

September 2003

Inquests

Proposals to change the Coroners system

The Luce Report, commissioned by the Home Office, was published this summer. It makes 122 recommendations for reforming and bringing up to date the procedures for certifying and investigating death and the office of H M Coroner. However, no system for investigating death could ever be free from controversy and these proposals will not satisfy everyone as the following points show.

- Coroners will be employed by a national body instead of being appointed by the local authority. *This may lead to a loss of links between the coroner and the local community.*
- Juries will be empanelled only in cases involving the death of someone compulsorily in the care of the state, or where the death may have been caused by agents of the state and Article 2 of the European Convention on Human Rights (the right to life) may have been breached. This would exclude juries from most clinical negligence cases and deaths in the workplace where they have a valuable role.
- There is no proposal to extend public funding to cover legal representation of family members or other interested parties at all inquests, although there will be more liberal interpretation of the criteria for public funding where a public authority is represented. *There will continue not to be 'equality of arms' for all participants in the inquest process.*

Evidence and procedure

There will be subtle changes in the distinctions between inquests and other forms of legal proceedings. For example, there will no longer be a right to refuse to answer questions which might lead to self-incrimination. Instead, a witness will be required to answer all questions in return for an undertaking that the testimony

will not be used against the witness in any criminal trial. This will increase the effectiveness of the inquest as an inquiry into the facts.

The rule against making submissions on matters of factual evidence is likely to be changed. There are also likely to be rules providing for disclosure of documents. In these ways, the inquest will become more like the civil litigation process.

Verdicts

The existing form of verdict will not be used in future. There will continue to be a form of classification of each death investigated at an inquest but this will not be in terms implying criminal or civil liability, or its absence. The inquest outcome is to be primarily a factual account of the cause and circumstances of the death.

However, there will be analysis of whether there were systemic failings, and of how the activities of individuals bore upon the death. These changes will give increasing scope for findings similar to the present verdict of 'system neglect'.

Suicides

Deaths by suicide will be handled differently, and will not routinely include a public inquest. The word 'suicide' will in future be avoided. Such deaths will be classified as 'death from a deliberate act of self-harm or injury'.

Other recommendations

Public concern at recent high-profile cases is reflected in some recommendations:

- Family members will have rights to information on timing and representation at autopsies, and regarding the retention of any organs or tissues.

Continued overleaf



Inquests continued

- A new process for verification and certification of death will require two professional opinions before disposal of the body (whether by burial or cremation) is authorised.
- Inquests after a disaster involving multiple deaths will be held by the head of the coronial jurisdiction or the equivalent.

In exceptionally complex or contentious cases inquests will be taken by a judge including, in certain cases, a High Court Judge sitting as coroner.

Future legislation

Ministers are considering their response to the recommendations in the Luce Report before the reforms are taken forward. They will also be influenced by the recommendations made by Dame Janet Smith in the Shipman Inquiry. The Home Office has not yet indicated when new legislation will be introduced.

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Our inquest services

RadcliffesLeBrasseur has developed a specific service to advise clients on inquests, meeting staff beforehand to brief them and explain the process. We attend inquests to represent our NHS and private clients and members of professional protection organisations and we provide the advocacy services ourselves.

Clinical trials

New regulations on consent in clinical trials

The Medicines for Human Use (Clinical Trials) Regulations 2003 ('the Regulations') will bring into force a European Directive¹ on clinical trials relating to medicinal products. The Regulations have important implications for clinical trials where research into medicinal products is involved. The scope of this article does not permit a full discussion of the Regulations and any healthcare body considering entering a clinical trial is advised to seek legal advice on their effect. However, some of the key issues raised are discussed below.

Adult patients

Where a trial is to involve adult competent patients, the proposed subjects must give informed consent to involvement in the trial, although the Regulations do not define the extent of information required to constitute 'informed consent'. These subjects are to have an interview with the authorised health

professional responsible for the conduct of the trial or an appropriately qualified member of the trial team. The interview must give the subject an opportunity to '*understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted*'.² The subject must be provided with a contact point where he may obtain further information about the trial.

Children aged under 16

Where proposed clinical trials concern children under 16 years old, the Regulations set down principles by which such trials are to be conducted. The trial has to be designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to disease and the child's stage of development. The risk and degree of distress '*must be specifically defined and constantly monitored*' and account taken of the patient's interests over any interests of science and society.

¹ Directive on Good Clinical Practice in Clinical Trials (2001/20/EC)

² The Medicine for Human Use (Clinical Trials) Regulations 2003, Schedule 1, Part 3

Clinical trials continued

A parent, or someone with parental responsibility, must give informed consent to the child taking part in the trial. That person must have an interview with the healthcare professional responsible for the trial for the purposes described above in relation to adult subjects. Such a person must also be given a contact point where he may obtain further information about the trial. Such a person is entitled to withdraw the child from the trial at any time by revoking informed consent.

