To consider

The Human Tissue Bill and other Legislative Developments

Issue

1. Our responses to recent Bills and other proposals for legislation.

Recommendations

2. To agree that we should:

   a. Continue to support the underlying principles of the Human Tissue Bill on obtaining consent from patients to the use of identifiable tissue and samples for use in research, while recognising the need to find means of doing so which does not impede the supply of material for research and education (paragraphs 10-24).

   b. Continue to comment on the Mental Incapacity Bill and Codes of Practice, and on the Mental Health Bill when it is published, basing policy on the guidance in our booklets on consent, confidentiality and on withholding and withdrawing life-prolonging treatment (paragraphs 25-28).

   c. Undertake briefing of members of both Houses of Parliament in line with the comments in paragraph 35 of this paper (paragraphs 29-35)

   d. Organise a meeting with Peers and others involved in cancer registries and related public health work (paragraphs 36-38)

   e. Monitor the progress of the Science and Technology Committee’s inquiry into human reproductive technology, and the House of Lords Committee on the Assisted Dying for the Terminally Ill Bill (paragraphs 39-40)

Further information

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Background

4. In October 2003 Council agreed that a key element of its strategy for the period until 2007 was to ‘strengthen our role as an authoritative and independent voice on issues facing doctors, patients and society.’ In response to this decision we have been working to raise our profile by engaging more actively in public debate, and where appropriate, by seeking to influence the development of new legislation.

5. A number of health-related Bills and other initiatives were announced in the Queen’s Speech and in separate statements made in November and December 2003. These included the Human Tissue Bill, the Children Bill, the Mental Incapacity Bill, the Mental Health Bill, a review of the Human Fertilisation and Embryology Act 1990, and the establishment of a Select Committee to review the issues in Lord Joffe’s Assisted Dying for the Terminally Ill Bill. This paper covers those areas where we have been involved or propose to be involved.

6. In responding to these initiatives we have drawn on policy developed between 1993 and 2003 and reflected in Good Medical Practice and the supporting booklets on consent, confidentiality and withholding and withdrawing life-prolonging treatment. Over the last ten years Council has focused on doctors’ obligation to treat patients with respect, to enable them to be fully involved in decisions about their care, and to decide how identifiable information about them would be used or disclosed. This approach reflects changes in public attitudes, Government policy, the outcomes of inquiries such as those into the events at Bristol Royal Infirmary and at Alder Hey, and developments in the law, for example, the Data Protection Act 1998 and the Human Rights Act 1998 both came into effect in this period.

7. Our guidance has not disregarded the practical problems doctors face. We have almost always provided advice on good practice to be followed ‘where practicable’. Further, we have taken the view that we should not see the interests of the individual and those of the wider community as in opposition. We have consistently argued that policies can and should be developed which encourage doctors and health care providers to give patients information and choice, while not impeding the provision of information, or tissue samples, for research, public health, teaching or other purposes. We have maintained the view that best practice is to involve patients in decisions, and that, for example, when faced with a request for information about a patient, asking the patient should always be the first option to be considered.

8. Our guidance has generally been well-received, although the research and public health communities have consistently expressed concerns about the impact of our guidance on their work. Much of the legislation being brought forward in this session involves questions about patient choice and how information about patients, or tissue taken from patients, is used. This in turn raises questions about the extent and scope of individuals’ rights, and the weight to be given to the need to develop new treatment, to teach and train doctors, and to plan and manage the NHS. It also raises questions about the resources, in both clinicians’ time and direct costs, of providing information and of seeking, recording and acting on patients’ consent.
9. Our comments on the Human Tissue Bill, and on other legislation, have been based on our published guidance and established policies.

Discussion

The Human Tissue Bill

10. The Human Tissue Bill was published on 3 December 2004. The Bill has progressed through second reading and committee stages and is awaiting parliamentary time for the Report Stage in the Commons. The date for this has not yet been announced.


12. The Bill arises from events at Bristol Royal Infirmary and the Royal Liverpool Children's Hospital (Alder Hey) which were explored during the Kennedy and Redfern inquiries. Those inquiries established that organs and tissue from children had been removed, stored and used without proper consent. A census by the Chief Medical Officer for England, an inquiry in Northern Ireland and the Isaacs Report showed that storage and use of organs and tissue from both adults and children without proper consent had been widespread.

13. The current legislation is spread across a number of Acts, lacks clarity, particularly in relation to retaining and using tissue from the deceased, and – apart from the Human Organ Transplants Act 1989 - includes no measures, or inadequate measures, for enforcement.

