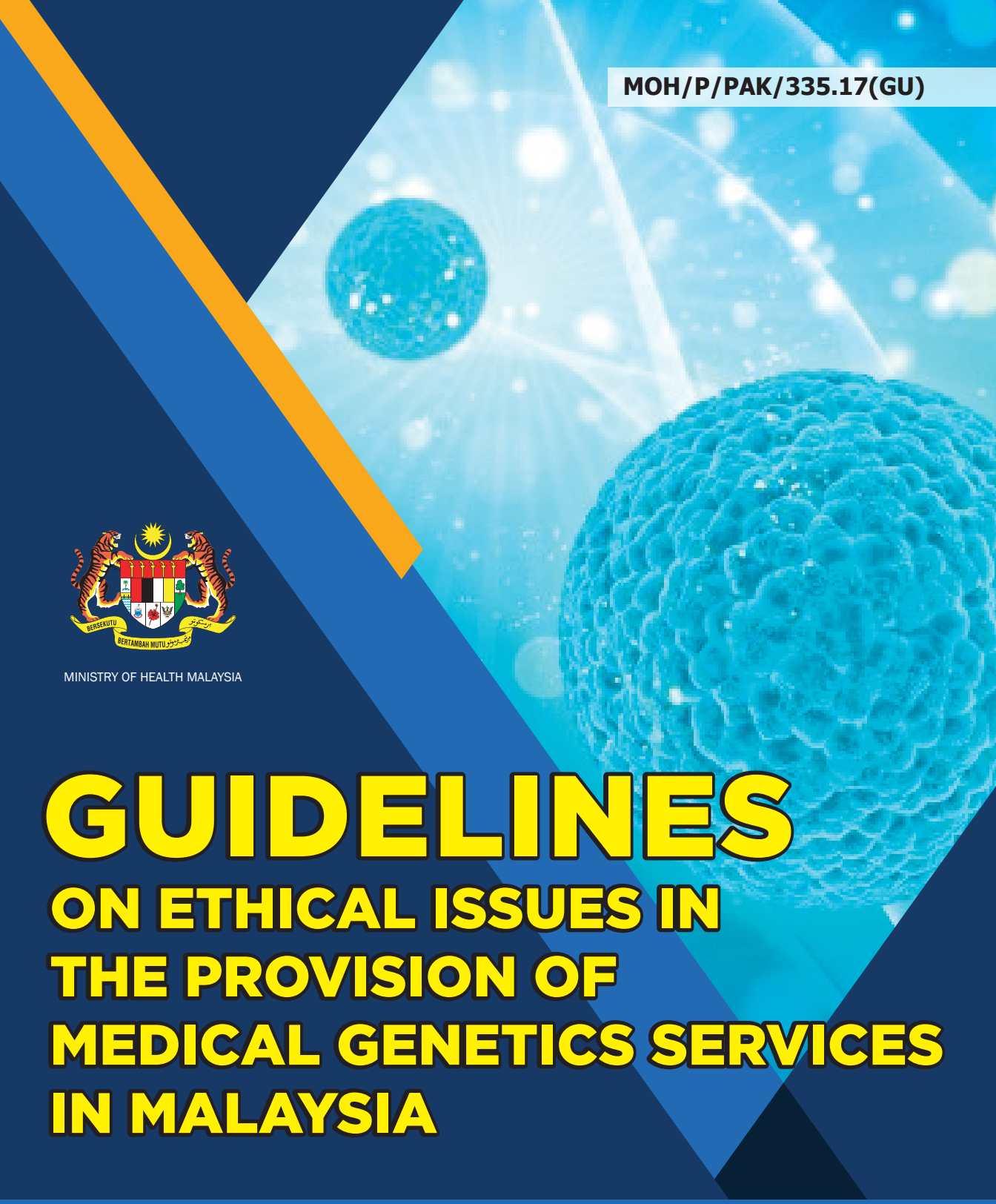
MOH/P/PAK/335.17(GU)



MINISTRY OF HEALTH MALAYSIA

GUIDELINES
ON ETHICAL ISSUES IN THE PROVISION OF MEDICAL GENETICS SERVICES IN MALAYSIA

O&G AND PAEDIATRIC SERVICES UNIT
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA

MOH/P/PAK/335.17(GU)

GUIDELINES ON ETHICAL ISSUES IN THE PROVISION OF MEDICAL GENETICS SERVICES IN MALAYSIA

O&G AND PAEDIATRIC SERVICES UNIT
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA

The Guidelines On Ethical Issues In The Provision Of Medical Genetics Services In Malaysia was prepared by the multidisciplinary team from Ministry of Health, universities and other related parties in collaboration with the Obstetric & Gynaecological and Paediatric Services Unit, Medical Services Development Section, Medical Development Division, Ministry of Health Malaysia

Published in December 2019

A catalogue record of this document is available from the Library and
Resource Unit of the Institute of Medical Research, Ministry of Health;

MOH/P/PAK/335.17(GU)

And also available from the National Library of Malaysia;

ISBN 978-967-0769-71-4

TABLE OF CONTENT

FOREWORD

BY

DIRECTOR-GENERAL OF HEALTH MALAYSIA

Malaysia as a developing country is currently burdened with lifestyle-related diseases, thus genetic disorders has taken a backseat in our health care system. Adoption of recommendations from WHO/ HGN/WAOBDP meeting of experts convened in 1999, may help improve the situation. Among the recommendations are :

1. Need to recognize the burden imposed by genetic disorders and birth defects.
2. Need for political will and commitment to support the implementation of genetic services.
3. Improve epidemiological knowledge about genetic disorders and birth defects.
4. Define the goals of genetic services in terms of both individual/family well-being and public health.
5. Improve prenatal and perinatal services.
6. Organize genetic services in a comprehensive and integrated manner, with roots in the primary health care level.
7. Select programmes and targets according to prevalence, severity and predicted outcomes.
8. Respect ethical principles and cultural diversity.
9. Train health professionals in medical genetics.
10. Educate the public in genetics.
11. Encourage the formation of parent/patient organizations.

To ensure a cost effective approach in genetics diseases, the country needs to implement genetic testing and screening in a manner that is sensitive to the population's cultural practices and religious views and in accordance with national legislation. We need also to address direction of resources in terms of prevention and surveillance of genetic diseases. This in turn will reduce health care costs in childhood and early adulthood.

Even when people are aware that genetic services are available, low awareness levels among health care providers present a challenge to effective public education. Lack of information and limited familiarity with genetic disorders and available genetic services present an obstacle for a proper diagnosis and treatment plan. Education of health professionals at a local level must go hand in hand with public education and this include the basic principles of genetic counseling, and the primary ethical, legal and social issues associated with medical genetic services.

