

12. ETHICS AND LEGAL ISSUE OF GENETIC TESTING

Jana Lukač Bajalo

University of Ljubljana, Faculty of Pharmacy, Ljubljana, Slovenia

12.1 Abstract

The Expert Group, invited by European Commission's Research Directorate-General, prepared 25 recommendations related to the use of genetic testing in health care systems and genetic testing as a method of research. This paper presents in detail the recommendations crucial for laboratory diagnostics and research. Genetic testing and genetic data, are a part of the spectrum of all health-care information, equally available to individuals and with identical high standards of quality and confidentiality. It is the individual's right to specify the scope of privacy and confidentiality with regard to all health-care information, including data originating from genetic testing, as well as with regard to biological samples as data carriers. The national Ethics Commission gives the opinion on ethics of any testing, including genetic testing for research purposes, in line with the recommendations of competent bodies of the EU, and the Code of Ethics applicable in the Member State. Test subjects must give informed consent for current or future tests. The recommendations for using the existing and forming new "biological databanks", cross-border exchange of samples, and samples of the deceased are also presented in the paper. The general public should be impartially informed in all forms possible, and public dialogue must take place within the general public on clinical applicability of genetic testing, on genetic screening and pharmacogenetics. Screen testing in the EU may differ between Member States, and it has to be verified and evaluated in regular intervals in each Member State within the framework of the public health-care system. Genetic counselling requires specifically trained experts and should be non-directed counselling with the objective of helping individuals or families to understand a genetic disease or to cope with it. Curricula at all levels of study programmes should include subjects regarding the progress and possibilities of genetic testing in medicine.

12.2 Introduction

Every person working in bioscience, whether it is related to humans (including patients and their biological samples), animals (including test animals), agricultural products (including those genetically modified), or the environment (in the narrow and broad sense of the word), must adhere to the principles of bioethics, meaning that (s)he is responsible for making ethical decisions the whole time. Ethical attitude towards particular phenomena, new discoveries, and new technologies is a process carried forward with varying speed in different environments. The biggest shift regarding ethical issues in biomedicine stems from sequencing of the human genome, and from new biotechnologies enabling new diagnostic approaches and new possibilities for treatment and prevention of diseases. Genetic testing is gaining recognition for the many advantages. Among their many uses, genetic tests most commonly present an opportunity for individuals to become informed about their genetic predisposition to disease and disability, important decisions about their future and for couples to be aware of the possible genetic characteristics of their unborn children., therefore supporting their right to make a informed choice. Genetic information can have important implications also for their relatives. Respecting a patient's confidentiality by not disclosing the results of a genetic test

to third parties can therefore conflict with the well-being of family members, who could benefit from this knowledge. Finding the right balance between the patient's privacy and confidentiality of genetic information, and what is in interests of family members, is an ongoing ethical and social challenge.

This predictive power makes genetic testing particularly liable for misuse. Employers and insurance companies have been known to deny individuals essential health care or employment based on knowledge of genetic disposition. This type of discrimination can be socially debilitating and have severe socio-economic consequences. Stemming from the informative potential of genetic testing some critical ethical, legal and social issues come to the forefront. It is important, therefore, to ensure the confidentiality of test results, and to establish legislation permitting only selective access to this information (1).

The Brussels-based European Commission's Research Directorate-General, was established in the EU in 2004. The Expert Group of experts from various backgrounds (representatives from the industry that produces or uses genetic tests, from patient organisations with clear interests in the subject, scientists and representatives from academic institutions with different backgrounds specialised in the field (law, philosophy, ethics, and medicine), prepared 25 recommendations related to the use of genetic testing in health care systems and genetic testing as a method of research. The participants came from various national backgrounds within Europe and numbers were well balanced between men and women. Eryl McNally, Member of the European Parliament, acted as Chair of the Group and ensured that the experts achieved the necessary and agreed recommendations which should be useful for decision-makers in Europe (2).

