TITLE (max 255 characters): CHALLENGES AND BENEFITS OF MEDICAL DEVICE CONNECTIVITY IN NEUROCRITICAL CARE

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ABSTRACT (max 500 words)

BACKGROUND:
In neurocritical care, interoperability of both medical devices and data is lacking despite the perceived benefits. Several efforts have been underway for the past decade to create a standardized, integrated information architecture. None have been widely adopted, underscoring the difficulty of achieving this goal.

We have taken a "bottom-up" approach by focusing on neurocritical care needs that can be solved with an integrated informatics platform, rather than starting "top-down" by first developing an all-encompassing standard. Our premise is that our approach will get life-saving technology to the warfighter in critical care faster than waiting for standards to be developed. Lessons learned in our work will contribute to ongoing standards development.

Brain injuries are complicated medical problems, with the highest cost when patients have poor outcomes. The multi-faceted, dynamic, and individualized nature of brain function post-injury requires data from disparate sources (device data, imaging, biomarkers, etc.) to extract real-time actionable information. This report focuses on our experience with device connectivity and informatics to address these issues, with the goal of contributing to emerging standards.

METHODS:
Two large studies are underway that use our data collection platform, TRACK-TBI (7 of 11 U.S. sites, 40 patients so far) and CENTER-TBI (13 of 28 sites in Europe, 62 patients so far). These studies aim to gather a wide range of data, including outcome measures and high-resolution data, in order to identify subgroups of patients for targeted treatments. The results of these studies require integration of diverse datasets across sites and management protocols. We have identified interoperability challenges as well as benefits for these trials.

RESULTS:
1. The variability and availability of measurements from devices across sites remains a barrier to uniform data collection but was minimized by our device connectivity solution.
2. We found a need for annotation standards, regarding clinical events.
3. Data transfer was hindered where systems were not networked, requiring resources and dedicated encrypted hard drives.

4. The lack of a sharable archive format for high-resolution data has delayed data aggregation.
5. The cost (time and resources) for successful data collection was greatly underestimated.
6. Harmonization of neuromonitoring data across domains with clinical, imaging, biomarker and outcome data requires significant IT resources.

CONCLUSION:
The use of our informatics platform facilitated the uniform collection of synchronized data across sites, however, there remain issues that need to be addressed by the neurocritical care community, rather than by a manufacturer. To this end, we have organized a Working Group on Neurocritical Care Informatics. The next step is to optimize the archiving and sharing of data through a high-resolution data management system, in order to take advantage of the collected information to answer scientific questions. An additional goal is to produce user-based recommendations that professional organizations and industry can use as reference when developing interoperability and informatics technology to accelerate the translation of trial results to actions benefitting the warfighter.

LEARNING OBJECTIVES: what should the attendee learn from this presentation? (Use action verbs such as Describe, Define, Analyze to begin the description of each learning objective. A learning objective is one sentence) (255 characters each)

1. Illustrate the effects of interoperability on high resolution data collection for research in neurocritical care

2. Present the benefits of using an integrated and standardized system for data collection in large clinical studies

3. Describe the neurocritical care needs that still need to be addressed in terms of data management