14. The Bill attempts to bring together, in one comprehensive piece of legislation, all issues relating to the collection, storage and use of human tissue. Its chief provisions are:

   a. The requirement to obtain appropriate consent for the collection, storage and use of tissue in or following post mortems and for use of ‘remnant’ material taken from living patients for research and some other functions.

   b. The introduction of criminal offences for misuse of tissue.

   c. The creation of the Human Tissue Authority to issue licences relating to the removal, storage, use and disposal of human material and to issue codes of practice on these issues.

   d. To give powers to the HTA to regulate all human organ transplants between living persons

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1 Tissue, or ‘relevant material’, in the Bill's terms, is defined as material which consists of or includes human cells, with the exception of gametes, hair and nails
e. The prohibition of commercial dealing in human material.

f. The establishment, under the HTA, of an Inspectorate of Anatomy and Pathology and an Inspectorate for Organs and Tissues for Human Use.

Appropriate consent

15. The Bill currently requires ‘appropriate’ consent to be obtained for any use of tissue from the deceased, except at the direction of a coroner, and for many uses of tissue taken from the living. The exceptions for living patients are: ‘clinical audit; education and training which is incidental to medical diagnosis or treatment; public health monitoring; and quality assurance’.

16. The use of relevant material without appropriate consent, or without a ‘reasonable belief’ that consent has been obtained is an offence, subject to a maximum penalty of imprisonment for a term not exceeding 12 months.

17. The focus of concern in the medical and research community has been the requirement to obtain appropriate consent to the storage and use of tissue and body fluids taken from living patients. The research community has been concerned, in particular, that consent will be needed to store and use material removed during a surgical or other procedure, and ‘remnant tissue’, that is material remaining when diagnostic tests have been completed. The chief points expressed to the Government were:

a. The practical difficulties, given that an estimated 3 million solid tissue samples and over 100 million blood samples are taken each year. It would be difficult or impossible, and would have enormous monetary and human resource costs, to obtain and record express consent for each sample, and to ensure that patients’ agreement or refusal was attached to each sample.

b. That the criminal offences created in the Bill would discourage the use of samples in research and teaching. In many cases it would be difficult for researchers to know whether or not they could demonstrate a ‘reasonable belief’ that consent had been obtained, and would be likely to interpret this conservatively in the light of the possible sanctions.

c. That it was difficult or impossible to distinguish between education and training which was ‘incidental to medical treatment or diagnosis’, and other education or training. It has been argued that, the training of pathologists could be hampered by concerns about committing criminal offences.

18. We share all of these concerns. There are clearly significant practical difficulties in seeking consent for the use of every sample and these should not be allowed to affect the provision of samples and tissue for education and research which is vital for the public health.

19. Our approach has been to seek solutions to these problems, and maintain, as far as possible, the principles set out in Good Medical Practice and our other booklets of guidance relating to trust and openness. Following these principles, we have taken the line that patients are entitled to information about how their tissue or
information will be used, and wherever practicable, be given the opportunity to give or withhold consent to the use of their tissue for these purposes.

20. We have therefore supported the principles which underpin the Bill, while acknowledging the practical difficulties which the current terms of the Bill represent. We have suggested that ‘implied consent’ might be used in place of express or explicit consent where the sample was taken on the basis of oral or implied consent. This would mean that patients would be told that samples or remnant tissue would be used for teaching and research, unless they objected. Information of this kind could be provided orally by health care professionals, or through leaflets or notices. This would mean that patients’ wishes would need to be recorded only in the minority of cases (estimated at between 6% and 14%) where patients objected. The President promoted this idea at a meeting with Ministers on 9 March 2004 and subsequently wrote, jointly with Professor David J Kerr, the Director of the National Translational Cancer Research Network, to Ms Rosie Winterton MP to provide a more detailed view (Annex A).

21. Our approach is broadly consistent with guidance from the BMA and other professional bodies. Extracts from guidance issued by the MRC, BMA, and Royal College of Pathologists is at Annex B. Patient and consumer opinion – as far as it is known - also appears to be in favour of enabling patients to decide how their tissue or samples can be used (Annex C). However, the Wellcome Trust, Cancer UK and, to a lesser degree, the MRC believe that the Bill as drafted poses insuperable problems and that all matters relating to tissue from the living should be removed from the Bill.

22. We understand that the Government will be tabling amendments to the Bill at the Report Stage. They have not yet been made public.

Future position

23. The Bill has yet to reach the Lords, where it is possible, depending on the nature of the Government’s amendments, that there will be some continuing opposition to requirements for any consent to the use of remnant samples in research and education.

