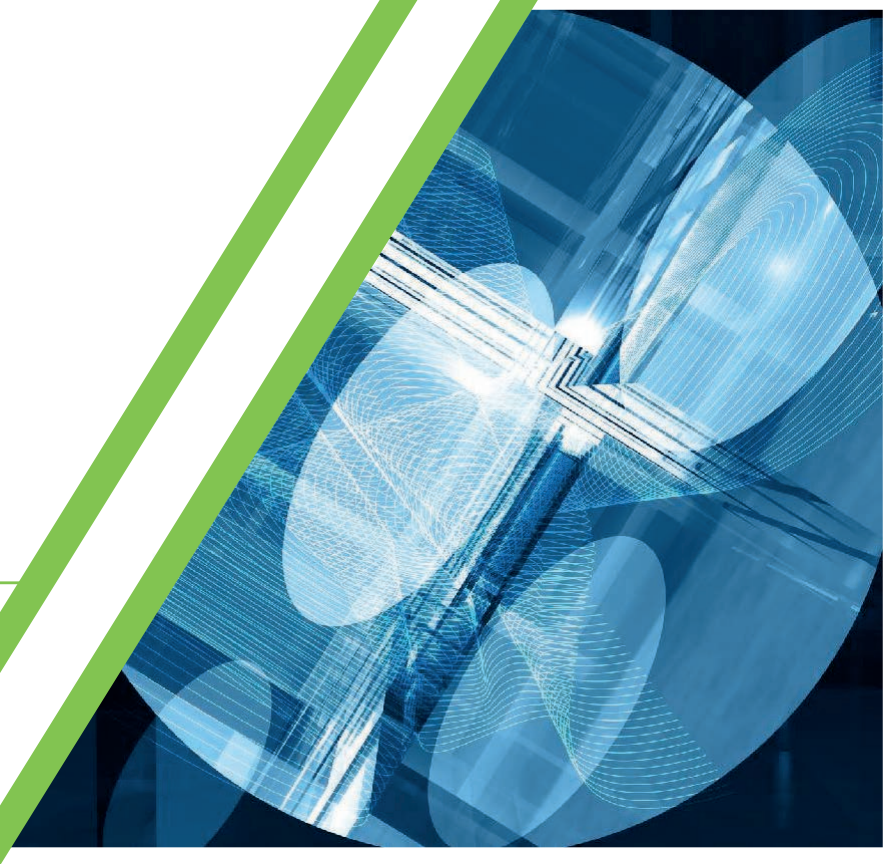
Recommendation of the Council on Quality Assurance in Molecular Genetic Testing



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Adopted on 10/05/2007

Background Information

The Recommendation on Quality Assurance in Molecular Genetic Testing was adopted by the OECD Council on 10 May 2007 on the proposal of the Committee for Scientific and Technological Policy. This Recommendation applies to quality assurance of molecular genetic testing offered in a clinical context. It addresses genetic testing for variations in germ line DNA sequences or products arising directly from changes in heritable genomic sequences that predict effects on the health, or influence the health management, of an individual. It focuses on molecular genetic testing for the diagnosis of a particular disease or condition and predictive genetic testing often carried out before any clinical signs of the disease or condition appear. It is relevant to tests for heritable DNA variants that predict the response profile of an individual to a drug or course of therapy and that affect susceptibility to disease, patient prognosis, counselling, treatment and family planning. It does not address testing carried out only for research purposes.

THE COUNCIL

HAVING REGARD to Article 5 b) of the Convention on the Organisations for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to Rule 18 b) of the Rules of Procedure;

HAVING REGARD to the Recommendation of the Council concerning Guidelines Governing Protection of Privacy and Transborder Flows of Personal Data of 23 September 1980 [C(80)58(Final)];

RECOGNISING that advances in biotechnology and genetics offer much promise for sustainable growth and development, as well as improved healthcare;

RECOGNISING that molecular genetic testing and the data that it generates will be increasingly fundamental not only to individual health care and public health but also to drug discovery and development;

RECOGNISING the benefits of cross border exchange of patient samples and personal information for molecular genetic testing;

