HEMPSONS SOLICITORS

Hempsons London 020 7839 0278
Hempsons Manchester 0161 228 0011
Hempsons Harrogate 01423 522 331
healthcare@hempsons.co.uk
www.hempsons.co.uk

Healthcare
News Brief

Issue Summer 2005

MRSA – claims and prosecutions

Rachel Kneale

If hospital managers and doctors thought that once the general election was concluded, the spotlight would move away from MRSA, they were wrong. Patricia Hewitt, the new Secretary of State made clear her intentions in announcing that the Health Improvement Bill would include legislation to make health executives personally and criminally liable for the deaths of patients caused by MRSA. The purpose of this article is to consider the present legal position both in the civil and criminal law in respect of patients who develop an MRSA infection while a patient in the NHS.

CIVIL CLAIMS

Perhaps surprisingly there are very few reported cases involving MRSA and specifically very few indeed in which infection control procedures have been found to have been inadequate or inadequately carried out. Those cases involving MRSA which have been reported have tended to be cases in which MRSA was a consequence of an inappropriate standard of care in management of the patient's condition, e.g. a failure to treat pressure sores which later became infected with MRSA resulting in an amputation (*Brown v Southend General Hospital NHS Trust*, LTLPI 4/6/2003), rather than cases in which infection control procedures have been found wanting.

The rarity of reported cases may reflect the Court's acceptance that developing an MRSA infection whilst a patient is not of itself evidence of negligence (although it may be going a bit far to suggest that hospital-acquired infection is always a fact of life, it is a fact of life that infection cannot be totally eradicated from hospitals) and therefore that, provided satisfactory infection control procedures are in place and carried out, it will be difficult for a patient to prove fault (a "breach of duty" in law). However, investigating and defending such claims can be costly and time consuming. Evidence will be required from those in infection control positions in relation to some or all of the following matters: infection rates and details of locations of cases; evidence of decontamination procedures being carried out for infected staff and patients; records of hygiene inspections; evidence of compliance with and appropriate Infection Control Protocol. Increasingly such protocols and procedures will need to comply with any DoH guidance on such matters at the relevant time, e.g. "*Winning Ways: working together to reduce healthcare related infection in England*".

The rarity of reported cases also reflects the difficulty in establishing causation. Not only will a patient have to prove, on the balance of probabilities, that the MRSA was acquired in hospital (itself a substantial hurdle given that many people harbour the bacterium on their body without developing an infection and given the increasing prevalence of community acquired strains of the bacterium) but also a patient must establish that any failure in the infection control procedures was, on the balance of probabilities the reason the patient developed the infection. With critically ill and frail patients that too is a substantial hurdle.

CRIMINAL LIABILITY

The precise nature of the Government's proposals may become clearer with publication of the Health Improvement Bill (not published at the time of writing). However, this area is likely to be as fraught with difficulties in imputing the necessary degree of knowledge and / or carelessness as has proved to be the case in relation to the existing and proposed new Corporate Manslaughter legislation, both of which apply to clinicians and managers within the NHS in any event. In the past, corporate manslaughter prosecutions have failed against large organisations where it has been impossible to establish that a causal link existed between a grossly negligent act and the "controlling mind" of the company. This would be as much the case for NHS Trusts as large companies. However, given the increasing requirements for NHS executives to ensure appropriate infection control measures (*HSC2000/002*), this may become easier in the future. It is not clear, however, why deaths resulting from MRSA should be singled out for special treatment from other hospital deaths, nor indeed why only cases resulting in death should be prosecuted.

CONCLUSIONS?

Hospital-acquired infections in general and MRSA in particular are likely to the subject of an increasing number of claims and possibly prosecutions in the future. With the increasingly directive nature and number of guidelines from the DoH, it is unlikely that the present low number of claims will continue, although given the ongoing difficulties in establishing causation, it will remain a difficult claim to prove. ■

Managing Violence - NICE guidelines on restraint

Julie Austin

NICE guideline 25, issued February 2005, is intended as a "comprehensive framework for how to assess risk and prevent violence; de-escalate and calm down a potentially violent situation; and intervene safely when violence occurs." These new guidelines follow recent adverse publicity arising from the deaths of mental health patients in the course of physical restraint.

The starting point is a comprehensive risk assessment. All mental health service providers must ensure that there is a full risk management strategy for all their services where problems with managing violence are likely to arise. The guidelines are aimed at psychiatric in-patient services and emergency departments, both of which are regularly confronted with violent behaviour amongst their service users.

