BACKGROUND

• The continuous, simultaneous evaluation of cerebral function and vital signs (multimodal monitoring) has become standard of care in many neuro ICUs.
• This has transformed neuro ICUs into data rich environments that would benefit from medical device connectivity.
• A “connected” multimodal monitoring environment would allow the use of advanced informatics, such as:
  - Clinical decision support
  - Automated event detection
  - Smart alarms
  - Personalized medicine
• Multimodal monitoring, which requires medical device connectivity, reportedly improves quality of care through the reduction of errors and increased detection of adverse events. However, widely adopted communication standards that facilitate these benefits are lacking.

LACK OF MEDICAL DEVICE CONNECTIVITY currently exists due to the heterogeneous nature of device interfaces:
  - Lack of adherence to manufacturer’s protocol specification documents
  - Undocumented behaviors
  - No widely adopted standards (communication/nomenclature)
  - Lack of version control

METHODS

• In order to accelerate the development of a “connected environment” in neurocritical care, clinicians, researchers and medical device manufacturers established in 2015 the Working Group on Neurocritical Care Informatics.
• Through an open meeting and continued discussion, a document “Recommendation: Medical Device Connectivity” was produced. Its objective is to provide guidance to medical device manufacturers desiring to design a communications protocol that allows external systems to acquire data from their devices.

SURVEY OF CURRENT STATUS

Moberg ICU Solutions conducted a survey of the current status of medical device connectivity in neurocritical care based on its experience in the development of device interfaces for its data integration platform (CNS Monitor). The following aspects were evaluated:

- Adherence to manufacturer’s protocol specification documents
- Overall quality of protocol implementation
- Acceptance rate of standards (communication/nomenclature)

Total number of digital device interfaces examined: 30 (2 device interfaces discarded because of their analog outputs)

RECOMMENDATIONS

• RECOMMENDATION 1: Utilize standard communication protocols when applicable/available.
• RECOMMENDATION 2: Utilize digital data communications.
• RECOMMENDATION 3: Ensure the following content is transmitted:
  - Device Identification, preferably in the form of UDI
  - Protocol Version Identification
  - Patient Identification
  - Data, including: Data Label, Data Units, Data Value
  - Events
  - Alert Conditions
  - Device System Status
• RECOMMENDATION 4: Attributes of the message structure:
  - REQUIRED
    - Be organized deterministically
    - Identify the units of the transmitted data
    - Contain the label for the transmitted data
  - DESIRABLE
    - Identifiable start of message sequence
    - Contain message type identifiers
    - Contain timestamp or sampling sequence number
    - Contain a message sequence number
    - Contain a message checksum
    - Employ numeric data bundling
    - Language-dependent content
• RECOMMENDATION 5: Conduct a needs assessment in the initial phase of designing a communications protocol.
• RECOMMENDATION 6: Choose a transport protocol according to the needs identified.
• RECOMMENDATION 7: Choose a protocol format according to the needs identified.
• RECOMMENDATION 8: Determine the directional nature of the communications protocol according to the needs identified.
• RECOMMENDATION 9: Thoroughly document.
• RECOMMENDATION 10: Develop validation tools.

Acknowledgement

For more information, contact Anna Rodriguez at anna@moberg.com or visit the Working Group on Neurocritical Care Informatics at www.SmartNeuroICU.org.

This work is in part supported by the US Army Medical Research and Materiel Command under Contract No.W81XWH-19-C-0055. The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.