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The brain monitoring with Information Technology (BrainIT) collaborative network: data validation results

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Abstract
Background The BrainIT group works collaboratively on developing standards for collection and analyses of data from brain injured patients towards providing a more efficient infrastructure for assessing new health technology.
Materials and methods Over a 2 year period, core dataset data (grouped by nine categories) were collected from 200 head-injured patients by local nursing staff. Data were uploaded by the BrainIT web and random samples of received data were selected automatically by computer for validation by data validation (DV) research nurse staff against gold standard sources held in the local centre. Validated data was compared with original data sent and percentage error rates calculated by data category.
Findings Comparisons, 19,461, were made in proportion to the size of the data received with the largest number checked in laboratory data (5,667) and the least in the surgery data (567). Error rates were generally less than or equal to 6%, the exception being the surgery data class where an unacceptably high error rate of 34% was found.

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Conclusions The BrainIT core dataset (with the exception of the surgery classification) is feasible and accurate to collect. The surgery classification needs to be revised.

Keywords Clinical network · TBI · Methodology · Internet

Background

The BrainIT group works collaboratively on developing standards for collection and analyses of data from brain injured patients towards providing a more efficient infrastructure for assessing new health technology (http://www.brainit.org). The group have defined a core dataset collected using PC based tools as part of an EC funded study (QLGT-2000-00454). A series of meetings spread over one year enabled the group to define a minimum set of data that can be collected from all patients with traumatic brain injury (TBI), which would be useful in most research projects conducted in this population of patients. The core-dataset includes nine categories:

1. *Demographic* and one-off clinical data (e.g.: pre-neurosurgical hospital data, first and worst CT scan data etc.),
2. *Daily management* data (e.g.: use of sedatives, analgesics, vasopressors, fluid input/output balance etc.),
3. *Laboratory* data (e.g.: blood gas, haematology, biochemistry data etc),
4. *Event* data (e.g.: nursing manouevres, physiotherapy, medical procedures (line insertion), calibrations etc.),
5. *Surgical* procedures,
6. *Monitoring* data summary (e.g.: type and placement location of ICP sensor, BP lines, etc.),
7. *Neuro Event* Summary (e.g.: GCS scores, pupil size and reactivity),
8. *Targeted Therapies* (e.g.: mannitol given for raised ICP, pressor given for arterial hypotension etc.),
9. *Vital monitoring* data (e.g.: minute by minute BP, ICP, SaO_2 etc.).

A three year follow up EC funded study (QLGC-2002-00160) enabled the group to develop IT methods to collect the core dataset and to assess the feasibility and accuracy for collection of this core-dataset from 22 neuro-intensive care centres [1]. Data validation research nurse staff were hired on a country by country basis to check samples of the collected data against gold standard clinical record sources in order to quantify the accuracy and therefore the feasibility for collection of the BrainIT core-dataset using the group IT based data collection methods. This paper describes the results of analysis of 200 patients data in whom validation data was also acquired independently by data validation research nurses. The error rates classed by data category are presented and discussed. These validation results calculated on a subset of patients provides an estimate of the data quality for future analyses on the full patient cohort of 350 patients collected as part of the EEC funded study.

Materials and methods

Over a 2 year period, core dataset data (grouped by nine categories: as presented in the background section) were collected from 200 head-injured patients by local nursing staff.

Clinical data is entered by bedside nursing staff on hand held PDA's which, in collaboration with Kelvin Connect Ltd [2], implemented the BrainIT core dataset definition in a flexible and easy to use hand-held PDA based system. A training course was held for the data validation nursing staff in Glasgow on the use of this data collection instrument which supported data entry in six European languages. An anonymisation routine removed patient identification elements from the collected data and labelled the patient data file with a unique BrainIT study code generated from the BrainIT web-site. A local database held in each centre linked the anonymised data to local centre patient id information which was needed during the data checking stage of the study. Anonymised data was uploaded via the BrainIT web upload services. A server side data converter tool converts data from centre based format into BrainIT data format generating nine data category files which are imported into the BrainIT database. A validation request tool samples 20% of the data sent for each data category and generates a validation request file listing the time-stamps and data items to be checked by local data validators. Data validators enter into a *data validation tool* the requested data items for checking from source documentation held in each local centre. Validation data is uploaded to the BrainIT data coordinating centre via the website and using data validation checking software tools, the validated data is checked against the data items originally sent from which percentage accuracy data is calculated. As part of this validation process, in addition to the categorical and numeric clinical data being checked for accuracy, we also assessed the minute by minute monitoring data too. Random samples of monitoring data channels uploaded (e.g.: ICP, SaO_2) were selected and validation staff asked to manually enter the hourly recorded values from the nurses chart (or local gold standard data source) for the first and last 24 h periods of bedside monitoring for a given patient for a given channel. These "validation" values could then be compared with a range of summary measures (e.g.: mean, median) from the computer based monitoring data acquired from the patient.

