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The *BrainIT* Group: concept *and* current status 2004

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Summary

Introduction. An open collaborative international network has been established which aims to improve inter-centre standards for collection of high-resolution, neurointensive care data on patients with traumatic brain injury. The group is also working towards the creation of an open access, detailed and validated database that will be useful for hypothesis generation. In Part A, we describe the underlying concept of the group and it's aims and in Part B we describe the current status of the groups development.

Methods. Four group meetings funded by the EEC have enabled definition of a "Core Dataset" to be collected from all centres regardless of specific project aim. A form based feasibility study was conducted and a prospective data collection exercise of core data using PC and hand held computer based methods is in progress.

Findings. A core-dataset was defined and can be downloaded from the *BrainIT* web-site (go to "*Core dataset*" link at: www.brainit.org). A form based feasibility study was conducted showing the overall feasibility for collection of the core data elements was high. Software tools for collection of the core dataset have been developed. Currently, 130 patient's data from 16 European centres have been recruited to the joint database as part of an EEC funded proof of concept study.

Interpretation. The *BrainIT* network provides a more standardised and higher resolution data collection mechanism for research groups, organisations and the device industry to conduct multicentre trials of new health care technology in patients with traumatic brain injury.

Keywords: Head injury; multi-centre network; health technology assessment; neurointensive care; ICP monitoring; cooperative network.

Part A: *BrainIT* group concept

Head injury has devastating economic and social consequences both to the victim and to the society that supports the victim [1]. When assessing head injured patients' outcome from new therapies or the application of new monitoring devices, a large number of patients are required [4]. Recruiting patients from multiple centres will significantly reduce the time to assess new therapy and monitoring. However, despite the existence of guidelines for the management of severely head injured patients [2], this group of patients is subject to considerable variability in care [3]. As a first step towards improving management standards in this population, both the inter and intra-centre variability in the management and treatment of these patients needs to be assessed on a multi-national basis, and to do so requires a more standardised and higher resolution methodology for acquiring patient management and monitoring information.

Group formation

The idea for the Brain Monitoring with Information Technology (*BrainIT*) group came from discussions arising during the 10th International Symposium on Raised Intracranial Pressure and Neuromonitoring in Brain Injury held in Williamsburg, USA in May 1997. A few participants at this meeting, with a specific interest in neuro-monitoring, agreed that a more open and collaborative approach to the assessment of new monitoring technology would be a more efficient approach then continuing our current practice of conducting small scale, single centre studies. From those initial meetings in Williamsburg, a web site was setup (www.brainit.org) and from the interest generated, it became clear that *many* were interested in the concept of an open collaborative approach to developing standards in this area. Currently there are over 100 members from 25 countries who have registered interest in the group via the website. It is possible to summarise the interests of the group into three main aims:

The main aims of the group are:

1. To develop and disseminate improved standards for the collection, analysis and reporting of intensive care monitoring data collected from brain injured patients.
2. To provide an efficient multi-centre infra-structure for generating quality evidence on the utility of new forms of intensive care monitoring and methods for improving the care and outcome of brain-injured patients.
3. To develop and use a standardised database as a tool for hypothesis generation and the development, testing and validation of new data analysis methodologies.

The BrainIT *group approach – what are the differences?*

The Ethos of the *BrainIT* group is one of fostering open and free collaboration. The approach used, which we believe is novel in this field of medicine involves the following key elements:

1. *Only* high-resolution minute-by-minute monitoring and detailed management data is collected using computer based data collection tools. A basic set of data collection software tools are provided to all data contributing members free of charge. In addition to the free tools offered, the group is collaborating with industry on the development of more sophisticated data collection technology. A technical sub-group works towards developing tools and methods to assist with standardising data collection, analysis and database tools across centres.
2. A project-by-project based collection of data, where members voluntarily donate their time and effort towards collection of data for specific projects in which they are enrolled. The BrainIT group Internet based facilities (Web page and Forum) allow members either individually or in groups to form their own projects, enlist interest from other members, attract grant funding and manage their own project. Individual project PI's are responsible for project management, funding and publication of their results.
3. The data model used differs from previous collaborative groups working within the field of traumatic brain injury in that data collected as part of individual projects is also donated to a joint database. Data collection tools used in projects collect, as a minimum, a "Core Dataset" which once collected and anonymised is added to a common database. The common database will be openly accessible, through the Internet, to all "Data Contributing" centres. The database will be able to be queried over the Internet and datasets of interest can be downloaded to any member who has also contributed data to the database.
4. A steering group with overall responsibility for group management, does not dictate project selection but can help with project design if required. An important function of the steering group is to track data analyses being performed on the joint database to ensure a high level of analysis is maintained. Only officially registered and planned analyses conducted on "validated" data can lead to publication and presentation at meetings. The steering group will ensure that database access, analysis and publication criteria are adhered to.
5. An important element of the BrainIT group approach is to continuously work towards the development of improved "standards" for multi-centre collection and analysis of data in this patient population. We have achieved a key first step in this process by defining minimum data validation standards and have developed a mechanism for checking the validity of data against original documentation using regionally hired "data validation" staff. The BrainIT network provides an infrastructure supporting data quality control for trials of management or monitoring similar to that required by the Pharmaceutical industry in the conduct of trials of new drugs.

A detailed BrainIT Group "Operational Strategy" document can be viewed and downloaded from the group web-page (www.brainit.org → go to Operating Strategy Link). A sub-set of this document is summarised below. Database access and joint publication criteria can be viewed and downloaded from the group web-page (www.brainit.org → go to Operating Strategy Link) (Fig. 1).

Regional coordination

Each region (usually one but occasionally more than one country sharing a common language) with more than one neuro-intensive care centre contributing data to the *BrainIT* database has a *regional* coor-