RECOGNISING that molecular genetic tests may be performed on asymptomatic individuals and that results may have relevance to important lifetime decisions both for the individuals being tested and for their family and children;

RECOGNISING that molecular genetic testing falls under the purview of general ethical and legal principles set out, *inter alia,* in the Universal Declaration on the Human Genome and Human Rights adopted by UNESCO in 1997; the International Declaration on Human Genetic Data adopted by UNESCO in 2003; and the Universal Declaration on Bioethics and Human Rights adopted by UNESCO in 2005;

RECOGNISING that providing for international equivalence in the field of quality assurance may contribute to public confidence and the availability of genetic services;

RECOGNISING that governments and relevant public and private institutions (profit and not-for-profit) in OECD Member countries and non-member economies may therefore benefit from specific international guidance on quality assurance in molecular genetic testing;

On the proposal of the Committee for Scientific and Technological Policy;

RECOMMENDS that Member countries promote quality assurance in molecular genetic testing and take due account of and implement the Guidelines on Quality Assurance in Molecular Genetic Testing set out in the Annex hereto and which constitutes an integral part of this Recommendation;

INVITES non-member economies to take due account of and disseminate this Recommendation among public and private (profit and not-for-profit) sector institutions that are involved in molecular genetic testing;

INVITES the Committee for Scientific and Technological Policy to review this Recommendation in the light of new genetic knowledge, technological advances, evolution of quality management and societal needs within four years of adoption and periodically thereafter;

INSTRUCTS the Committee for Scientific and Technological Policy to monitor the implementation of this Recommendation and to report thereon to Council within four years of its adoption.

ANNEX

PRINCIPLES AND BEST PRACTICES FOR QUALITY ASSURANCE IN MOLECULAR GENETIC TESTING

1. Scope

This Recommendation applies to quality assurance of molecular genetic testing offered in a clinical context. It addresses genetic testing for variations in germ line DNA sequences or products arising directly from changes in heritable genomic sequences that predict effects on the health, or influence the health management, of an individual.

It focuses on molecular genetic testing for the diagnosis of a particular disease or condition and predictive genetic testing often carried out before any clinical signs of the disease or condition appear. It is relevant to tests for heritable DNA variants that predict the response profile of an individual to a drug or course of therapy and that affect susceptibility to disease, patient prognosis, counselling, treatment and family planning. It does not address testing carried out only for research purposes.

2. Principles and Best Practices

A. General Principles and Best Practices for Molecular Genetic Testing

Principles

A.1 Applicable legal, ethical, and professional standards should be respected in the practice of molecular genetic testing.

A.2 Molecular genetic testing should be delivered within the framework of health care.

A.3 All molecular genetic testing services should be provided and practised under a quality assurance framework.

A.4 Informed consent to test should be the norm and should be obtained in compliance with applicable legal, ethical, and professional standards.

A.5 Pre and post test counselling should be available. It should be proportionate and appropriate to the characteristics of the test, the test limitations, the potential for harm, and the relevance of test results to individuals and their relatives.

A.6 Personal genetic information should be subject to privacy protection and security in accordance with applicable law.

A.7 The benefits of cross border exchange of patient samples and personal information for molecular genetic testing should be recognised.

A.8 The use, storage, transfer and disposal of patient samples collected for molecular genetic testing should be subject to applicable legal, ethical and professional standards.

A.9 Advertising, promotional and technical claims for molecular genetic tests and devices should accurately describe the characteristics and limitations of the tests offered.

Best Practices

A.i Regulatory and professional bodies should, as appropriate, review whether the instruments available to manage a quality assurance framework require adaptation and interpretation for laboratories providing molecular genetic testing.

A.ii Laboratories should make available information on the analytical and clinical validity of tests.

A.iii Molecular genetic test results should be reported back to the referring health care professional to enable counselling and healthcare decision-making.

B. Quality Assurance Systems in Molecular Genetic Testing

Principles

B.1 Governments and regulatory bodies should recognise that accreditation of medical laboratories is an effective procedure for assuring quality.

B.2 All molecular genetic testing results for clinical care purposes should be reported by competent laboratories, as established by accreditation or other equivalent recognition consistent with these Guidelines.

