Considerations Regarding Underutilization of FDA Cleared Devices in Military Environments

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BACKGROUND

- To help support a discussion on Implementation of TBI Innovations, DoD wanted to informally explore utilization and barriers to utilization of FDA cleared devices to aid in the assessment of head injury
- Health Affairs' Warfighter Brain Health (WBH) office reviewed eight FDA-cleared devices
- One (neurocognitive assessment tool) of the eight identified devices were actively being utilized within the DoD.
- On February 22, 2024, Health Affairs, WBH Office discussed this topic with the Traumatic Brain Injury Advisory Committee (TAC) Core group consisting of brain health/TBI subject matter experts

FDA Cleared Devices

The WBH Office separated the 8 cleared TBI devices/tools into 4 categories:

1. Neurocognitive assessment tools
2. Eye tracking devices
3. Biomarker measuring devices
4. Brain monitoring/measuring devices

DoD Feedback
Neurocognitive Assessment Tools:

- Concerns about misinterpreting and misusing the information.
  - Diagnostic vice Assessment data
- Better guidance on integrating tools into patient care is needed.
- Interoperability with existing IT systems to incorporate results.
- Test should be mobile and able to pull baseline to conduct comparative analysis.
- Interpretation of results challenges. Cannot require specialty services for interpretation

DoD Feedback
Eye Tracking Devices:

- Skepticism about the value of isolated objective measures like eye tracking for concussion assessment.
- Concerns about investing in technologies that do not significantly contribute to concussion management.
- Creates a challenge using such tools if they do not outperform existing clinical methods.
- Manufacturers need to make the “intended use,” clear for end-users.
- Better quality evidence derived from larger, unbiased studies in specific settings is needed to determine the context and utility of these devices.
- Devices may lack validation for clinical diagnosis but could be valuable for functional evaluation, especially in understanding warfighters’ task-specific needs.
- Emphasized the need for collaboration with the vision and performance communities to assess these devices from a performance lens.
- There is an absence of a gold standard for eye tracking metrics.

DoD Feedback
Biomarker Measuring Devices:

- Device has usefulness in determining the need for CT scan based on its negative predictive value for intracranial bleeds.
- Valuable for battlefield care and decisions in prolonged field care and lack of air superiority scenarios
- Resources considerations needed to conduct biomarker testing
- Issues rooted in training, where the inclination is to perform CT scans for fear of missing something. Confidence in alternative devices will take time.
- NIH Classification Meeting outcomes with role of Biomarkers will help

DoD Feedback
Brain Monitor/Measure Devices:

- Military unique issues with equipment (must be of high value to be carried to far forward environments)
  - Brain monitoring headsets can be problematic, not practical in the prehospital environment.
- Better quality evidence derived from larger, unbiased studies in specific settings is needed to determine the context and utility of these devices.
- Determine the most appropriate setting for the device. Difficult to try to deploy in multiple settings that have different requirements.
- It is crucial to understand the acquisition process to facilitate the deployment of TBI devices. There needs to be a clear process for evaluation and acquisition, as there are gaps in existing processes.

High Level Considerations to Maximize Utilization

- Develop the requirements based on needs assessments to identify necessary tools and techniques for unique populations, different environments of care, and where the innovation is best poised to assist in healthcare process (assessment, diagnosis, treatment, recovery, prognostication)
  - Requirements will address many of the barriers identified
- Create a centralized process for submitting, evaluating to include suitability and field testing and prioritizing TBI devices