INTBIR Working Group: Data management, Data analysis & Clinical Endpoints

Outcomes survey

Purpose: Since the inception of InTBIR a central aim has been to promote the use of common data elements (CDEs), and create opportunities for collaboration between projects. The TBI outcomes CDEs were initially developed for adults and paediatrics by separate consensus groups, and then subsequently expanded to cover studies of different types. As a result the current list of outcome CDEs includes over 180 measures divided into 24 assessment domains.

The aim of the survey was to identify CDE outcomes that are being used in projects, and to establish how far endpoints are shared. PIs were asked to provide a list of outcomes used, and CDEs were identified, and classified into domains. Information concerning outcomes was collected for all eleven 'founding' InTBIR projects.

Results: Over 120 outcomes are being used across the projects, of which more than one third belong to the CDEs. InTBIR projects can be divided into those in which outcomes primarily come from the paediatric CDEs (6 projects) and those in which they come predominantly from the adult CDEs (5 projects). Within these two subgroups there are multiple outcomes that are shared across projects: 12 paediatric CDE outcomes are shared by two or more projects, and 18 adult CDE instruments are shared. The most popular domains of assessment across all projects are: global outcomes (83% of projects), neuropsychological impairment (73%), health-related quality of life (73%), and post-concussive/ TBI related symptoms (64%).

Conclusions: The survey provides detailed information about outcomes used in InTBIR studies, and is helpful when planning collaboration between projects; for example, it has been used to identify the potential for pooling data for the Genetic Associations In Neurotrauma (GAIN) project. There is good agreement concerning domains of assessment across projects. Although different instruments are identified in adult and paediatric CDEs, many share similar underlying constructs, and this opens the possibility of mapping between outcomes for group studies. There is work still to be done on selecting and standardising outcomes for TBI, and evidence from ongoing InTBIR studies can play a key role in this process.

Data Quality Survey

Purpose: The working group carried out a survey of the processes implemented across InTBIR projects to ensure data quality. All told, 30,000 participants are projected to take part in InTBIR projects, and the majority of projects are collecting 500 or more variables per core patient. Assembling these rich databases involves a very substantial data collection and curation exercise. A short survey tool was circulated to PIs consisting of a list of items relating to data quality, including specific steps that have been taken within individual projects.

Results: A response was received from nine of the eleven 'founding' InTBIR projects. The main points from the survey are:-
• All of the projects included formal training for staff at the beginning of data collection, either web-based, face-to-face, or both.
• All projects had a data dictionary defining the meaning of each variable, and for two projects this was available on-screen at data input.
• Checks on data entry included site visits to monitor forms (80% of projects), independent review of completed forms before entry (55%), and double entry of data (33%).

- All but one project reported central monitoring of consistency of data. Where monitoring was done it always involved checks on date inconsistency, logical inconsistency, and out of range values. Less commonly (50%) warnings on borderline values were included.
- Most projects included a record of the reasons for missing data (78%), and a track of changes in the data entered (85%).

Conclusions: InTBIR projects cover a wide range of designs, and it is encouraging that there is substantial convergence in implementation of methods to ensure data quality. It is notable, however, that projects are often independently developing solutions to the same data curation issues. This is an area in which there is very little direct guidance for investigators, and there are opportunities for sharing experience and pooling best practice within InTBIR.