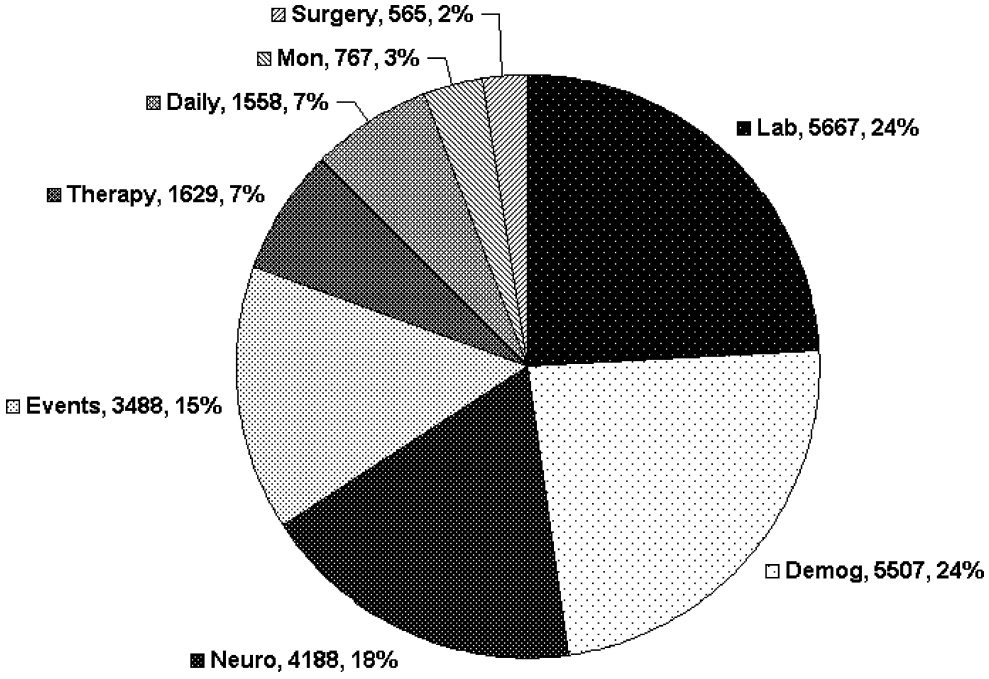

Fig. 1 Pie chart showing the distribution of the 19,461 data validation comparisons which were made in proportion to the size of the data received with the largest number checked in laboratory data (5,667) and the least in the surgery data (567)

Results

In total, 19,461 comparisons were made between collected data elements and source documentation data. The number of comparisons made per data category was in proportion to the size of the data received for that category with the largest number checked in laboratory data (5,667) and the least in the surgery data (567) (Fig. 1). Table 1 summarises error rates by data class. Error rates were generally less than or equal to 6%, the exception being the surgery data class where an unacceptably high error rate of 34% was found.

In the surgery data category, nursing staff had to choose surgical procedures from a fixed list of procedure types: *(1) ICP placement, (2) Evacuation of Mass Lesion, (3) Elevation of depressed skull fracture, (4) Removal of foreign body,(5) Anterior Fossa repair for CSF Leak, (6) Placement of Extra Ventricular Drain, (7) Active external decompression (with bone removal and duroplastia), (8) Other*. This classification system was used in an attempt at simplification and reducing the burden of data entry. However, through discussions with local nursing and data validation staff it was found that there was particular confusion over *when* to record ICP sensor placement and the presence of skull fractures as the primary surgical procedure. Typically, these procedures occur during the same operative procedure as for example "evacuation of mass lesion". Confusion over coding these two procedures accounted for the majority of errors in this data category.