The direct to consumer genetic testing with aggressive commercialization is a real genetic issue that needs to be addressed appropriately. It is important to note that such testing is unlikely to provide the level of information, counseling and support that should be provided with genetic tests.

As of date, national legislations on direct to consumer testing are seen in several European countries including Belgium, the Netherlands, Switzerland, Portugal, France, Germany and United Kingdom. Malaysia needs to address this issue as well because it is important for us not only to protect our public from possible unscrupulous and scientifically unsound genetic practice, we also need to ensure that only clinically useful tests are promoted and less useful tests are discouraged. This is not only for direct to consumer genetic testing but also for every genetic test being performed in the public health care setting. It is necessary to develop an assessment procedure to address the usefulness of genetic tests.

Our current healthcare system is fairly fragile and evolving. With genomic innovation and progress it is likely that strains and limitations will be placed on system and providers. It is important therefore for Ministry Of Health, genetic professionals, academic medical centers, universities, public and private hospitals work hand in hand to fill in gaps to describe, monitor and evaluate provision of genetic services in Malaysia now and in the future.

We all have a stake in our genetic future.

DATUK DR. NOOR HISHAM BIN ABDULLAH
Director-General of Health Malaysia

FOREWORD

BY

DEPUTY DIRECTOR-GENERAL OF HEALTH

MALAYSIA (MEDICAL)

The International Human Genome Project that was completed in 2003 has hastened genetic discoveries. Recent advances in genetic technologies have pushed achievement in genetics to a greater height that was unimaginable just a few years ago. More and more genetic research is carried out not only on rare diseases but also on common diseases such as cancer, diabetes and hypertension. As mortality and morbidity decline, genetics will assume a larger role. Personalized medicine and targeted therapies fast becoming the focus in many areas in medicine.

All of these rapid advances in genetics will bring with it a new set of ethical issues in addition to exacerbating the old ones such as disclosure of genetic information or informed consent in genetic testing. Translating advances in genetics to the bedside require not only effective and competent genetic services but also ethical ones to safeguard patient's rights and to ensure patients enjoy the benefit of such services equitably without any harm.

The First edition of Ethical Guidelines in Genetic Services in Malaysia was drafted in 2006. It is timely to review this and to produce an updated version that also addresses the new genetics and its ethical dilemmas.

DATUK DR. HJ. ROHAIZAT BIN HJ. YON
Deputy Director-General of Health Malaysia (Medical)

FOREWORD

BY

DIRECTOR OF MEDICAL DEVELOPMENT DIVISION

Rapid growth in the area of medical genetics is providing a wealth of new options for dealing with genetic disease. These knowledge and technologic advances raise various, sometimes unprecedented, ethical dilemmas which must be resolved by providers of genetic services and individuals who receive those services, as well as society in general.

The fundamental ethical principal of autonomy (self-determination), beneficence (to do good), non-maleficence (not to do harm) and justice (fairness for patient) apply also to medical genetics. However, an ethical issue in medical genetics poses more challenges because genetic information may affect an entire family, rather than only the individual. The ethical responsibilities of the providers of genetic services include balancing the privacy and confidentiality of the individual and prevention of harm to others.

Genetic testing will play an increasingly important role in health care. The genetic tests are either diagnostic (prenatal and postnatal) or predictive (carrier testing, pre-symptomatic testing) and can even play a significant part in therapeutic approaches. The providers of genetic services who orders genetic tests should be aware of when it is appropriate to test, which particular test to order, and what information the test can provide, the limitations of the test, how to interpret positive and negative results in light of the patients medical or family history, and the medical management options available. To test a child about adult onset disorders will be unethical as it leads to social discrimination and should ideally be postponed till the child reaches the age of consent.

Y.BHG. DATO' DR. HJ. BAHARI BIN DATO' TOK MUDA HJ. AWANG NGAH
Director of Medical Development Division

GLOSSARY

1. **Autonomy**
   ~ self-determination of individuals.

2. **Beneficence**
   ~ giving highest priority to the welfare of persons and maximizing benefits to their health.

3. **Full disclosure**
   ~ of test results includes ambiguous test results, new and controversial interpretations, and differences among health professional colleagues in regards to test interpretation.

4. **Genetic counseling**
   ~ is the provision of accurate, full and unbiased information in a caring, professional relationship that offers guidance, but allows individuals and families to come to their own decisions.

5. **Genetic screening**
   ~ refers to tests offered to a population group to identify asymptomatic individuals at an increased risk from a particular adverse outcome.

   (Examples are phenylalanine screening for Phenylketonuria in newborn babies and the use of maternal serum biochemical markers in pregnant women to screen for fetus with Down Syndrome).

6. **Genetic testing**
   ~ genetic testing is a type of medical test that identifies changes in chromosomes, genes or proteins. Most of the time, testing is used to find changes that are associated with inherited disorders. The results of a genetic test can confirm a suspected genetic condition or help determine a person's chance of developing or passing on a genetic disorder. Several hundred genetic tests are currently in use, and more are being developed.

7. **Whole genome screening**
   ~ whole genome screening and testing is a test that captures the full range or all genetic alterations in DNA unlike genetic testing techniques that only focus on a single gene or a part of the DNA. It is a powerful technique for obtaining reference sequence information of an individual. Its use can be dramatically expanded to rapidly identify genomic variations, which can be linked with phenotypes to obtain new biological insights.

8. **Justice**
   ~ treating persons with fairness and equity, and distributing the benefits and burden of health care as fairly as possible in society.

9. **Non-directiveness**
   ~ non-directiveness refers to the nature of the genetic counseling process. According to the principle of non-directiveness, the genetic counselor has the responsibility to provide the client with accurate information about a test or outcome but should remain neutral and not try to influence the decisions made by the client.

10. **Non-discriminatory language**
    ~ emphasizes the personhood of those with genetic conditions and avoiding dehumanization or stigmatization. Thus, for example, someone with Down syndrome is best described as a person or a child with Down syndrome rather than a "Down syndrome child" or a "Down syndrome case".

11. **Non-maleficence**
    ~ avoiding and preventing harm to persons or, at least, minimizing harm.

12. **Pre-symptomatic testing**
    ~ refers to identification of healthy individuals who have inherited a gene for a late onset disease, and if so may develop the disorder if they live long enough (eg. Huntington disease).

