

InTBIR Data Analytics Workgroup

Membership

- Mark Goldhammer
- Hester Lingsma
- Guido Bertolini
- Ewout Steyerberg
- Nancy Temkin
- Keith Yates
- Louis French
- Joe Giacino

Conference Calls

- Six conference calls
- Topics included
 - Clinical Endpoints/completeness
 - Collaborative/coordinate data analysis across studies
 - Common CER Analyses

Common CER Questions Survey

Question	Part of your original study proposal?	Addressable in your study?
Does routine follow-up after Emergency Dept improve outcome in patients with mild TBI?	Yes/no	Yes/no
Does early (partial or complete) surgical resection of contusions improve clinical course and outcome in patients with TBI admitted in ICU in whom ICP elevation is a clinical problem?	Yes/no	Yes/no
Determine the effect of CSF diversion strategies on outcome (Compare the effectiveness of first-line intracranial hypertension strategies)	Yes/no	Yes/no
Determine the effect of hyperosmolar therapies on outcome (Compare the effectiveness of first-line intracranial hypertension strategies)	Yes/no	Yes/no
Determine the effect of prophylactic HV (CO ₂ < 30 mm Hg) on outcome (Compare the effectiveness of strategies that mitigate iatrogenic ischemia and hypoxia)	Yes/no	Yes/no
Does the provision of a rehabilitation intervention to children and adolescents with persistent post-concussion symptoms lead to better outcomes than standard monitoring of symptoms?	Yes/no	Yes/no

Common CER Questions Survey

- Research question
- Hypothesis
- Patient population (inclusion and exclusion criteria)
- Intervention (independent variable tested)
- Comparator (control group)
- Outcomes (primary and secondary)
- Timing (when does the intervention take place)
- Setting (where does the intervention take place)
- Analytical approach (*e.g how do you plan to adjust for confounders, which confounders will you adjust for, which statistical model etc.*)

Survey Results (Example c/o Roger Zemek)

Question	Part of your original study proposal?	Addressable in your study?
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Does early (partial or complete) surgical resection of contusions improve clinical course and outcome in patients with TBI admitted in ICU in whom ICP elevation is a clinical problem?	no	no
Determine the effect of CSF diversion strategies on outcome (Compare the effectiveness of first-line intracranial hypertension strategies)	no	no
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Determine the effect of prophylactic HV (CO ₂ < 30 mm Hg) on outcome (Compare the effectiveness of strategies that mitigate iatrogenic ischemia and hypoxia)	no	no
Does the provision of a rehabilitation intervention to children and adolescents with persistent post-concussion symptoms lead to better outcomes than standard monitoring of symptoms?	no	Yes

Survey Results (Example c/o Roger Zemek)

- **Research question:** Does routine follow-up after Emergency Dept improve outcome in patients with mild TBI?
- **Hypothesis:** My hypothesis is that is that routine follow-up (for the participants enrolled in our multicentre cohort) does not improve outcome. This is because the old guidelines (which were current at the time of recruitment and follow-up) recommended rest until symptom-free, whereas the latest evidence suggests that early physical activity is associated with better outcomes (thus resulting in newer guideline recommendations).
- **Patient population (inclusion and exclusion criteria):** Eligible patients were aged 5.00 through 17.99 years, presented to a participating ED with a head injury within the preceding 48 hours, and met concussion diagnostic criteria consistent with the 4th Zurich consensus statement. Concussion was defined as a complex pathophysiological process caused by direct blow to the head, face, neck or elsewhere on the body with an impulsive force transmitted to the head (which may or may not have involved loss of consciousness), resulting in a brain injury with one or more symptoms in one or more of the following clinical domains: somatic, cognitive, emotional/behavioural, or sleep (eTable1). Patients were excluded for the following: Glasgow Coma Scale score ≤ 13 ; structural abnormality on neuroimaging if performed; neurosurgical intervention; intubation or intensive care unit admission; multi-system injury requiring hospitalization; procedural sedation; severe pre-existing neurological developmental delay resulting in communication difficulties; intoxication; absence of trauma as primary event; previously enrolled; insurmountable language barrier; inability to follow-up by phone or electronic mail.

Survey Results (Example c/o Roger Zemek)

- **Intervention (independent variable tested):** N/A cohort study
- **Comparator (control group):** N/A cohort study
- **Outcomes (primary and secondary):**
 - Primary outcome measure. The primary outcome is the proportion of children aged 5 –17 years who have PCS at one-month follow-up. A PCS case is defined as an increase from pre- concussion baseline of three or more symptoms on the validated PCSI at one-month (consistent with the ICD-10 definition of PCS).
 - Secondary outcome measure:
 - -PCSI Outcomes at 1 week, 2 week, 8 week, and 12 weeks post-injury
 - -Return to school
 - -Return to sport
 - -Quality of life
 - -Physician follow-up

Common CER Questions Survey: Next Steps

- The Committee will review survey response
- Identify common CER questions
- Bring investigators together to develop collaborations, common and novel analytics approaches.