**The EpiNet Project - Invitation to Participate in Investigator-led Clinical Research**

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**Formation of EpiNet Study Group.**

In 2007, several neurologists published in this journal a short paper under the provocative title: ‘How to get the answer to nearly everything.’ (Bergin et al, 2007) Subsequently, a group of epileptologists established the ‘EpiNet Study Group.’ Meetings of the group were held at the 28th International Epilepsy Congress in Budapest in July 2009, and at the American Epilepsy Society meeting in Boston in December 2009 to map out a way forward. We are establishing an international epilepsy database that can be accessed via the Internet, and intend to use it to perform observational studies, and to organise clinical trials into the management of epilepsy.

The group is keen to recruit new participants.

**New Zealand Pilot Study**

From June 2007 until December 2008, the New Zealand League against Epilepsy undertook a pilot study in which the methodology underpinning this approach was tested. This has now been reported (*Epilepsia, published on line, 3rd Nov 2009*). In summary, a database was created that could be accessed via the Internet by any neurologist or paediatric neurologist in New Zealand. Investigators entered patient data and follow up data directly into the study database. 137 patients with epilepsy were registered via the Internet into the on-line database during the first 6 months of this study. In a proof-of-concept study, an algorithm was written to select patients who had failed to respond to the first anti-epileptic drug (AED) prescribed, and 14 patients were successfully randomised to receive a different AED. Randomisation of suitable patients was performed via the Internet, while the patients were still in the routine clinic.

**International Database**

Following the success of the New Zealand Pilot Study, a new database has been constructed so that investigators can enter data directly into the database from anywhere in the world. We have constructed an on-line questionnaire, which is both user-friendly and comprehensive. Although primarily for research purposes, the database is also designed to provide a useful clinical tool for clinicians who use it. All information entered is made available in summary form, so that it can be printed out and given to the patient or primary caregiver, and put in the patient’s notes. In addition, clinicians will be provided with an on-line database of all their patients. Feedback has been obtained regarding the database and questionnaire from neurologists practicing in New Zealand, Australia, Great Britain, Italy, Belgium, France, Switzerland, the United States, Jamaica, Canada, India and Kenya.

This website will be able to be viewed at [www.epinet.co.nz](http://www.epinet.co.nz) from May 2010.

**International pilot study**

Neurologists and paediatric neurologists from countries in Europe, North America, Asia and Oceania have agreed to participate in an international pilot study. Doctors will enrol patients into a patient register over a 6-month period. Patients will not be entered into any trials in this particular phase of the project, but follow up data will be collected whenever patients are seen again. This study is being undertaken to extensively test the web-based platform. We will be seeking feedback from investigators to ensure that the website will be suitable for research purposes. We will then set up registers of patients with specific clinical problems and epilepsy syndromes, while developing protocols for clinical trials, and dealing with regulatory issues and ethical concerns.

**Security of data**

Great care has been taken to ensure that the database is completely secure; it is accessed via a secure website and data is encrypted. Access to the website is password protected. The database is housed on a separate Local Area Network (LAN) on a secure server in Auckland, New Zealand. These features surpass the minimum requirements for transfer of personal medical information.

Approval from each countries privacy commissioner or equivalent agency, and local institutional review bodies will be sought before any data is transmitted. Patients need to give their explicit informed consent before any personal data can be transmitted.

**Validation**

We need to ensure that all information entered into the database is accurate, and that follow-up data is faithfully recorded. We therefore plan to undertake a validation study, in which we will circulate a set of case histories to all investigators. We will determine how much variability there is in responses and will measure kappa statistics. This will enable us to accredit investigators, and confirm that all those participating are ‘speaking the same language.’ We anticipate that similar accreditation exercises will take place when specific trials are established in the future.

Neurologists who do not want to participate in the validation process will still be able to use the website. However, information on these patients will not be entered into the communal research database until the doctors have been accredited as investigators.

**Memorandum of Understanding.**

We want this project to be a true collaboration with all investigators taking ownership of the project. To this end we have composed a series of bylaws or “rules of engagement.” These are available on the website. Important principles underlying the project include the following:

* All data belongs to the collaboration as a whole
* The project will be overseen by a steering committee
* Any participants will be able to propose a trial or register, and apply to the steering committee to review data regarding a particular patient group
* All studies will get approval of local ethics committees / institutional review boards
* All papers will be written on behalf of the EpiNet Group.

An interim steering committee has been formed, to oversee the project until the end of 2011.

This group comprises:

* Peter Bergin, (Chairman, New Zealand)
* Ettore Beghi (Italy)
* Sam Berkovic (Australia)
* Wendyl d’Souza (Australia)
* Jorge Burneo (Canada)
* Mark Richardson (Great Britain)
* Lynette Sadleir (New Zealand)

We would encourage others who have an interest in performing investigator-initiated clinical trials to contact us and join the collaboration.

**Disclosures:**

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

None of the authors has any conflict of interest to disclose.

**References**

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