The child subject does not have a right to consent to involvement in the trial, but must have received information, regarding the trial, its risks and benefits, according to his capacity to understand from staff with professional experience of children. Where a child indicates that he does not wish to be involved in a trial, the healthcare professional responsible for the trial will consider those wishes, taking into account the child's capability to form an opinion and assess the information about the trial.

A clinical trial involving child subjects must relate directly to a clinical condition from which the child suffers, or be of such a nature that it can only be carried out on children. Some direct benefit for the children involved in the clinical trial is to be obtained from the trial. This is a difficult condition to satisfy in view of the nature of clinical trials (see below).

Incapacitated adults

The Regulations also make provision for incapacitated adults to be involved in clinical trials. Such a patient's legal representative can give informed consent to involvement in a trial. This is a departure from existing English law. A 'legal representative' is defined in the Regulations.

Similar procedures apply to the legal representative as to the parent of a child involved in a clinical study. The legal representative is to be provided with a contact point to obtain further information about the trial, and must be informed of the right to withdraw the subject from the trial at any time.

An adult incompetent patient must receive information regarding the trial, its risks and benefits according to his capacity to understand. Where the

subject indicates that he does not wish to participate, or wishes to be withdrawn from a trial, the healthcare professional responsible for conducting the trial must consider his wish, having regard to his capacity.

The Regulations also provide that where such patients are to be involved in a trial there must be grounds for '*expecting that administering the medicinal product to be tested in the trial will produce a benefit to the subject outweighing the risks or produce no risk at all*'. This is likely to be a very difficult assessment to reach at the outset of the trial as the very purpose of the trial will involve testing the efficacy and risks/benefits balance of the medicinal product. The Regulations also provide that the clinical trial must be related directly to a life threatening or debilitating condition from which the subject suffers.

The Regulations set down principles relating to the conduct of trials involving adult incompetent patients in similar terms to those principles relating to child patients.

Commencement

The Regulations are to be laid before Parliament in October 2003 and are planned to come into force on 1 May 2004. At the time of writing, the transitional provisions have not yet been published.

RadcliffesLeBrasseur is monitoring developments closely.

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Our legal services

RadcliffesLeBrasseur has considerable experience in advising on all aspects of clinical trial agreements on behalf of healthcare bodies including issues such as consent and indemnification. Should you require any further information please contact Alexandra Johnstone or Andrew Parsons.



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Private Dentistry

Government's action plan

Private dentistry has been put under the microscope by the Office of Fair Trading (OFT) following a complaint lodged by the Consumer Association in 2001 which alleged that competition was ineffective. Now the OFT report on the private dentistry market has resulted in an Action Plan for Private Dentistry, published by the Government in June 2003.

Information for patients

The Government will work with the General Dental Council (GDC) and the Commission for Healthcare Audit and Inspection (CHAI) to ensure that:

- all professional staff in dental practices are registered and comply with the existing requirements in the GDC's guidance 'Maintaining Standards' on the provision of information to patients, and
- the guidance is enforced to ensure that dental practices:
 - Clearly display to consumers indicative prices for key services
 - Give patients written treatment plans
 - Issue itemised accounts for treatment carried out
 - Prominently display the services available under the NHS, and those available privately
 - Make available Department of Health information on NHS treatments
 - Ensure patients know whether they will be treated under the NHS or privately; what the options are; and the reasons for offering private treatment
 - Use appropriate consent forms for mixing NHS and private dentistry
 - Routinely forward patients' records when patients change dentists

The OFT is to carry out an awareness campaign to publicise the entitlement of patients to receive this information.

Clinical pathways

The Government will support the development of evidence based clinical pathways in treatment provision. It is hoped that the use of clinical pathways in combination with new remuneration arrangements will address current concerns about incentives for dentists to under or over treat patients.

Complaints procedures

The Government will work with the GDC and other bodies on the introduction of a private dentistry complaints scheme.

The GDC will be given a range of additional sanctions to impose on dentists – sanctions that will be relative to the type and gravity of professional misconduct. They will be introduced during 2004.

Changes and consultation

The Government is committed to lifting the restriction on the number of corporate bodies that can carry out the business of dentistry, and it will consult on a number of proposals in its action plan.

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Legal services to dentistry

RadcliffesLeBrasseur provides a full range of legal services to the dental profession. Its clients include dental defence organisations as well as individual dentists. Our advice covers regulatory law, professional misconduct, medical negligence claims, and commercial law in relation to dental practices.

If you require any further information regarding the issues mentioned in this bulletin, please contact info@rlb-law.com

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