We also checked the detection rate of acute events (e.g.: nursing management, physiotherapy, blood samples etc.). It was found that short duration events were rarely missed but longer duration events such as transfer to CT or theatre were more likely to be not recorded. Through discussions with local nursing and data validation staff it is believed that the intense nursing activity just prior to and following a transfer is more likely to lead to omissions in recording these events on research systems.

Figure 2 shows a scatter plot of computer monitored minute by minute ICP data averaged over 60 min (ICPavg) plotted against nurses chart end hour values (ICPvalid) collected by the data validation nurses. There is a good correlation between the two sets of data with a linear

Table 1 Percentage error rate by data type class with description of common error types

Data class	Error rate (%)	Common errors
Laboratory	2	pCO_2, FiO_2 value
Demographic	4	Monitoring on arrival at neurosurgery, intubation on arrival at neurosurgery
Neuro observations	5	Pupil Size, GCSv (code 1 Vs Unknown)
Monitoring summary	5	ICP type, ICP Location
Daily management summary	5	Infusion type (bolus vs infusion or both), drug number (1, > 1)
Targeted therapy	6	Non-standard target, no Target specified
Surgeries	34	ICP placement, Skull no., mass lesion

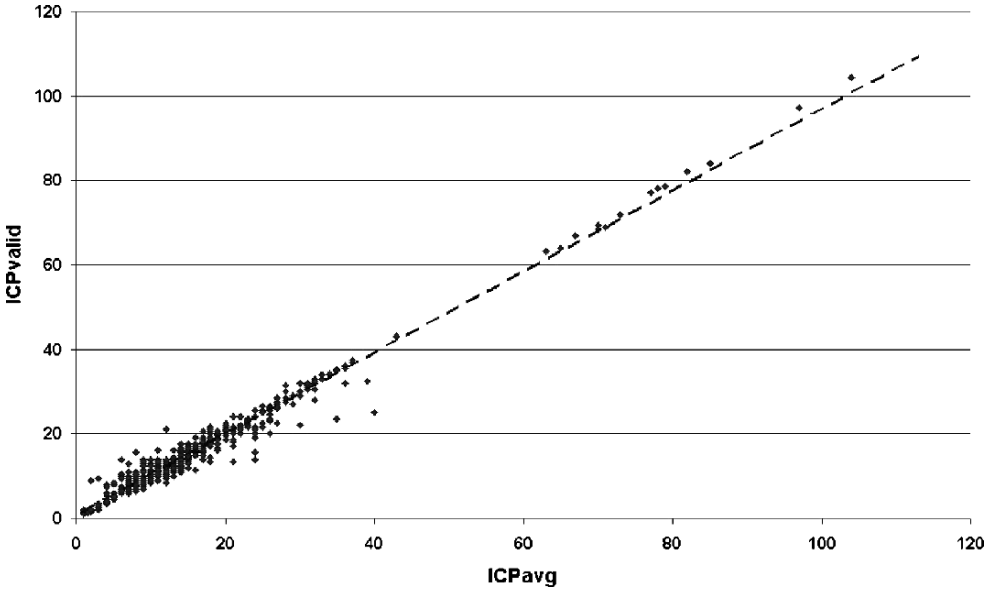

Fig. 2 Scatter plot of computer monitored minute by minute ICP data averaged over 60 min (ICPavg) plotted against nurses chart end hour values (ICP-valid). Linear regression best fit R^2 value=0.9773

regression best fit R^2 value of 0.9773. Figure 3 is an Altman and Bland plot showing the average bias (−0.15 mmHg) and 95% confidence limits (0.12, −0.45) for the computer monitored end hour averaged data Vs the nurses chart end hourly recorded values collected by the validation nurses.

Discussion

Good clinical practice dictates that as part of clinical trial design, acquired data must be checked for accuracy against gold standard data sources. This is often implemented through either employing a contract research organisation or independent research nurse staff to perform this duty. In large multi-centre clinical trials, costs to hire research nurse data validation staff can become prohibitively expensive and feasible only if significant industry or research council funding support is provided. Now with the adoption of the new medical device standard ISO-14155, even small medical device studies are expected to provide some form of check on the accuracy of data.

