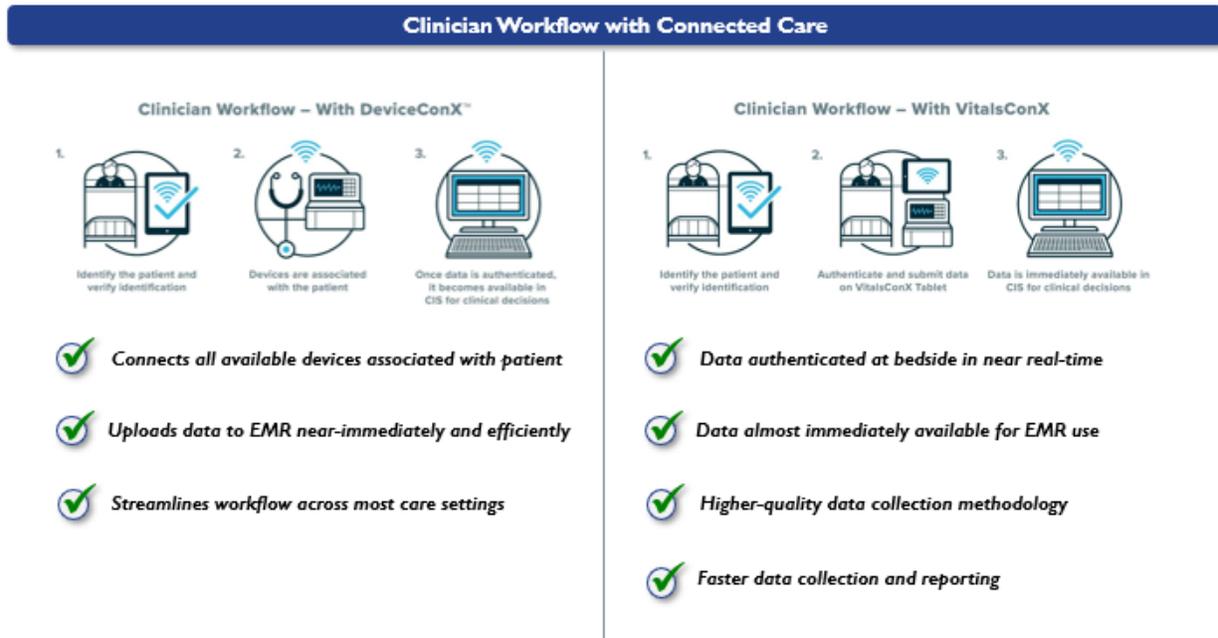


Shuttle Cable



With DeviceConX implemented, the hospital workflow is dramatically improved. The benefits are three-fold: more effective direct patient care with fewer errors, decreased likelihood of adverse events, and increased staff productivity. Collectively, this creates

the necessary foundation for optimal system-to-system interoperability and, eventually, the data necessary to power truly value-based care delivery as shown below.



Section 3 Experience and Global Footprint, Partnerships

Experience and Global Footprint

NantHealth is not a newcomer to this field; we have been implementing our flexible, software-based medical device integration across the continuum of care since our founding in 2008. We are currently a leader in this space in terms of domestic US market share and we have an expanding and fiercely loyal client base. To date, we have implemented our solution in over 390 facilities across the US and 4 sites internationally, integrating over 40,000 medical devices with an estimated 15 billion transactions (messages) being exchanged annually.



Public-Private Partnerships

NantHealth is pleased to partner with numerous private and public sector organizations within the United States such as New York City Health and Hospitals Corporation as well as many international organizations in response to a need for vendor-neutral medical device integration.

One of our international governmental partners published an invitation for a public procurement of medical device integration for the biggest hospitals in the its region. The long-term objective was to accelerate the use of medical device data in the clinical care processes for quality improvement programs as well as for research and innovation. The project consisted of a vendor-neutral, multi-modal, hospital-wide import system that stores and exposes standardized high definition medical device data throughout the entire care flow.

Section 4, Q1: 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?

NantHealth's vision for addressing interoperability issues between medical devices, data and platforms begins with a deep focus on the overall continuum of care – interoperability and a seamless flow of digital information from hospital's/provider's medical device data to the patient's in-home device data – all captured in electronic medical records. Ideally, all medical devices will output data with a vendor-neutral approach until such time that all devices become standardized. We believe this can help put the care back into the clinician's hands and alleviate the burden and potential human error of manually entering data at the site of care.

Notably, while all devices have data output, they 'speak' different languages. A vendor-neutral approach would allow for facilities to become less dependent upon managing feeds from different vendors and can ensure they have one device integration platform that allows them to capture data across the continuum.

Section 5, Q2: Who are the relevant parties and their contributions to your interoperability solution?

