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Continuing professional development: Medico-legal aspects of epilepsy

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Generally protection against possible litigation and good clinical practice go hand in hand. Situations in which the law has special relevance for people with epilepsy, those who work with them, and their clinicians are reviewed with special reference to the topics of driving, employment, duties of social carers, the clinician's everyday role, the responsibilities of researchers and epilepsy and the criminal law. What constitutes professional negligence is discussed, with special reference to the United Kingdom. Clinicians are advised to think clearly, write clearly, communicate clearly and have a good relationship with their patients.

Key words: epilepsy; driving; automatism; litigation; jurisprudence; risk.

INTRODUCTION

As Tim Betts states in the accompanying article, public attitudes to medical care and responsibility have altered over the past couple of decades. Epileptology, like the rest of medicine, is practised against a changing backdrop of litigation. There is less implicit trust in doctors, greater expectation of outcomes, more risks involved in achieving these outcomes, and an increasing need for practitioners to ensure that, when brought to task, all their actions can be seen to be appropriate and in the patient's best interests. The whole area makes good media copy. One study that looked at this noted[1]: 'although it is encouraging that legal aspects of epilepsy are receiving media attention, this attention could be used in a more positive manner in promoting awareness, rather than many of the cases examined which appeared to use negative images in order to pander to popular audience appeal'. But such is life.

The functions of legal systems include seeking remedies for problems in a context of fairness and protection of rights, including protection of the vulnerable from exploitation. The outcome of a legal process where there is a dispute between parties may inevitably fail to satisfy some of those involved. As has been pointed out[2] a doctor involved with epilepsy may be legally involved in three particular ways, as an agent of social control, as an advocate for the patient, and as the target of liability or malpractice litigation. Other clinicians such as nurses or psychologists may be involved within these broad areas. The law also has a wider perspective for people with epilepsy and those involved in their care. Areas in which the clinical practice of epileptology moves into a legal arena may be considered as the range of responsibilities exercised by those involved. These will cover driving, employment, various aspects of the clinician's normal role, specialist aspects such as the application of criminal law and epilepsy as a defence, and the responsibilities of researchers. After discussing each of these in turn we will conclude with a note on professional negligence and how it is defined.

DRIVING

Most countries allow people with epilepsy to drive ordinary family vehicles if they have been free from seizures for a certain period, although a few still operate a blanket ban. In the United Kingdom a person

with epilepsy may be granted an ordinary licence for Group 1 vehicles (motor cars and motorcycles) if free from all types of seizure for 1 year, or if seizures have only occurred in sleep for at least 3 years. It is important to note that in addition to these rules, in which some doctors are well rehearsed, there is an additional provision that the driving of a vehicle must not be likely to endanger the public. This last condition may be relevant where there are other factors, such as neurological or psychiatric illness, or drug side effects, that may affect the ability to drive. Stricter criteria apply for Group 2 licences (large goods vehicles, passenger carrying vehicles over 3.5 tonnes, and eight seats or more, for hire or reward), and the person must have had no epileptic seizures of any kind for the previous 10 years, and also have taken no antiepileptic medication during this period. Additionally, there must be no continuing liability to epileptic seizures. These regulations apply to all seizure types, including isolated auras. The 3 Hz spike-wave EEG discharges of primary generalized epilepsy used to be regarded in the same way as seizures for this purpose, although other epileptiform EEG phenomena were not (unless part of a clinical seizure); however, recent editions of the regulations make no mention of this. An isolated seizure without a previous diagnosis of epilepsy would still acquire a 1-year ban. Provoked seizures (for example those occurring in the context of tricyclic antidepressant medication, or with acute head injury or acute stroke) are dealt with by the licensing authority on an individual basis. Where antiepileptic medication is being withdrawn in someone who is seizure free for more than 12 months and who holds a Group 1 licence, it is advised that the person abstains from driving from the commencement of the period of withdrawal until 6 months after the drug withdrawal is complete, although it is not necessary for the licence to be surrendered.

Different jurisdictions have varying laws. In Arizona USA the required seizure-free interval was changed from 12 months to 3 months in 1994. Early data suggested that this was followed by a small but significant increase in crashes, but further studies are required[3].

