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Ownership and uses of human tissue: Does the Nuffield bioethics report accord with opinion of surgical inpatients?

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Abstract

Objective—To compare opinion of surgical inpatients with the conclusions of the report of the Nuffield Council on Bioethics regarding the ownership and uses of human tissue.

Design—Survey of results of questionnaires completed by patients.

Setting—Large teaching hospital.

Subjects—384 postoperative adult surgical patients.

Results—There was strong support among patients for the use of tissues in medical education, research, and science with the exception of those tissues which may transmit disease to others. Few patients (39; 10%) believed that they retained ownership of tissue removed at surgery. Most believed that the tissue belonged to the hospital (103; 27%), to nobody (103; 27%), or to the laboratory (77; 20%). Most patients had not been given any information about the possible uses of their tissues after removal.

Conclusions—Surgical inpatients seem to endorse the conclusions of the Nuffield report regarding the ownership and uses of human tissue. The recommendations regarding patient information and consent procedures should be implemented at the earliest opportunity.

Introduction

The working party of the Nuffield Council on Bioethics, which examined the ethical and legal issues surrounding human tissue, proposed that tissue removed from patients in the course of treatment should be considered abandoned and that the possibility that tissue may be stored, used in the treatment of others, or used in medical education and research should be indicated in general terms in standard consent procedures for medical and surgical

interventions entailing the removal of tissue for diagnosis or treatment.¹ If patients and the public were to have extremely divergent views from the working party then some of the complex issues surrounding the uses of human tissue would require reconsideration.

We provide the first detailed assessment of opinion of patients in the United Kingdom about the ownership of human tissue removed during treatment and the uses to which that tissue may, can, or should be put.

Patients and methods

Questionnaire design—The questionnaire contained no questions relating to specific research applications or the use of cadaveric, fetal, or reproductive tissue. Respondents were required to tick a box within a limited range of options (see tables 1 and 2). Case records were reviewed to determine the nature of surgical procedures and final histological diagnoses if tissue had been removed. The current hospital consent form contains no reference to the ownership or to the subsequent disposal, storage, or other uses of tissue removed during investigation or treatment, but completed consent forms were examined to determine whether references to such issues had been added during consent procedures.

Questionnaire terminology—Preliminary work clearly indicated that the term "tissue" was poorly understood. The term "diseased part of the body" was found to be an acceptable alternative for tissue within the questionnaire.

Subjects—The survey population consisted of 450 adult patients after they had undergone general surgery or an orthopaedic or urological operation during a seven week period in a large teaching centre. Twenty nine patients were too unwell to participate. Two medical students hand delivered questionnaires with an explanatory letter. The study was approved by the South Sheffield Research Ethics Committee.

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Results

RESPONSE RATE AND ANALYSIS

A total of 384 questionnaires were returned (response rate 91%). More respondents were men (58% v 42% women). There were 38 respondents aged between 18 and 34 years; 65 aged between 35 and 49; 119 aged between 50 and 65; 127 aged between 66 and 79; and 35 aged 80 and over. The 60 respondents who had procedures which did not entail the removal of tissue were not excluded from the sample. No consent forms contained any reference to the ownership or to the subsequent disposal, storage, or other uses of removed tissue.

QUESTIONNAIRE RESPONSES

The importance of careful tissue examination to the diagnosis and management of cancer and other diseases was well understood (table 1, items 1, 2, 4, and 5). Most respondents believed that their tissue could be used in medical research and in undergraduate and postgraduate medical education (items 3, 6, and 7). Few respondents thought that tissue would be either preserved and kept or thrown away immediately after the operation (items 10 and 11). Transplantation and the preparation of hormones were not commonly considered to be uses for tissue removed at surgery (items 12 and 13), and many respondents commented that their tissue would be diseased and therefore unsuitable for such uses. Strong support was observed for most of the suggested uses for tissue with exceptions of transplantation and hormone preparation (table 2, items 9 and 10).