The strategy must be supported by ongoing competency training for all staff to enable them to recognise anger, potential aggression, antecedents and risk factors of disturbed/ violent behaviour, and to monitor their own verbal and non-verbal behaviour. Training must include methods of anticipating, de-escalating or coping with disturbed/ violent behaviour. Obviously what is appropriate training will depend on the assessment of risk in the services usually provided by the Trust and the overall risk management strategies adopted.

The guidelines recommend that rapid tranquillisation, physical restraint and seclusion should only be considered once de-escalation and other strategies have failed to calm the service user. These are not regarded as strictly therapeutic or primary treatment techniques, but rather as management strategies.

Whatever type of intervention is used, it has to be a reasonable and proportionate response to the risk posed by the service user. When deciding which interventions to use, there are several key factors of relevance: clinical need, safety of service users, and the safety of others, including staff. These sorts of judgments are, by their very nature, made "in the heat of the moment". They are difficult and, when they go wrong, they must be reviewed and are likely to be challenged. However, if there has been good training, staff keep their knowledge and skills updated, and the strategies they are expected to follow have been well thought out, then that should go some way towards ensuring that optimal decisions are made when confronted with a real problem as well as justifying what was done in retrospect.

In the more difficult instances where physical intervention (such as restraint) or seclusion need to be used, or where rapid tranquillisation is to be administered, then staff must also be trained in appropriate life support techniques, such as use of defibrillators. Furthermore, where restraint is used then one team member should be specifically responsible for protecting and supporting the head and neck, where required, and also act as team leader for the physical intervention process, ensuring that the airway and breathing are not compromised and that vital signs are monitored. This is a clear and detailed response to the problems that have arisen in recent high-profile cases where during the course of such restraint the service user has died.

The recommended minimum standard of training in relation to physical intervention or seclusion is Basic Life Support (BLS- Resuscitation Council UK), and for use of rapid tranquillisation Immediate Life Support (ILS - Resuscitation Council UK).

As part of the management strategy, as well as the provision of a quality service, service users are required to be told:

- which identified staff member is assigned to them;
- why they have been admitted and information about any formal detention;
- their rights in relation to treatment, complaints and access to independent advocacy;
- what may happen if they become disturbed or violent.

The guidelines require this information to be provided for each admission and repeated as necessary, as well as being recorded in the notes.

Those who are identified as being at risk of disturbed or violent behaviour must be given the opportunity to have their needs and wishes recorded in the form of an advance directive. Such an advance directive must fit into the context of the overall care plan, and it should state clearly what interventions the service user would and would not wish to receive. The advance directive should be reviewed periodically.

It is not clear how easy it will be to follow an advance directive in practice when a violent situation suddenly arises, and there is no time to check what it says. It can easily be envisaged that there may be occasions when the numbers or experience of the staff able to handle difficult situations may be limited, or facilities may be limited. Again, perhaps it is intended that proper training and advance planning for the risks in each case will ameliorate any practical problems with implementing such advance directives. If the service user has explicitly turned down the use of a technique which has to be used at the time, then staff are going to have to be able to justify carefully anything they then do that is against the terms of a clear advance directive.

Another concern for Trusts will be whether other service users or their staff will be put at greater risk by observing the terms of an advance directive that limits what can be done, where the optimal techniques for the occasion have been declared unacceptable to the service user. Again, this will have to be considered very carefully at the outset, and any actual breaches of the advance directive will have to be carefully justified. Detailed record-keeping is going to be important in such situations. ■

Further information on NICE guideline 25 may be found on the NICE web site:

"Violence: The short-term management of disturbed behaviour in psychiatric in-patient settings and emergency departments"

www.nice.org.uk/page.aspx?o=244477

Hempsons London 020 7839 0278
healthcare@hempsons.co.uk

Hempsons Manchester 0161 228 0011
healthcare@hempsons.co.uk

Hempsons Harrogate 01423 522 331
healthcare@hempsons.co.uk

Catherine Smeethe

Corporate Manslaughter Update

It was announced in the Queen's speech that the government is going to take forward proposals to introduce an offence of corporate manslaughter. This is something that has been in the pipeline since 1996. Now however a draft bill has been published and the deadline for responses is 17 June 2005.

Currently the law applying to corporations requires the "controlling mind" of the company, usually a director, to be guilty of gross negligence manslaughter before the corporation can be prosecuted. If the bill becomes law this will be replaced by an offence of corporate manslaughter based on serious failures in the way senior managers organised or managed the organisation's activities.