On the UK driving licence there is a clearly written instruction that the licensing agency must be informed of any change in the person's medical condition. Thus the onus to inform lies with the patient. However the doctor managing the epilepsy has a duty to explain the situation to the patient. There is evidence that both people with epilepsy and their doctors are often unaware of these important regulations[4], even though ignorance of the law is not generally regarded as an excuse.

Patients' knowledge is often inadequate especially in the area of driving[5,6] and there is much literature that attests to a low level of knowledge about the condition among people with epilepsy that is attributed to lack of information from professionals[7,8].

A situation may arise where someone with epilepsy fails to report the condition to the licensing agency, and the doctor is aware of it and considers that the patient is a serious risk to self or others. This is one of the rare occasions where a breach of confidentiality is justified in the public interest. Indeed, in the UK the doctor is regarded as having an obligation to report such a case personally. It is important to ensure before doing this that the patient understands the legal requirements. In such cases the doctor should inform the patient (preferably in writing) of the intention to report to the licensing agency, and should record this in the patient's notes. If the doctor is aware that the patient is continuing to drive despite the licence being revoked, it may be appropriate to inform the local police. It is advisable in such circumstances to discuss the matter with an adviser from the doctor's defence organization.

A more common situation is the one where a person has a current driving licence, is seizure free and taking medication, and where it is considered clinically advisable to change medication to avoid potential adverse medication effects. For example, there are circumstances in which some doctors may recommend changing valproate to lamotrigine in women. In such cases it is important to inform the patient of the risk of loss of driving licence for 1 year if a seizure occurs. Not to do so would be considered as a shortfall on the doctor's part. Needless to say the information given should be recorded in the notes. There is an increasing tendency to share with the patient the correspondence between the hospital and the GP, and this would also be an opportunity to ensure that the advice is properly recorded.

A question may arise about the status of people who have non-epileptic attack disorder (NEAD, or pseudoseizures). One US study[9] showed that people with NEAD had no increased crash rate over the normal population; this study was however possibly flawed because the sample was very small and highly selected, there was no epilepsy control group, and it did not address the tricky question of dual diagnosis. Experience would suggest that if there is any doubt about the diagnosis, the epilepsy regulations should apply. If on the other hand the NEAD represents another definite diagnosis such as post-traumatic stress disorder, with no evidence of epilepsy, it should be treated as the other condition. In such cases our experience has been that the licensing agency in the UK treats this like other causes of non-epileptic collapse and imposes a 6-month ban.

EMPLOYMENT

People with epilepsy cannot become airline pilots, or join the Royal Navy or Fire Service. The police will not recruit people who continue to have seizures, although those with a past history may be considered. Applicants to the teaching profession in the UK must be seizure free for 2 years. Teachers in state schools who develop epilepsy may be stopped from teaching certain practical or technical subjects. In these cases the person with epilepsy has a responsibility to inform the employers or potential employers. Failure to do so could result in loss of employment. In these and other cases there has not previously been any significantly useful legal recourse for people refused a job because of their epilepsy, or dismissed on health grounds. However, the 1996 UK Disability Discrimination Act (DDA) was a small but significant step forward in civil rights protection for people with disabilities, and made it illegal for employers to discriminate on the basis of disability. There have now been several successful appeals against unfair dismissal on the grounds of epilepsy under the DDA, although the law continues to evolve. The establishment of the Disability Rights Commission will play a part in this. In the USA there is a wider-ranging legislation, the Americans with Disabilities Act (1990), experience with which may yet influence developments elsewhere in the world.

RISK ASSESSMENT IN SOCIAL CARE SITUATIONS

Recently the proprietors of a social care home were successfully prosecuted after a resident with severe epilepsy and intellectual disability died after having a seizure while bathing with what was deemed inadequate supervision[10]. This is a significant case emphasizing the responsibilities of social carers and the importance of realistic risk assessments. Good practice would involve adequate liaison between different agencies such as health and social services, and tragic cases such as this may focus the minds of those who are responsible for planning services.

THE CLINICIAN'S EVERYDAY ROLE

In the current 'defensive' culture of clinical practice, clarity is the watchword; if we think clearly, write clearly, communicate clearly and have a good relationship with our patients we are less likely to get into trouble. We must also be able to justify our clinical approach.

