In April 2013, two policy documents on the regulation of genetic services have been issued in Germany, one by the German Ethics Council and one by the Genetic Diagnostics Commission.

The German Ethics Council Opinion Paper on the Future of Genetic Diagnosis

The German Ethics Council’s mission is to “monitor and comment on the ethical, social, scientific, medical and legal issues arising in connection with research and development, in particular in the field of the life sciences and their application to man, as well as the likely consequences for the individual and society”. The German Ethics Council is composed of 26 members, appointed by the President of the Bundestag [German Federal Parliament] for a four-year term, half of them being nominated by the Bundestag and the other half by the Federal Government.

The Council has issued the following press release: “In response to a commission by the Federal Government, the German Ethics Council has compiled an Opinion on the future of genetic diagnosis. On the basis of the right of people affected by a genetic test to know, their right not to know and their right of informational self-determination, the Council recommends in particular measures for the improvement of information, explanation and counselling. Other proposed requirements include special provisions on the conduct of prenatal genetic diagnosis, protection of those lacking the capacity to give consent, the quality of genetic tests and their funding within the healthcare system. The Council not only offers recommendations for political and legislative action, but also aspires to stimulate public debate on future developments in genetic diagnosis.

Owing to falling costs, faster analyses and the advent of direct-to-consumer genetic testing via the internet, more and more people now have access to genetic diagnosis. In addition, it is becoming ever easier to obtain comprehensive genetic information about an individual or group of individuals, to the extent even of complete genome sequencing. In the case of an unborn child, genetic diagnosis without the iatrogenic risk of miscarriage is possible by means of tests on the mother’s blood.

Findings of differing significance are derived from the large volume of genetic data by a variety of evaluations. Some of these are highly valuable for healthcare purposes, others present disturbing information on untreatable conditions, while the relevance of still others is unclear. The risk of misinterpretation and misunderstanding is substantial if genetic diagnosis is not offered and conducted at a high level of quality and with due allowance also for non-genetic factors.

In this situation, the Ethics Council suggests various measures for the protection of self-determination and health and for the preservation of fairness and solidarity in both the healthcare system and society at large.

In 23 recommendations on genetic diagnosis in general, the German Ethics Council calls, firstly, for improvements in the provision of information to the public and in the training, advanced training and continuing training of healthcare professionals in relation to the available genetic tests, their importance and the significance of their results.

Secondly, the Council recommends a number of amendments to the Genetic Diagnosis Act in order to guarantee high standards of explanation and counselling in the light of recent developments. In this regard it addresses matters such as excessive information and secondary findings, information to family members, and the interests of people who lack the capacity to give consent. In particular, the
Council’s majority recommendation is that in future medical explanation and counselling should be mandatory even in the case of genetic tests conducted for non-medical purposes, as such tests too may yield medically relevant results.

Thirdly, to mitigate the risks of direct-to-consumer genetic tests and the possible psychological burden of their results, the Ethics Council calls for improved, EU-wide measures to provide for independent consumer information and for patient and consumer protection.

In addition, the Council presents recommendations on whether and to what extent the healthcare system should cover the cost of diagnostic procedures used in the context of therapy, on technical quality assurance, on the funding of research and on research and health policy.

In nine recommendations on prenatal diagnosis, the Ethics Council first of all notes that parents who decide to go ahead with the birth of a disabled child should be highly valued in society, and calls for more relief for affected families. The Council considers it essential that the conduct of prenatal genetic tests should be conditional upon subsequent ultrasound examinations carried out for the purpose of differentiation and by independent psychosocial counselling. It further recommends that funds be allocated to concomitant socioempirical and ethical research on prenatal genetic diagnosis.

The majority of the members of the Ethics Council in addition consider that prenatal genetic diagnosis should be permitted only where an increased risk of a disorder of genetic origin exists. In their view it is essential to ensure that no genetic information concerning the unborn child that is unconnected with pathology and no details of possible carrier status that are irrelevant to the health of the child itself are disclosed.

Should genetic information on the unborn child already be available during pregnancy within the first twelve weeks of fertilization, the majority of the members of the Ethics Council further consider mandatory pre-termination counselling pursuant to Section 218a(1) of the Penal Code (the “counselling solution”) to be inadequate and call for the introduction of a more extensive system of protection.

This view is rejected by eight members of the Council, who propose in a dissenting position statement that an expectant mother should not experience obstacles in gaining access to genetic information about her unborn child if she considers this to be essential in enabling her to reach a responsible decision. For this reason, these members oppose the suggested restrictions on prenatal genetic diagnosis. In addition, they recommend an amendment to the Genetic Diagnosis Act that would in future also allow the unborn child to be examined for late-onset disorders.