12.3 The 25 recommendations

The following 25 recommendations are organised into three chapters addressing:

- General framework;
- Implementation of genetic testing in healthcare systems; and
- Genetic testing as a research tool.

12.3.1 General framework

1. Need for universal standard definitions

There are various definitions of genetic testing and genetic data. Clarification of the issues at stake is an important prerequisite to any debate or official position.

Recommendation 1

That:

- a) any official statement or position should refer precisely to an explicit definition of the terms used or topic addressed;
- b) a consensus definition of genetic testing should be developed globally by all respective public and private bodies involved (including the World Health Organisation, the Organisation for Economic Co-operation and Development, the European Commission, the International Federation of Genetic Societies, and the International Conference on Harmonisation);
- c) the European Commission should consider taking the initiative on this topic.
A broad definition was used for genetic testing, i.e. "any test that yields genetic data". Genetic data or information relate to inherited or acquired properties that are transmitted

during cell division and that affect subsequent generations of offspring (“germlinal genetic data”) or cells and tissues (“somatic genetic data”). The Group focused mainly on genetic data transmissible at the germlinal level, pertaining to heritable diseases or traits, and not on somatic genetic data which are subject to increasing interest as tools for identification of disease mechanisms and pathways, disease classification and identification of targets for new medicines.

2. Germinal and somatic genetic testing

Further issues are at stake with respect to non-germlinal (somatic) testing that require more indepth reflection and investigation.

Recommendation 2

That:

- a) a specific working group be set up to discuss further issues relevant to genetic testing for acquired genetic properties.

3. “Genetic exceptionalism”

The sentiment that genetic data are different from other medical information (“genetic exceptionalism”) is inappropriate. Genetic information is part of the entire spectrum of all health information and does not represent a separate category as such. All medical data, including genetic data, must be afforded equally high standards of quality and confidentiality at all times. However, the current public perception that genetic information is somehow different is acknowledged by the Group. This perception is due to a number of factors. These include historical reasons (eugenics), the current predominance of predictive genetic tests for rare monogenic diseases which may give rise to particularly sensitive information affecting patients’ relatives, the fact that no treatment is available yet for most monogenic diseases, potential loss of control over samples, plus a number of other reasons. Current efforts to establish guidelines, recommendations, rules, regulatory texts and laws that apply specifically to genetic testing and data handling should be viewed as an understandable response to specific public concerns. They are, however, only acceptable as a stepping stone to more considered and inclusive legal and regulatory frameworks that encompass all medical data and testing, and which reflect advancements made in healthcare provision.

Recommendation 3

That:

- a) “genetic exceptionalism” should be avoided, internationally, in the context of the EU and at the level of its Member States. However, the public perception that genetic testing is different needs to be acknowledged and addressed;
- b) all medical data, including genetic data, must satisfy equally high standards of quality and confidentiality;
- c) in order to track the evolution of public perception of genetic testing and to identify issues for future debate:
 - further research on ethical and social perceptions of genetic testing is necessary and should be promoted by the European Commission and national bodies; and
 - questions relevant to genetic testing should be included in pan-European surveys such as the Eurobarometer.

4. Public information and education

The new knowledge has to be disseminated quickly. As the scientific background is complex and not always easy to understand, it is imperative that opportunities for education are

organised for both the public and the media. It is important to increase public awareness, education and understanding of genetic concepts. Genetic research and its clinical applications should be represented in an impartial way, and realistic expectations as to what they can achieve should be set.

Recommendation 4

That:

- a) materials and resources be developed and made available at the EU, national, and local level to provide information about genetic testing, genetic screening, and pharmacogenetics through a variety of media;
- b) science curricula at all levels (from primary to university level and vocational training) include reference to progress and potential in the field of medical genetics;
- c) national education systems ensure an adequate supply of appropriately trained scientists and teachers, including technicians and clinicians, to ensure that benefits arising from genetic research and genetic testing can be made real and delivered to all EU citizens;
- d) concerted efforts to promote dialogue, education, information and debate be encouraged;
- e) the 'Science and Society' component of the EC research and development framework be strengthened further.