Firstly, the diagnosis should be properly made. There has been litigation around failure to adequately investigate the aetiology of seizures which turned out to be symptomatic, such as those associated with hypoglycaemia or hypocalcaemia.

When prescribing antiepileptic drugs (AEDs) patients should be warned that some adverse effects such as sedation are more likely to occur in the first few days of treatment. If failure to do this (and record that the advice was given) is associated with patients putting themselves in situations where there is risk to self or others, the doctor may be deemed responsible. In the UK the British National Formulary (BNF) is often used as a standard in legal cases. Courts would probably expect that patients should also be routinely warned of serious side effects as listed in the BNF. Failure to follow accepted guidelines, such as those for visual field screening in people taking vigabatrin, might be construed as negligent if an adverse consequence resulted. This last responsibility is very clear for hospital doctors, but in cases where the only follow-up is with the GP, then the GP is the responsible medical officer. Doctors should also be aware of drug interactions especially those related to enzyme-inducing AEDs, and they should know which AEDs are not enzyme inducers.

One particular example of this is the prescribing of the oral contraceptive (OC). Enzyme-inducing AEDs reduce the efficacy of OCs. The management of this, though uncomplicated, is beyond the scope of this article. Women with epilepsy may be told that the OC is safe with their AED when it is not, or they may be told that they cannot have the OC when they can. Valproate, for example, is not an enzyme inducer. Nevertheless we know of cases where doctors have told women that they cannot have the OC with valproate. Carbamazepine is an enzyme inducer. Even today women are sometimes prescribed normal doses of OC with carbamazepine, and have inadequate contraceptive control. Both situations, if they led to adverse consequences and litigation, are indefensible. But the same doctor does not always prescribe the AED and the OC, so whose responsibility is it to ensure these topics are properly covered? Legally, usually the responsibility is taken as belonging to the doctor who prescribed the second drug. If the GP adds the OC to someone already taking an AED, then it is the GP's responsibility; if the hospital doctor starts an AED in a woman taking the OC it is the hospital doctor's responsibility.

A related area which attracts medico-legal attention is the management of pregnancy, and in particular the subject of AED teratogenicity. Pre-conceptual counselling is good practice; recording it in the notes is essential. Having written information that can be given to the patient is helpful, as long as it is accurate. Guide-

lines exist for managing women's issues in epilepsy, and the content of these ought to be familiar to doctors who treat women with epilepsy[11]. For GPs (and hospital doctors) an excellent account is given in Malcolm Taylor's book[12].

The doctor also has a responsibility to write prescriptions clearly and unambiguously. Dispensing pharmacists also bear a responsibility, which may lay them open to litigation[13]. Most epileptologists would probably agree about the desirability of maintaining brand continuity of AEDs. Seizure-associated accident resulting from brand or generic substitution of an AED could be regarded as the responsibility of the person who caused the substitution (usually the doctor, but in some cases the pharmacist).

Even if the doctor knows what is going on this does not mean that the patient fully understands the regime, and this can result in even the best-kept medical records being inaccurate[14]. Not sorting this out, and not making sure there is proper communication, could render the doctor liable.

CRIMINAL LAW AND EPILEPSY AS A DEFENCE

Before 1991 in the UK the topic of legal aspects of automatism in epilepsy could occupy much space in a review such as this, but with the Criminal Procedure (Insanity and Unfitness to Plead) Act matters have become more straightforward. For guilt to be established it has to be shown that the person did the deed (*actus reus*) and intended to do it or did it out of recklessness (*mens rea*). Legal (as opposed to medical) automatism occurs if *actus reus* is established but *mens rea* is absent. These legal automatisms could be *sane*, arising from an extrinsic cause such as hypoglycaemia in a person with diabetes who took too much insulin or *insane*, arising from an intrinsic cause such as epilepsy (or, paradoxically, hypoglycaemia in a person with an insulinoma). Whereas offences committed during sane automatism could result in discharge, those committed during insane automatisms used to attract hospital and restriction orders under Sections 37 and 41 of the Mental Health Act. Falk-Pedersen[15], in a recent review of the international position, stated 'The distinction made in the common law tradition between sane and insane automatisms, and in particular the labelling of epileptic automatisms as insane, are legal concepts which surprise and even astonish lawyers of other traditions, whether they work within a civil law system or one with elements both from civil law and common law.' Fortunately, under the 1991 Act, a finding of insane automatism in English law leaves the court with a wider range of possible outcomes, including hospital treatment, guardianship, supervision and treatment, or absolute discharge.

