



**Minute of the meeting  
of the Ethical Committee of the M. Iashvili Central Children  
Hospital**

Tbilisi

30.07.2013

M. Iashvili Central Children Hospital ethical committee meeting minute #1/13.

The meeting was attended by 7 members of the ethical committee of M.Iashvili Central Children Hospital

**Chairman of the meeting:** Dr.Ivane Chkhaidze

**Secretary of the meeting:** Dr.Gvanca Jajanidze

**Agenda:**

To assess the importance of the study „Development of Integrated International Multicenter Internet-based Electronic Database of Epilepsy (EpiNet)“. Principal Investigator: Prof. N. Tatishvili. Head of Neuroscience Department of the M. Iashvili Children Central Hospital, Tbilisi, Georgia.

**Information was given:**

By Dr. Tamar Kipiani.

**The EpiNet project and Database**

The EpiNet study group has been set up to undertake investigator-led clinical research in epilepsy. The EpiNet study group comprises an international consortium of epileptologists and neurologists who intend to collaborate to try to learn more about the optimal clinical management of patients with epilepsy.

The EpiNet study group has created a secure, international epilepsy database that can be accessed via the internet. The database has been established to follow large groups of patients with specific types of epilepsy or specific problems.

### **Control of the data.**

Information regarding the EpiNet collaboration is available at the following website: [www.epinet.co.nz](http://www.epinet.co.nz). In addition, a demonstration questionnaire can be accessed at this website (Note that the formal EpiNet database is hosted on a secure site, but the demonstration site is in the public domain.)

### **EpiNet Database**

The website and database were developed by a New Zealand Information Technology company, 'Enigma', who are based on the North Shore in Auckland. Enigma have considerable experience using the Internet to collect data regarding patients' health issues, and using published guidelines to advise doctors regarding an individual patient's management

The EpiNet database is versatile, easy to use, and comprehensive. Information is collected according to a range of axes, including seizure type, electro-clinical syndrome, etiology, investigations, and treatment history. Information is also sought regarding other health issues that might impact on the prognosis of the epilepsy or its treatment

### **Open-ended EpiNet database**

We are now undertaken to the next phase of the EpiNet project. We have received approval from the New Zealand Multi-Regional Ethics Committee to develop the EpiNet database as an open-ended epilepsy database, into which doctors will be able to register any patient with epilepsy (MEC/11/EXP/070). We intend to follow patients indefinitely. Follow-up data will be collected whenever the patients are seen again.

The database that will be used for this next phase of the EpiNet project is the same database that has been used for the International Pilot study. Several changes have been

made to the EpiNet platform as a result of feedback we have received during the pilot study. We intend to make further modifications to the database and forms after the completion of the Pilot study. However, none of these changes involve any fundamental alteration to the structure of the database, but involve changes that will make the collection of the data faster and more user-friendly.

## **Research**

The study that is outlined in this document is purely observational in nature. Investigators will give whatever treatment they think is clinically indicated, and they will record this treatment and the response to the treatment in the EpiNet record. Investigators will not be instructed to give any particular treatment, and no clinical trials are included in this phase of the study.

Each patient is given a unique study number, which allows study organizers to interact with the recruiting doctors regarding particular patient's records, without disclosing personal details. In addition, this number means that hard copies of results of investigations can be sent to a central agency without any personal data needing to be transmitted. This will enable checks to be performed on the accuracy of data entered.

The database has been designed to identify patients who will be suitable for other research projects. Indeed, the entire EpiNet project has been established as a way to facilitate low cost, investigator-led randomised controlled trials. Investigators are therefore specifically asked if patients would be suitable for randomised controlled trials. We intend to write algorithms to identify patients who would be eligible for trials that we hope to undertake in the future; we would then contact the doctor who enrolled the patient (the primary investigator for that patient) and ask him or her to discuss the study with the patient. We do not intend to contact patients directly. We are not recording details of addresses, phone numbers or e-mail addresses within the EpiNet database, though investigators could, of course find these details from their own records.

The current application relates to the open-ended database itself, and any registries that are established with the EpiNet database. We will make separate applications to the relevant ethics committee when we want to run any formal clinical trials.

## **Clinical Utility**

From its inception, the EpiNet project has been designed to improve patients' clinical care, while at the same time providing a platform for clinical research.

All the information that is contained in a record is immediately made available to clinicians in a user-friendly summary. This means that results of all the patient's investigations, and the full drug history, is available in a single document. This will result in improved clinical management of these patients, since the clinician will not have to search back through old notes to find this information. Many patients with refractory epilepsy have had multiple combinations of multiple drugs over many years, and reviewing this information in a short clinic appointment is very difficult. The summary can be easily printed out and given to the patient or sent to the patient's general practitioner.

A minimal amount of personal and demographic data is collected: name, date of birth, local hospital number (or equivalent), sex, and ethnicity. Personal data is encrypted using AES128 bit encryption. This data is collected so that the record can be an adjunct to the official clinical record. Personal data is collected so that when clinical information is provided back to the registering doctor, it is obvious who the information relates to.

Since the patient data is being stored in an online database, the record could potentially be accessed from anywhere in the world

### **Confidentiality and Informed consent.**

All patients who have been enrolled in the International pilot study have given written informed consent.

However, the New Zealand Multi-Regional Ethics Committee has given permission to proceed to the next phase of the study without this requirement. We have agreed that we will notify patients that we are recording details regarding their epilepsy into the EpiNet database, and the reasons for doing so. We will inform them that we will be able to identify patients who might be suitable for other research studies. Patients will be informed that they are able to opt-out of the database if they so wish.

The EpiNet database fulfils all the requirements of the New Zealand Privacy Code:

We are only collecting information that is directly related to patients' health;

We will only use the data for the purpose for which we are collecting it.

Patients will be informed: that their information is being stored; why the information is being stored; that they have the option of withdrawing from the process.

**Opinion was expressed by:**

Dr. N. Tskhakaia and Dr.O.Rusadze. They mentioned that the study is very interesting and it is very important for our clinic to participate in the multinational project..

**It was concluded:**

The observational project „Development of Integrated International Multicenter Internet-based Electronic Database of Epilepsy (EpiNet)“, The EpiNet project; an open-ended, observational study of epilepsy is approved by the Local Council of the Iashvili central children hospital and investigators can carry out the research.

Chairman of the meeting

Ivane Chkhaidze

Secretary of the meeting

Gvanca Jajanidze