In total 104 respondents believed that the hospital owned the tissue, but a similar proportion thought that nobody owned it (103). Fewer patients believed that the laboratory owned the tissue (77) and fewer still that they themselves owned the tissue (37). The sex of the patient (χ^2 8.2; 5 df; $P>0.05$), the site of surgery (26.4; 20 df; $P>0.05$), the removal of tissue (8.3; 5 df; $P>0.05$), and malignant diagnoses (5.8; 5 df; $P>0.05$) were not related to views on the ownership of tissue, but patients aged under 65 years were more likely to believe that the hospital owned the tissue than those aged over 65 (12.5; 5 df; $0.01<P<0.05$).

Of those patients who believed that they owned the tissue themselves, 30 still supported its use in teaching and research. No significant differences in the level of support for these and the other suggested applications were identified between those patients who believed that they owned the tissue themselves and the other

Table 2—Ranked responses to the question "If you could decide what happens to the diseased part of your body removed during an operation, which of the following would you agree to?"

Item	Yes	No	Unsure	No answer
1 Teaching medical students	332	6	24	22
2 Helping doctors give the correct treatment	327	7	29	21
3 Diagnosing cancer	320	9	37	18
4 Medical research	319	6	33	26
5 Teaching doctors	316	14	29	25
6 Diagnosing diseases	306	10	45	23
7 Testing new treatments	273	24	58	29
8 Testing new drugs	252	27	63	32
9 Making hormones for treating others	147	106	97	34
10 Transplantation	121	165	65	33

respondents. Many respondents indicated that proper use of the tissue was more important than who owns it. One hundred and thirty four respondents stated that they were not aware of having ever received any information regarding the ownership and uses of human tissue removed during surgery.

Discussion

Human tissue is often removed from the body in the course of diagnosis or treatment, and there may be tissue left over after sufficient has been sampled for diagnostic purposes. Such left over tissue and any material archived during the course of diagnosis and treatment has in the past been made available for the purposes of medical research, education, and audit without the specific consent of the patient from whom the tissue has been removed.

Legislation governing the removal and use of cadaveric human tissue has been in existence for many years, but the lack of systematic review of the uses of human tissue removed from living patients has created problems. The working party of the Nuffield Council on Bioethics was timely in its examination of the relevant ethical and legal issues in relation to the human tissue not covered by specific recent legislation or regulation.¹ The working party concluded that tissue removed with consent during the course of treatment should be regarded as having been abandoned and that the possibility that tissue may be stored, archived, and subsequently used in the treatment of the patient or others, or in medical research and education, should be indicated in general terms in standard consent procedures.

The difficulties in determining the ownership of tissue removed with consent during the course of treatment (or even whether property rights should apply to human tissue as implied by the use of the term "abandoned") are emphasised by our observations which support the conclusions of the working party regarding abandonment. Most patients believed that such tissue comes into the possession of the hospital authority or that it ceases to belong to any individual or institution. A much smaller proportion concurred with the view of some commentators that the tissue remains the property of the patient.² The applications for which tissue might be used seemed to be more important to respondents than the issue of ownership.

Our results also support the working party's conclusions that consent to treatment is inevitably general but should always refer to the possibility that removed tissue may be discarded or stored and, if stored, that it may at some time be used for diagnosis, further treatment, research, teaching, or study. Most patients in this study supported the use of their tissue in most areas of medical education and research with the

Table 1—Ranked responses of 384 patients to the question "Which of the following do you think happens to the diseased part of the body removed during an operation?"

Item	Yes	No	Unsure	No answer
1 It is investigated to see if it contains any disease	297	14	57	16
2 It is studied using a microscope	247	20	95	22
3 It is used to teach medical students about disease	246	29	90	19
4 It is analysed to test for cancer	233	36	98	17
5 It is used to help doctors give the correct treatment	233	34	95	22
6 It is used in medical research	212	33	116	23
7 It is used to train doctors	170	50	138	26
8 It is used to test new drugs	73	110	172	29
9 It is used to practise surgical operations	69	119	171	25
10 It is thrown away immediately after the operation	57	121	178	28
11 It is preserved and kept	34	183	140	27
12 It is used to obtain hormones that can be used to treat others	21	171	161	31
13 It is used for transplantation	21	266	68	29

exception of those applications which could transmit disease to others. Individual consent for specific uses would seem unnecessary and impracticable, particularly in relation to material stored anonymously in pathological archives and increasingly in residual tissue banks. The specifics of future research applications are not known at the time of storage and therefore the use of such material cannot sensibly be subject to specific informed consent.