The new law will apply to corporate bodies, which would include companies, NHS Trusts and local authorities, but would not apply to unincorporated associations such as partnerships. It would not cover GP practices if these are run as partnerships. It would extend to many bodies currently covered by Crown immunity such as government departments including the Department of Health. The application to the Department of Health and to individual trusts would however be limited by the exclusion of public functions and public policy matters from the duty of care.

Management failure would need to be a gross breach of a duty of care and is defined as conduct falling far below what could reasonably be expected. The duty of care must be in relation to employees, in the corporation's capacity as occupier of land or in connection with the supply of goods and services or the carrying on by the organisation of any other activity on a commercial basis. Exercising exclusively public functions is specifically excluded. No duty of care would arise in respect of decisions as to matters of public policy including the allocation of public resources or the weighing of competing public interests.

In deciding whether there is a gross breach of a duty of care, a jury would have to consider whether the organisation failed to comply with health and safety legislation and whether senior managers intended the organisation to profit from any such failure.

The proposed penalties are an unlimited fine and the imposition of an order requiring the organisation to remedy the breaches that led to the death. Breach of such an order would be punishable by a further fine. The bill would not create any further liability for individuals, so sentences of imprisonment would not be appropriate. The offence of gross negligence manslaughter applying to individuals however is to remain, so individual doctors could continue to be prosecuted if there is evidence of gross negligence.

The proposed legislation would make it easier for corporations to be prosecuted for manslaughter by extending the range of people who must be responsible for the failure from one "controlling mind" to senior management. It may however be difficult to prove that failings were at senior management level if many decisions are delegated. As far as penalties are concerned it is already open to the courts to impose unlimited fines for serious breaches of health and safety legislation. Fines under the new legislation could potentially be higher but the most significant change is likely to be in the impact of the label "manslaughter" on both defendants and the families of the deceased.

These proposals would not create any new regulatory burden, but it would be wise to check that existing health and safety legislation is being complied with as the bill refers specifically to this as a factor to be taken into account. Provided suitable safeguards are already in place, these proposals, if enacted, should not involve any significant changes or expenditure on the part of NHS Trusts. ■

Risk Management - Sedation

We were recently involved in a fatal case concerning endoscopic retrograde cholangiopancreatography (ERCP) performed by a Consultant Physician and Gastroenterologist, under sedation.

We obtained expert evidence from a Physician/Gastroenterologist and an Anaesthetist.

The Physician was of the view that the levels of drugs administered and the manner and order in which they were given was in accordance with what a responsible body of Gastroenterologists would have done. The view of both the expert Gastroenterologist, and the clinician involved, was that the BSG Guidelines and Manufacturers Guidelines were unrealistic in practice.

The expert Anaesthetist reported that the Midazolam and Fentanyl were not given in accordance with the Manufacturer's Guidelines, and the total dose of Midazolam used was twice as great as the maximum dose the manufacturers recommended. He accepted that many Gastroenterologists carried out sedation in a manner similar to this case.

The case highlighted a major difference in clinical practice between (apparently) the majority of Gastroenterologists, and what Anaesthetists view as safe sedation.

Following this:

- There has been greater involvement with the Directorate of Anaesthetics, and monitoring equipment has been purchased (rather than sole use of pulse oximetry during ERCP which was not sufficiently adequate). The improved monitoring equipment records blood pressure, ECG and oxygen saturation and provides a printout which is filed in the patient's case notes. That degree of monitoring is now in excess of the recommendations of the BSG.
- Whenever ERCPs are being performed, a Consultant Gastroenterologist must be immediately available to assist if necessary.
- There have been improvements in the accommodation/recovery area to allow for more space.
- There are specific criteria listed for performing ERCPs. All requests are seen by a Consultant Gastroenterologist.
- There are strict requirements concerning the consent of a patient for ERCP, and an information leaflet is handed to each patient. There is a checklist for completion prior to the performance of the ERCP, which is filed in the case notes. Gastroenterology Nurses are being specifically trained for the obtaining of consent for such procedures. The amnesic effect of sedation is mentioned in the patient information leaflet.
- All new Endoscopists have to attend a training course including training in sedation.
- An Intravenous Sedation Protocol has been compiled by the Gastroenterology Department and approved by the Clinical Management Board to ensure compliance with BSC Guidelines. A document "Procedure for the Care of Patients Undergoing ERCP" has also been prepared. ■

Kate Hay

HEMPSONS SOLICITORS

Hempsons London 020 7839 0278
Hempsons Manchester 0161 228 0011
Hempsons Harrogate 01423 522 331
healthcare@hempsons.co.uk
www.hempsons.co.uk

Healthcare News Brief

A Potential Side Effect of *Chester v Afshar*

Dr. Tania Francis

Could *Chester v Afshar* apply to clinical negligence cases other than those involving failure to warn of the risks of surgery?

