COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

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At the CPME Board Meeting in Winchester on 24 October 2009, CPME adopted the following policy document "Use of Health Related Genetic Information outside the Health Service" (CPME 2009/170 Final EN)

Use of Health Related Genetic Information outside the Health Service

Introduction

The ever increasing range and sophistication of genetic information now available offer many potential direct health benefits but also have potential relevance outside the area of direct patient care. This paper addresses the issues which arise specifically from the increased ability to identify and predict disease susceptibility using genetic testing.

We primarily focus on the use of such data by the insurance industry, but point out that many other agencies might seek to use such genetic information and that any future legal proposals should apply to all. Examples of such other agencies include a range of official or state agencies outside direct healthcare services, current and future employers, educational institutions, financial institutions, pension funds and others.

Three main concerns arise:

- The ownership of genetic information
- The right to confidentiality as against the right of other people affected by that information to be given it
- The possibility of discrimination against those with significant genetic susceptibility to disease.

Ownership of Genetic Information

There is a long tradition based on ethical and legal principles concerning the confidentiality of medical information. This strictly circumscribes the use of such information outside the doctor-patient relationship. Genetic information raises specific issues because of its potential implications, which include:

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- The impact on the individual
- The impact on families
- The need to encourage sharing of information with people who may be affected
- Genetic data provide a unique identifier that can confirm or deny a close relationship
- The data has predictive power across generations
- Small samples increase the possibility of testing without consent.

It remains essential to provide the greatest protection possible to such sensitive personal information, while recognising that health and welfare of others may be directly affected by the sharing or failure to share information from genetic testing or systematic family histories. Generally, genetic testing is done only for therapeutic or research purposes. In the former case, with the patient's consent, doctors having such information may share it with other health personnel needing it, because of their proper involvement in the medical care of the patient. In the latter case, standard consent procedures should apply if patients are genetically tested for research purposes.

Restricting the use of such information to direct health service providers should be a goal of legislation related to personal data protection. Several EU countries have addressed this issue in legislation, most recently Norway where control of access to genetic information has been comprehensively regulated.

<u>The right to confidentiality versus the rights of others</u>

The first consideration here is that there is a hierarchy of 'others' potentially involved. The immediate implications of genetic testing will impact personally on the lives of present and future family, who will be the main concern in this discussion. Others might include health professionals concerned to protect the health of the patient's relatives, especially if the patient did not want them to know of their own test status. Outside of the direct health care system the insurance industry, given its culture of risk assessment, might well want to know the outcomes of genetic tests for potentially affected kindreds.

Any genetic testing requires careful and full counselling of the patient beforehand and best practice requires this will include issues relating to the implications of genetic test results for other family members. Equally these other family members will also require pre-test counselling on all aspects the particular disease in question and also the wider implications for life in general. The amount of professional time involved should demand that decisions about genetic testing should rest with the patient in consultation with the doctor.

It might be suggested that a family member who could demonstrate their test eliminated the risk of a particular disorder, should not be denied the value of being able to obtain insurance at standard or favourable rates. Unfortunately the corollary of this argument would demand that refusal to undergo testing would exclude the individual from insurance or allow it only at punitive cost. This raises the spectre of discrimination against individuals on the basis of their family background, which we would consider abhorrent. Knowledge of disease carrier status by insurance providers also risks making insurance conditional on further invasive tests (colonoscopy at specified intervals for heritable bowel cancer or prophylactic therapeutic procedures (colectomy or bilateral mastectomy for heritable bowel or breast cancer). The addition of such financial pressures on individuals who will already be under serious strain relating to their own and their family's health is also socially abhorrent.

The need for physicians and other healthcare workers directly involved in care of patients and families with heritable conditions to be able to access all information in order to protect the interests of other family members must also be addressed. We believe that this should be covered in national legislation in such a way as to protect rights and interests of the patient, other family members and health professionals directly involved in their care.

<u>The possibility of discrimination against those with significant genetic susceptibility to disease</u>

Knowledge that an individual has a heritable disorder confirmed by genetic testing or that he/she is a carrier of a genetic disorder, opens the real possibility of personal discrimination by individuals or organisations. The range of organisations outlined in our introduction is wide but the insurance industry is of particular concern because of its close relationship in the field of health insurance and because many genetic diseases carry considerable financial implications not just relating to direct healthcare costs but to other aspects of insurance including life insurance, income protection, mortgage insurance, social security insurance, and various types of supplementary cover used to provide benefits over and above state social security schemes.
The abuse of information from genetic testing risks the creation of an uninsurable "underclass". We would see this a form of discrimination based on genetic or family background and as such abhorrent to a humanitarian value system. We would further see any suggestions as to use of genetic testing in special cases as also representing a form of discrimination; an example might be the creation of lists of specific conditions for which genetic testing would be a precondition
<u>It is our view that insurance companies should not have any access to information obtained by genetic testing or detailed family pedigree.</u>

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Recommendations

Regulation of the interaction between biotechnology and personal data protection is of such importance and technicality that voluntary agreements between patients, doctors and the insurance industry are not an appropriate approach.

National governments should enact legislation relating to the application of biotechnology in human medicine to ensure that such biotechnology is used for the benefit of everyone in an inclusive society. The principles should be based on respect for human dignity, human rights and personal integrity and without any discrimination on the basis of genetic constitution, and on the ethical norms that form part of our Western cultural heritage.

Such legislation should prohibit the use of health related genetic information outside the health service and make it illegal to request, receive, be in possession of or use information on another person obtained through genetic testing or by systematic surveys of hereditary disease within a family.
Such legislation should define postnatal genetic testing as presymptomatic genetic testing, and also predictive genetic testing and testing to determine whether or not a person is a carrier of hereditary disease that will only be expressed in later generations (carrier testing).

Such legislation should prohibit the asking of questions as to whether or not genetic testing or systematic surveys of hereditary disease within a family have been carried out.

Such legislation should exempt healthcare personnel who need genetic information for diagnostic and/or therapeutic purposes from the prohibitions, always ensuring that the patient's consent has been given.

Such legislation should include provision for the Ministry of Health to legally authorise Health Care institutions in which genetic testing is carried out for medical or research purposes. If genetic testing is carried out for research purposes, consent must be obtained from the person from whom the information is to be obtained.

Such legislation should include a general prohibition against all use of personal genetic information by official authorities, current and future employers, educational institutions, financial institutions, pension funds and insurance companies and other institutions who may wish to acquire health information.