24. We propose to continue to take the view that it is right in principle to involve patients in decisions about how samples are used, particularly where the samples remain linked to their names or other identifying data. However, it is important that this is done in a way which does not impose unacceptable burdens on clinicians or which otherwise prevent an adequate supply of samples for research and education. This might be achieved, for example, by enabling patient choice through an ‘opt-out’ (that is by using implied consent) and by removing criminal sanctions from the Bill, and introducing other, less draconian means of enforcement.

Recommendation: We should continue to support the underlying principles of the Human Tissue Bill on obtaining consent from patients to the use of identifiable tissue and samples for use in research, while recognising the need to find means of doing so which does not impede the supply of material for research and education.
25. The Government published the Draft Mental Incapacity Bill on 27 June 2003. The Bill sets out proposals to reform the law in England and Wales, to clarify the decision-making process where an adult lacks capacity to make decisions. The Bill covers decisions about a person’s property and financial affairs and their healthcare and welfare needs. It has significant implications for doctors’ practice and their relationships with patients and their families and carers. For example, it introduces a new power for adults to appoint an attorney with legal power to make healthcare decisions on their behalf. A summary of the terms of the Bill is at Annex D.

26. The Government set up a Joint Parliamentary Committee to scrutinise the draft proposals during summer 2003. We submitted written evidence to the Committee with help from Dr Rosalind Ranson and Dr Pearl Hettiaratchy (a former Council member). We supported the overall direction and intention of the Bill, but had a number of reservations about the terms of the draft clauses. In particular, we noted that many crucial issues (for example on defining best interests and on the working of advance directives) would not become clear until the details were addressed in Codes of Practice, which had not yet been drafted. We indicated that we would welcome the opportunity to be involved in the development of the Codes of Practice. We want to try to ensure that emerging legal requirements are consistent with the obligations we place on doctors.

27. The Department of Constitutional Affairs is now redrafting the Bill and, at the same time, preparing Codes of Practice. They are seeking comments and advice on both the terms of the Bill and the Codes of Practice, as each section is completed. The intention is to present the Bill to Parliament in summer 2004. The timescale for comment on new material has usually been less than a week, which makes it difficult to consider the issues in any depth. We are continuing to obtain help from Dr Ranson and Dr Hettiaratchy and would welcome assistance from other Council members, in view of the scope of the Codes of Practice.

28. A draft Mental Health Bill was issued for consultation in June 2002. We responded with a number of concerns about the terms of the Bill. Since then the focus has moved to the incapacity legislation, and we understand that further work on the Mental Health Bill will be undertaken following agreement on the content of the Mental Incapacity Bill.

**Recommendation:** To continue to comment on the Mental Incapacity Bill and Codes of Practice, and on the Mental Health Bill when it is published, basing policy on the guidance in our booklets on consent, confidentiality and on withholding and withdrawing life-prolonging treatment.

**Children Bill**

29. The Children Bill was published in 4 March 2004. It takes forward a number of initiatives proposed in the Green Paper *Every Child Matters*. The Bill covers England and Wales. We expressed some concerns about the proposals set out in the Green Paper, particularly those relating to the collection and disclosure of health information about children and their parents.
30. The Bill includes a number of provisions for co-operation between agencies to promote and safeguard the well-being of children. The agencies include education, health, social care and criminal justice organisations. This part of the Bill also gives powers to the Secretary of State to set up a national database, or to require local authorities to set up local databases, of information about children and their families, including information about the services they receive and any matters which raise a ‘cause for concern’. Arrangements for disclosure to databases, and disclosure from databases and between agencies will be defined by regulations, which have yet to be drafted. However, the Bill gives the Secretary of State powers to ‘require or permit’ disclosures to be made to databases or from them, without consent from the child, if competent, or a person with parental responsibility. If the Secretary of State used the entire scope of the powers in the Bill, it would mean that health records relating to children, and relevant information relating to the health of those caring for them, such as mental health, addiction, problems with relationships etc, would be collected on a national or local database.

31. Our existing guidance promotes confidentiality as part of relationships of trust between doctors and patients. Our guidance provides for disclosure without consent, where this will protect someone from serious harm or for other reasons which are in the public interest.

32. The Bill takes a different approach, which suggests that information should be exchanged and disclosed in order to promote the well-being or welfare of a child (not only to protect a child from harm). It seems likely from the Green Paper that information relating to ‘causes for concern’ will be shared amongst agencies in contact with the child. However the threshold for inclusion of information on the database, or its disclosure, have not been made clear.

