

HITRD RFI Responses, March 15, 2019

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

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Response to the HITRD IWG Request for Information (RFI):

Action on Interoperability of Medical Devices, Data and Platforms to Enhance Patient Care

Submitted by:

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Dr. Sims is an anesthesiologist who is the inventor of multiple technologies for patient safety. These have been commercially developed and are in routine clinical use worldwide. Particularly relevant to this Response, Dr. Sims has had a central role in advancing design and safety features of modern clinical infusion pumps.

Dr. Peterfreund is an anesthesiologist with extensive experience in anesthesia patient safety, with a particular focus on medication errors. He leads a team studying the performance of infusion pumps in clinically relevant models and developing novel software technologies to manage clinical infusions.

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Summary Statement:

Integrated systems to manage drug delivery by pump driven, continuous intravenous infusion of critical medications will be an important advance in treatment efficacy and patient safety.

Software managing multiple infusions can overcome the problems of drug delivery lag times, dose variation, and medication errors including inadvertent bolus delivery and drug under- or over- dose.

Physiologic closed loop control of drug infusions can be achieved with algorithms able to accept data from a variety of sensors and then direct pump output to achieve the desired physiologic effect. Ideally it would be possible to combine interoperable medication infusion pumps, vital signs monitors, and supervisory algorithms to deploy these capabilities at the patient's bedside.

Critically ill patients in the ICU and anesthetized patients in the operating room commonly receive life-supporting medications by pump-driven continuous intravenous infusion. Many patients receive multiple simultaneous medication infusions to support blood pressure, cardiac performance, heart rate and rhythm, as well as consciousness and analgesia. With present technology, individual clinicians manually control the output of separate, stand-alone, infusion pumps. Quantitative laboratory data from models of clinical infusions demonstrate long lag times to achieve intended levels of drug delivery and also the potential for dose variation and error. These findings have clinical implications for treatment efficacy and medication safety, particularly in the neonatal and pediatric patient population (Kim et al, 2017).

External control of infusion pumps by algorithms executed by computer provides an opportunity to mitigate against the flaws of manual control of individual infusion pumps. Published research reports provide proof of these concepts (Parker et al, 2015). In principle, the output of several pumps can be simultaneously and precisely managed and coordinated.

Control technology would optimally operate across the platforms of pumps from different manufacturers. Also in principle, the control technology could receive data from a variety of sensors and use these data in closed loop or semi-autonomous systems (An et al, 2017). For example, sensors could monitor a patient's blood pressure and feed the information centrally to the control software (Dumont, 2013). The control software would then manage the infusion pumps to deliver the infused drugs at rates which achieve the intended physiologic responses. Technology for external control of infusion pumps has clinical implications for providing sophisticated medical care in remote locations.

The overall vision of this Response is to recommend creation of systems integrating sensors, control and reporting interfaces, and actuators (infusion pumps) to enhance the safety and performance of pump-driven clinical infusions. Realizing this vision requires coordinate function and interoperability of multiple components across different platforms, which is not currently available. Commercial manufacturer support is essential. Mathematical modeling of infusions is the foundation for creating computer executed control algorithms. Next generation commercial infusion pumps must accept external control by computer based on these algorithms. The algorithms must be able to accept data from a variety of sensors specifically capable of directing data to central controllers which then direct pump output to achieve the desired physiologic effect.

We suggest that a key role for the government agencies which cooperated to create this RFI is organizing the conference anticipated for June/July 2019 to hold sessions formally considering:

1-- The question of whether infusion pumps (or other medical devices) should have an intrinsic, FDA-required, capability or protocol by which they can safely be controlled by an external computer/algorithm system specifically designed for their functions.

2--PCLC (physiological closed loop control) systems and safety/efficacy requirements for interoperable components of these systems.

3- Establishing lists of performance metrics for external control systems and also for PCLC systems. The session(s) would also establish reporting requirements to collect baseline data for these metrics and to capture safety events.

A second key role for the government agencies is to create an authority tasked to implement the recommendations emerging from the proposed conference sessions.

References

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