5. Public dialogue

Dialogue should have a defined scope, be multidisciplinary, organised transparently and carefully designed to involve all relevant and interested stakeholders in an egalitarian fashion. Participants in the dialogue should be encouraged to be open-minded, willing to listen, respectful of local cultural values, and should treat this dialogue as an exchange of opinions rather than as an opportunity for proselytising. An effective dialogue will require discussion leaders to ensure that all participants in the debate are given equal opportunities to voice their respective positions, and that provision is made for questions and answers.

Recommendation 5

That:

- a) opportunities for public dialogue between different stakeholders be organised, offering participants equal opportunities for expression;
- b) different formats of dialogue and debate be organised as no single format will fit all purposes and all publics.

12.3.2 Implementation of genetic testing in healthcare systems

6. Medical genetic testing and its context

Provision of genetic testing in the context of human healthcare requires appropriate procedures for obtaining informed consent, equitable access to testing as well as to appropriate counselling, and protection of confidentiality and privacy. These requirements will ensure that genetic testing offers new possibilities for individual choice rather than generating further constraints.

The Group acknowledges the present activity of the Council of Europe (3) on such matters. Predictive genetic testing has real potential to provide options for personal choice. However, it is imperative to recognise both the right to know and the right not to know as important individual rights. Equitable access to information and to quality genetic services must be assured. In addition, measures must be taken to prevent undesirable societal consequences as a result of genetic testing. The application of genetic testing for non-medical reasons requires careful consideration with regard to its potential consequences for society.

Recommendation 6

That:

- a) medically relevant genetic testing be considered an integral part of health service provision;
- b) medically relevant genetic testing should never be imposed and should always be a matter of free personal choice;
- c) comprehensive information about the availability of genetic tests be freely available from a range of reputable sources including public authorities, physicians, and patient groups;
- d) national healthcare systems ensure that genetic testing will be accessible equitably to all who need it.

7. Quality assurance

Genetic-testing services in Europe, while based on high-quality scientific know-how, tend to suffer from an intolerably high level of technical error and poor reporting. This is caused by a lack of both structuring and complementarity at European level and by the absence of a common European objective to provide quality services to all its citizens now and in the future. Diverse and heterogeneous quality schemes, a lack of reference systems, and differing Member State regulations, have added to the overall fragmentation of services. Nevertheless, genetic services face an ever-increasing number of requests for testing, while widespread susceptibility testing and pharmacogenetic tests are lurking on the horizon. In the context of human healthcare, a test should only be offered when it has been shown to perform reliably and when there is a sound medical reason to consider it. A system for the validation of tests should be established.

Recommendation 7

That:

- a) the European Union institutes a consistent regulatory framework to assure specific standards of quality for all genetic-testing services and their providers, including a system of accreditation for genetic-testing laboratories;
- b) test providers ensure that the information provided is accurate, by conforming with internationally agreed quality standards;
- c) national healthcare systems establish consistent quality requirements for genetic testing.

8. Population screening programmes

Genetic screening for increased disease risk will progressively become possible for common disorders. Offering screening to specific subgroups of the population for certain disorders may be beneficial, but may also carry risks. There must be agreement between medical professionals, patients, and the community that the benefits outweigh the risks. There is a need for meaningful information and regulation with respect to the provision of genetic screening on a population-wide level as well as the testing of certain subgroups within that population.

Recommendation 8

That:

- a) measures be put in place to ensure that tests are meaningful: the condition screened for must be serious, the test highly predictive, and follow-up actions must be available in terms of healthcare interventions (including reproductive choices);

- b) the relevance of the genetic condition being screened for be validated and regularly evaluated within the framework of the public health context (this may differ from country to country in the EU);
- c) the appropriate medical environment for providing information prior to testing and relevant post-test counselling be in place prior to offering such screening;
- d) pilot programmes be performed prior to general introduction of the screening;
- e) the economic dimension of envisaged screening programmes should be considered carefully.

