

academic genetic research and 1276 to commercial genetic research; 31 and 66 respectively refused. Among those who consented to academic research 292 wanted to be asked about each new future study. The authors conclude that it is feasible to seek consent and that few people refuse.

Why should we seek consent for using left over tissue samples?

Both these studies are relevant to this week's For and Against article, which is on whether consent needs to be sought for using leftover body material stored in laboratories. Paul van Diest argues that consent is not necessary because the principle of autonomy does not really apply when such body material would otherwise be discarded (p 648). Julian Savulescu, however, argues that patients do feel "used" when their material is used without their consent.

When is it legitimate to exclude patients' data from study results?

Investigators in clinical trials are faced with difficulty when patients are inappropriately randomised into a trial or when information on patients' eligibility for inclusion is not available at the time of randomisation. Can such patients be excluded from the analysis of the study's outcomes without biasing the measure of effect? Fergusson and colleagues (p 652) consider that it may be acceptable to exclude patients

after randomisation when investigators made mistakes in implementing eligibility criteria or when patients never received the intervention. But patients randomised because of excessively broad inclusion criteria who prove not to have the target condition should not be excluded. They recommend that investigators should specify any foreseeable post randomisation exclusions and that an independent committee should make the decision about such exclusions.

Partners may need to be screened for diseases of their spouses



Marital partners of people with some diseases may need to be screened because they are at increased risk of the same disease. In a large, general practice based, cross sectional study, Hippisley-Cox and colleagues (p 636) found that participants whose marital partner had asthma, depression, hypertension, hyperlipidaemia, or peptic ulcer disease were at increased risk of having the same disease. Shared environmental causes may be implicated in the development of diseases, in addition to genetic or distant exposures and shared behaviours with respect to seeking health care.

Editor's choice

Consent for research on stored body samples

Sometimes intellectual debates can become very emotional very quickly. Twice I've been involved in something close to a shouting match over whether it is acceptable to test stored body specimens without consent. The word "Nazi" was soon used, and the beliefs of protagonists diverged rather than converged. As testing specimens that have been kept is common practice, we thought we ought to commission a debate.

As a prelude to the debate we have some data. Birgitta Stegmayr and Kjell Asplund went back to people who had participated in research 10 years earlier and asked for consent for genetic research on their stored blood sample (p 634). Over 90% said yes, and only 2.2% specifically said no. Almost the same proportions said yes to industrial research. A second short report illustrates how research on stored samples can be useful. David Hilton and colleagues have looked at over 8000 appendix and tonsil samples removed between 1995 and 1999 and tested for prion protein (p 633). They found a single occurrence, giving a prevalence of prion protein accumulation of 120 per million among people aged 10-50 between 1995 and 1999. This is the first estimate of the number of people who may be a potential source of variant Creutzfeldt-Jakob disease by iatrogenic spread.

In the debate, Paul van Diest, a professor of oncological pathology, argues the case for testing without consent provided that the material is anonymised; enough material is left for the patient's own needs; and the reuse is for useful non-commercial research and is reviewed by a scientific review board (p 648). People should also be informed, he says, when samples are collected that material may be reused in the future, something that isn't always done. Van Diest argues that the principle of solidarity, helping others, is more important than the right of self determination over discarded material.

Julian Savulescu, a professor of applied ethics, argues that consent must be obtained (p 649). Patients may be harmed by information that is discovered about them. Consent is important to respect autonomy: "When we involve people in our projects without their consent we use them as means to our own ends." Seeking consent builds public confidence in medicine and research.

Both protagonists make strong cases, illustrating perhaps why debates over this issue can become so heated. We look forward to hearing what readers have to say, and we urge you to vote on the issue on www.bmj.com

Had he not died last week, we might have asked Douglas Black (p 661) to comment on this debate. His deep wisdom on ethical matters was much valued by doctors, but he will also be remembered for his humanity and bone dry wit. Born in the Shetlands, a son of the manse, he had, he said "the twin advantages of poverty and culture." He had time and means to think. All his life he battled with bureaucrats, meaning that "my respect for politicians had ample room in which to grow."

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