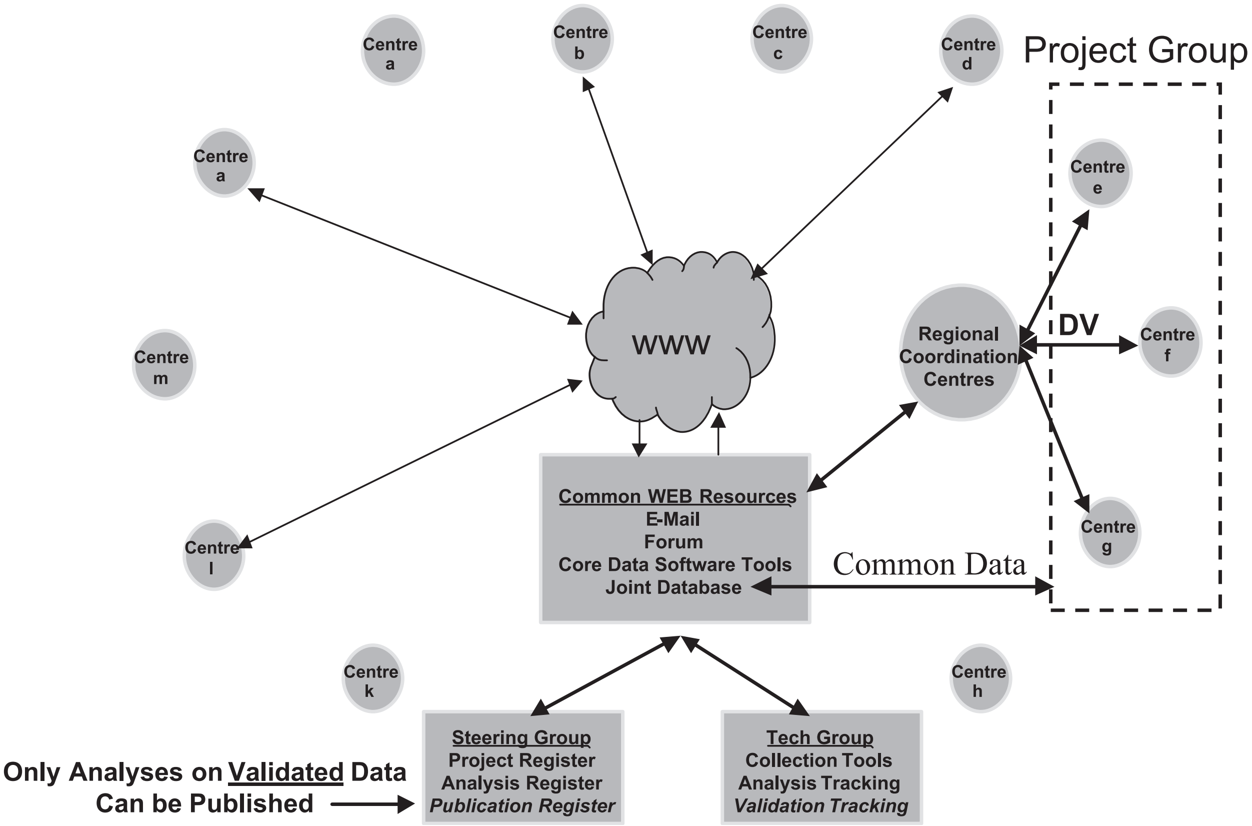

Fig. 1. *Graphical Representation of BrainIT Group Concept*. Using the Internet as a mechanism linking individual investigators, the *BrainIT* group provide web resources (mailbase forum, discussion forum and free access to common data collection tools) to foster formation of project groups. Project groups are responsible for managing, funding and publishing their own work. Collected data is anonymous and donated to a common database for the benefit of the entire network. Any data-contributing centre can access the entire common database useful for post-hoc hypothesis testing and generation. Only "Validated" data can lead to publication and the BrainIT group provides a region-by-region based mechanism for hiring and managing Data Validation (*DV*) staff to validate project group data. Validation costs will be generated from a range of resources, including a contribution from grant funding sourced from individual project group grants. Project and analysis duplication is prevented by a Steering group maintaining and managing a project and analysis register. A technical group helps develop data collection, analysis and database tools

dinator providing coordination support for centres within their region. They also hire, train and support "Data Validation" staff (funding dependant), used to travel to local centres to train local centre staff in the use of *BrainIT* data collection and analysis tools, as well as, conducting data validation exercises. *See the Operational Strategy Document for an overview of BrainIT Data Validation Approach.*

Group funding

The major resource cost of the BrainIT group is for the hiring and travel support of Data Validation Staff. These staff are currently grant funded. Grant funding will, for the most part, remain the predominate source of support, however, other sources of support are being considered including by industry and public donation. As the group expands and more project groups form and bring in their own funding, it may be possible to create a central DV staff resource fund based upon a fixed percentage of project funding.

Part B: current status 2004

Paper-based feasibility study

A paper form based feasibility study was conducted. Eighteen centres (82%) returned completed forms by the set deadline. Overall the feasibility for collection