9. Genetic counselling

The provision of specialised genetic counselling is considered an essential requirement for certain genetic tests, particularly for highly predictive tests for serious disorders. Provision of such counselling requires professionals who have received specific training. In other instances, the physician or other non-specialised members of the healthcare team may provide the patient with the relevant information. The provision of simple, printed information that can be consulted by the individual after counselling has been shown to be extremely valuable, so such materials should always be available. Non-directive counselling must be the rule. The main goal of genetic counselling is to help individuals or families understand or cope with genetic disease, not to decrease the incidence of genetic disease. Appropriate explanations and sufficient time should be allocated to people in need of support. General information about genetic testing and counselling is part of regular medical practice and relevant education must be provided to physicians. Specialised counselling should be devoted to individual situations where it is of particular relevance.

The Group acknowledges, however, that while there should be a common basis of shared principles regarding standards of genetic counselling, practices will vary depending on cultural settings and values and therefore a certain heterogeneity of practices will continue to exist throughout the EU.

Recommendation 9

That:

- a) in the context of healthcare, genetic testing be accompanied by the provision of key information and, where appropriate, by the offer of individualised counselling and medical advice (in the case of highly predictive genetic tests for serious disorders, the offer of specific counselling should be mandatory, and patients should be strongly encouraged to take advantage of it);
- b) specific educational programmes on counselling and exchange of experience in the field be organised at the European level;
- c) specific qualifications and quality standards for those engaged in the provision of specific genetic counselling, whether clinicians or non-clinicians, be established and made mandatory;
- d) appropriate financial means for such training and the subsequent accreditation be made available;
- e) Europe-wide general standards for fundamental principles of genetic counselling be developed by relevant medical professional groups, with due consideration given to patients' views.

10. Data protection: confidentiality, privacy and autonomy

Public concern regarding genetic testing is grounded to some extent in the fear of misuse of genetic data and of inappropriate access to such data by third parties. Confidentiality and privacy with regard to all personal medical data, including those derived from genetic testing,

are basic rights and must be respected. An individual's right to determine the extent of privacy and confidentiality that he or she will be afforded encompasses both access to personal information and data and to tissue samples as carriers of information. The individual has both the right to know and not to know. Affording legal protection in this field is of paramount importance and the existing EU Data Protection Directive (4) provides an appropriate framework for the need to protect personal data.

Recommendation 10

That:

- a) genetic data of importance in a clinical and/or family context should receive the same level of protection as other comparably sensitive medical data;
- b) the relevance for other family members has to be addressed;
- c) the importance of a patient's right to know or not to know be recognised and mechanisms incorporated into professional practice that respect this. In the context of genetic testing, encompassing information provision, counselling, informed consent procedures, and communication of test results, practices should be established to meet this need;
- d) these issues are of particular relevance to vulnerable populations, whether in the EU or elsewhere in the world.

11. Protection from discrimination

Irrespective of confidentiality issues, personal medical data including genetic data must not be used to discriminate unfairly against individuals. The Group acknowledges the risk of discrimination as a result of genetic testing but notes that the field of discrimination extends far beyond genetics. Such discrimination may affect individuals, families or larger groups. Regarding prevention of discrimination in insurance and employment, the Group refers to the work of other bodies such as the European Group on Ethics in Science and New Technologies (5), the Council of Europe (3), and the European Society of Human Genetics (6).

Recommendation 11

That:

- a) data derived from genetic sources should not be used in ways that disadvantage or discriminate unfairly against individuals, families or groups in either clinical or non-clinical contexts, including employment, insurance, access to social integration, and opportunities for general well-being;
- b) EU-level regulations addressing these issues should be promoted;
- c) timely access to genetic testing should be based on need and appropriately resourced with no discrimination based on gender, ethnic origin, social or economic status.

