

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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Funding: None.

- 1 Nuffield Council on Bioethics. *Human tissue: ethical and legal issues*. London: Nuffield Council on Bioethics, 1995.
- 2 Dickens BM. Living tissue and organ donors and property law. *J Contemp Health Law Policy* 1992;8:73-93.
- 3 NHS Management Executive. *A guide to consent for examination or treatment*. London: Department of Health, 1990.

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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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Table 1—Variation in cholesterol lowering management criteria in guidelines submitted by 40 authorities

Element in recommendations	No of guidelines in which element was included
Specific management regimens according to degree of overall risk	Specified in 23
Repeat cholesterol measurement before treatment	Recommended in 31
Full lipid profile before treatment	Recommended in 28
Upper limit of "acceptable" total cholesterol level	Specified in 32; varied from 5.2 to 6.5 mmol/l (median 5.2)
Total cholesterol level at which dietitian should be consulted	Specified in 15; varied from 6.5 to 8.0 mmol/l (median 7.8)
Total cholesterol level at which referral to lipid clinic should be considered	Specified in 14; varied from 6.5 to 10 mmol/l (median 7.8)
Total cholesterol level at which drugs should be considered	Specified in 28; varied from 6.5 to 10 mmol/l (median 7.8)

policies or guidelines, and only about half of those had done so collaboratively.

In view of the high potential cost of cholesterol management for large numbers of patients there is a need to make priorities based on clear criteria for both testing and treatment.² For testing, this requires an explicit definition of each risk factor and of the various combinations comprising "high overall risk." For treatment, it requires explicit criteria based on overall risk status (not merely serum cholesterol concentration), agreed in

accordance with current evidence of cost effectiveness. Clear, explicit guidelines, developed collaboratively with those who will be using them, have been shown to facilitate, albeit not to guarantee, more consistent practice.³ All health authorities, through their directors of public health working with general practitioners, physicians, and lipidologists, should ensure that suitable local policies and guidelines for cholesterol management are agreed, disseminated, and monitored.

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1 Cholesterol Screening and Treatment. *Effective health care bulletin No 6*. Leeds: University of Leeds, 1993.

2 Pharos PDP, Hollingworth W. Cost effectiveness of lowering cholesterol concentration with statins in patients with and without pre-existing coronary heart disease: life table method applied to health authority population. *BMJ* 1996;312:1443-8.

3 Implementing Clinical Guidelines. *Effective health care bulletin No 8*. Leeds: University of Leeds, 1994.

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NHS breast screening programme: is the high incidence of interval cancers inevitable?

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In the NHS breast screening programme women are screened every three years; those presenting with breast cancer within three years of a negative test are considered to have an interval cancer. Unexpectedly high rates of interval cancers have been reported from the programme,^{1,2} but opinion is divided about what should be done.³ It is accepted that not all interval cancers could have been detected at the time of screening and that some will be true interval cancers, appearing de novo between screening rounds. We report how the occurrence of true interval cancers varies with time from screening.

Subjects, methods, and results

Interval cancers occurring before 31 March 1994 in women screened from 1 April 1988 to 31 March 1993 at the Manchester and Wigan breast screening services were identified,¹ and a mammogram taken at the time of diagnosis was sought for all these cancers. Screening films were mounted on roller viewers by clerical staff; no attempt was made to replicate the screening situation, but some negative mammograms from women known not to have breast cancer were included (amounting to 10% of the total). The screening films were reviewed by three radiologists from a centre not involved in the initial assessment

and consensus was reached on the presence or absence of a significant abnormality, the location of which was then checked by reference to the diagnostic films. An interval cancer was classified as a false negative when the same suspicious abnormality was present on both screening and diagnostic mammograms, as a true interval cancer when an abnormality was present only on the diagnostic mammogram, and as radiologically occult if no abnormality was present on either film. No attempt was made to classify interval cancers when a diagnostic mammogram was unavailable. Only interval cancers occurring in years for which cancer registration was complete were included in the analysis.

Two hundred and sixty interval cancers were identified; 13 were excluded as they were still awaiting radiological evaluation. Of the remaining 247 cases, 130 (53%) had a diagnostic mammogram and could be classified: 26 (39%), 51 (58%), and 53 (58%) of these presented in the first, second, and third year respectively after a negative screen. Four radiologically occult cancers have been excluded from table 1, which shows the frequency of true and false negative interval cancers with time from screening. The proportion of true interval cancers increased significantly with year from screening ($\chi^2=12.75$; $df=2$; $P<0.002$).

Comment

Almost half of all interval cancers are diagnosed in the third year after screening.^{1,2} We found that the frequency of true interval cancers increases with time from screening and in the third year comprises 80% of all classifiable interval cancers. The absence of a diagnostic mammogram in many cases is an unsatisfactory but widespread finding in the NHS breast screening programme, and it is impossible to opine on the distribution of true and false negative interval cancers in these tumours. The proportion of interval cancers which can be classified has increased over time with greater clinical awareness of the importance of obtaining a diagnostic mammogram and increased provision of diagnostic mammography sets. We can, however, draw broad comparisons with other European screening programmes and trials with similar overall interval cancer rates, bearing in mind that these have a

Table 1—Frequency of true and false negative interval cancers in relation to time from screening

Time from screening (months):	0-12 n = 25	13-24 n = 50	25-36 n = 51
True interval cancers	10 (40%)	35 (70%)	41 (80%)
False negative	15 (60%)	15 (30%)	10 (20%)