

Request from Dr Peter Bergin, President of the New Zealand chapter of the ILAE

A group of us in New Zealand want to determine if it is possible to coordinate randomised controlled trials using the internet. That is the final objective, but we need to work towards this goal in small steps. In the next phase, we are wanting to see whether a website we are developing could be used to identify patients with epilepsy who would be suitable for randomised controlled trials.

We are looking for international collaborators who would be prepared to register patients, and who also have sufficient enthusiasm to guide the study through the local ethics committee. At present, there would be no financial reward for participating, but participants would likely get to be authors on any papers produced. I would be happy to send over documents we will be submitting to the NZ Ethics committee, and to help with writing submissions for your committees.

Several of us in NZ wrote an article which has just been published in *Epilepsia* outlining the idea (*Epilepsia* 2007;48(7):1415-1417 – PDF available from PBergin@adhb.govt.nz)

Our idea is that doctors would log on to the website whenever they see a patient for whom they are unsure of the optimal treatment. The computer would have a series of checklists that would check immediately whether this particular patient met the criteria for any of the trials linked with the project. If so, the patient would be randomised there and then. Whether entered into a trial or not, follow up data would be gathered into a prospective database. This data would be available for review by any of the investigators participating in the study.

A group of us in New Zealand are undertaking a pilot study looking at this approach; we are randomising patients who have failed to respond to a first antiepileptic drug. They are being randomised to one of 3 different alternative drugs, depending on the seizure syndrome and the drug they have used previously.

We are now keen to move the project forward. In the next phase, we are wanting to identify approximately 20 different centres in various parts of the world where neurologists / paediatric neurologists will enter details of patients into the prospective register, using the on-line data collection system that we have developed. At this stage, we will not be performing any randomised controlled trials. However we hope to register 1000 patients who would be suitable for trials, (if the trials existed) - this would be an average of 50 patients per centre, assuming 20 centres. (approx 2 / week for 6 months) These would be patients where there is no evidence to tell us what is the best treatment - currently the majority of people with epilepsy. The intention of this phase is to show that this approach works. Once we had done this, we would plan to run randomised controlled trials. Any of the participants would be able to recommend a trial that they feel should be undertaken.

All the information entered for a participant's patients will be available to that doctor automatically, so the website will function as a database for any centre that does not already have one. Information on individual patients will be available whenever a doctor logs on again for that patient. This will provide a summary that will be particularly useful for complicated patients.

It is likely that the project would need approval of the local ethics committee, as patients / parents would likely need to give their consent to have their details sent over the internet to a

central server. (This is certainly the case in NZ.) However, information is encrypted and a secure website is used - similar to that used for internet banking. This has satisfied the New Zealand Multi-region ethics committee and the New Zealand Privacy commissioner, who have given nationwide approval for our pilot study. In the pilot study we are already running in New Zealand, it takes about 8 minutes to fill in the on-line form. Most of this could be done by a research assistant or nurse, though the details would need to be checked by a suitably qualified neurologist.

Would any members of the ESA be interested in taking part? So far I have had positive responses from centres in London, Wales, Cleveland, Belgium, Jamaica, Italy and India, in addition to local centres.

I would be very pleased to get any feedback ESA members are interested in giving, even if you are not interested in taking part

With best wishes

Peter Bergin
President of the New Zealand chapter of the ILAE