ICU ORGANIZATION AND TECHNOLOGY

Poster 57

A Conceptual Framework for a Technical Interoperability Standard Promoting Highly Efficient Network-Based Clinical Trials and Collaborative Research

Eric S. Rosenthal[1], M. Brandon M. Westover[1], Anna A. Rodriguez[2], Dick D. Moberg[2].

[1]*Massachusetts General Hospital, Department of Neurology, Boston, MA, USA,* [2]*Moberg Research, Inc. , Ambler, PA, USA.*

Introduction:

Clinical trials in neurocritical care require a predictable set of baseline, monitoring, treatment, and clinical outcomes data. However, interoperability standards restrict automated real-time streaming of this data, resulting in inefficiencies performing clinical trials, preventing real-time clinical trial oversight and constraining collaborative research. We investigated available data systems and developed a conceptual framework for clinical trial oversight and collaborative research in neurocritical care.

Methods:

Examining current traumatic brain injury interventional trials, we considered technical interoperability standards and data flow elements required for a system capable of network-based clinical trial oversight and collaborative analytic research. We elaborated a vendor-neutral interoperability schema for data extraction, repositories, analysis, annotation, and visualization.

Results:

The proposed conceptual solution is described. Nodes of data acquisition include: 1) continuously streaming devices including physiologic monitors and infusion pumps; 2) discrete data from high-penetrance EHR and laboratory platforms; and 3) biospecimen, radiology, and clinical outcomes repositories. An application program interface performs function calls to utilize individual episodes of data. A data management system queries and manages multiple patient records for batch processing of on-demand or pre-specified queries. A user interface toolkit enables annotation, analysis, and visualization for real-time or post-hoc assessment of raw and derived parameters (e.g., percent time in target range or on-protocol compliance). We enumerate the variety of current nodes requiring interoperability interfaces, and propose an open standard to promote a highly efficient platform for network-based clinical research, featuring automated case report form data extraction, a programmable interface for oversight and early warning detection, and a platform for annotation and crowdsourcing of novel algorithms.

Conclusions:

This conceptual architecture for a modular, vendor-neutral, data collection and management system for the acute care of patients in neurocritical care offers scalable efficiencies that promote network-based clinical trials in neurocritical care and offer new functionality for real-time oversight and collaborative analytics.