Abstract
Chronic Effects of Neurotrauma Consortium (CENC) Study 1:
Observational Study on Late Neurologic Effects of OEF/OIF/OND Combat
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Objectives: This study's overall goal is to establish a large, longitudinal cohort of U.S. Veterans or active duty service members (SMs) previously deployed in support of Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn (OEF/OIF/OND), including those exposed and unexposed to mild traumatic brain injuries (mTBIs), and measure their chronic sequelae and comorbidities. All subjects will undergo an initial comprehensive assessment to determine their TBI status along with the prevalence, type, and intensity of chronic sequelae from TBI and associated comorbidities. All subjects will undergo periodic in-person and telephone reassessment to monitor the status of the sequelae and comorbidities and to assess for evidence of neurologic (cognitive, behavioral, physical) decline.

Research Design: This study will longitudinally assess the prevalence, natural history, and response to interventions of chronic symptoms, conditions, and associated comorbidities after mTBI. Cross-sectional analyses will also assess the effect of time post-injury on chronic symptoms, conditions, associated comorbidities, and evidence of neurodegeneration after mTBI.
A total of 1,100 Veterans or SMs who were previously deployed in OEF/OIF/OND will be recruited and enrolled from multiple regional VA-university research sites. Approximately 80% will have sustained one or more mTBIs ("exposed") with and without chronic sequelae or comorbidities, while 20% will have no history of mTBIs ("unexposed").

Methodology: All consented subjects will undergo a comprehensive in-person evaluation that has been developed by the Consortium using select core National Institutes of Health (NIH) Toolbox measures plus additional relevant evaluations. The assessment will include a review of all available Department of Defense (DoD) medical data and injury report(s), self-report questionnaires of health, demographics and moderating factors, TBI and posttraumatic stress disorder (PTSD) structured interviews, neuroimaging, biomarker battery, neuroendocrine screen, neuropsychological measures, self-report symptom and outcomes measures, assessment of special senses (vision, smell, hearing), movement disorder screen, pain rating, and an evaluation of gait, balance, and coordination. An index date will be established for each participant based on the worst mTBI during combat or similar predefined reference event. The comprehensive evaluation will be repeated, in-person at years 1, 3, 5 then every 5 years after the index date. An annual brief phone re-evaluation that focuses on a screen of cognition, behavior, social functioning, and seizure episodes will be performed during interval years. In addition, a brief phone evaluation (BTACT) will also be done in close proximity of the in-person evaluation. Subjects will also be informed that they/their significant others may elect to donate their brains for neuropathologic evaluation if they expire during the study period, which will be detailed in a separate protocol and informed consent.

Findings: N/A

Clinical Relationships: Because the vast majority of TBIs in the military and VA system are mild, a prospective study of cognitive and other outcomes from mild injury is necessary to determine the long-term risks posed to Veterans.

Impact/Significance: N/A