To our knowledge, this study conducted by the BrainIT group is one of only a few projects to attempt to prospectively assess the data capture error rate within an academic environment [4]. We have shown that it is feasible to collect the BrainIT dataset from multiple centres in an international setting with IT based methods and the accuracy of the data collected is greater than or equal to 94%, with the exception of the surgery data type which

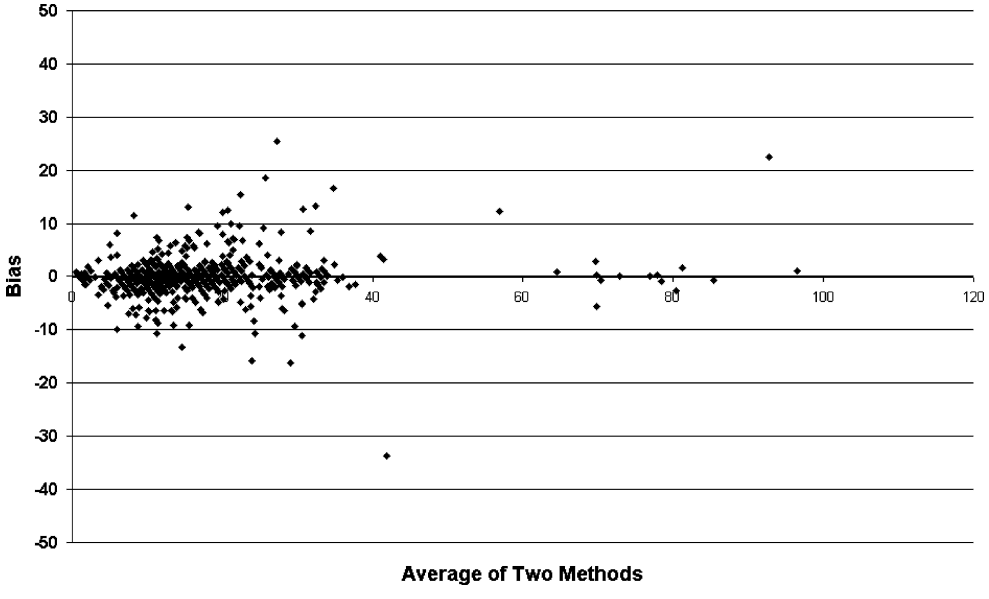

Fig. 3 Altman and Bland plot showing the average bias (−0.15 mmHg) and 95% confidence limits (0.12, −0.45) for the computer monitored end hour averaged data Vs the nurses chart end hourly recorded values collected by the validation nurses

must be revised. We have also shown that computer collected minute by minute vital signs data, summarised as end hour averages, correlated well with nursing chart end hour recordings. This allows the end hour averaged computer records to be used in database analyses assessing nurses chart recorded detection of events with computer based sampling. These validation results calculated on a subset of patients provides an estimate of the data quality for future analyses on the full patient cohort of 350 patients collected as part of the EEC funded study which was conducted over the same time period by the same staff using the same data methods. Clearly though, future data collection projects will generate datasets under differing data collection conditions and will require a separate validation stage if we wish to maintain our confidence in the level of data accuracy. However, the costs of maintaining such a data validation network is prohibitively high. To maintain a full time data validation nurse within each participating country costs in excess of 1 Million Euro's per year. Such large running costs for an academic network is not sustainable in the long term and a more cost-effective solution for data validation must be found.

One promising approach being adopted by the BrainIT group is developing collaborative research with experts in Grid based secure access technology. Grid technology covers more than just access to networks of high end servers in order to solve computationally intensive problems. There is a considerable amount of expertise and middleware software solutions now available that provide secure access to distributed medical datasets so that the right people see the correct data in the appropriate context [3]. Such an approach, once local and national IT policy staff are satisfied with the security, will enable remote data validation systems to directly query hospital based gold standard data sources for data checking. Clearly some data validation staff will still be required to support system queries but increased use of automatic data validation procedures should significantly reduce the cost burden to conduct multi-centre clinical trials. Towards this end, the BrainIT group as part of an EEC funded framework VII project plan to assess such an approach in 6 neuro-intensive care centres equipped with the latest Grid technology.

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Conflict of interest statement We declare that we have no conflict of interest.

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