The Development of the AAMI Standard for a "Forensic Data Logger for an Integrated Clinical Environment (ICE)"

Presenting Author: Michael B. Jaffe, PhD. Medical Device Interoperability and Cybersecurity Program (MD PnP), member of AAMI IOWG.
Co-Authors: Julian M. Goldman, M.D., Massachusetts General Hospital Dept. of Anesthesia, Medical Device Interoperability and Cybersecurity Program (MD PnP), co-chair of AAMI IOWG; Sandy Weininger, PhD., Office of Science and Engineering Laboratories, FDA/CDRH, Silver Spring, MD 20993, USA, co-chair of AAMI IOWG.

Need/Genesis: Between the 19th and 20th century, it has been noted that the view of transportation accidents changed from the accidents being an impediment, to that of a catalyst for technological progress (Siegel, 2005) as a result of the availability of comprehensive system-based data logging (i.e. "black box recorders" or flight data recorders). Microprocessor-based medical devices typically have had some level of internal data logging capabilities for decades. The logs usually contain device performance metrics for technical troubleshooting and maintenance. Device data logs are downloaded when needed for forensic purposes, for example to assess device failures. But even if a single device log is fairly "complete" for that single device, a time-coordinated log of the entire clinical picture, which requires data from all devices in use, is not available. Forensic data logging is necessary for quality improvement and to address responsibility and liability concerns when a heterogeneous (multi-vendor) interoperable system is used for clinical care. The need for reliable data logging from all devices in-use is becoming increasingly important as the reliance on clinical decision support increases, and autonomous and closed loop system become more prevalent. Currently, device data logs are not standardized as to content or format which makes analysis of the individual logs difficult and complicates aggregation of individual logs into a single system-wide database of time-aligned events. In addition, device logs are often stored in proprietary formats that can only be accessed with the assistance of the device manufacturer.

Developing the Standard: Over the last two years the Interoperability Working Group (IOWG, SM-WG03) of the Association for the Advancement of Medical Instrumentation (AAMI) has been convening manufacturers, regulators and clinicians in order to promulgate a novel standard that will help enable the development of reliable and safe heterogenous interoperable systems. The standard for a forensic data logger titled "Forensic Data Logger for an Integrated Clinical Environment (ICE)" (part of the "ICE" family of standards) is intended to address essential needs for achieving safe and secure device interoperability. A forensic data logger was identified in the Integrated Clinical Environment (ICE) standard (ASTM F2761-09) to provided essential data to address liability concerns and support safety in an ICE. (This rationale is documented in the data logger draft standard.) Patient waveform and parameter data, images and video, configuration, settings and the capabilities of each connected monitoring and therapeutic device and all interactions with each device by the patient and clinicians (e.g. button presses) and between devices could be logged and time-synchronized. The data store can be retrieved, replayed, and reconstructed. The drafting committee have sought to develop this standard to meet high-level requirements initially outlined in ICE (ASTM F2761), in

alignment with related requirements under development in AAMI-UL 2800 standards. The content of the draft standard is based in part on research performed by the program on Medical Device "Plug-and-Play" Interoperability & Cybersecurity (MD PnP) at the Massachusetts General Hospital, supported in part by the Department of Defense*.

The Standard: The writing and organizing of the new ICE forensic data logging standard required an extended period of investigating (a) existing data loggers used in clinical practice and research, (b) data loggers and their associated standards in other fields, (c) the state of computing, memory, and networking technologies and (d) applicable use cases that the standard was seeking to address. Many companies offer data logging capabilities for their product or platform but have not yet addressed comprehensively capturing the entire patient care system of devices. This will require additional data and meta-data from each connected device to be made available to allow forensic analysis. In view of the standardization of data loggers that has occurred in the transportation field in the past few decades, standards for aircraft flight data recorders (EuroCAE), automobile event recorders (IEEE) and other transportation mode recorders were consulted for relevant requirements related to data acquisition, storage and reliability. The availability of low-cost memory, increased availability of cloud storage, and high-speed wireless networks has allowed the focus to be on identifying the "right data", rather than on technical or cost constraints. The airplane "black box" recorder model and needs for capturing the clinical environment before and during adverse events or near misses was the initial primary driver for the work. It quickly became clear that several additional categories of use cases – including assessment of connectivity, performance, quality improvement, and safety needed to be addressed and such are discussed at length as well.

References:

1. EUROCAE ED-55 - Minimum Operational Performance Specification for Flight Data Recorder Systems.
2. Medical Devices and Medical SystemsEssential Safety Requirements for Equipment Comprising the Patient-Centric Integrated Clinical Environment (ICE) Part 1: General Requirements and Conceptual Model, document ASTM F2761-09, 2013.
3. IEEE 1616. IEEE Standard for Motor Vehicle Event Data Recorders (MVEDRs), 2004.
4. Siegel, G. Technologies of Accident: Forensic Media, Crash Analysis, and the Redefinition of Progress. University of North Carolina at Chapel Hill, Doctor of Philosophy Department of Communication Studies, 2005.
5. Weininger S, Jaffe MB, Rausch T, Goldman JM. Capturing Essential Information to Achieve Safe Interoperability. Anesth Analg, 124 (1): 83–94, 2017.
6. Weininger S, Jaffe MB, Robkin M, Goldman JM. The importance of state and context in safe interoperable medical systems. Journal of Translational Engineering in Health and Medicine, 4: 2016.

*This research was supported in part by the Department of Defense US Army Medical Research and Material Command under award number W81XWH-17-C-0251. Views and opinions of, and endorsed by the authors do not reflect those of the US Army or the Department of Defense.