13. **Re-contact**
    ~ means keeping abreast of new developments and re-contacting individuals or families on a timely basis regarding any new developments relevant to their health or reproduction, unless otherwise instructed by the individuals or family.

14. **Susceptibility testing**
    ~ identifies healthy individuals who may have inherited a genetic predisposition that puts them at increased risk of developing a multifactorial disease, such as ischaemic heart disease, Alzheimer disease or cancer, but who, even so, may never develop the disease in question.

15. **Definition of a child**
    ~ means a person under the age of eighteen years (Child Act 2001).

16. **Incompetent adult :**
    ~ any mental illness, arrested or incomplete development of the mind, psychiatric disorder or any other disorder or disability of the mind however acquired (Mental Health Act 2001).

Chapter 1 : PRE-AMBLE INTRODUCTION

This guideline is for persons involved in the delivery of genetic services (Clinical & Laboratory) and other interested members of the public. It covers ethical aspects of genetic healthcare delivery in relation to health and diseases. It also aims to ensure all the practices are in line with the prevailing legal, religious and cultural practices and beliefs. It is intended to provide a guide to good ethical practice in the provision of healthcare and genetic testing services.

Chapter 2 : SUMMARY

The advances in human genetics that have occurred recently have revolutionized the knowledge of the role of inheritance in health and disease. We now know that our DNA determines not only the cause of catastrophic single-gene disorders, which affect millions of persons worldwide, but also predisposes to cancer, heart disease, psychiatric disorders and even to some infectious diseases. However, these advances will only be acceptable if their application is carried out ethically, with regards to autonomy, justice, education and the beliefs and laws of each nation. Therefore ethical consideration in genetic service should be given due regards so that the population can benefit from the advances of genetic knowledge without any harm.

In general it is ethically imperative that genetic data should only be used to the advantage of members of a family or ethnic group, and never to stigmatize or discriminate against them.

There shall be no compulsory genetic testing of adult individuals or population. Every test shall be offered in such a way that individuals and families are free to refuse or accept according to their wishes and moral beliefs. All testing should be preceded by adequate information about the purpose and possible outcomes of the test and potential choices that may arise. Children should be tested only when there are medical benefits, as in the case of newborn screening when early treatment will be of benefit to the child.

Prenatal diagnosis should be offered to those who need it, but there must be no pressure on couples to accept such testing, nor to use the results of the test to compel either continuing or terminating a pregnancy when the fetus is affected with a genetic disorder.

In addition, prenatal diagnosis should be done only to give parents and physicians information about the health of the fetus. The use of prenatal diagnosis for paternity testing and gender selection are not acceptable (non-maleficence) except for cases of rape or incest, and sex-linked disorders.

Decisions in the context of reproduction should rest with those being tested, not with physicians or the government.

The woman should be an important decision-maker in all matters related to reproduction.

Genetic services for the prevention, diagnosis and treatment of disease should be available to all, and should be provided first to those whose needs are greatest.

Genetic data should only be used to advantage and empower an individual or family, and for better treatment or prevention of disease. Genetic data relevant to health care should be collected and kept by medical geneticists or personal clinicians in secure confidential files. Genetic data should not be given out to insurance companies, employers, schools or government, other than after the full informed consent of the person tested.

Genetic counseling should be available to all, and shall be as non-directive as possible. It is essential before any testing is carried out, and should continue afterwards if the results entail choices for the person and family tested. Education about genetics for the public and health care professionals is of paramount importance.

The general principles of medical genetics outlined below are modified from the recommendations of WHO as followed by many countries in the world.

Chapter 3 : GOALS AND PRACTICES OF MEDICAL GENETICS

Medical genetics is the field of medicine that is most centrally involved in providing services to persons with genetic conditions and their families. The goals of medical genetic services are to help people with a genetic disadvantage and their families to live and reproduce as normally as possible, to make informed choices in reproductive and health matters, to assist people to obtain access to relevant medical services (diagnostic, therapeutic, rehabilitative or preventive) or social support systems, to help them adapt to their unique situation, and to become informed on relevant new developments.

Medical genetic services should be organized at all levels of all medical care and should be directed by specially trained clinicians. Actions may be conducted by a variety of health personnel according to the level of care and the particular organization of health delivery in each society. The different members of the genetic team may include geneticists (clinical and non-clinical), nurses, primary care physicians, specially trained health care workers or genetic counselors, social workers and laboratory personnel.

Genetic services in Malaysia are still evolving and not widely available to every layer of the population. However, whenever and wherever the genetic services are available, the ethical guidelines should be adhered to.

Chapter 4 : ETHICAL PRINCIPLES IN MEDICAL GENETICS

Genetic tests are now offered by a wider group of medical practitioners beyond trained medical geneticists including general practitioners, oncologists, surgeons, pediatricians, O&G specialists etc. All practitioners offering genetic test should recognize that the impact extends beyond those of the conventional structure of medicine and the physician-patient relationship.

For example :

1. genetic information may affect an entire family, rather than only the individual;

2. genetic discoveries may be predictive of future adverse events in an individual's or family member's health;

3. genetic information and the choices of the present may affect future generations; and

4. medical genetics has a tradition of non-directiveness in counseling

The ethical principles of respect for the autonomy of persons, beneficence, non-maleficence and justice apply also to genetics testing. Practitioners should abide with prevailing regulations and directive related to genetic testing and is aware of social implications of such tests.

The application of the above-mentioned ethical principles to genetic services is as follows:

1. Fair allocation of public resources to those who need them most (justice).

2. Freedom of religious and cultural belief choices in matters relevant to genetics within the existing legal framework. The woman should be an important decision-maker in reproductive matters (autonomy).

3. Voluntary approach necessary in services, including approaches to testing and treatment; avoidance of coercion by government, society or physicians (autonomy).

4. Respect for human diversity and for those whose views are in the minority (autonomy, non-maleficence).

5. Respect for people's basic intelligence, regardless of their knowledge (autonomy).

6. Genetic education for the public, medical and other health professionals, teachers, clergy and other persons who are sources of religious information (beneficence).

7. Close cooperation with patient and parent organization (autonomy).

8. Prevention of unfair discrimination or favouritism in employment, insurance or schooling based on genetic information (non-maleficence).

9. Teamwork with other professionals through a network of referrals. When possible, help individuals and families to become informed members of the team (beneficence, autonomy).

10. Use of non-discriminatory language that respects individuals as persons (autonomy).

11. Timely provision of indicated services or follow up treatment (non-maleficence, beneficence).

12. Refraining from providing tests or procedures not medically indicated (non-maleficence).

13. Providing on-going quality control of services, including laboratory procedures (non-maleficence).

Chapter 5 : GENETIC COUNSELING

Genetic counseling should be provided by specially trained individuals and may include geneticists (clinical and non-clinical), nurses, medical specialists or genetic counselors.

