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Editorial Comment

The ethical management of genetic testing

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When we consider the ethical issues associated with any emerging form of clinical practice, it is all too easy to overlook the most obvious—the need for clinicians to familiarise themselves with such areas and ensure that their own patients benefit from these developments. This is definitely the case in cancer genetics, but obviously, where genetic testing is appropriate, other ethical issues must also be considered.

In a minority of cancer patients (probably 5–10%), genetic factors may have played a major role in the development of the cancer. With the recent advances in molecular genetic techniques, it is often possible to define the exact nature of such a genetic predisposition to cancer and hence very accurately estimate an individual's risks. Over the past few years, an increasing number of genes associated with predisposition to both common cancers such as breast, colon and ovarian, as well as to rarer forms, have been localised on the genome and many of the genes and the associated mutations have been isolated and characterised.

Some of the ethical considerations arising from our ability to provide genetic information for late-onset disorders are different from those arising from early-onset single-gene disorders [1].

The key areas for consideration include:

- Duty of Care
  - Are at risk individuals identified from personal and family history of cancer
  - Are they appropriately counselled or referred for such counselling
  - Are they offered 'evidence based' information on their risks, on the usefulness of gene testing, on the availability and value of surveillance and on other management options in gene carriers [2].

The key ethical principles of a genetic counselling service as described in the Nuffield Council of Bioethics Report emphasise [3]:

(a) the voluntary nature of genetic testing, and the freedom and responsibility of the individual or couple to decide;
(b) the importance of ensuring that the individual or others offered screening understand the purpose of the test and the significance of a positive result;
(c) an assurance of confidentiality in the handling of results, coupled with an emphasis on the responsibility of individuals with a positive (abnormal) result to inform partners and family members; and
(d) the fact that consent to screening, or to a subsequent confirmatory test, does not imply consent to any specific treatment, or to the termination of a pregnancy.

1. Genetic counselling for "at risk" individuals and families

Genetic counselling may be described as the process of determining the occurrence, or risk of occurrence, of a genetic disorder within a family, communicating the results of the pedigree and risk assessment and providing appropriate non-directive information and advice about future courses of action.

Genetic counsellors should educate and support 'at risk' individuals within families, encourage health promotion practices and reassure those who over-estimate risk and monitor psychological assessment.

2. The individual and the individual's extended family

Any assessment of the genetically determined risk of cancer for an individual will inevitably require the

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assembly of detailed information about that individual and their extended family. It is essential to protect the interests of the individual and members of their extended family who may not know or wish to know that they are considered to be at risk.

It is, however, equally important the other individuals within such families have access to appropriate services themselves and that guidelines for risk assessment and testing are utilised to provide a comparable service to all family members regardless of the centre in which they are seen.

3. Insurance issues

Several European countries have no legislation or guidelines on insurance for individuals found to be at an increased risk of suffering from cancers on the basis of genetic predisposition. Countries who do have guidelines often have a moratorium on the use of genetic tests. For example, in France, the moratorium is for up to 5 years, whilst in The Netherlands, there is an indefinite moratorium [4].

In the UK, the Human Genetics Commission published a statement in May 2001 recommending interim recommendations on the use of genetic information in insurance. As a result, since November 2001, there has been an insurance industry moratorium on the use of DNA results for life insurance policies under £500000 and £300000 for other policies. A review of the moratorium is due to take place in late 2006.

4. Gene patenting

Another issue currently of concern is gene patenting and its implications for clinical practice. On both sides of the Atlantic, despite existing law and directives, the principle that gene sequences should be patentable are being challenged [5]. For *BRCA1*, a patent has been awarded in the USA and Europe to Myriad Genetics Inc, a company in Salt Lake City. However, many countries continue to offer Health Service testing performed in their own laboratories despite these patents. The question continues to be asked whether genes can be 'owned', even for a limited period, by any group—commercial, governmental or charitable [5].

In some countries, commercial operators provide the bulk of medical laboratory services and compete with each other, and sometimes with non-commercial laboratories, on the basis of quality and cost. In the case of commercial testing for mutations in *BRCA1* and *BRCA2*, there is general agreement that samples should be submitted following pretest counselling via a registered medical practitioner [6].

5. Conclusions

The rapidly increasing availability of genetic testing is producing many complex clinical situations and dilemmas. This is nowhere more apparent than in the genetics of common cancers, including breast cancer, which is the fastest growing area of genetic medicine. Appropriate management of individuals and their families should allow ethical dilemmas to be predicted and dealt with in a sensitive and timely manner.

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