Abstract Title: A Medical Device Information Data Sheet (MDIDS) to Support the Interoperability of Externally Controllable Infusion Pumps for Tele-Critical Care[1]

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Problem and Motivation. Medical device remote control technologies can enable remote experts to contribute to patient care during tele-critical care during public health emergencies like COVID-19 to address the shortage of local clinical expertise. The benefit of such technologies may be further amplified if one remote-control application can operate multiple interoperable medical devices (e.g. multiple types of ventilators or IV pumps) to support the typical diversity of deployed medical devices in one institution. However, due to the variation in capabilities of different makes/models of the same device type, this unified remote control capability requires the standardization of the data interfaces of similar devices to provide sufficient information about these devices to enable safe remote control.

Methods: Medical Device Interface Data Sheets (MDIDS) [1] can provide a useful tool for documenting current and future device interface requirements and capabilities. We examined several clinical use scenarios where externally controllable infusion pumps are used to support tele-critical care, based on which we generalized an MDIDS for remotely controllable infusion pumps. To validate this generic MDIDS, we cross-checked it with the capabilities of several externally controllable infusion pumps: the NeuroWave Accupump, Eitan Medical Sapphire, and the BD Alaris GH.

Results: During the development of the generic remotely controllerable infusion pump MDIDS, we were able to identify the common and specific data elements that different infusion pumps need to provide at their data interfaces, considering the great diversity in these devices related to infusion mechanism, infusion programming methods, device alarms and alerts, and system settings. The resulting MDIDS includes over 100 data elements, many of which are essential for safety, including those common across different pump types (e.g., maximum settable infusion rate, occlusion alarm) and those specific to certain pump types (e.g., syringe size for syringe pumps).

We developed the generic MDIDS as the theoretical basis and developed an application in our OpenICE open-source interoperability research platform [2] to remotely control the above three infusion pumps either via serial communication (representing controlling the infusion pump at a distance limited by a physical wired connection inside or outside the patient room) or across the Internet using the web extension service of OpenICE (representing situations where remote experts have no physical access to the patient).

Conclusion. MDIDS for externally controllable medical devices can provide a solid basis to improve the safety and interoperability of medical device remote control technologies in the tele-critical care context. They can also benefit the research, development, and testing of physiological closed-loop control systems. We applied the MDIDS methodology to infusion pumps and ventilators to support the integration of these devices to the U.S. Army Telemedicine & Advanced Technology Research Center (TATRC) National Emergency Tele-Critical Care System.

References:

1. Goldman JM, Weininger S, Jaffe MB. Applying medical device informatics to enable safe and secure interoperable systems: medical device interface data sheets. Anes Analg 2020 Sep; 131(3):969-976.
2. Arney D, Plourde J, Goldman JM. OpenICE medical device interoperability platform overview and requirement analysis. Biomedical Engineering/Biomedizinische Technik. 2018 Feb;63(1):39-47.

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