

Regulation under French law of genetic testing in medical practice

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Introduction


- ◆ The genetic information: a predictive, probabilistic, familial information, which, in many cases, is of no therapeutic benefit
- ◆ This is why it needs specific legislation
- ◆ Law of July 29, 1994 – August 6, 2004 and their decrees of enactment



GENETIC TESTING ON PEOPLE


1. A strictly controlled access

- ◆ **Only within the context of an individual medical consultation:** only the prescribing physician is authorized to communicate the results of the test
- ◆ The **freely expressed will** of the individual to have the test performed is the decisive criterion (article 16-10 of the Civil Code and R. 1131-4 of the Public Health Code)
- ◆ To be able to give informed consent, the individual must be provided with **complete information on the nature and finality of the test** (article 16-10 of the Civil Code and R. 1131-4 of the PHC)

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- ◆ Special protocol for asymptomatic individuals with family history
 - ◆ No test for minors or people under guardianship unless the individual or his/her family can benefit personally from immediate curative or preventive measures

2. Problems related to the familial nature of genetic information

- ◆ When a risk or a genetic disease has been detected in an individual, it may also be present in his genetically related family members and this information may be of benefit to the latter if effective treatment or prevention options exist (e.g OTC)



What should be the physician's attitude if a patient refuses to disclose this information to members of his family?

Can the liability of a patient who doesn't say anything be incurred if his/her silence results in prejudice being caused?

Article L. 1131-1 of the PHC

- ◆ The law of August 6, 2004 allows no exceptions to the physician's obligation to respect the patient's medical privacy in the case of genetic risk, nor does it impose any obligation on the patient to inform his family directly
- ◆ The physician has to inform its patient of the risks involved by its silence if effective treatment or prevention options exist
- ◆ The patient can transmit medical information anonymously via the Agence de la Biomédecine
- ◆ This procedure has not been used to date because of its complexity, and there is very little likelihood that it ever will be



GENETIC TESTS PERFORMED IN FETUSES AND EMBRYOS

1. Prenatal diagnosis (PND)

- ◆ It aims to detect a serious disorder in the embryo or fetus during pregnancy
- ◆ When the disorder is deemed serious and incurable, pregnancy termination for medical reasons can be performed
- ◆ Seriousness and incurability are certified by a Multidisciplinary Center for Prenatal Diagnosis (CPDPN) at the request of the patient: this certification enables the woman to terminate her pregnancy, only if she wishes to do so

2. Preimplantation genetic diagnosis (PGD)

- ◆ PGD is based on the genetic analysis of one or two embryonic cells taken from embryos created by in vitro fertilization
- ◆ This technique avoids having to make a prenatal diagnosis and a possible termination of pregnancy due to the disorder in question, because only embryos that do not bear the genetic defect are transferred into the uterus of the woman

Conditions of PGD under French law (article L. 2131-4 of the Code of Public Health)

- ◆ The couple, **as a result of its family situation**, has a high probability of giving birth to a child with a particularly severe genetic disease. The disease must be recognised as incurable at the time of diagnosis, as certified by a physician working in a CPDPN
- ◆ The abnormality or abnormalities causing such a disease have been **previously and accurately identified** either in one of the parents, or in an immediate ascendant in the case of a late-onset seriously invalidating disease that is prematurely life-threatening (reference to Huntington disease)
- ◆ The law specifies that diagnostic tests must specifically target the **disease identified**. This precautionary measure is designed to avoid general preimplantation genetic "screening" and guard against the spectrum of eugenism

The ethical problem of evaluating criteria of incurability and severity within the context of PGD and PND

- ◆ French lawmakers did not wish to draw up a list of diseases eligible for preimplantation genetic diagnosis or pregnancy termination
- ◆ Evaluating the severity and the curability of a disease can, however, be very a very thorny issue in some cases: variable expression (Neurofibromatosis, Tuberous Sclerosis), diseases destined to manifest itself later (genetic cancer: BRCA1 and BRCA2 genes), imprecision of the notion of incurability
- ◆ The Conseil d'Etat upheld this concept of an open choice to allow medical authorities sufficient freedom of decision and to avoid the preconceived idea that a life is not worth living

3. New indication for PGD: the selection of embryos based on histocompatibility groups (article L. 2131-4-1 of the Public Health Code)



Scientific advances have made it possible to select embryos according to their histocompatibility antigens (HLA) so that they will be histocompatible with an older sibling known to have a disease and requiring a bone marrow transplant

This new possibility has given rise to an extremely heated ethical debate. Those who oppose HLA selection emphasize that this amounts to conceiving human life as a means to treat an older sibling, with no benefit what so ever, to the younger donor sibling

Conclusion

- ◆ Current legislation governing genetic testing has not raised serious opposition or criticism and is unlikely to undergo major changes when the Bioethics law is reexamined
- ◆ There is, however, a risk that the rules designed to protect the individual will be bypassed or abused, notably by the possibility for anyone to purchase a genetic test freely via the internet

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