Medical Device Manufacturers – Medical device data is the input to our solution. They contribute by providing device protocol documentation so that NantHealth’s medical device integration engine can appropriately query patient physiological data from the medical device and transfer it to a format and unit of measure that the destination end point will accept. The NantHealth medical device driver library is updated quarterly with new drivers and if a driver has not yet been developed, NantHealth typically can turn it around in 12 weeks or less. NantHealth relies on the device manufacturer to provide a medical device for lab testing as well as device protocol documentation for the engineering team to develop the unique drivers for each device type.

Electronic Medical Record Vendors –The EMR software accepts the patient physiological data output of our solution and acts as the patient chart for the storage of a patient’s health record. NantHealth relies on EMR vendors for end-to-end integration testing of each parameter and each device our healthcare providers utilize in order to ensure that the data shows up in the appropriate location and with the appropriate unit of measure for trending over time.

IT Staff of Providers and Home Health Programs – These are the customers of our products whose end-users are typically information technology experts inside the healthcare facilities. Their job is to provide the access to user authentication and authorization, wi-fi settings, and other settings that enable the integration of data across disparate vendors.

Section 6, Q3: What are the challenges and impediments to making interoperability happen? How might these issues be addressed and by whom?

Ending data sharing impediments – The 21st Century Cures Act, signed in 2016, facilitates the open sharing of information for research and clinical purposes, provides funding and support for study networks, and strengthens patient protections for identifiable sensitive information. The Act is a positive step, yet there is much to be done before the goals of broad data sharing and utilization can be achieved. One example is the access to EMR data by medical device and other software vendors. The ONC is tasked with publishing guidelines for data rights. Once data access becomes easier, all vendors will be able to share data that will enable greater insights into how to provide the best quality of care for patients.

Through the normalization of data interoperability can be achieved. Unfortunately, most medical device vendors have impediments through government regulation and standards that do not allow them to focus on more than device operation and functional

requirements. The ability to standardize data would allow for true interoperability. The function behind the HL7 standards have been working for many years to achieve this but vendors have not been able to put valuable resources into this foray. This is where a vendor-neutral medical device integrator such as NantHealth can provide those translations and help achieve the interoperability between devices and data repositories.

Enabling Partnerships – To truly enable interoperability, vendors must work together in collaboration with each other and tech partners. Partnerships can be made easier through greater adoption of communications standards such as HL7 FHIR, and adoption of standard methods for identifying patients and devices, etc. Alliances between medical device companies and tech partners will be key to cloud-centered, big data driven healthcare.

Data Overload – The plethora of data available to clinicians and administrators today is often unmanageable. The industry must find ways to bring meaning to the data to help prioritize patients. Medical device vendors can tackle issues such as alarm fatigue, summary reporting of analytics/metrics, etc.

Home Health Data Integration – As patients are discharged from the hospital and move into the home, they may take with them medical devices for the capturing of vital sign data (BP cuffs, scales) and/or for the provision of treatment (home dialysis machines, heart monitors). In theory everyone recognizes value of that patient acquired data as an important data source for better continuity of care for chronically ill and aging patients. However, several barriers have not been surmounted including getting data into the right place and making sure it is timely enough (and not so timely as to create alarm fatigue or create events that cannot be cared for.) In addition, reimbursement trends must continue including the continuance of telehealth parity laws in all 50 states.

Section 7, Q4: 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.

A vision of sustained interoperability in the hospital and into the community is certainly feasible if coordinated with all stakeholders and with a patient centric approach. NantHealth is in agreement that the ability to integrate at multiple levels of input and output is key. This requires integration not only at the device level but also with electronic medical records and the state and federal records as well. This network of data and data sharing will make for a viable cross functional platform for the future.

Summary

At NantHealth, our mission is to optimize patient outcomes and enable value-based care through advancements in technology and precision medicine. With our innovative Connected Care products, we do this through our ability to connect vendor-neutral medical devices to a wide variety of electronic medical record (EMR) platforms without vendor lock-in that would restrict future technology investment. We strive to improve patient care through automated collection and bedside authentication of patient medical device data that dramatically reduces the likelihood of errors inherent in manual vitals transcription. Our flexible data collection methods, coupled with configurable user interface, are capable of relaying medical device data as well as observations, assessments, and manually-entered parameters to endpoint clinical systems. This interoperability results in increased clinician productivity and satisfaction while allowing the care team to focus on patient care delivery instead of performing manual administrative tasks and error-prone data entry.

To date, NantHealth has connected over 390 hospitals across the US and internationally, representing 40,600 medical devices connected. We process over 15 billion transactions annually and are proud of our customer retention of 99%!

We are appreciative for the opportunity to provide this information and look forward to further contribution moving forward.

Respectfully submitted,

/ signed */*

Director, Government Business Unit

Website & Attachments

<https://nanthealth.com/connected-care/>



Connected Care
brochure download



NantHealthCaseStu
dy-Chicago Medical