12. Ethnicity and genetics

There may be differentiation of patient populations, based on ethnic groupings, with respect to genetic testing. Some genetic variants are more common in certain populations or groups in the EU and elsewhere. Specific attention should be paid to such groups in the context of test development and in the conditions set up for the use of these tests, both to ensure fair access and to avoid stigmatisation or stereotyping. Specifically, genetic tests are inappropriate to determine ethnicity and must never be used for this purpose.

Recommendation 12

That:

- a) genetic tests be clinically evaluated in the populations in which they are to be used;

- b) those who are involved in genetic research, the provision of genetic testing and healthcare policy-making be sensitive to the risks of stereotyping and stigmatisation based on ethnic origin, and recognise and respect ethnic and cultural sensitivities;
- c) minority ethnic groups should not be excluded from access to those genetic tests appropriate for them.

13. Gender issues and genetics

There are well-established differences between men and women regarding the risk of certain disorders, including genetic diseases. The Group considers that specific gender issues may arise in the context of genetic testing. However, little evidence for this exists so far.

Recommendation 13

That:

- a) further studies at EU level address the impact of genetic testing, in particular in societies where women and men are given different rights or privileges;
- b) governments and society be aware of the possible consequences of the application of genetic testing to aid reproductive choice for prospective sex selection;
- c) criteria be established at EU level to ensure that no gender discrimination occurs in the course of, or as a result of, EU-funded research projects.

14. Social, cultural and economic consequences

Relatively little information is presently available at EU level on the impact of genetic testing on health systems and on health economics.

Recommendation 14

That:

- a) the European Commission funds more research relating to the impact of genetic testing on the social, cultural and economic aspects of healthcare provision.

15. Professional development

The responsibilities of primary and specialised care providers will expand as genetic testing, including pharmacogenetics, evolves. This will require appropriate changes in medical school curricula. Other healthcare professionals will also require enhanced initial professional education and continuing professional development in the area of genetics.

Recommendation 15

That:

- a) initial educational and professional requirements be coordinated in all countries of the European Union;
- b) continued professional training be offered for healthcare professionals.

16. Partnerships and collaborations

The Group considers that all stakeholders, including governmental authorities, scientists, healthcare providers, industry and patient organisations should work together in a partnership approach to optimise future advances in healthcare that may become possible as a result of genetic testing, such as new treatment options and disease prevention. For effective development of new genetic tests and diagnostics, a productive interchange between academic scientists and those working in the healthcare industry will continue to be essential.

Recommendation 16

That:

- a) the European Union stimulates and supports partnerships between stakeholders;
- b) a framework for transparent collaboration between industry and academic scientists be established.

17. Regulatory framework and criteria for test development and use

The Group considers that a more explicit regulatory framework for test development needs to be set up throughout the EU.

Recommendation 17

That:

- a) the regulatory framework for genetic testing be further developed by the EU and other international organisations in a way that recognises both the need for new tests and the importance of safety, clinical validity and reliability;
- b) all newly developed tests must conform to the standards established before introduction into clinical use, based on a review process by an organisation or body independent of the test developer to ensure that the patient will benefit from the test;
- c) priority-setting for the development of accurate genetic tests be guided by the degree of unmet medical need, independently of disease prevalence;
- d) the EC takes measures to facilitate the availability of genetic testing for rare diseases as well as for more common diseases;
- e) the EC actively promotes the regulatory framework on these topics.

18. Rare diseases

The Group acknowledges that few countries have instituted screening programmes for serious rare diseases.

Recommendation 18

That:

- a) an EU-wide network for diagnostic testing of rare genetic diseases be created and financially supported as a matter of urgency;
- b) an EU-level incentive system for the systematic development of genetic tests for rare diseases be created and financially supported;
- c) for rare but serious diseases for which treatment is available, Member States introduce universal neonatal screening as a priority.