In another dissenting position statement, four Council members express the view that non-invasive prenatal genetic tests should neither be supported by public funds nor be included in the list of benefits provided by the statutory and private health insurance funds, because this would contravene the obligation, entered into under the UN Convention on the Rights of Persons with Disabilities, to ensure that the rights of people with physical and mental disabilities are comprehensively protected.

The Opinion can be accessed online (in German) at http://www.ethikrat.org/dateien/pdf/stellungnahme-zukunft-der-genetischen-diagnostik.pdf.
An English version will be available in due course.” (http://www.ethikrat.org/files/press-release-2013-03.pdf)

Four recommendations of the German Ethics Council, not specifically mentioned in its press release, should be of particular interest to genetic health care professionals across Europe:

The German Ethics Council recommends to establish a publicly financed and sustained information platform for available genetic tests (Recommendation A2). It is conceivable that the EuroGentest Clinical Utility Gene Cards in conjunction with the Orphanet directories could serve as building blocks of such a platform.

The German Ethics Council recommends to evaluate other countries’ experience with (non-medically trained) genetic counselors and the potential for introducing this profession also in Germany, where so far only medical doctors are allowed to provide genetic counseling (Recommendation A5).

The German Ethics Council recommends to minimize unsolicited genetic information already at the stage of choosing the appropriate analytical tools (Recommendation A8).

The German Ethics Council recommends mandatory accreditation of clinical genetic laboratories (Recommendation A17).

The German Genetic Diagnostics Commission Tri-annual Report

The German gene diagnostics act (Gendiagnostikgesetz, GenDG) was set in force by July 31, 2009. As a novelty in German medical legislation, the act required a Gene Diagnostics Commission (GEKO) to be established at the Robert-Koch-Institut, Berlin. The tasks of GEKO are defined by §23 GenDG: GEKO has to issue a number of guidelines related to individual paragraphs of the act¹ and to monitor the scientific and societal development in the area of genetics. Every three years, GEKO has to release an activity report and a critical review of the actual situation in this field.

Key to the philosophy of GenDG is the protection of the citizens’ autonomy with respect to the use of their genetic data. The law regulates in detail the use of genetic information and materials in the course of genetic testing for medical purposes, for paternity testing, for screening programs, in private insurance and in working contracts. All genetic testing – except for paternity issues – is subject to indication and prescription by a licensed physician. Emphasis is put on adequate information, counseling and consent of the patient by the “responsible” physician. As had been foreseen by the legislators, the volume of qualified genetic counseling required by the law for predictive and prenatal testing, could not be met by the relatively small number of board certified medical geneticists. Therefore, §23 of GenDG requested GEKO to issue a guideline on the requirements for competence in genetic counseling within the scope of each medical subspecialty (“fachgebundene genetische Beratung”). This guideline was highly controversial from the beginning. On one hand, it interfered with the authority of the Bundesärztekammer (BÄK, Federal Chamber of Physicians) to regulate medical postgraduate curricula and continuous medical education (CME), on the other hand, medical geneticists were concerned that this guideline would potentially open up their subspecialty to the entire medical community. With its guideline, GEKO has designed the

¹ The guidelines issued so far by GEKO and the Activity Report 2009-2012 can be found at: www.rki.de (in German)
content of a 72-hr curriculum of lectures in basic and medical genetics and practical training in counseling and communication skills which is meant to be embedded in postgraduate curricula ("Weiterbildungsordnung"). For the time being, the course can also be taken as part of CME. Time will tell whether the implementation of this guideline meets the intentions of GenDG.

In its first activity report for the years 2009 to 2012\(^1\), GEKO has given account of its proceedings and altogether seven guidelines issued in the reporting period and has reviewed the development in genetics since the launch of the law. In particular, GEKO has focused on the genome-wide screening technologies such as array-based molecular karyotyping and next-generation sequencing (NGS) which have gained so much momentum since 2009. GEKO felt that the growing use of these technologies adds further weight to the necessity of adequate genetic counseling and information as requested by GenDG. In extension of the existing practice and current guidelines, GEKO sees a need to further develop the concepts of informed consent to cover the incidental findings inherent to these screening methods. This is particularly relevant for prenatal applications such as non-invasive prenatal diagnosis by NGS (NIPD) when parents have to take far-reaching decisions under time-pressure. However, GEKO holds the opinion that these developments are well covered by GenDG and do not require further legislative steps.

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