Although 90% of the respondents in this study believed that removed tissue belonged to others or to no one, a considerable minority believed that they retained ownership of removed tissue. To clarify the situation for all patients we would support the recommendation that consent forms and explanatory material for patients should be modified so that hospitals inform patients that consent for investigation or treatment also covers any acceptable further uses of tissue. Many consent forms, including our own, do not contain any reference to the subsequent use of removed tissue except for the description of the operation, investigation, or treatment which is completed by the attending clinician.³

Many factors may have combined to produce the high response rate in this study; including genuine patient interest in the subject, the simple design of the questionnaire, and the personal delivery and collection of the questionnaires. Another factor may have been that participation provided patients an opportunity to demonstrate gratitude towards those concerned in the therapeutic process. In this respect postoperative patients may represent a biased group of subjects, and the study is weakened by the absence of appropriate controls. Further studies may be necessary to confirm these findings in other groups. We would also emphasise that our observations and conclusions, like those of the

Key messages

- A working party of the Nuffield Council on Bioethics proposed that tissues removed from patients in the course of treatment should be considered abandoned and that consent for their use in research should be obtained in standard consent procedures
- Most surgical inpatients seem to concur with the conclusions and recommendations of the working party regarding the uses of such human tissue
- Alterations to patient consent forms and additional patient education represent reasonable requirements for continued and appropriately regulated access to human tissue for the purposes of medical education, research, and audit

Nuffield working group, may not represent those of societies outside of the United Kingdom. Cultural and religious influences may severely restrict the use of human tissue in some countries.

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Variation in local policies and guidelines for cholesterol management: national survey

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Raised serum cholesterol concentrations are known to be an important risk factor for coronary heart disease. In 1993 an authoritative systematic review of effective cholesterol management was disseminated to health authorities and boards throughout the United Kingdom.¹ The review recommended that population cholesterol screening should be discouraged and cholesterol lowering treatment targeted at those patients at highest overall risk of coronary heart disease according to a range of risk factors. In 1994 we conducted a national survey to assess variations in local cholesterol management policies and clinical guidelines and the extent to which they reflected the recommendations.

Methods and results

A questionnaire was sent to the director of public health (or chief administrative medical officer) of all 151 health authorities or boards in the United Kingdom. Respondents were also asked to submit copies of local clinical guidelines. The responses were analysed using EPIINFO 6.1.

Completed questionnaires were received from 142 (94%) of the authorities. Only 70 reported the existence of a local written policy or guidelines covering cholesterol management, though 26 reported that policies were under development. Of the 70 with existing policies 55 reported that they included clinical criteria

for cholesterol testing in general practice, referral to a dietitian or lipidologist, and hyperlipidaemia management—that is, they included clinical guidelines. However, only 34 reported a collaborative approach to developing such policies—for example, with family health services authorities, general practitioners, laboratories, and pharmacists. Only 13 had procedures for monitoring the implementation of the policies.

Of the 40 guidelines submitted, 37 advocated selective testing of individuals at high overall risk of coronary heart disease (as recommended in the review bulletin), rather than screening whole populations. Nevertheless, there was much variation in the risk factors specified and how they were defined. Seven guidelines discussed the concept of “high overall risk” but failed to specify any risk factors. Three guidelines did not mention pre-existing coronary heart disease, two did not mention a family history of hyperlipidaemia or premature coronary heart disease, and one suggested that cholesterol testing should be extended to “women without risk factors.” Only one guideline proposed the use of a composite risk factor scoring system. The age range recommended for testing also varied greatly: the lower limit varied from 16 to 35 years and the upper from 55 to 70. The cholesterol lowering management criteria also showed striking variation (table 1). Although 35 of the 40 submitted guidelines gave clinical criteria for cholesterol lowering drug treatment, there was much variation in the advice given.

Comment

This study revealed great variation and inconsistency in local criteria for cholesterol testing and treatment throughout the United Kingdom, despite the previous widely disseminated review recommendations. Only about half of responding districts had developed

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