Genetic counseling should be non-directive and has two major elements. The first is the provision of accurate, full and unbiased information that individuals and families may use in making decisions. The second is an understanding, empathic relationship that offers guidance and helps people to work towards their own decisions.

Ethical principles applied to genetic counseling are as follows:

1. Respect for persons and families, including full disclosure of accurate and unbiased information to the individual (anatomy). – Respect for the individual's decisions (autonomy).

2. Preservation of family integrity (autonomy, non-maleficence).

3. Protection of the privacy of individuals and families from unjustified intrusions by employers, insurers, and schools (non-maleficence).

4. Information to individuals and families about possible misuse of genetic information by institutional third parties (non-maleficence).

5. Informing individuals that it is the individual's ethical duty to tell blood relatives that the relatives may be at genetic risk (non-maleficence).

6. Informing individuals about the wisdom of disclosing their carrier status to a spouse/ partner if children are intended, and the possibility of harmful effects on the marriage from disclosure (non-maleficence).

7. Informing people of their moral duties to disclose a genetic status that may affect public safety (non-maleficence).

8. Unbiased presentation of information, to the extent that this is possible (autonomy).

9. Non-directive approach, except when treatment is available (autonomy, beneficence).

10. Children and adolescents to be involved in decision affecting them whenever possible (autonomy).

11. Duty to re-contact if appropriate and desired (non-maleficence, beneficence, autonomy).

Chapter 6 : GENETIC TESTING

The main objective of genetic screening and testing is to prevent disease or secure early diagnosis and treatment. In all cases, individuals whose screens indicate that they are at higher risk, must be offered either a definitive diagnostic test and a clinical care plan which either prevents the disease or improve survival. Population screening programs or screening of unaffected family members (cascade screening) are offered only when proven methods of treatment or prevention are available and screening should be preceded by educational programs. Population-based screening should be part of a national programme.

Besides single gene testing, major advances in DNA sequencing technology have made it possible to do large-scale sequencing, multi gene panel testing, whole exome sequencing (WES) and whole genome sequencing (WGS) in an effort to identify gene mutations that may provide information for individuals to make an informed decision.

Indication For Genetic Testing

Screening
To identify individuals who are at higher risks of certain genetic diseases for which early diagnosis and treatment are available.

Diagnostic
To confirm the diagnosis of a genetic disease or condition

Disease prediction
Predictive genetic testing helps to determine the chances that a healthy individual with or without a family history of certain genetic disease might develop that disease

Prognostic and choice of treatment
If the testing reveals a known disease or condition, it may provide information about prognosis and choice of treatment.

Research
Whole genome sequencing allows researchers to analyze the entire human genome of an individual and therefore detect disease-related genetic variants. Genomics research usually aims to identify and understand the mutations and variants found in the human genome.

Ethical guidelines for genetic testing are listed as follows :

1. The four principles of ethics (autonomy, non-maleficence, beneficence and justice) must be upheld.

2. Genetic screening and testing should be voluntary, not mandatory, with the exception noted in the point below regarding newborn screening (autonomy).

3. Genetic screening and testing should be preceded by adequate information about the purpose and possible outcomes of the screen or test and potential choices to be made (autonomy, non-maleficence).

4. Anonymous screening for epidemiological purposes may be conducted after notification of the population to be screened (autonomy).

5. Results should not be disclosed to employers, insurers, schools or other parties without the individual's consent, in order to avoid possible discrimination (autonomy, non-maleficence).

6. In rare cases where disclosure may be in the best interest of the individual or for public safety, the health provider may work with the individual towards a decision by him or her (beneficence, non-maleficence, justice).

7. Test results particularly when unfavourable should be followed by genetic counseling (autonomy, beneficence).

8. If treatment or prevention is available, this should be offered as soon as possible (beneficence, non-maleficence).

9. Newborn screening should be universal or mandatory only if early diagnosis and treatment will benefit the newborn (beneficence, justice).

10. If it has been decided to offer carrier screening for a particular disorder, preconception screening would be preferable to antenatal screening.

11. Carrier screening in schools should not be contemplated until satisfactory solutions have been identified to the potential problems: confidentiality, the risk of stigmatization among young people at a very sensitive time in their lives, and difficulties of ensuring that adequate support mechanism are in place.

12. Genetic screening and testing should be performed by accredited diagnostic laboratories, government diagnostics genetic laboratories, registered research laboratories and academic laboratories after genetic counseling is provided.

13. There is a need for a precise informed consent involving ethical and legal issues i.e. privacy, confidentiality, potential risks and benefits of disclosing the individual's genetic data. (autonomy, non-maleficence, beneficence)

14. Genetic screening and testing should be preceded by adequate information about the purpose and the expected outcomes of testing, the likelihood and type of incidental results that could be generated, and what results will or will not be disclosed to the patient (autonomy, non-maleficence).

15. As part of the pre-test counseling, a clear distinction should be made between clinical and research-based testing. In many cases, findings will include variants of unknown significance which may not be disease-related and is a subject for research; in such instances a protocol approved by an institutional review board must be in place and appropriate prior informed consent obtained from the participant (non-maleficence).

16. Each and every component of the laboratory test (sequence acquisition, bioinformatics filtering, results interpretation, and reporting) should be performed in a laboratory managed by individual(s) with appropriate medical genetics and genomics training. There should be an active dialogue between the laboratory and the ordering physician.

17. The important health data should not be provided without the full involvement of registered medical practitioner to avoid potential inaccurate risk estimates.

Chapter 7 : INFORMED CONSENT FOR GENETIC TESTING

The ethical requirements of informed consent differ between a clinical situation and a research setting. Followings are ethical guidelines applicable in clinical practice and research situations respectively :

1. Applicable to clinical practice :-

   Genetic testing in clinical practice should be voluntary and should occur in the context of a comprehensive genetic service and valid process of informed consent, with an explanation of the following elements

   1.1 the purpose of the test,
   1.2 the chance that it will give a correct prediction,
   1.3 the implications of the test results for the individuals,
   1.4 the tested person's options and alternatives,
   1.5 the potential benefits and risks, including social and psychological im pact,
   1.6 that social risks include discrimination by insurers and employers (even though this may be illegal), and
   1.7 that whatever decision the individuals and families make, their care will not be jeopardized.