19. Pharmacogenetics

The term 'pharmacogenetics' describes the study of differences between individuals in drug response (efficacy or adverse reactions) which result directly from variations in DNA sequences and in differences in protein sequence, structure, or gene expression that are the direct consequence of such DNA variations. The main aim of pharmacogenetics is to help deliver medicines to patients who are most likely to benefit and least likely to experience adverse reactions. Although pharmacogenetics is currently still in a mainly exploratory phase, an increase in its application in healthcare is expected and appropriate measures should be prepared in time for this evolution.

Recommendation 19

That:

- a) national health authorities play a more active part in encouraging development of the field of pharmacogenetics:

- by providing particular incentives to enable the development of pharmacogenetic tests and associated therapeutics which are clinically desirable but which may not be economically viable; and
 - by enhancing the possibilities of co-operation between industry, patients, and academia in this field;
- b) an appropriate harmonised legal, regulatory, and healthcare policy framework for pharmacogenetics be developed at EU level, taking into account research, therapy development, and clinical practice.

12.3.3 Genetic testing as a research tool

A large part of research relevant to genetic testing relies on the use and exchange of human tissue samples and associated data because all biological samples contain DNA. These may allow, to a variable degree, identification of the individuals who are the source of the samples and data. Genetic studies also rely on genealogical, population, clinical, and personal data. The Group has concentrated on research aspects in terms of sample and data resources of human origin as indispensable means for the identification, validation, and development of genetic testing for potential clinical use, including pharmacogenetics, and on the relevant ethical, legal, and societal issues.

20. Existing and new ‘biobanks’

The term ‘biobank’ is used variably to designate several types of collections of biological samples. The Group has considered biobank collections to mean the biological samples themselves, plus the related databases, allowing a certain level of accessibility, availability and exchange for scientific studies. Public trust in research surrounding genetic testing is largely dependent on how the use of samples and data in and from such biobanks is undertaken and communicated. This applies in particular to the areas of informed consent, storage, data protection and the degree of anonymity of samples, the communication of study results and, where appropriate, of individual test results. A harmonised approach to these issues at EU level is considered desirable. The Group is aware that the Council of Europe is developing an activity regarding storage and research use of biological material and related data. Depending on their scope and context, official identification and registration of such biobanking activities, as well as assurance of their long-term financial sustainability, are desirable and may be required. There is a need for education about biobanking and for guidelines to assure quality control of both the collections and the ethical management of such repositories. For the study and validation of the association of genes with specific diseases, including the development of diagnostic products, devices and other tools, access to well-characterised human tissue samples for research and development use is essential.

Recommendation 20

That:

- a) guidelines be developed and coordinated across the EU to ensure that the use of samples, including those from archival collections, is not unduly delayed or impeded, particularly if proper consideration of their level of identification has been taken into account;
- b) action be taken by Member States to ensure that approval by a competent review committee is obtained before research is undertaken;
- c) an inventory of existing biobanks across the EU be created, indicating standards and rules of access, to identify which of their contents may or may not be used for genetic studies;
- d) a system be implemented to evaluate and monitor the current usage of existing biobanks throughout the EU;

- e) the task force on 'biological resource centres' set up by the OECD be followed closely by the European Commission regarding development of standards;
- f) the European Commission closely follows this activity.

21. Collections of human biological material and associated data and their uses

It should be noted that biobanking issues extend far beyond genetic testing. Few Member States have a well-developed legal framework in this domain. There is currently no EU directive regulating the use of tissue and cell conservation for research purposes.

Recommendation 21

That:

- a) the European Commission follows closely relevant activities and developments of the Member States in this field and in the global context;
- b) action be taken at the EU level, in coordination with other initiatives, to follow and address regulatory issues related to collections of human biological material and associated data and their uses.

22. Cross-border exchange of samples

Cross-border exchange of samples and data is important to improve European co-operation in this field. Ethical questions, such as validity of informed consent, play an important role in this transfer.

Recommendation 22

That:

- a) the European Commission evaluates the need for, and the feasibility of, developing harmonised standards for the research use of human samples and associated data (including informed consent issues), taking into account relevant international conventions on cross-border exchange of samples.

