

HITRD RFI Responses, March 15, 2019

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

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Name: Ross Leder

Organization: Crew Clinical LLC

Nature of Business: Crew Clinical is a 3rd party provider of Healthcare Technology Management services for healthcare delivery organizations (hospitals, clinics and rehab facilities). We specialize in the IT and cybersecurity operational aspects of managing medical equipment – specifically:

- Middleware device data integration systems such as CapsuleTech
- Event management aggregators, such as IntelliSpace Event Management & Connexall
- Custom data warehousing solutions – to capture medical device data for research and quality improvement purposes

Individual Experience: Ross Leder

- 3 years with Cerner Corporation, a major healthcare information technology supplier. With Cerner, Ross was responsible for implementation and support of bedside medical equipment integration infrastructures at Naples Community Healthcare System in Naples, FL
- 6 years with University of Chicago Medical Center – extensive hands-on experience supporting HL7 & webservice interfaces. Ross also supported remote telemetry surveillance technologies and event notification services as part of the in-house equipment management “Clinical Engineering” Team.

Responses:

(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?

- Medical equipment and information system suppliers must further adopt and contribute to the standard nomenclature framework efforts like Integrating Healthcare Enterprise (IHE) and HL7 international “FHIR”. In recent years many major suppliers have begun to do so – this uniformity has made support and implementation of integrated data much easier and less costly for healthcare organizations. The federal government can influence suppliers of medical equipment and software systems to further adopt these standards by **leveraging the purchasing power of major government health care delivery operations such as the VA Medical Centers or Department of Defense** by perhaps listing IHE/FHIR standard compatibilities as a required or preferred technology features in capital RFPs.
- Much focus is given to the data interoperability use cases that support clinical documentation and research use cases - - an additional focus area that needs more attention is linkage between the EMR and asset inventory management systems internal support teams rely on for tracking equipment maintenance activities. EMR systems should have standard outbound feeds that report relevant utilization data back to the Computerized Maintenance Management System (CMMS) so equipment service activities can be driven off of use rather than simply fixed interval service windows. Additional benefits could be realized by the sharing of this information such as

traceability for defective devices and a better sense of device location in lieu of advanced location systems like RTLS.

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

- Integrating the Healthcare Enterprise (IHE.net)
- Advancing Safety in Health Technology (aami.org)
- HL7 International (hl7.org)
- Electronic medical record suppliers (Epic, Cerner, Meditech)
- Medical Device suppliers
- 3rd Party Service companies (Crew Clinical, TriMedX, Crothall)

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

- Connectivity is a major issue – in the field, how devices communicate is quite a hodge-podge of different approaches ranging from comprehensive OEM application systems to 3rd party “work-arounds” that essentially rely on serial to tcp/ip modems and custom proprietary drivers that need to be tested and upgraded in tandem with the manufacturers.
- The majority of these issues ought to be put on the suppliers to centralize fleet device data to an application server that interfaces using standards-based frameworks

(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.

- It’s certainly very idealistic. Much of it can and will be accomplished. Couple thoughts:
 - Start with getting data out of device and into a centralized record (emr/research warehouses/CMMS). Propagating data such as settings, and therapeutic parameters like dosage into the is much harder and may introduce more risk.
 - Careful with “loss of fidelity” as comparing the signal data from one manufacturers device to another is not always valid since the device itself is responsible for translating that raw data into clinically relevant information. It’s okay to “reconstruct” the wave at a lower **standard** fidelity that equipment manufactures can certify as comparable.
 - Big fan of the “black-box” concept... would however open a whole “can of worms” medical malpractice forensics at the individual level that might sink a lot of time and dollars. I think this would best serve regulators and manufacturers in determining product recalls and field corrections across a fleet of actively deployed devices.

Anyhow – hope my brief thoughts here are useful... really wanted to spend more time in my response but my week got the better of me. Would love to join the conference in DC this June/July. Please keep me posted.

-Ross S Leder, CEO Crew Clinical LLC.