

HITRD RFI Responses, March 15, 2019

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

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March 15, 2019

Mr. Alex Thai
National Coordination Office
2415 Eisenhower Avenue
Alexandria, VA 22314

Re: Request for Information: Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care

Dear Mr. Thai:

ZOLL Medical Corporation¹ (“ZOLL”), an Asahi Kasei Group Company, submits these comments to the National Science Foundation (NSF) Request for Information (“RFI”),² and we welcome the opportunity to participate in this proceeding whose goal “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.”

Corporate Background

ZOLL develops and markets medical devices and software solutions that help advance emergency care and save lives, while increasing clinical and operational efficiencies. With products for defibrillation and monitoring, circulation and CPR feedback, data management, therapeutic temperature management, and ventilation. Our products and services provide a comprehensive set of technologies to aid hospital-based clinicians, first responders, military personnel, and even lay rescuers who may be called upon to treat victims requiring emergent resuscitation and acute critical care.

Our company sponsors and actively collaborates with academic institutions, government agencies, and other industry partners to develop new life saving and sustaining technologies, diagnostic methodologies, and treatment protocols. ZOLL actively conducts basic and clinical research in resuscitation science, as well as closed-loop control of medical devices that interface with physiological systems.

¹ www.zoll.com

² Request for Information: Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care, Fed. Reg. Vol. 84, No. 32, p. 4544 (Feb. 15, 2019)(“RFI”).

I. ZOLL Shares the Vision Presented in the RFI

The path to achieving the NSF vision requires a phased approach that provides for a cumulative progression of interoperable capability. This will allow governments, standards organizations, industry, end users and academia to establish the resources needed to develop and validate new regulations, consensus standards, standards of care and practice guidelines that ensure safe and effective patient management and data integrity.

Our proposed phases for this vision include:

1. Simple Data Sharing – new standards will define basic data from both monitoring and therapeutic devices, including: device data, discrete condensed clinical data and text-based alarm information. Data would be provided as a post-case summary. Implementing simple data sharing will significantly improve documentation of clinical progression and therapeutic interventions.
2. Medical Device Communication Standard(s) – these standards would define communication in all modalities and environments of patient care: device/device, device/mobile system (e.g. ambulance), device/fixed system (e.g. hospital), mobile system/fixed system, etc.

Requirements for interoperable devices and networks should include:

 - 2.1. Devices will need to connect securely, be authorized by the network, report identification including options and revision.
 - 2.2. Connected devices will need to use a specified protocol for the transmission of information, *e.g.*, HL7, FHIR.
 - 2.3. In care settings where device usage and patient movement are fluid (e.g. emergencies or patient transfers between levels of care), ascertaining data attribution to the correct patient is critical as any misattribution could cause harm to the patient. While individual devices can be identified with a Unique Device Identifier (UDI), there is no comparable identifier available for patients at this time. The vision of universal interoperability of medical devices to a large extent relies on the availability of a unique patient identifier.
 - 2.4. Patient data networks will need to exclude other traffic to ensure bandwidth and timeliness of data delivery. Within the patient data network there is a need for prioritization of data delivery for critical information. Proprietary systems currently handle this in a variety of ways. The interoperable network will support methods to identify the time sensitive nature of some data and ensure it is only used when valid. An example of this is arterial blood gas data from the operating room stat lab being delivered to the anesthesia workstation, or procedure that is triggered by an electric cardiogram analysis.
3. Device Data Standards – new consensus standards that define the data formats for standard physiologic monitoring and therapeutic signals. Such standards would allow real-time capture and analysis of high-resolution data from all devices that provide care.

4. Device Command Standards – a series of device-specific standards that define core commands for therapeutic and diagnostic devices. These standards are essential for achieving the NSF vision targets for remote monitoring/control and physiologic closed-loop control.
5. Other Standards – regulatory requirements/standards that allow for verification & validation to standards rather than discrete lists of accessories. In addition, usability engineering standards must be developed to define interface and performance nomenclature to ensure that users operate different devices with equal effectiveness.

A multidisciplinary working group tasked to develop interoperability solutions must focus on developing global consensus. Modern medical devices and technology compete in a global market. Therefore, this paradigm shift must include both domestic and international stakeholders to ensure commercial viability. Shaping future markets by phased implementation of new regulations and standards will drive investment and create new devices that address new market opportunities while lowering the overall cost of healthcare as economies of scale and efficiency are realized.

II. Relevant Parties and Key Contributor to the Interoperability Solution

1. Global Government Regulatory Agencies – global governments interested in achieving the NSF vision. New regulations catalyze industry to develop new compliant technologies, thereby prompting end-user adoption. Fully interoperable systems will also improve adverse event monitoring and/or trends in device performance or usage thereby enhancing post-market safety. Common, aggregated data from a range of similar devices, *i.e.*, a monitor or I.V pump, could also facilitate larger, and possibly less expensive, clinical trials as data from a range of populations is made available through enhanced and standardized electronic medical records.
2. Standards Organizations – ISO, AAMI, IEEE³, and others must define consensus standards for the technical and clinical objectives for interoperability, fostering development of compliant devices that will be monitored via use of next generation broadband technologies using secured access over the Internet. They also must mandate the performance criteria that allow for regulatory clearance and customer acceptance. These standards are critical to the vision of interoperability as manufacturers will no longer be able to validate devices across every conceivable clinical embodiment. Compliance with the standards will serve as the final check before users are free to aggregate any collection of devices that they determine are appropriate for the patient in their care. Universal adoption of a given standard will be critical to ensuring patient safety and data security in today's cyber environment.

