

EpiNet Study Group - Who are we?

The EpiNet Study Group is a group of doctors and associated research assistants who have an interest in epilepsy, and who intend to join together to undertake research into the optimal management of patients with epilepsy.

Objective

We intend to use the Internet to establish a multi-centre, international data base that will be used to establish registers of patients with epilepsy, and to co-ordinate clinical trials into the management of epilepsy. The aim of the collaboration is to obtain good quality evidence to guide the clinical practice of the management of epilepsy.

Underlying Principles

This is a non-profit making venture. The principles underlying the project are:

- 1) We will share data with the primary purpose of improving the care of patients with epilepsy.
- 2) All data produced by the research will belong to the consortium of investigators (the EpiNet study group).
- 3) Access to the data will be controlled by the investigator who entered the data.
- 4) All research will be performed to the highest ethical standards, and consent for all studies will be obtained from appropriate ethics committees.
- 5) The well-being of the individual patients participating in the project is paramount.
- 6) The work of the EpiNet study group will be fully transparent. As much as possible, decisions will be made by consensus. However, a steering committee will oversee the project, and will make a final decision if there is disagreement.
- 7) Research will be performed independently of pharmaceutical companies. Specifically, pharmaceutical companies will not be involved in the design of trials or have any say in decisions regarding publication or authorship of papers.
- 8) Participation in the project is entirely voluntary. Doctors are not obliged to enrol patients in studies, and patients are not obliged to participate. Patients are free to choose not to participate; *however*
- 9) Doctors / researchers will recognise that accurate data entry and complete follow up are required to ensure optimal quality of the research. Doctors will therefore only

participate in studies if they expect to be able to complete specific requirements of the particular study.

Goals

- 10) The goals of the project are:
 - (i) To set up a prospective register of patients with epilepsy for research projects
 - (ii) To undertake randomised controlled trials to determine which of several alternative treatments is optimal for patients with particular characteristics. Randomised controlled trials will be performed in accordance with the CONSORT guidelines.
 - (iii) To ultimately provide information regarding best available care to individual doctors

How will we perform the research?

- 11) Data regarding patients will be entered into an Internet-based database. The database will be secure and password protected. Access to the database will be restricted to members of the study group. Transmission of patient data will only be permitted if the appropriate ethics committee and / or institutional review board approves this.
- 12) All patients will be given a unique study number which will be used for identification purposes. Personal data may be collected, but will not be transmitted without the approval of the relevant ethics committee.
- 13) It will **not** be possible for investigators who are not involved in the patient's care to access the individual patient's identifying data, unless the patient gives specific authorisation.
- 14) It will be possible for administrators to identify the doctor who has entered a specific patient, though not the personal data regarding this patient. It will be possible for administrators to identify all patients entered by a specific individual and / or department, and compare results for these patients with the entire cohort of a particular study or with other patients with similar diagnostic criteria, for the purposes of audit.
- 15) Each investigator will be able to identify all patients for whom they have entered data; this resource will therefore provide the investigator with a personal database. It will also be possible to provide larger scale databases to groups of investigators, if co-investigators agree; for instance, all patients registered from a specific centre, region or country. Access to this information will be controlled by the steering committee.
- 16) Randomised controlled trials will be initiated to address specific research questions. Any co-investigator is able to propose a randomised controlled trial, and have input into the design of the trial. Trials will be performed and reported in accordance with the CONSORT guidelines. To ensure important questions are addressed and participating

patients are not overburdened, the steering committee will ultimately determine the feasibility and appropriateness of a study, and determine the priority and timing of individual studies.

- 17) Studies may be blinded or unblinded.
- 18) Hard copies of data may be requested to be sent to a central agency for audit purposes. In these circumstances, personal identifying data will be removed, so that faxed data will be de-identified.
- 19) Investigators may be reimbursed actual costs of procedures and time involved in the research, but this will vary from trial to trial. Some studies are likely to provide no reimbursement of costs.
- 20) Information stored in the database will be able to be reviewed by investigators / co-investigators for research purposes. Any individual or centre can analyse and publish their own patients' data without steering committee approval, though they should acknowledge involvement of the EpiNet Study group. Co-investigators can apply to access the de-identified data in the larger database. Permission to access this information must be sought from the steering committee, and will not be unreasonably withheld.
- 21) Applications to review information regarding a specific patient group will be made public to all co-investigators.
- 22) All papers arising from this project will be written on behalf of the collaboration as a whole ("The EpiNet Study group"). A writing committee will be appointed by the steering committee for each paper arising from the work of the group. All doctors who have enrolled patients will be listed in papers reporting outcomes of clinical trials. Any doctor who has contributed more than 5% of patients participating in a particular study will be invited to join the writing committee

Informed Consent

- 23) Data regarding patients can be stored in the database without obtaining their explicit informed consent if the relevant authorities in each country (ethics committee, institutional review board and /or privacy officer) approve of this. Otherwise, data will only be transmitted after the patients or their legal guardians have given their informed consent.
- 24) Written informed consent will be required from a patient before he / she is entered into any randomised controlled trial
- 25) If parents have given consent for their children to participate, a new consent will be sought from the children when they reach the age of 16.

Obligations on Investigators / co-investigators

- 26) Doctors / researchers will enter data regarding patients in good faith, recognising that the value of the project depends on complete and accurate record keeping; therefore
- 27) Doctors / researchers will commit to filling in follow-up forms as required by study protocols. Doctors / researchers may be excluded from participation in further studies if they do not complete follow up forms appropriately.
- 28) Doctors / researchers will send hard copies of data to a central agency for external validation, as requested by the study protocols.
- 29) We encourage participation by as many doctors as possible; however, we recognise that it is critical that accurate information is entered into the database, and participation is therefore not an automatic right. Doctors / researchers may have differing levels of accreditation, depending on their level of specialisation. Levels of accreditation will be determined by the steering committee, or those to whom the steering committee delegates this authority.
- 30) Doctors / researchers will commit to retaining the primary data in an accessible manner for purposes of subsequent audit and meta-analyses.

Steering Committee

- 31) A steering committee will oversee the project.
Amongst other tasks, the steering committee will:
 - i) supervise the conduct of all studies. The steering committee may appoint separate committees for the oversight of any particular study.
 - ii) determine priorities of possible studies;
 - iii) consider any scientific project proposed by any member of the collaboration, and solicit questions to be addressed;
 - iv) determine, in conjunction with the trial coordinators, who should be accredited to participate in any particular trial;
 - v) determine rules regarding authorship of any papers.
 - vi) oversee funding of the project. For some studies, investigators may be required to approach public or private funding bodies. The steering committee will approach pharmaceutical companies, where indicated.