Violent acts associated with seizures are extremely rare, though not unknown[16]. There is at least one case of baby stealing described in the literature[17]. An epilepsy defence is sometimes offered for less serious charges such as shoplifting. It is of course quite possible that someone could pick up something and walk off with it towards the end of a complex partial seizure, without any intention to do so. Fenwick[18] has suggested the following guidelines, which might help when providing a professional opinion to a court in such a case:

(1) The defendant should be shown to have had epilepsy before the offence was committed.

(2) The offence should not be premeditated.

(3) After the episode, the defendant should show confusion.

(4) After the episode, the defendant should seek help (if appropriate) and should not hide the evidence.

(5) There must be amnesia for the act.

(6) Witnesses should testify to confusion during or immediately after the episode.

RESPONSIBILITIES OF RESEARCHERS

Most clinical trials are carried out in an atmosphere of meticulous (some might say excessive) documentation, but there are potential medico-legal risks if subjects are inadequately informed or feel coerced into partaking. In one recent study of parents whose children took part in a randomized controlled study[19], it was suggested that 25% of subjects felt obliged to participate. This could cause problems if there was an adverse outcome to the trial. It was concluded that there were various ways in which parents' understanding of the process might be improved, e.g. by designing easier to understand consent forms, and that measures should be taken to avoid parents feeling obliged to participate, rather than giving true informed consent.

PROFESSIONAL NEGLIGENCE

For negligence to be established in English law, the plaintiff must establish: (a) that a duty of care was owed to him or her; (b) that the defendant was in breach of that duty; and (c) that the breach of duty caused the injury of which the plaintiff is complaining. The burden of proof lies with the plaintiff. However, in

civil cases proof only has to be on the balance of probability and not as in criminal cases, beyond reasonable doubt. If consent has been given to a procedure or examination, this might be defence to a criminal charge of assault, but it may not be a defence to a civil claim for damages.

So what constitutes negligence? In the so-called ***Bolam*** defence[20] the practitioner is not guilty of negligence if he or she has acted in accordance with a practice accepted as proper by a responsible body of professionals skilled in that particular art. This 'responsible body' need not be numerically large as long as it can be shown to be responsible. The defence allows for the possibility that not all practitioners may agree, and is sometimes known as the 'two schools of thought defence'. However, the action of the defendant still needs to be shown to be responsible; just calling colleagues in support who would have done the same thing is no good if their reasons do not stand up to analysis, and some judges have taken this view.

A question arises where novel or experimental treatment is being tried. The burden of proof is still on the plaintiff, but the practitioner would have to demonstrate the reasoning, research and planning that led up to the procedure.

Where a mistake occurs in a medical context but is not a question of professional skill (records lost, slides, specimens mixed up), the mistake is one of incompetence and is indefensible.

The alternative to Bolam has been called the ***Canterbury*** argument after a landmark case in the USA[21]. Here the judgement concluded:

(1) Every human of adult years and sound mind has the right to determine what shall be done with his or her body.

(2) 'Consent' is the informed exercise of a choice . . . entailing the opportunity to evaluate knowledgeably the options available and the risks attendant on each.

(3) The doctor must therefore disclose all material risks.

(4) But the doctor may exercise 'therapeutic privilege' (if a reasonable medical assessment indicates that disclosure would pose serious threat of psychological detriment to the patient).

The question therefore is what is a material risk? In the Canterbury judgement this is to be determined by the 'prudent patient' test. Thus 'a risk is material when a reasonable person, in what a physician knows or should know to be the patient's position, would be likely to attach significance to the cluster of risks in deciding whether or not to forgo the proposed therapy'. The Canterbury argument has not been totally successfully transformed into English Law. In an important case[22] the Bolam defence was successfully used where someone had not been warned before consenting to an operation of the risk of an uncommon but serious complication, which she then developed. The House of Lords decision on this has however been controversial, and in some other cases judges have taken the view exemplified by one who said[23] 'although some surgeons may not have been warning patients similar in situation to the plaintiff of the risk that omission was neither reasonable nor responsible'.

