HITRD RFI Responses, March 15, 2019

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

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Dear: Alex Thai

Re: The NITRD Health Information Technology Research and Development Interagency Working Group (HITRD IWG)

Name and title: Dan C Pettus, Vice President Connectivity, Medication Management Systems, BD

Can comments be published publicly: Yes

Contact:
Dan C. Pettus
[redacted]

Disclosure: Dan Pettus is employed at BD and involved with developing modular smart intravenous (IV) infusion systems with associated closed-loop interoperable wireless connectivity. Comments herein are Dan's individual response, independent of BD.

Comments:

Medical errors continue to persist in the healthcare industry. Non-connected, medical devices contribute to the problem as clinicians cannot take advantage of real-time, end-to-end, clinical and workflow information when using isolated patient medical devices. In order to improve clinical outcomes, vendor interchangeable connected medical devices is unquestionably a worthy goal. Having access to medical device data anywhere and anytime it is needed, for safe and efficient patient care, holds the promise to noticeably improve clinical outcomes and reduce costs.

Interoperability has been used to describe everything from clinic and acute-care medical records synchronization to integrating medical device data. Specifically, in the medical device segment, Interoperability is used interchangeably to describe unidirectional device data connectivity, such as a cuff blood pressure device, to extremely complex auto-programming of an acute-care infusion pump.

It may be possible to use the Unique Device Identification (UDI) as a method to provide interface data mapping and normalization from one vendor to another in unidirectional interfaced devices as a blood pressure device. However, vendor independence using the UDI may not yet be practical with the complexity of closed-loop infusion auto-programming.

In the AAMI publication *"Worth the Effort? Closed-Loop Infusion Pump Integration with the EMR*" *, using experiences from successful implementations, the authors describe what it takes for full closed-loop infusion interoperability and how medical device

connectivity is only a part of the total solution. Not only must the data exchange normalization and interface mapping occur, this type of Interoperability mandates synchronization from EMR master formulary to the infusion device where each individual vendor may have differing requirements. In addition, reconciliation for IV concentrations, dose measurements, secondary or piggyback methods, weight-based vs. non-weight-based orders, etc., along with the different user interface workflow approaches from disparate infusion vendors will need to be addressed before true Interoperability vendor independence can be achieved.

Medical device Interoperability is a broad topic. It's too important of a subject to overlook and any advancements through communication and standardization efforts should be encourage. Harmonization with work being done from Integrating the Healthcare Enterprise (IHE) and Fast Healthcare Interoperability Resources (FHIR) technology groups as a method to promote connectivity, is one example of driving standards. Nonetheless, we must also provide edification on the different levels of medical device Interoperability from unidirectional data interfaces to workflow altering closed-loop infusion auto-programming. Is it possible to achieve true vendor independence for something as complex as an infusion auto-programming interoperability system? Maybe. However, it may require much more than technical connectivity alone.

* Dan C. Pettus and Tim Vanderveen (*2013*) Biomedical Instrumentation & Technology: Nov./Dec. 2013, Vol. 47, No. 6, pp. 467-477