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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

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My vision for medical device interoperability closely matches the vision put forward in the HITRD-RFI document. Seamless transport of people from the field through triage, surgery, intensive care and other healthcare settings is a major benefit. Easy addition and removal of medical devices to and from the patient as the situation changes will preserve caregiver time and attention. Increased monitoring in currently unmonitored settings, along with more detailed medical records, may improve care in many ways.

In addition, medical device interoperability will enable a new generation of smart alarms. Recent developments in signal processing, sensor fusion and machine learning are particularly promising. Interoperability is crucial for prototyping, testing and deploying such systems.

The sophistication of differential equation based medical simulation has improved greatly in the last decade, but even the best simulation models lack real-world validation. Medical device interoperability facilitates simulation model testing. Validated medical simulation models are necessary for robust closed-loop control in medical treatment and can further improve smart alarms. Medical device interoperability will directly provide the sensors and actuators for autonomous health care delivery.

In my opinion, the primary reason medical device interoperability has not become ubiquitous is that equipment manufacturers do not perceive interoperability to be in their best short-term interest. Manufacturers will not have an incentive to produce interoperable devices until a large number of customers require them. A published standard, along with a high-quality reference implementation and a test suite to validate compliance will lower the cost of producing interoperable devices and give customers the ability to specify requirements for interoperability.

I believe the HITRD-RFI vision for medical device interoperability is achievable. Medical device interoperability can be based on existing technology used for the

Internet. World Wide Web based protocols and Internet of Things protocols provide security and use widely used, well tested, easy to implement, fully interoperable software libraries. This is the direction taken by Health Level Seven International (HL7) with Fast Healthcare Interoperability Resources (FHIR).

One problem for medical device interoperability is solved: the nomenclature for data items. ISO-IEEE11073 defines numerical and character string identifiers for nearly all medical device data types. ISO-IEEE11073 is a descendent of the Medical Information Bus (MIB). ISO-IEEE11073 identifiers are nearly unambiguous and have stood the test of time. ISO-IEEE11073 identifiers may be used for communicating streams of data values. IEEE 754 floating point numbers may be used for time stamps and data values. ML7 nomenclature and FIHR data formats may be used for more complex messages and for communication with electronic medical record systems.

Use of existing Internet technologies can reduce the cost of producing interoperable devices. ISO-IEEE11073 identifiers may be combined with modern data structures and current Internet of Things protocols such as Constrained Application Protocol (CoAP) and Message Queueing Telemetry Transport (MQTT). CoAP is built on Hypertext Transport Protocol (HTTP) used in the World Wide Web. MQTT is a simple publish and subscribe protocol build on User Datagram Protocol (UDP) used in many other Internet services. HTTP incorporates secure communications. UDP must be used with a separate security layer.

I believe that the best way forward is for an independent lab to produce a relatively simple medical device interoperability framework based on the existing ISO-IEEE11073, FHIR, CoAP and MQTT standards along with a high-quality reference implementation and a suite of compliance tests. The reference implementation may be written in C with bindings for C++, Java and Python. The reference implementation should conform to Open Web Application Security (OWASP) recommendations. The reference implementation should model best practices for software design, software updates and certificate management.