Data Management & Analytics WG

InTBIR provides an opportunity to accelerate research in traumatic brain injury and tackle issues that could not otherwise be addressed. This can come, for example, through joint analyses to address questions that cannot be answered with smaller or single site databases, and through sharing data, experience and lessons learned in handling complex TBI datasets. The Data Management and Analytics WG has been advancing this agenda through work on a variety of topics that potentially offer benefit to the TBI research community.

Progress 2016 to 2018

The WG convened as two parallel subgroups over the period from 2016 to 2018.

The Data Analytics WG

Work in this subgroup focussed on:

- Preparing a series of TBI methods papers for a supplement in the Journal of Neurotrauma
  Pooling methodological expertise in TBI is a clear win from the InTBIR collaboration. This project is at an advanced stage. Topics include: Biomarkers for TBI, Prognostic models, Subgroup analyses, Missing data, and Study design

- Formulating a process for joint analyses of data from InTBIR projects.
  Data sharing between projects appears to be a simple and direct way in which joint research could be conducted. However, discussion within the WG has shown that in practice there can be substantial barriers to this process. WG discussion therefore has concentrated on alternative ways of conducting joint analyses. The result was a proposal for federated learning: a two-step process, which involved first analysing each study locally using the same analytical approach, and second pooling the results into meta-analysis. Importantly it was demonstrated that the statistical power of a two-step process was similar to that of simply analysing aggregated data. The two-step process is an important concept that avoids the difficulties that may be encountered in transferring data. There are three concrete projects ongoing on this topic: federated analysis of the effect of anti-platelets and anti-coagulants on outcome in TRACK-TBI and CENTER-TBI, federated analysis of the effect of sex on outcome in TRACK-TBI and CENTER-TBI; a paper on the federated learning approach and its advantages and disadvantages.

- Comparative Effectiveness Research questions that could potentially be addressed within InTBIR
  The aim was to identify questions that cannot be satisfactorily answered from individual studies but potentially can be addressed by joint analyses. These are clinically important issues that benefit from increased statistical power through collaboration between projects. Through surveys among the InTBIR studies on the data collected and a-priori specified research questions, the six top questions were identified:
  (1) Routine follow-up versus no follow-up for mild TBI
  (2) Early resection versus late.
  (3) Continuous CSF diversion versus other strategies for managing ICP.
  (4) Hyper-osmolar therapies vs mannitol
  (5) Prophylactic hyper-ventilation vs other therapies
  (6) Rehabilitation intervention for post concussion symptoms versus standard monitoring

- Data dashboards

     The aim was to collect demographic and clinical descriptors from studies and present these in an accessible form, that would potentially be useful for stakeholders and other researchers. Summaries of data available from ten TBI projects were developed and are posted on the InTBIR website. Data included the total number of cases and domains of data collection for each project and breakdowns of age and gender.

Data Management WG

The main topics that have been addressed by this group are:

- Outcomes used across InTBIR projects.

     Establishing the extent of shared use of common data elements (CDE) and other variables is helpful in understanding the potential for joint analyses across InTBIR studies. A survey was carried out focussing on the outcomes used in InTBIR projects. The work found that projects were using 119 outcomes that are in the CDEs; the most commonly assessed domains are global outcome, neuropsychological impairment, health-related quality of life, and TBI symptoms. Although, a wide variety of assessments are employed, there is substantial overlap in the domains assessed; the main divide is between tools used in adult and pediatric studies. The availability of information concerning outcomes has proved useful in further planning of collaborative research, including the development of the Genetic Associations in Neurotrauma (GAIN) consortium project. This topic could also be used to inform future versions of the CDE's.

- Data quality survey

     A survey was undertaken in 2016 of steps taken in InTBIR projects for ensuring data quality. The survey identified core methods used by projects and established that there was a gap in the availability of documentation on best practices in data curation for TBI projects.

- Data Acquisition, Quality and Curation in Observational Research Designs (DAQCORD)

     The DAQCORD project began in 2017, and is developing a set of data quality indicators designed for complex observational databases. The project has grown out of experiences with data curation within InTBIR, and potentially the advice generalizes to topics beyond TBI. The results potentially serve as 1) a guide for designing studies, and 2) a self-assessment tool and standardized report.   The WG organized a Delphi process to select appropriate items for the tool, and held a consensus meeting in Bethesda in 2017.

Opportunities and priorities for the WG in 2019

A number of target WG activities were discussed at the InTBIR Annual Meeting in Brussels and in a subsequent teleconference on 3rd December 2018. These include finalizing ongoing projects within existing resources, work that could be undertaken if administrative support was available, and ambitious ideas for research collaboration that potentially require additional funding.

TBI Methods papers
Finalizing these papers is regarded as a high priority, and an important contribution to the field. There was discussion on whether these papers could more strongly be presented as written on behalf of InTBIR.

InTBIR Infographic
An infographic describing the main features of participating InTBIR projects would help to promote the research activity to funders and outside bodies. This can build on the substantial work that has already been done to create data dashboards.

Data Dictionaries
Data dictionaries are a valuable resource because they define in detail the variables available within a project. The WG discussed first collating dictionaries from projects and then mapping these to the common data elements framework. Collecting data dictionaries should be fairly straightforward, but mapping these, though worthwhile, is a time consuming exercise. Some models were available in work done for the FITBIR database, the development of Metadata for TED project, and the mapping exercise that had been conducted for InTBIR outcomes.

Joint analyses and cross-study questions
The opportunity for joint analyses on questions that cannot be addressed by single studies is a key component of InTBIR. Discussion identified a range of topics that might benefit:

Comparative Effectiveness Research: In addition to the work already done developing questions for CER, there are opportunities for other work capitalizing on the InTBIR resource, such as comparison of pharmaceutical treatments in mild TBI.

TBI Genomics: The GAIN study is an ambitious project that will use data from InTBIR projects to obtain sufficient numbers to carry out the first genome-wide association study (GWAS) in TBI. This project is ongoing and could form a model for conduct of joint analyses on other topics.

TBI across the lifespan: Characterizing TBI across age groups – paediatric through to adult – would have obvious potential value. It represents a challenge for harmonizing the data collected in projects.

TBI Prognosis: Clear opportunities exist for collaboration on developing prognostic models in TBI using InTBIR resources. The IMPACT prognostic model and the 5P prediction chart are well-developed approaches that could be applied in other studies. The findings from the TBI-Prognosis study will also inform this area when results become available.

Biomarkers and Imaging: Discussions on these topics are ongoing in other InTBIR WGs.

DACQORD project
The steering committee for the project continues to have regular teleconferences with the aim of concluding the initial phase of the project. Analysis of the third round of the Delphi process has been completed, and a final selection of items has been made. The aim is to prepare a publication on the first phase of the project and beta-test the tool on several research studies.

Main aims for 2019

- Create an overview of the data available InTBIR studies and prepare summary infographics for the website.

- Formulate a strategy for generating and coordinating questions for joint analyses and facilitate implementation of cross-study research.
- Complete the first phase of the DAQCORD project, including a publication on the work, and move on to development of applications of the tool.