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On 16 September 2010, CPME Executive Committee adopted the CPME comments to the Revision of directive 98/79/EC on *In Vitro* Diagnosis Medical Devices (CPME 2010/097 Final)

Genetic Tests

CPME Comments to the Revision of directive 98/79/EC on *In Vitro* Diagnosis Medical Devices

The scope of the directive

The **Standing Committee of European Doctors (CPME)** welcomes the opportunity to react to the Revision of directive 98/79/EC on *In Vitro* Diagnostic Medical Devices. CPME's opinion is that the IVD directive should be extended to cover all genetic tests, also those with no direct or indirect medical purpose. It is of utmost importance to have clear requirements to quality, scientific evidence and clinical validity and utility of these tests. CPME does not support exclusion of some categories of tests, e.g. paternity, as the grounds of this selection are not apparent to us.

Against this background, our response below focuses on the sections of the directive related to genetic testing, and highlights the ethical concerns of European Doctors on this issue.

Introduction

Genetic tests are difficult to carry out and interpret, and their results may have far reaching consequences for the patients and their relatives. They often create ethical dilemmas for patients, their relatives, as well as for health professionals, which relate to patient self-determination, counselling and data protection.
Patients who suspect they might be susceptible to a monogenic disorder should consult a specially trained physician in order to obtain comprehensive advice and, if necessary, access to genetic or psychological counselling.
With regard to possible polygenic multi-factorial disorders, the informative value of genome tests is currently seen as too small to be of clinical value. Individuals should therefore be recommended not to seek information about their personal genetic risk of being affected by a multi-factorial condition. However if a person decides to undergo genetic testing for multi-factorial conditions, he/she should obtain information about the precise purpose of the test, and what it entails. Before taking such a test, individuals should obtain the necessary medical

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information from a physician with experience in genetics and who is familiar with the test procedures, in order to identify and minimise the risks involved.

CPME considers that genetic tests provided over the internet are problematic and fraught with significant risks. Therefore, CPME advises consumers against using such services and recommends addressing their questions concerning genetic testing to competent healthcare professionals.

The reason is twofold. First, CPME is particularly concerned about the data confidentiality and believes consumers should be better informed on the fact that confidentiality of internet based genetic tests *cannot* be guaranteed, even when protected by a password.
Parents or legal guardians should refrain from submitting for internet-based genetic analysis DNA samples taken from minors, or from persons without the capacity to consent.

Second, consumers having used internet-based genetic tests are left to cope by themselves with the results, which can be misinterpret and/or can lead to distress when the person is informed she is at high risk to develop a severe, sometimes life threatening disease.

Moreover, CPME believes that relevant professional bodies and teaching institutions should provide their members with adequate educational material. Topics on genetic testing should be integrated into medical training, in order to address the increased need of experts both in counselling and interpreting the results of genetic tests.

Predictive tests

Multi-factorial genetic test
Most modern "lifestyle diseases" such as cancer, cardiovascular diseases, type II diabetes etc. are caused by multiple, genetic and non-genetic factors. Because the interaction of these factors and the exact roles they play in disease aetiology are not yet fully understood, the predictive power of genetic tests for multi-factorial diseases is often low. It could therefore cause unwarranted anxiety to people if they are provided with information they have problems to interpret correctly.

On the other hand, CPME understands the individual's right to seek information about his/her own health and to be provided with information that can influence his/her quality of life. Individuals should have the right to self-determination and independent decision making about their lifestyle. For example, in the case that a genetic test reveals that a person is at an increased risk of suffering from cardiovascular disease, he/she should have the right to this information in order to be able to adjust her lifestyle and lower that risk.

Therefore, CPME wants to underline the essential prerequisites for multi-factorial genetic predictive tests: first, the genetic information offered must be correct, and second, individuals interested in taking a genetic test must be adequately informed about the nature of the tests and their limited informative value.

Monogenetic tests
Tests for monogenic disorders should only be carried out in cases where it is known that a disease is prevalent in a family. First, a family's history must be examined, and in-depth genetic counselling must be carried out. CPME believes that such testing should only take place after the patient has received genetic counselling and explicitly stated his or her wish to

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be tested. The ethical considerations of testing for monogenic diseases should also include other family members, as it will have implications for them.

Informed consent

CPME strongly advocates that genetic analysis should never be carried out without the written consent of the person to be examined. The patient must have been given medical advice regarding the nature, scope and informative value of the test by a specialised physician trained in human genetics/medical genetics. The person to be tested must have freely consented to the genetic analysis on the basis of the full information given to him/her.
CPME does not believe that commercial providers of direct to consumer tests of the genome can sufficiently fulfil these requirements and fear that the confidentiality of patient data could be severely compromised. Should the company that has analysed the test seek to store the data in their data bank, the person that was tested would have no guarantee that the genetic information is not used for other purposes later, without his or her consent.

Data protection

Another ethical question raised by genetic testing is whether the test results should be available to other health institutions, for example the person's general practitioner.
CPME believes it should be the patient who decides. Only with the patient's consent, doctors having access to such information may then share it with other health professionals needing it, because of their proper involvement in the medical care of the patient.
Nowadays, most of the general practitioners do not have the required competences to adequately follow up genetic information. When that is the case, the general practitioner should seek advice from competent counsellors or refer the patient.

CPME believes that restricting the use of genetic information to direct health service providers should be a goal of legislation related to personal data protection.

Use of health related genetic information outside the health services

Direct to consumer genetic testing raises considerable problems regarding the protection of data and privacy. CPME considers that genetic tests provided over the internet are problematic and fraught with significant risks and therefore, CPME advises consumers against using such services and recommends addressing their questions concerning genetic testing to competent healthcare professionals.

Particularly, the storage of data and the possibility that it could be accessed by institutions outside the health services pose a high risk.
Indeed, the ever increasing range of sophistication of genetic information now available offer many potential direct health benefits but also have potential relevance outside the area of patient care. Agencies that would probably be interested in receiving this information would include insurance companies, pensions funds, current and future employers, financial institutions, etc.
CPME advocates that governments should enact legislation prohibiting 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. (See CPME policy on the use of health related genetic information outside the health service CPME 2009/170 Final)

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The right to be informed

The genome analysis may disclose surplus information about diseases that cannot be prevented or treated nowadays. This raises a number of questions and could cause dilemmas for the health professionals analysing the tests. Should the patient be informed about diseases that have no effective treatments nowadays? On the other hand, such information could help the patient to plan his or her life, for example decide not to have children to prevent the disease to pass on to the offspring. It should also be taken into account that in the future, effective treatment for the disease may be developed. Health professionals might also be 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.

Therefore, CPME strongly believes that genetic testing requires careful and full counseling of the patient beforehand. Before the test is taken, it should be agreed with the patient what kind of information he or she should receive. Best practice requires the pre-test counseling 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 counseling 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.

Increased need for experts

Persons asking for genetic testing will need professional counselling before and after the test. Today there is a lack of health professionals with this special competence, and there is a lack of physicians that can interpret the results of genetic tests. Should the directive be extended to include results obtained by analysis of the genome, there will be a significant need for educating more experts both in counselling and interpreting the results of the test.

The Standing Committee of European Doctors (CPME) *aims to promote the highest standards of medical training and medical practice in order to achieve the highest quality of health care for all patients in Europe. CPME is also concerned with the promotion of public health, the relationship between patients and doctors and the free movement of doctors within the European Union.*
CPME is the representative organisation of over 1.3 million European doctors through its full members, the most representative National Medical Associations of 27 countries in Europe. CPME works closely together with its other members, four National Medical Associations from associated and observer countries as well as with specialized European medical associations.

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