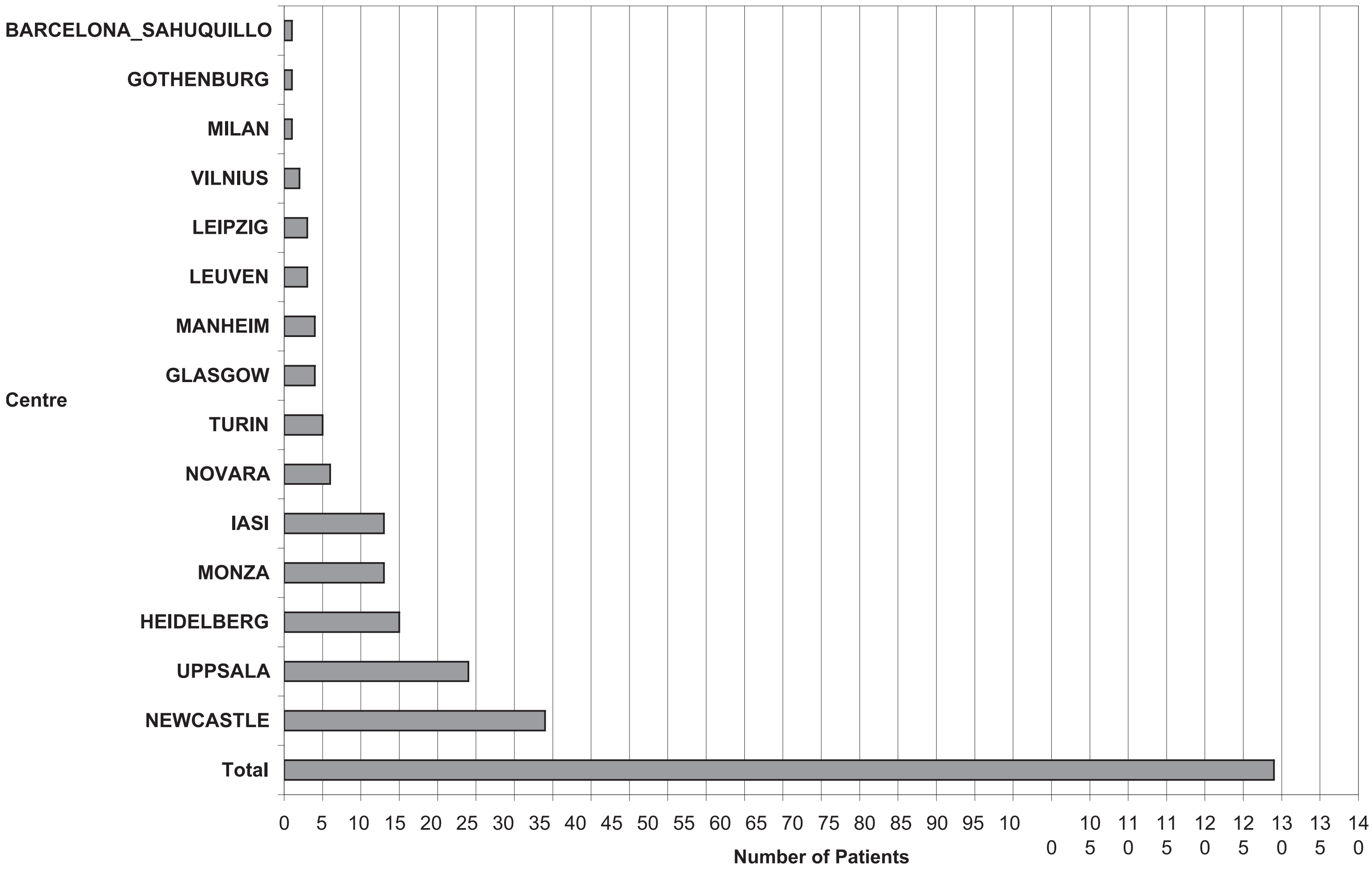

Fig. 2. Graph showing current recruitment by centre for the EEC funded proof of concept study

of the core data elements was high with only 10 of the 64 questions (16%) showing missing data. Of those 10 fields with missing data, the average number of centres not responding was 12% and the median 6%. An SQL database to hold the data has been designed and implemented Software tools for collection of the core dataset have been developed. Ethics approval has been granted for collection of multi-centre data as part of a pilot data collection study.

Proof of concept pilot data collection study

In October 2002, the *BrainIT* group received 3 year EEC research infrastructure support under the Quality of Life and Management of Living Resources Programme. This support enabled:

- Creation of a "Regional" Coordination Structure consisting of 6 country-specific coordinating centres via which data validation staff are hired and regional project and data acquisition is coordinated.
- Hire staff to Develop, Install and Train local centres in new IT tools to collect core dataset
- Prospectively collect (*and Validate using specially hired and trained staff*) at least 5 patients/year of core data from 30 centres across 13 EEC countries:
  - UK (7), Germany (4), Italy (4), Sweden (3), Spain (3), Lithuania (2), Belgium (1), Netherlands (1), France (1), Denmark (1), Switzerland (1), Czech (1), Romania (1)

Figure 2 above shows the current status of patient recruitment.

Discussion

This paper has outlined the concept underlying the BrainIT group approach to collaboration and describes the group's efforts to define and test the feasibility for collection of a core-dataset. The current status of a prospective proof of concept data collection study is described. Collectively working towards raising data collection and analysis standards is a critical aim of the BrainIT group and the current work towards defining minimum data validation standards and developing a mechanism for checking the validity of data against original documentation using regionally hired "data validation" staff will provide an infrastructure supporting data quality control for trials of management or monitoring similar to that required by the Pharmaceutical industry in the conduct of trials of new drugs.

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