2. Applicable to research :-

   The research must first and foremost be approved by the local/institutional research and ethics committee prior to commencement of the research itself

   Elements of a valid informed consent process include an explanation of :

   2.1 the experimental nature and purpose of the study
   2.2 why the individual is invited to participate, and that participation is voluntary
   2.3 the tests involved, samples required and sampling procedures
   2.4 the discomforts and risks (if any) of the test to both the individual and the family
   2.5 the uncertainty of the results for prediction and accurate genetic counselling
   2.6 the possible benefits to others and to science
   2.7 the secrecy of personal data provided by the individual as stipulated in Personal Data Protection Act 2010 (ACT 709)
   2.8 the confidentiality of records identifying the tested individual

2.9 whom to contact for questions about research or in the event of research injury
2.10 the right of the individual to withdraw at any time
2.11 the right of the individual and family to unrestricted health care, even if the individual withdraws.
2.12 the right of the individual to be informed about sample storage (tissue, DNA, blood) for study purposes, duration of storage for the specific study and the possibility it will be used for follow up purposes in the future
2.13 The limitations of analysis with data from genetic testing, and
2.14 the individual has the right to request for his/her sample be removed.

For all genetic testing, valid and informed consent must be available prior to testing. For individuals who are not capable of giving consent please refer to Guideline on Consent by Malaysia Medical Council.

Children

A person with parental responsibility may lawfully give consent on behalf of a young child who lacks the capacity to make personal decision provided the test is considered to be in the child's best interests. (Below 18 years old)

Chapter 8 : PRESYMPTOMATIC AND SUSCEPTIBILITY TESTING

Pre-symptomatic testing in the absence of the therapeutic options should be available if the following conditions are met :

1. The information provided by testing will be used to prevent harm to the person tested, or to spouse, family, prospective children or others.

2. The person is fully informed about the limitations of testing, including possibilities of uninformative results, and inability to predict exact age of onset or (sometimes) severity of symptoms.

3. The person's biological parents are mentally capable of giving consent.

4. Testing is accompanied by a counseling program of appropriate length and intensity for the disorder.

With regards to requests for testing of children, in the absence of medical benefit through prevention or treatment, pre-symptomatic or susceptibility tests for adult-onset disorders are usually best postponed until adulthood, when the young adult can make her/his own decision. In counseling, geneticists need to explain to parents the potential benefits and potential harms of testing children.

Ethical guidelines for pre-symptomatic and susceptibility testing are as follows :

1. Genetic susceptibility testing of persons with a family history of heart disease, cancer or other common diseases of possible genetic origin should be encouraged, provided that information from the test can be used effectively for prevention or treatment (beneficence).

2. All susceptibility testing should be voluntary, preceded by adequate information and based on informed consent (autonomy).

3. Pre-symptomatic testing should be available for adults at risk who want it, even in the absence of treatment, after proper counseling and informed consent (autonomy).

4. Testing of children or adolescents should be carried out only if there are potential medical benefits to the child or adolescent (autonomy, beneficence, non-maleficence).

5. Employers, insurers, schools, government agencies or other institutional third parties should not be given access to test results (non-maleficence).

Chapter 9 : DISCLOSURE AND CONFIDENTIALITY

Disclosure and confidentiality issues are some of the most frequent ethical issues appearing in medical genetics. Because of the possibility of harm from disclosure to institutional third parties, utmost care must be taken to protect confidentiality. However, a genetic diagnosis in an individual may indicate genetic risks in his/her relatives. In those circumstances, the genetic service provider should encourage the individual to inform the relatives to seek genetic counseling.

Guidelines on issues of disclosure and confidentiality are as follows:

1. Professionals should disclose to tested individuals all test results relevant to their health or the health of a fetus. Adequate information is a prerequisite for free choice and is necessary to the open communication and trust that should mark the relationship between the provider and the person counseled.

2. Tests results including normal results, should be communicated to the tested person without undue delay.

3. Test results not directly relevant to health such as non-paternity, or the sex of the fetus in the absence of x-linked disorder, may be withheld if this appears necessary to protect a vulnerable party or if prescribed by national law.

4. The wish of individuals and families not to know genetic information, including test results, should be respected, except in testing of newborn babies or children of treatable conditions.

5. Information that could cause grave psychological or social harm may be temporarily withheld. Within the general duty of disclosure, the counselor may exercise judgement about when a tested person is ready to receive information.

6. If a couple intends to have children, individuals should be encouraged to share genetic information with their partners.

7. Where appropriate, as part of their general duty to educate, counselors should inform people that genetic information may be useful to their relatives and may invite individuals to inform the relatives to seek genetic counseling.

8. The provision of genetic information to relatives about the family so as to learn their own genetic risks should be possible, especially when a serious burden can be avoided.

9. Results of carrier test, pre-symptomatic tests, susceptibility tests and prenatal tests should be kept confidential from employers, health insurers, schools and government agencies. People should not be penalized or rewarded for their genetic constitutions. Information about a symptomatic condition may be disclosed as part of general medical information, in accordance with laws and practices in the country.

10. Registries. (refer Chapter 13)

11. Information is only released to a third party with the individual's consent unless instructed by the court. A copy of the consent should be retained in medical record.

Chapter 10 : PRENATAL DIAGNOSIS

Prenatal diagnosis of genetic disorders and fetal anomalies has expanded significantly for hundreds of condition through DNA analysis of fetal cells, and the increased use of ultrasound and maternal serum biochemical screening. The purpose of prenatal diagnosis is to rule out the presence in the fetus of a particular medical condition for which the pregnancy is at an increased risk. This information is provided to the couple to assist in their decision-making process regarding the available options, such as carrying the pregnancy to term, preparing for a difficult delivery and special newborn care, or termination of pregnancy (refer to Guideline on Termination of Pregnancy (TOP) For Hospitals in the Ministry of Health 2012).

Genetic counseling is particularly important prior to prenatal diagnosis and, after a result indicating an affected fetus, to secure fully informed choices. Information about the purposes, benefits and limitations of maternal serum biochemical screening and first trimester ultrasound screening must be given when offering the tests, including the fact that any abnormal screening result will need confirmatory testing by invasive prenatal diagnosis and may potentially lead to a decision about abortion.

Ethical guidelines for the provision of prenatal diagnosis and counseling related to it are as follows :

1. Equitable distribution of genetic services, including prenatal diagnosis, is owed first to those with the greatest medical need, regardless of ability to pay or any other considerations (justice).

2. Prenatal diagnosis should be voluntary in nature. The prospective parents should decide whether a genetic disorder warrants prenatal diagnosis or termination of a pregnancy with an affected fetus (autonomy).

