Managing Severe TBI without ICP Monitoring - Guidelines, Development and Testing

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Management of intracranial hypertension (ICH) in patients with severe traumatic brain injury (TBI) is crucial to their survival and optimal recovery. The evidence-based Guidelines for the Management of Severe Traumatic Brain Injury, 3rd Edition, recommends the use of intracranial pressure (ICP) monitors to assess ICH and to know when and how to intervene. Unfortunately, in most areas of the world there is no access to ICP monitor technology. This means that most people with severe TBI are treated without use of ICP monitoring. There are no guidelines and no literature on how to treat severe TBI without use of ICP monitors.

The objective of this project is to create guidelines for the treatment of severe TBI in the absence of ICP monitoring and to test them. We propose to derive these guidelines by working with a team of clinicians that practice in austere environments in low-to-middle income countries (LMICs) and who routinely make decisions based either on a treatment protocol, their clinical experience, or both. We will use a new, systematic and innovative technology and process to accomplish consensus for the guidelines among the clinicians. We will implement the Consensus-Based Guidelines (CBG) in resource-poor centers, some of which have prior exposure to less well developed *ad hoc* protocols for treatment of TBI, and others that do not have prior exposure. We will test the influence of the CBG on outcomes of severe TBI in a before/after design in these two sets of centers. In the first two years, patients will be treated according to the *ad hoc* protocol or according to individual clinician best judgment. Then the Guidelines will be developed, all sites will be trained in their use, and they will be used to guide treatment in all sites for the next 2 years. We will evaluate the effect of using an *ad hoc* protocol by comparing outcomes between the two sets of centers before the Guidelines are developed. In each set of centers we will evaluate the effect of using the consensus-based guideline protocol compared to either no protocol or the *ad hoc* protocol by comparing the outcomes in the first and second periods. Finally, we will evaluate how much more the consensus-based protocol effects outcome than the *ad hoc* protocol by comparing the difference from the first to the second period between the two sets of sites In accomplishing the study objectives, we will create and test a guideline for the treatment of severe TBI that could be used globally to improve outcomes for these patients. We will validate in LMICs a new systematic and innovative technology and process to accomplish consensus that was derived in an HIC. Finally, we will train personnel in centers new to research in how to conduct high-quality scientific studies, and will extend the training for the personnel with whom we have been working, solidifying previous capacity-building efforts, and initiating new efforts.