This is all very theoretical: how does it apply to the practice of epileptology? Following evidence-based guidelines will help avoid pitfalls, as will marshalling and recording the reasons for occasionally deviating from them. Communication with patients and their families remains all-important. The mantra remains 'think clearly, write clearly, communicate clearly and have a good relationship with patients'.

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23. Smith v. Tunbridge Wells Health Authority [1994] 5 Med LR321.

Self-assessment questions

1. Drivers with a history of epilepsy in the UK:

   (a) must have been seizure free for at least 10 years to hold a Group 2 licence.

   (b) may still be taking antiepileptic medication and hold a Group 2 licence.

   (c) must have been seizure free for 3 years to hold a Group 1 licence.

   (d) may not drive or hold a current licence if an EEG in the past year has shown 3 Hz spike-wave discharges.

   (e) should voluntarily abstain from driving if medication is being withdrawn until 6 months after the last dose.

2. In UK medical negligence litigation:

   (a) the defendant has to prove that most other doctors would have done the same.

   (b) the defendant has to prove that he or she was not responsible for the injury of which the plaintiff complains.

   (c) the plaintiff has to prove beyond reasonable doubt that the defendant breached a duty of care and caused an injury to the plaintiff.

   (d) if it can be shown that the plaintiff consented to the procedure in question no action can succeed against the defendant.

   (e) an action for negligence will succeed if it can be shown that the doctor has not disclosed all material risks before obtaining consent to a procedure.

3. The following are true:

   (a) legal automatism is defined as *mens rea* in the absence of *actus reus*.

   (b) under the 1991 Criminal Procedure (Insanity and Unfitness to Plead) Act, a finding that an offence was committed under an insane automatism must result in compulsory detention under the Mental Health Act.

   (c) if it is proved that the accused committed an offence while in a confused state following a seizure, this will result in an absolute discharge.

   (d) if insane automatism is proved the court has a variety of disposals available.

   (e) an action occurring during hypoglycaemia in insulin-dependent diabetes is an example of insane automatism.

Answers

1. (a) is true.
   (b) is false: for Group 2 licences (or large goods vehicles, passenger carrying vehicles over 3.5 tonnes, and eight seats or more, for hire or reward), the driver must have not taken antiepileptic medication for 10 years as well as being seizure free for that period.
   (c) is false: for Group 1 licences (motor cars and motorcycles) the person must be either free from all types of seizure for 1 year, or seizures must have only occurred in sleep for at least 3 years.
   (d) is false: while preparing this paper, the authors sought clarification from the Licensing Agency about this particular point. It seems the current view is that if someone has a seizure during an EEG the Agency needs to be informed. However, if there is epileptic activity on the EEG which is not clinically apparent, the driving entitlement is not affected.
   (e) is true.
2. (a) is false: the defendant would be helped by showing that a responsible body of practitioners would have acted the same way. This body need not be numerically large, but it would have to be shown to be responsible.
   (b) is false: the burden of proof is on the plaintiff, not the defendant.
   (c) is false: in civil cases, such as negligence litigation, the proof is based on balance of probability, and this does not have to be demonstrated ‘beyond reasonable doubt’, a condition which applies in criminal cases.
   (d) is false: if consent has been given to a procedure or examination, this might be defence to a criminal charge of assault, but it may not be a defence to a civil claim for damages.
   (e) is false: this is not necessarily true in English law, although it has been taken as a principle in US law.
3. (a) is false: it is the other way round.
   (b) is false: the 1991 Criminal Procedure (Insanity and Unfitness to Plead) Act reversed this state of affairs and made a wider variety of disposals available to the court.
   (c) is false: this is only one of a variety of disposals available, which include hospital treatment, guardianship, supervision and treatment, and absolute discharge.
   (d) is true.
   (e) is false: this is an example of sane automatism.