3. If prenatal diagnosis is medically indicated, it should be available regardless of a couple's stated views on abortion. Prenatal diagnosis may, in some cases, be used to prepare for the birth of a child with a disorder. Prenatal diagnosis for adult-onset disorders may require special counselling, so as to avoid testing of children who may be carried to term.

4. Prenatal diagnosis is carried out only to give parents and physicians information about the health of the fetus. The use of prenatal diagnosis for paternity testing and gender selection are not acceptable (non-maleficence) except for cases of rape or incest, and sex-linked disorders.

5. Prenatal diagnosis solely for relief of maternal anxiety, in the absence of medical indications, should have lower priority in the allocation of resources than prenatal diagnosis with medical indications (justice).

6. Counseling should precede prenatal diagnosis (non-maleficence).

7. Physicians should disclose all clinically relevant findings to the woman or couple, including the full range of variability in manifestations of the condition under discussion (autonomy).

8. The woman's and /or the couple's choices in a pregnancy with an affected fetus should be respected and protected, within the framework of the family and of the laws, culture and social structure of the country. The couple, not the health professional, should make the choice (autonomy).

Pre-test counseling makes post-test counseling (for those of an affected fetus) much less difficult because prospective parents are better prepared. Counseling should include the following items, as a minimum :

1. Name(s) and general characteristics of the major disorder(s) that the test may identify. The list of disorders need not be exhaustive. The characteristics of the disorder(s) should be described also in terms of their effects on the future child, on the parents and on the family life.

2. Possibilities for treatment of the disorder(s) after birth and availability of supportive care

3. Description of the likelihood (risk) that the fetus may have the disorder(s). Risks should be expressed in several ways (as a percentage, as a proportion and verbally).

4. The possibility of unfavourable test results or of fortuitous or unexpected findings.

5. Alternatives available to those with an affected fetus, for example, carrying the fetus to term and caring for the child at home; placing the child in an institutional setting, if available; placing the child for adoption; termination of pregnancy; prenatal treatment of the fetus or early treatment after birth.

6. The possibility of uncertain laboratory or imaging results.

7. Information that, because most conditions diagnosed in the fetus cannot be treated before birth, knowing about the existence of a condition may not help the fetus.

Information that the test does not guarantee a healthy baby, because there are many disorders that cannot be identified before birth, or professionals may not know that a family is at risk of a specific disorder (in addition to the disorder that motivated the examination).

1. The medical risks to the fetus and mother posed by the testing procedure.

2. Non-medical risks, if any (e.g. to parental employment or health care, where applicable).

3. Information that non-invasive screens used early in pregnancy, such as maternal serum alpha fetoprotein screening, may be the first step on the road to prenatal diagnosis.

4. Cost of the test for the mother or couple, if applicable.

5. Names and address of genetic support groups or organizations for persons with genetic disorders that individuals can contact if they wish.

Chapter 11 : BANKED DNA

Stored DNA or tissue or blood samples may provide useful information for examination of genetic disorders in families or for research. Information from DNA specimens may be of importance for relatives and not only for the person from whom DNA originates. Therefore, access to stored DNA by family members needs to be considered.

*Existing stored specimens or samples, such as those in university or hospital department or collections of blood spots, need to be subjected for re-consent or re-contact.

In developing policies about samples to be collected in the future, it is helpful to keep the following issues in mind :

1. protection of individuals from possible discrimination by employers and insurers, etc.;

2. possible benefits to the individuals from research findings;

3. the possibility of multiple use of the same sample in different and unforeseen research project;

4. possible sharing of samples among collaborators, including international collaborators and commercial entities;

5. advantages and disadvantages for individuals and researchers of removing all identifiers (including coded numbers) for a sample.

However, requirement for re-consent can be waived upon approval by the respective institutional ethics board.

A blanket informed consent that would allow use of a sample for genetic research in general, including future as yet unspecified projects, appear to be the most efficient and economical approach, avoiding costly re-contact before each new project. The consent should specify that family members may request access to a sample to learn their own genetic status but not that of the donor. While spouses may not have such a right of access, their concerns should be considered. All samples should be used with appropriate regard for confidentiality.

Followings are guidelines for access to banked DNA:

1. A blanket informed consent that would allow use of a sample in future project is the most efficient approach.

2. Control of DNA may be familial, not only individual. Blood relatives may have access to stored DNA for the purpose of learning their own genetic status, but not for purposes of learning the donor status.

3. Family members may request access regardless of whether they contributed financially to the banking of the DNA.

4. DNA should be stored as long as it could be of benefit to living or future relatives or fetuses.

5. Attempts should be made to inform families, at regular intervals, of new developments in testing and treatment. Donors should inform DNA banks of current addresses for follow-up.

6. After all relatives have died or all attempts to contact survivors have failed, DNA may be destroyed.

7. Spouses should not have access to DNA banks without the donor's consent, but may be informed that DNA has been banked. If a couple is considering having children, it is the moral obligation of the party whose DNA has been banked to provide the spouse with any relevant information.

8. Except for forensic purposes or instances when information is directly relevant to public safety, there should be no access for institutions without the donor's consent. Insurance companies, employers, schools, government agencies and other institutional third parties that may be able to coerce consent should not be allowed access, even with the individual's consent.

9. Qualified researches should have access if identifying characteristics are removed.

10. Potentially valuable specimens that could be useful to concern families in the future should be saved and should be available.

Biomedical research in human genetics can lead to the development of diagnostic and pharmaceutical products. Patents may be necessary to raise funding to develop such products commercially. Patenting has the potential to impede international collaboration, especially between developing and developed countries, to the ultimate detriment of service delivery to those with genetic disorders. Genetics differs from many areas of research in that important new knowledge can come from a family, or an ethnic group, with a particular genetic variant. If this leads to the development of a diagnostic test or new therapies, equity requires that the donors or the community generally, should receive some benefit.

Chapter 12 : PRE-IMPLANTATION GENETIC DIAGNOSIS

Although not directly related to medical genetics, various types of assisted reproduction are often discussed in connection with genetic counseling. Couples who are at risk of having a child with a genetic disorder may choose alternative options. Whichever reproductive alternatives are offered must be consistent not only with cultural traditions and beliefs of the country, but also the overall autonomy of individuals and families. In this context, reproductive cloning, which is not in accord with currently accepted international ethical standards is not allowed.

