



Epilepsy Scotland Consultation Response

CSO Health Research strategy 2014

August 2014

Epilepsy Scotland

Epilepsy Scotland works with people affected by epilepsy to raise awareness of epilepsy issues, ensure that services are developed to meet their varied needs and that their voice is heard. It provides information, support and services to the 54,000 people in Scotland who have epilepsy, and their families/carers. The charity also informs and influences policies that affect the health, education and social welfare of these people. As a charity which has also received Scottish Government funding towards research into information needs around epilepsy, Epilepsy Scotland welcomes the opportunity to comment on this draft strategy.

Question 8: Would a trial register be of benefit to patients seeking trials? Would it be an effective way to partner patients with researchers? Is there a danger that expectations of taking part could be unfairly raised?

Epilepsy Scotland would welcome improved access to clinical trials for people with epilepsy in Scotland. We believe that a Scottish Clinical Trials Register would, in principle, benefit patients seeking to participate in trials. We recognise and echo the concern that there would be a danger of patients' expectations of being accepted

into trials being falsely or unfairly raised. It may be that this is an inherent risk in the creation of such a register. For that reason, we would suggest ensuring that the website:

- Contains clear, accessible, Plain English summaries of:
 - the trials recruiting, what they involve for the patient, timescales and eligibility criteria etc.
 - broadly speaking, what kind of physical or psychological testing may have to be undertaken to help ascertain whether they are eligible or not for entry to the study
 - what clinical trials are, how they work
 - what happens once the person has registered interest in a trial and what information they can expect to receive
 - general points to consider when thinking of participating in a trial, such as safety, advantages, risks and privacy.
- Has clear instructions on how to search for trials and how to read/understand study summaries and results
- Makes clear how the individual's details/data will be handled once they have registered interest
- Makes clear that even though the person may perceive that they meet the trial eligibility criteria, there may be further factors which prevent participation
- Makes clear that applying to take part in the trial does not guarantee participation
- Makes clear that the person can withdraw from a clinical trial at any time.

In addition to the contacts listed for particular studies, the website should have a point of contact for general questions about taking part in clinical trials and associated issues.

The Cancer Research UK trials database portal contains good examples of how to communicate clearly with patients about clinical trials:

<http://www.cancerresearchuk.org/cancer-help/trials/>

Question 9: Would using electronic NHS patient records to alert GPs to research studies for which their patients may be eligible be a service the NHS should offer? If so, would a process where NHS records are only accessed by identified NHS staff working in secure facilities, and only passing potential participant names to their GPs or hospital consultants for consideration, be a suitable way to proceed?

Epilepsy Scotland believes that, with robust safeguards in place, this is a proposal which could benefit patients in Scotland. Comments received from our stakeholders on this issue have generally been supportive. However there are a number of concerns which we feel require to be addressed. These include:

- Would permission be sought from individuals for their records to be searched for this purpose in the future?
- What safeguards would be in place to ensure staff are accessing data only in accordance with defined search criteria?
- Are there time or resource implications for GPs helping to recruit people to trials?
- What safeguards would be in place to ensure that patients do not feel in any way compelled to take part because they are being approached by their own consultant or GP?
- It can be difficult for lay people to form a contextualized and objective understanding of risk and how it relates to their own condition. It may be particularly difficult for people who have tried all available treatment options, who are terminally ill or whose condition is very significantly impairing their quality of life, to form an objective understanding of the risks associated with taking part in research. How would the CSO try to ensure that potential risks are adequately and contextually explained and that people are enabled to be as objective as possible in their assessment of these?
- Around 20% of people with epilepsy also have a learning disability. People with learning disability tend to have more refractory epilepsies which are more likely to be resistant to treatment. They have lower rates of seizure freedom and higher rates of multiple anti-epilepsy drug use and treatment failure, and therefore the types of epilepsy often sought in candidates for clinical trials of epilepsy drugs. The person's learning disability may or may not be formally

diagnosed and documented and they may or may not have recorded contact with learning disability services. What measures would be put in place around approaching and recruiting patients for clinical trials relating to conditions where learning disability is common?

Question 13: Are there other key areas of partnership CSO should be seeking to build?

Epilepsy Scotland would encourage the CSO to explore further partnerships with the third sector. We feel it would be valuable for the CSO to build relationships not only with medical research charities or charities conducting or funding clinical research, but charities conducting social health research around conditions, including qualitative studies. These charities are also in an excellent position to help advise on:

- the wider, psychosocial and quality of life implications of health conditions
- the priorities of individuals living with and managing these conditions
- the potential impact of research outputs.

We would therefore welcome the CSO making the third sector a key area of future partnership.