³ International Organization for Standardization (ISO), Association for the Advancement of Medical Instrumentation (AAMI), Institute of Electrical and Electronics Engineers (IEEE).

3. Medical Device Industry – industry remains the source of medical technology and while innovation and new products drive sales, the liability for technical failure will always reside with the manufacturer. Manufacturers share in the NSF vision; however as we now see with driverless vehicles, the lay public holds new technology to a much higher standard than existing technology despite the significant reduction in overall risk. Adoption of uniform international device regulations and standards will reduce development costs for manufacturers fostering innovation while reducing its time to market.
4. Insurance Industry and other Payors – successful adoption of the vision will require that healthcare providers are reimbursed when they provide care that meets the new standards. Standardized electronic health records should improve efficiencies for reimbursement and allow for more accurate prediction by underwriters as they develop cost estimates for coverage.
5. End Users and Professional Societies – ultimately, it is end users that will incorporate new devices and technology into their care systems. Any effort must ensure that the goals and deliverables are appropriately defined and prioritized for users and their patients. Individual clinician, health systems and professional medical societies that collectively define the management of patients must play an active role.
6. Academia – the NSF vision describes an ideal care environment that appears both appropriate and inevitable. The technical challenges needed to achieve the vision will require comprehensive validation. In parallel, like all medical advancement, adoption and implementation of updated standards of care will require new research that confirms and informs the new care paradigm. Human factors and other clinical research must demonstrate improvement in specified clinical outcomes, quality metrics and cost.

III. Challenges and Impediments to Interoperability

There are significant challenges to achieving this interoperable vision, as reviewed above. However, our collective responsibility for patients requires a concerted and sustained commitment. The first critical step will be to create a roadmap, developed through stakeholder consensus, that defines a series of expanding milestones and associated changes to regulations and standards which will ultimately result in a fully interoperable health system. Achieving the NSF vision will not be easy and will take many years to complete, Morris, et. al.⁴ reported the time required to translate scientific discoveries into patient benefit is 17 years. While advances in communication technology provide both solutions and optimism for future healthcare, the effort must take the time to identify the knowledge gaps⁵ that preclude an immediate solution and therefore define the work ahead. Keeping expectations high while recognizing the significance of the challenge

⁴ Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question: understanding time lags in translational research. *J R Soc Med.* 2011;104:510–520. doi: 10.1258/jrsm.2011.110180.

⁵ Regulatory, consensus standards, standards of care, scientific evidence, etc.

to governments, manufacturers and the other stakeholders as well as developing a realistic timeline with evolving interoperability capability will ensure that NSF vision is realized and that patients as well as the stakeholders benefit from the new model.

IV. Viability of the Federal Vision

The vision is viable and ostensibly shared by other stakeholders. However, like all profound changes, significant development, cooperation and investments will be required. In its regulatory role, governments have the ability to encourage and if needed, compel others to participate. With annual healthcare spending in excess of \$3.5 trillion and a projected 5.5% annual growth rate⁶, the federal government's role as user and insurer will allow it to create the market for the new devices and technologies. In this capacity, the government also has the ability to drive the efficiencies that can significantly reduce the cost of healthcare. Immediate access to a patient's comprehensive health record will speed the diagnosis and treatment of conditions thereby improving the quality of care.

The supposition that healthcare is lagging behind other sectors in the development of autonomous and interoperable systems is incorrect. Automated and "smart" systems that save lives and improve care are in use throughout healthcare and lay environments. Automated external defibrillators (AEDs), telehealth networks, remote robotic surgical systems, physiologic closed-loop control and other autonomous systems are in use and being actively developed to augment, and where needed, act in place of a human care providers. Focus on achievements in the other sectors ignores a fundamental requirement of the proposed vision, interoperability between devices and systems from multiple manufacturers. In the cases cited in the RFI, the systems are developed and validated as a collective, similar to existing medical devices. Requiring all driverless vehicles to use cameras or other sensor systems from any source would significantly prolong their development and introduction. Likewise, the same will occur in the field of next generation medical devices unless requirements ensure nonproprietary and interoperable standards that drive innovation while lowering costs for manufacturers and consumers.

ZOLL has always acted based on a commitment to developing solutions that enable our users to provide the best care possible. We welcome the opportunity to collaborate with the government and other stakeholders in achieving a fully interoperable healthcare system.

Respectfully submitted,

*/*signed*/*

Dr. Ulrich Herken , V.P. Scientific and Clinical Affairs


ZOLL Point of Contact (POC) for Follow Up

⁶ <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html>