33. Clearly, it is vital that children are protected from neglect or abuse, and we would not wish to raise any objection to arrangements which are designed to identify, at an early stage, children who may be at risk. Equally, it is without question desirable that the welfare and well-being of children are promoted by all the professionals and agencies with whom they have contact.

34. Nonetheless, the intention of the Bill is clearly to encourage routine recording and disclosure of health information about children, and includes powers for the Secretary of State to require doctors to disclose information, even where there would currently be no public interest justification, in terms of the common law, for doing so.

35. We will want to welcome the general thrust of the Bill, and the greater priority it gives to the needs of children. In commenting on the Bill, we may also wish to make the point that confidentiality between doctors and patients has benefits as well as disadvantages. In bringing forward proposals which may alter the nature of the relationship between doctors and patients, careful thought should be given to the ‘unintended’ consequences. In particular, thought might be given to:

a. Any evidence that fear of intervention from social services or the police may deter parents or carers from seeking medical care when their children have been hurt (whether accidentally or non-accidentally) or are unwell.
b. Whether ‘cause for concern’ can be defined in a way which precludes any form of discrimination against religious or ethnic groups, or those, such as travellers, who have adopted an unconventional lifestyle.

c. Whether collecting information on every child will be effective. Information about children at risk may become lost in the enormous amount of data and records held on a national, or even on a local database.

d. Whether collecting information about children from a number of sources is ethically acceptable, particularly as there would be considerable privacy concerns about similar databases relating to adults. There is no indication in the Bill about what would happen to records when a child reaches adulthood.

**Recommendation:** To undertake briefing of members of both Houses of Parliament in line with the comments in paragraph 35 of this paper.

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**Cancer Registries**

36. Baroness Finlay of Llandaff is seeking support for a private members’ Bill which would circumvent the current common law requirements relating to the disclosure of identifiable information about patients with cancer, or who have been tested for cancer. At present, the need for doctors to obtain consent to such disclosures, or be prepared to justify the disclosure as being in the public interest, is suspended by a regulation made under s60 of the Health and Social Care Act 2001. However, regulations under this Act are subject to review, and are intended to provide only temporary support for disclosures while arrangements are made either to anonymise data, or to put in place procedures to seek and record consent.

37. We issued guidance in 2000 advising doctors that they must inform patients before disclosing information to a cancer registry and that, wherever it was practicable to do so, they should seek consent for the disclosure. Our most recent guidance is in the form of a frequently asked question (Annex E). This allows greater freedom to disclose information where patients have been informed about the disclosure and reasonable steps have been taken to act on objections. The obligation to inform patients is likely in any case to be a ‘fair processing’ requirement of the Data Protection Act 2002.

38. We understand that an all-party parliamentary group meeting was held earlier this year, to consider the need for legislation requiring disclosures to cancer registers. To continue participation in this debate, we propose to host a meeting with Peers and the research community to explain our position and listen to any the concerns about our current guidance. We can then consider whether we should change our stance and support the proposal to make disclosure of information to cancer registries mandatory, irrespective of the wishes of individual patients.

**Recommendation:** To agree that we should organise a meeting with Peers and others involved in cancer registries and related public health work.
Other developments

Assisted Dying for the Terminally Ill Bill

39. A Select Committee has now been set up to consider the Bill, which was introduced in the Lords in 2003 by Lord Joffe. The Committee will have power to appoint specialist advisers; and will meet first on Wednesday 7 July 2004. We intend to keep a watching brief on this Committee. We have not previously given advice on matters which contravene the law, such as euthanasia and assisted suicide. We, therefore, have no policy to draw on for evidence to the Committee. However, it is possible that the scope of the Inquiry will broaden into other areas, such as withdrawing treatment, and we will submit evidence when or if these issues are raised.

Review of the Human Fertilisation and Embryology Act 1990

40. The Science and Technology Committee is considering a wide range of issues, including the provisions for late abortions, which are included in the Act. The Terms of Reference for the Inquiry are at Annex F. The Committee is inviting written evidence, and will begin oral hearings in June 2004. We do not propose to submit evidence to this inquiry, as we have no specific guidance or policy in this area. Again, however, we will keep a watching brief, to see whether the Committee covers issues of direct relevance to our work.

**Recommendation:** We should monitor the progress of the Science and Technology Committee’s inquiry into human reproductive technology, and the House of Lords Committee on the Assisted Dying for the Terminally Ill Bill.

Resource implications

41. A meeting for Peers will incur direct catering and possibly facilities hire costs. We do not expect costs to exceed £1,000.

Equality

42. None arising from this paper.