Pre-Implantation Genetic Diagnosis (PGD) is a procedure involving genetic testing and selection of embryos produced by in-vitro fertilization (IVF). Once an embryo is created using IVF technique, a cell is removed from the embryo after about three days and tested for specific genetic abnormalities. Usually healthy embryos will be transferred to the mother's womb and embryos with abnormalities will be destroyed. In pre-implantation genetic testing, the foetal cells are tested even before pregnancy occurs, thus avoiding the dilemma of termination of pregnancy as pregnancy has not yet occurred. PGD, has enabled the diagnosis of more than 200 genetic diseases and detection of embryonal sex to avoid the transmission of sex-linked diseases such as Down Syndrome and haemophillia, allowing only unaffected embryos to be transferred into the womb.

MMC Guidelines on Assisted Reproduction Technology (ART)

Malaysian Medical Council (MMC) has agreed on the 13th June 2006 to endorse Assisted Reproduction Technology (ART) Guidelines for use in government and private hospitals in Malaysia. The ethical issue on sex selection and PGD are also addressed in this Guideline on Assisted Reproduction. According to the guideline, sex selection for social reasons is not permitted. Sex selection however is allowed if a particular sex predisposes to a serious genetic condition e.g. Haemophillia, Duchenne Muscular Dystrophy, Fragile X Syndrome. The guidelines also mentioned that PGD should be used for only severe and life-threatening genetic diseases. It would be unethical to analyse and select the inherited characteristics of embryos (e.g. intelligence, height, hair and eye colour), any social or physiological characteristics or any other conditions that are not associated with diasability or a serious medical condition. Embryos are destroyed in the process of PGD, either by not being implanted or by damage through the biopsy. Each human embryo is to be treated with the utmost respect and dignity.

Centres proposing research involving the use of embryos should seek approval from relevant authorities through existing channels in the Ministry Of Health. Pre-implantation genetic diagnosis to create 'designer babies' (those with specific physical, social or specific gender characteristics, not for the reason of avoiding serious medical illness) is considered prohibited unacceptable practice as outlined in the Guidelines for ART.

Presently, fertility centres in the country have the ability to conduct ART in an unregulated way. Although there are no laws and legislations governing the practice of medicine in the field of infertility in Malaysia, ART has been introduced to a limited scale largely in private hospitals. Any method of ART practiced must therefore guard against any mixing of the genes in order to preserve the inheritance of genes and heredity. Every newborn child must relate unequivocally to a biological and legal farther and mother. In ART programs, the excess pre-embryos produced can be frozen and stored in liquid nitrogen, a technique called cryopreservation. Cryopreservation should only be allowed in specially designated sperm and pre-embryo banks or ART centres accredited by Ministry Of Health. An accurate and full proof system of documentation must be in place to guard against mixing of lineages and commercialism.

Chapter 13 : GENETIC REGISTERS AND DATABASES

Genetic Registers

Genetic registers come in various forms but most contain information about people affected by a genetic disorder who have sought advice from a genetic center. Some register also include information about other family members who may be at risk, even though those individuals may be unaware of their at risk status and do not know that information about them will be recorded on the register.

1. Consent

The rationale and working of a genetic register should be explained to the patient prior to seeking consent to the recording of information about them on the register. It will usually be the interest of the family members to be included in a genetic register provided the information is kept confidential since this may allow them to be contacted and informed of their at risk status. If the relative subsequently contact the registry, he or she will be asked to consent to the information being retained in the register and if the consent is not forthcoming, all the data relating to the individual should be deleted. Should the implications of the information held on the register change, renewed consent should be sought.

2. Confidentiality and access

Proper security and measures should be in place to ensure the confidentiality of the information contained on the genetic register. Access to the information recorded on the genetic register should be on the basis of a clear “need to know” in the interest of the particular patient.

3. Research

Information contained on the genetic register should not be used for research purposes without the consent of the individual/organisation to whom it relates to.

4. Inappropriate use

Any inappropriate use of genetic registers and databases will be subjected to the review and action by the responsible and relevant authorities.

Genetic Databases

Genetic databases are repositories that contain variation information for DNA, genes and proteins that have disease relevance. This includes summary data extracted from published papers in peer reviewed journals on candidate genes and genome-wide association study (GWAS) studies.

Examples of genetic databases from technical standpoint :-

1. Genome-wide mutation databases.

   The genome-wide databases contain pooled information on all genes and incorporate advanced tools for gene analysis with user interface. Examples of established genome-wide databases are Online Mendelian Inheritance in Man (OMIM), Human Gene Mutation Database (HGMD) and Ensembl.

2. Locus-specific databases (LSDBs).

   LSDBs provide information about causative mutations and phenotypic patterns associated with a specific mutation, enabling researchers to define an optimal strategy for mutation detection.

3. National and Ethnic Mutation databases (NEMDBs)

   NEMDBs provide information on disease-causing mutations and their frequencies in different population groups within a country.

These databases include curated database, predictive database, literature database and integrative database.

The main function of genetic databases is to search for causal associations between genetic and health, which will contribute hugely to research, health care, and counselling. It elucidates gene function, estimates the prevalence of in populations, differentiates subtypes of diseases, traces the way genes predispose to or protect against illnesses, and medical intervention.

The data that are usually stored in genetic databases are molecular genetic and genomic data, clinical data, data on health, lifestyle and environment as well as genealogical data.

The following ethical issues pertaining to the genetic databases need to be addressed by those who plan to start or managing a genetic database :

1. A protocol, approved by the institutional ethics committee describing the approach to participating subjects, eliciting medical histories and information about their relatives and how their identity will be kept anonymous.

2. Any response to requests for personal data by the authorities must take into consideration the confidentiality of the data and adhere to the Personal Data Protection Act 2010 (Act 709).

3. The shared nature and ownership of genetic information in the database. The data ownership issues highlight potential challenges to preserving data integrity. While the ideal is to promote scientific openness, there are situations where it may not be appropriate (especially in the case of human participants) to share data. The key is for researchers to know various issues impacting ownership and sharing of their research data and make decisions that promote scientific inquiry and protect the interests of the parties involved. There should not be a blanket ruling in data sharing and researchers should clarify at the beginning of a project if data can or cannot be shared, under what circumstances, by and with whom, and for what purposes.

4. Disclaimer regarding the limitations of genetic testing, inappropriate applications of genetic testing and limitations of the database.

5. Caution against the potential for discrimination and setting boundaries in applications of the genetics technology, DNA databanks and patenting of genes.

Chapter 14 : DIRECT TO CONSUMER (DTC) GENETIC TESTING

Genetic tests are increasingly being offered directly to the consumer without any pre and/or post-test counseling by a qualified genetic counselor.