23. Informed consent

Consent issues for samples from individuals and groups entering new collections may differ from those applicable to existing collections, where contact may not have been maintained with the source individuals over the years. Explicit written consent is the rule but may not always be feasible for future uses of the samples and/or data not envisaged at the time of collection. The issues at stake include respect for individual or community autonomy regarding their control over the use of samples, the distribution and flow of data and samples across national borders, and methods that are both compatible with the nature of the research yet respect human rights. Various existing and practices exist in the EU. Professionals working in human genetics have developed recommendations and several ethical bodies have taken positions. Genetic data represent personal information which may or may not have individual medical relevance, as well as medical or cultural relevance at the community level. Biological samples and associated or derived genetic or medical information of any kind and of any origin must not be collected, stored or used without obtaining informed consent based on adequate process and procedure, including appropriate approval by relevant review bodies, and consideration of community-related aspects where appropriate, regardless of the purpose of the collection and the level of anonymity. Samples for genetic diversity studies should only be obtained in compliance with local or national 'traditions' and regulations or laws. The sources of samples and individual data and the relevant agreement regarding their use should be documented in all protocols and publications. The informed consent process and procedures used should be fully transparent with regard to the planned research, including

policies on provision of test results to individuals and to the population, as well as to the handling of samples and to the rights of sample donors. The Group considers that views of both patients and patient organisations, and public debate about biobanks, in particular with regard to consent issues, should be explored further.

Recommendation 23

That:

- a) the European Commission promotes opportunities for dialogue between stakeholders to support exchange of experience throughout Europe on issues of sample and data use for research, at the individual, family and population level;
- b) the European Commission funds multidisciplinary research into the ethical, legal and social issues related to informed consent procedures for human genetic research and other relevant areas essential for any evolving research in genetics.

24. Samples from the deceased

As regards samples and genetic data from the deceased, the Group considers that in the case of the overriding interest of one or more blood relatives, even in the absence of consent given before death, their use could be legitimate: absence of consent should not be considered as equivalent to non-consent. Furthermore, their use should be permitted, when made anonymous, for research, development of genetic tests, and for teaching purposes.

Recommendation 24

That:

- a) Member States take actions to promote the right of access to samples and data from a deceased person, in the case of overriding interest for blood relatives;
- b) Member States take actions to allow the use of anonymous samples from the deceased for the purposes of genetic research, development of new genetic tests, as well as for teaching purposes.

25. Consent procedures for children and vulnerable individuals in human genetic research

As regards the participation of children or vulnerable people in genetic studies, the principle of acting in their best interest applies and specific protection is the rule, as in any research on humans. An important issue raised by long-term conservation and use of data and samples obtained from children relates to the question of when assent or consent, respectively, need to be obtained. The Group recognises that few data are available on “what children think” and how information should best be presented to them.

Recommendation 25

That:

- a) the use of tissue and accompanying data from minors or vulnerable individuals in research be permitted if, in so doing, their interests are served;
- b) specific consideration be given to children’s views, the information provided to them, and issues of children’s assent and/or consent.

12.4 Conclusion

Ethical attitude towards particular phenomena, new discoveries, and new technologies is a process carried forward with varying speed in different countries. Expectations are, that ethical attitude towards genetic testing in health care systems and genetic testing as a method of research in EU Member States will carry forward with a proper speed!

Recommended literature:

1. Mefhan B. Bioethics, an introduction for the biosciences, Oxford University Press 2005;3-227, ISBN 0-19-926715-4 978-0-19-926715-6
2. European Commission: EUR 21120 – 25 recommendations on the ethical, legal and social implications of genetic testing, Luxembourg: Office for Official Publications of the European Communities 2004 – 25 pp, ISBN 92-894-7308-8
3. <http://conventions.coe.int>
4. Directive 95/46/EC
5. <http://europa.eu.int/>
6. <http://www.eshg.org/>