Chester v. Afshar [2004] UKHL 41 concerned the failure of a surgeon to warn a patient of the risks of surgery. You will all be familiar with the story. Mr Afshar was found not to have warned Miss Chester of the risk of paralysis following spinal surgery. That risk eventuated, without any negligence on the part of Mr Afshar. Miss Chester did not claim that she would not have undergone the surgery if she had know of the risk, merely that she would have sought a second and possibly a third opinion before going ahead with it. She would then have had the surgery on another day, and as the risk of paralysis was 1-2%, it is more likely than not that she would not have suffered the complication. Under the usual causation rules, Miss Chester would have been unsuccessful. However the House of Lords applied the principle established in *Fairchild v Glenhaven Funeral Services* [2003] 1 AC 32 that, in exceptional circumstances, the causation rules may be modified on policy grounds. They did this in order to prevent a perceived injustice, that is, that a negligent failure to warn might carry no penalty.

The question is, could the reasoning from *Chester* be applied to other clinical negligence cases?

The Court of Appeal has in the last six months declined to apply *Chester v. Afshar* in two other failure to advise cases - *White v. Paul Davidson & Taylor* [2004] EWCA Civ 1511 (solicitors) and *Beary v. Pall Mall Investments* [2005] EWCA Civ 415 (financial advisors). In *White*, Arden LJ explained the Court's reasoning, saying that "[t]he principle of informed consent to medical procedures has special importance in the law". In *Beary*, Dyson LJ said that *Chester* was "justified by the particular policy considerations that are in play where there is a breach of the doctor's duty to advise a patient of the disadvantages and dangers of proposed treatment."

Although doctors may gain little consolation from the fact that their profession is as yet the only one to be affected by the ruling in *Chester*, it is at least reassuring to note that in both these cases, *Chester* was interpreted as applying only to failure to warn cases. It seems therefore unlikely that the normal rules on causation would be changed in other clinical negligence cases.

However, a question remains. Could the principle in *Chester v. Afshar* apply to warnings about treatment other than surgery, for example when prescribing or administering medication?

Let us imagine a hypothetical case (and please forgive any medical inaccuracies). A patient consults a doctor with a fairly serious condition, say atrial fibrillation (AF). The doctor (for perfectly sensible reasons) prescribes flecainide. Flecainide has a potential side effect of serious arrythmia, and this can occur in a patient with a normal heart, without any negligence on the part of the doctor. The patient suffers this side effect, and sues the doctor for the ensuing damage (perhaps a stroke). The doctor may not have mentioned the risk of this side effect - perhaps he considered it too rare, or less important than the risk of stroke associated with untreated AF. In any event, say it is found that the doctor was negligent in failing to warn the patient adequately of the risks of taking the drug. However, the patient would have agreed to the flecainide even if warned, although he would have obtained a second or third opinion first. Classic principles would dictate that the patient would lose on causation. However, a claimant might now seek to apply *Chester v Afshar*. Would they succeed? If we look at the wording used by the Court of Appeal in *White* ("*medical procedures*") and *Beary* ("*treatment*"), we might conclude that they would. It could of course be argued that, as the Judges in those two cases were not considering medical cases, they were not being too careful about the precise words they used. We will have to wait and see.

The advice after *Chester* was that surgeons should carefully record in the patient's notes the risks of which they have warned the patient, and ask the patient to sign that record. The implication of *Chester* applying to other medical treatment is that all doctors might have to follow this advice when prescribing any drug with potentially serious side effects. ...and this in itself would be a serious side effect of *Chester.*

Dr Tania Francis, *Trainee Solicitor*

New Consent Booklet for the NHS

Launching at the NHS Confederation Annual Conference 2005, this brief guide for the NHS follows close on the heels of the popular Information Rights booklet and covers the areas of capacity, consent, incapable patients, advance directives, children and consent, the Mental Health Act 1983 and useful sources of related information. It is available by reference to c.hill-archer@hempsons.co.uk, cost £5 (incl. P&P).