B.3 Accreditation and other equivalent recognition should be based on internationally recognised standards and guidelines to facilitate mutual recognition of molecular genetic testing services.

B.4 The requirements adopted by legal, regulatory and professional bodies for laboratories to be recognised as competent through an accreditation or equivalent recognition should be accessible, clearly stated, and effective.

B.5 Regulation and incentives should be introduced to facilitate the development and implementation of accreditation or other equivalent recognition.

B.6 Impediments to achieving the requirements for accreditation or other equivalent recognition should be identified and addressed.

B.7 Governments and/or regulatory bodies should ensure that systems are in place to monitor and address instances where laboratories do not meet quality assurance requirements.

B.8 Governments should encourage international collaboration for the development, verification, availability and use of reference materials for molecular genetic testing.

B.9 Governments should encourage international collaboration for the development and validation of molecular genetic tests.

Best practices

B.i All laboratories reporting molecular genetic testing results for clinical care purposes should be accredited or hold an equivalent recognition. Research laboratories carrying out molecular genetic testing which are not accredited nor hold an equivalent recognition should arrange for such results to be verified and reported by a laboratory holding such an accreditation or recognition.

B.ii Internationally accepted standard terminology and nomenclature should be adopted and used consistently with respect to quality assurance systems.

B.iii Technical assessors acting on behalf of accreditation bodies or bodies delivering equivalent recognition should have qualifications, training and experience relevant to molecular genetic testing.

B.iv Laboratories should have policies and procedures to document the analytical validity of all tests performed.

B.v Laboratories should have policies and procedures to regularly evaluate internal quality control measures and to document findings and any corrective actions taken to address deficiencies.

B.vi Laboratories should make available to service users current evidence concerning the clinical validity and utility of the tests they offer.

B.vii Developers, manufacturers, health care professionals and laboratories, as well as other relevant groups, should collaborate to establish the clinical validity and utility of tests, particularly for rare conditions.

B.viii Laboratories should co-operate with relevant national and international institutions to collect, develop, verify and make available reference materials for molecular genetic tests.

B.ix Laboratories should use available reference materials and/or family-specific (private) mutation controls where appropriate and available.

C. Proficiency Testing: Monitoring the Quality of Laboratory Performance

Principles

C.1 The performance of laboratories offering clinical molecular genetic tests should be measured.

C.2 Governments, regulatory and professional bodies should support the availability of and access to proficiency testing.

C.3 Providers of proficiency testing schemes should be competent to provide such schemes, as established by accreditation or equivalent recognition.

C.4 Accreditation or equivalent recognition should be the basis for the international recognition of proficiency testing scheme providers.

C.5 Governments, regulatory and professional bodies should take steps to encourage laboratories to participate in accredited proficiency testing schemes or, when not available, to use alternative methods to assess the quality of the tests they perform.

C.6 Systems to monitor laboratory performance, and address persistent poor performance, should be in place.

Best Practices

C.i Proficiency testing providers and professional bodies should collaborate to establish acceptable performance levels for laboratories offering molecular genetic tests.

C.ii Regulatory and professional bodies responsible for monitoring laboratory performance against agreed standards should identify persistent poor performance and ensure that timely corrective actions are taken and documented.

C.iii Proficiency testing schemes should be structured to assess all phases of the laboratory process, including result reporting.

C.iv Providers of proficiency testing should develop and modify proficiency testing schemes to take into account the evolution of analytical methods.

C.v Laboratories should participate in a proficiency testing scheme for every disease for which they test, where such schemes are available. When not available, they should participate in alternative methods relevant to the tests they perform.

C.vi Laboratories should make the fact that they participate in proficiency testing publicly known.

C.vii Individual laboratory performance in proficiency testing schemes may be disclosed on a voluntary basis by the laboratory concerned but should not be made public by proficiency testing scheme providers unless so required by law.

D. Quality of Result Reporting

Principles

D.1 All laboratories should issue molecular genetic testing results in the form of a written and/or electronic report to the referring clinician or health professional.

D.2 Within jurisdictions where reports may be issued directly to patients, governments, regulatory and professional bodies should encourage all laboratories performing clinical molecular genetic tests to recommend that patients consult an appropriate clinician or health care professional to help them understand the implications of the test result.

