substantial part, of those activities." A gross breach occurs "if the failure in question constitutes conduct falling far below what can reasonably be expected of the organisation in the circumstances."

Traditionally, manslaughter has been considered an offence capable of being committed only by a person and not by a corporate body. Lord Justice Bingham tentatively opined as far back as 1987, however, that an indictment could lie against a company as well as an individual.⁴ After the sinking in the English Channel of the car ferry *Herald of Free Enterprise* (which led to the deaths of 187 passengers) Mr Justice Turner in 1991 concluded that a company could be deemed guilty of the offence of manslaughter, provided that there was somebody within the company who was responsible for controlling the relevant activities that led to those deaths.⁵

It is not easy for the prosecution to show that the relevant acts have been committed by persons as the "controlling mind" responsible for the gross negligence that caused loss of life, as evidenced by several unsuccessful actions. As a result, actions against large companies have all failed after high profile public disasters such as the sinking of the *Herald of Free Enterprise*, the fire at King's Cross underground station in London, and the fire at the North Sea Piper Alpha oil platform.⁶

With smaller companies, finding a controlling mind is less of an obstacle. A company was convicted for corporate manslaughter in respect of four teenage students who drowned on a leisure canoeing trip.⁷ Although convictions for the offence of corporate manslaughter have been few, companies and organisations may well be prosecuted and substantially fined for offences under the Health and Safety at Work Act 1974, and guidance for this has been set down and reinforced by the court of appeal.⁸⁻⁹ As a result, organisations have been fined subsequent to prosecution involving fatalities resulting in a failure to meet required standards of care for their clients.¹⁰⁻¹²

The indictment in the case at Southampton General Hospital was based on a failure of the trust to ensure that patients were not exposed to risk in health and safety, take up references for clinical staff, supervise adequately the working of junior doctors, implement protocols for handover of the care of patients, and develop lines of communication for nursing staff to report concerns. By the trust pleading guilty to an amended charge of failing

to adequately manage and supervise the doctors in this case, the other issues have not been subject to scrutiny by the court. These could have relevance in similar actions for other NHS trusts in the future. In response to the Southampton case, the lead clinical coordinator for the National Confidential Enquiry into Patient Outcomes and Death said that these problems cannot be tackled by individual doctors but require careful planning by clinical teams, trusts, and, in some cases, strategic health authorities.²

Senior medical and managerial staff in the NHS would do well to take note of this, to give high priority to complying with health and safety law, and to prepare themselves for the implications of an indictment of corporate killing. Directors and managers may be personally indicted for breaches under section 37 of the Health and Safety at Work Act 1974. Senior healthcare professionals and managers of trusts might find themselves in the dock charged with corporate manslaughter. Health and safety risk management should be integrated into all activities of NHS trusts, with a particular emphasis on the supervision of junior doctors and other staff in training grades. Policy documents should be drafted carefully, and schemes for delegation to junior medical staff must be underpinned by a robust system of training and review.

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Consent for research in hyperacute stroke

Essential studies in the first six hours are hampered by rules on consent

Stroke accounts for 11% of deaths in England and Wales each year.¹ Without improvements in strategies for prevention or treatment in an increasingly ageing society the incidence of vascular events, particularly stroke, will increase by 33% by 2020.² Yet, according to the National Audit Office, "An emergency response to stroke with efficient and effective acute care is generally lacking."¹

Increased research capacity will be essential to developing such a response, and the recently established Stroke Research Network aims to develop this capacity

to improve prevention, treatment, and rehabilitation in stroke. But recent European legislation may curtail participation by patients with stroke in such clinical trials.

The Medicines for Human Use (Clinical Trials) Regulations 2004³ implement the European Union Clinical Trials Directive (2001/20/EC),⁴ potentially restricting research with incapacitated adults. A considerable proportion of patients with stroke are unable to give informed consent owing to their neurological impairment. Most interventions in acute stroke have short therapeutic time windows, hence the maxim

"Time is brain." Prolonged interruption of cerebral blood flow before intervention inevitably causes loss of neurones. To achieve maximum benefit, most experimental treatments must be given within three to six hours after acute stroke in the "hyperacute" period.

When a potential research participant lacks the necessary mental capacity to consent to participation in a trial, the regulations require informed consent to be given by a legal representative. Currently, English law does not cover the concept of such legal representation, nor does it recognise the notion of proxy consent. English law will change in this respect when the Mental Capacity Act 2005 comes into force, but this will not resolve the problem fully. The act does not define any family hierarchy, and thus there will still be uncertainty about who should take precedence when there is disagreement between family members.⁵ In a recent French study of 56 patients entering acute stroke trials, only 23 patients were able to provide consent.⁶ The responsibility for consent usually rested with relatives, of whom over half felt uncomfortable because of psychological stress induced by the need for urgent decision making.

Researchers argue that there is often insufficient time to identify a legal representative to provide consent before entering an incapacitated patient into a trial.⁷ Data from the Medical Research Council corticosteroid randomisation after significant head injury (CRASH) trial illustrate the delay incurred when proxy consent is mandatory.⁸ Time from injury to randomisation was just over one hour in hospitals allowing waived consent, compared with almost two hours in those where proxy consent was sought, and recruitment rates were lower in the group whose relatives were required to give such consent.

The requirement for proxy consent could jeopardise both the quantity and quality of future research on hyperacute stroke. A consultation document from the Medicines and Healthcare products Regulatory Agency (MHRA) last year suggested an amendment to the regulations which would provide an exception to this general requirement.⁹ But, even if the next of kin were able to act as legal representatives in this way, several ethical concerns will remain unresolved.

Is it wrong to recruit research participants with such acute medical problems?¹⁰ The International Conference on Harmonisation's tripartite guideline for good clinical practice requires that patients or relatives must be allowed time to consider all treatment options and the implications of taking part in a study, to ask questions, and to seek further advice if necessary.¹¹

In the hyperacute phase, next of kin are often shocked and distraught to learn of their relative's potentially life threatening or severely incapacitating illness. The impact of anxiety and distress on the consideration of complex information regarding participation in research may be further complicated by the potential burden of guilt in making such a decision for a family member. Psychosocial issues, conflict of interests, or divergence between personal preferences and the likely preferences of the patient and other relatives may all influence such a representative's ability to decide. Refusal may protect patients from the risks of research but may also deny them potentially beneficial treatments. Giving primacy to individual autonomy leads to a default position that assumes that

incapacitated patients would not wish to participate in research without personally giving prospective consent. But the ethical principles of beneficence or social justice justify arguing the contrary position, namely that citizens have a moral obligation or at least a civic duty to participate in medical research provided that safeguards against malpractice are in place.¹²

The proposed amendments by the MRHA⁹—currently out for consultation—will have substantial implications for the conduct of all research in the UK in the hyperacute phase of conditions which reduce mental capacity. In turn, this could affect subsequent health outcomes. This consultation exercise provides a chance to reconsider the ethics of including incapacitated patients in research and should be conducted with this in mind.

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