D.3 Governments and regulators should require that in issuing and archiving reports, all laboratories comply with applicable law and regulations, including those concerning the confidentiality of information.

D.4 The interpretation of molecular genetic test results should be appropriate to the individual patient and clinical situation and should be based on objective evidence.

Best Practices

D.i Reports should communicate information effectively taking into account that the recipient may not be a specialist health care professional.

D.ii Reports should be timely, accurate, concise, comprehensive, and communicate all essential information to enable effective decision-making by patients and health care professionals.

D.iii Reports should use applicable internationally accepted terminology and nomenclature including identification of reference sequences.

D.iv Laboratories should inform service users of the patient and family information the laboratory requires to ensure the appropriateness of the test request and to interpret the results.

D.v In jurisdictions that allow laboratories to enter reports into a conventional or electronic patient record, all essential and relevant elements should be included.

D.vi Reports should include at a minimum the following information:

1. Identification that unequivocally links the report to the patient;
2. The name of the referring health care professional and contact information;
3. The indication for testing and specific medical information where it is relevant to test interpretation;
4. The test performed and the methodology used (including the scope of the analysis, the limitations of the test and its analytical sensitivity and specificity);
5. The primary sample type where necessary for the interpretation;
6. The date of receipt of the sample;
7. The name and location of laboratory(ies), including any referral laboratory(ies), which performed the actual testing on the sample;

8. The test result;

9. An interpretation of the result in the context of the indication for testing and all other information provided to the laboratory;

10. The identity of the individual approving the report;

11. Laboratory contact information;

12. The date of issue of the report.

D.vii Where appropriate, the test report should also include the following information:

1. A recommendation for genetic counselling by a qualified health care professional;

2. Implications for other family members;

3. Recommendations for follow up testing.

D.viii All the essential and relevant elements of test results and interpretation reported by a referral laboratory should be included in the report to the health care professional who ordered the test.

E. Education and Training Standards for Laboratory Personnel

Principles

E.1 Laboratory personnel should have appropriate professional qualifications that meet recognised standards, underpinned by education and training, to assure laboratory competence in the provision of molecular genetic testing.

E.2 Standards for laboratory accreditation or other equivalent recognition should require that all molecular genetics personnel have a combination of education, training, skills and experience that ensures their competence.

E.3 Existing specialist education and training programmes relevant to molecular genetic testing that meet recognised standards should be formally adopted by governments, regulatory and/or professional bodies.

E4 Development of educational and training programmes should be encouraged where they do not exist.

E5 Relevant government or professional authorities should recognise medical genetics as a discipline comprising both a clinical and a laboratory specialty.

E.6 Where governments, regulators and professional bodies recognise medical and scientific qualifications awarded by foreign institutions, such recognition should be extended, as appropriate, to equivalent qualifications in molecular genetic testing.

E.7 All personnel involved in molecular genetic testing should practice within the framework formed by applicable legal, ethical and professional standards.

Best Practices

E.i Measures to assure professional competence should be established. These measures should be comparable to those applied in other areas of laboratory medicine. They should include systems to validate requirements for education, training, qualifications and skills specific to molecular genetic testing.

E.ii Appropriate specialist qualifications, education and training standards for individuals directing molecular genetics laboratories should be established. The minimum qualification required to direct a laboratory should be an MD or PhD or a recognised equivalent qualification. Educational requirements should include formal training in molecular genetics and where available, certification in the specialty of clinical laboratory molecular genetics, or another relevant discipline.

E.iii Laboratory directors should ensure that all laboratory personnel have relevant training and have their competence documented prior to performing molecular genetic testing for the purpose of reporting a diagnostic result on any patient material.

E.iv Education and training in genetics should be recognised by regulatory and/or professional bodies as an essential element to strengthen professional competence to deliver molecular genetic testing.

E.v Laboratory directors should ensure that all personnel involved in molecular genetic testing participate in continuing education and training programmes appropriate to their roles and designed to further develop and maintain competence.

E.vi Comparison of specialist education and training systems between jurisdictions should be facilitated as a means to establish equivalence.

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- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.