When the test is a genetic test in the context of inherited or heritable disorders, that test should only be provided to consumers who are given a suitable opportunity to receive pre- and post-test counselling by a qualified genetic counselor.

In relation to DTC testing, the test provider should provide easily understood, accurate, current, appropriate and adequate information, which is also available in accessible formats, to consumers before obtaining consent for a genetic test. The following should be provided prior to testing :

1. General information about genetics.
2. Role of genetics, environmental factors, lifestyle choices and other factors in health and disease.
3. Specific information about the offered genetic tests.
4. Information about the presentation of results in statistical form.
5. Information about measures taken by the test provider and laboratories to ensure the confidentiality of personal records and security of biological samples, period of storage of the biological sample and personal records, whether personal genetic information may be passed on to third parties.
6. Information about procedures for handling and resolving consumer complaints.
7. A statement that the results of the test may reveal information about genetic relationships.
8. A statement that the results of the genetic test might have implications when purchasing life insurance.
9. If the DTC test involves whole genome testing then a statement on its implications to insurance, employment, risks to diseases and family relationship must be made and the issues explained to the consumers.

Professional organizations and support groups (NGOs) should educate their members regarding the types of genetic tests offered on a DTC basis, so that providers can counsel their patients about the value and limitations of DTC testing.

Chapter 15 : INSURANCE

It is plausible that individuals with a positive genetic result may be refused insurance or charged excessively high premiums, making people reluctant to seek testing which may be of benefit to them in other ways. There is a concern that if genetic information is used by insurance companies, individuals will be less willing to participate in research projects or to share the results of genetic test with their primary physician and relatives.

1. Family history
   Virtually all health and life insurance proposal forms request details of family history and, as with existing conditions, an individual's failure to reveal a known family history of a genetic disorder would be a fraud and may invalidate the policy. Insurance companies should not refuse health insurance coverage or charge higher health insurance premiums based on family history of genetic disorders.

2. Request for testing
   Mandatory genetic testing for insurance purposes should not be permitted.

3. Confidentiality
   Particular care needs to be taken to protect the confidentiality of genetic information.

4. Informing patients
   Anyone considering genetic testing must be informed of the potential use of that information by insurance companies. It is therefore essential that those providing information about genetic testing are aware of the complexities.

REFERENCES

1. MMC Guideline, Consent For Treatment Of Patients By Registered Medical Practitioners, 2013.

2. Guidelines On Ethical Issues In Medical Genetic Services In Malaysia, 1st Edition, Ministry Of Health Malaysia, 2007.

3. Medical genetic services in developing countries: The Ethical, Legal and Social Implications of genetic testing and screening, World Health Organization, 2006.

4. Guideline Of The Malaysian Medical Council - MMC Guideline 010/2006: Medical Genetics And Genetic Services, Malaysian Medical Council, 2006.

5. Guideline On Termination Of Pregnancy (TOP) For Hospitals In The Ministry Of Health, Ministry Of Health Malaysia, 2012.

6. Wertz, Fletcher, Berg, Review of Ethical Issues in Medical Genetics, World Health Organization, 2003.

7. ACMG Board Of Directors, Clinical Utility Of Genetic And Genomic Services : A Position Statement Of The American College of Medical Genetics and Genomics, Genetics in Medicine (2015) 17, 505-507.

8. Medical Genetic Testing, Information for health professionals, Australian Government, National Health And Medical Research Council, 2010.

Appendix 1

Genetic Consent Form To Store or Test A DNA sample

Patient's name:
Patient's ID no :
Sex : Male / Female
DOB :
Address:

During thus consultation, we have discussed the following issues, and you have agreed to the uses shown below. Please cross out the words 'Discussed', Agreed', 'Not applicable' as appropriate for each use.

1.	I agree to analysis of my / my child's sample for	Discussed	Agreed	Not applicable
2.	I agree to my / my child's sample being stored in case future tests are needed	Discussed	Agreed	Not applicable
3.	I would like to be contacted before further tests are done on the stored sample if new tests become available	Discussed	Agreed	Not applicable

OR

4.	I am happy for further diagnostic tests on the stored sample to be undertaken without being contacted	Discussed	Agreed	Not applicable
5.	I agree that information and tests results may be shared to help other family members	Discussed	Agreed	Not applicable

Please confirm your agreement by adding your signature to this form below :

Signed : ..... Date : .....

Name (Print) (Patient/Parent) : .....

Consent obtained by :

Signed : ..... Date : .....

Name(Print):.....Jobtitle:.....

We may keep any leftover samples to check the quality of our results for other patients. We make sure that nobody knows whose sample is being used to help us this way.
Adapted from Joint Committee on Medical Genetics 2006 : Consent and confidentiality in general practice: guidance on testing and sharing genetic information.

Appendix 2

CONSENT FOR MOLECULAR DIAGNOSTICS SERVICES

Patients name:.....Patients ID:.....

The samples that I provide together with the request form are to be used for molecular genetic testing of :

.....
.....
(Specify the disorder or disease to be tested)

- The molecular genetic testing may provide a diagnosis of or indication of risk for me or my offspring for the disorder or disease specified above.
- I understand the molecular genetic testing may not yield results for any combination of the following reasons : 1) unavailable blood or tissue samples from critical family members; 2) uninformativeness of the available genetic markers; 3) maternal contamination of prenatal samples; 4) technical reasons.
- I understand that DNA analysis may yield information on biological paternity, the results of which will not be disclosed to me unless biological paternity is relevant for counseling for the reason which I have submitted this DNA sample. I agree to provide a family history to the best of my knowledge.
- I AGREE/DO NOT AGREE to have my samples or DNA extracted from my samples be used for the purpose of research and development or quality control in diagnostics laboratory.
- Additional samples may need to be collected from me in the absence of results, or if the results are inconclusive.
- The DNA extracted from my (my child's) samples will be stored in the DNA bank at the Institute for Medical Research or its responsible delegate.
- I understand that any information identifying me (my child) will be kept confidential and that any exchange of samples or information will be coded.

Your signature on this form indicates that you have understood to your satisfaction the information regarding molecular genetic testing and agree to participate. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities. If you have further questions concerning matters related to this consent, please discuss them with your medical geneticist, genetic counselor, or referring physician.

_____

(Signature of patient or legal guardian and date)

_____

(Signature of witness and date)

DRAFTING COMMITTEE FOR THE GUIDELINES ON ETHICAL ISSUES IN THE PROVISION OF MEDICAL GENETICS SERVICES IN MALAYSIA

Advisors :

Y.Bhg. Datuk Dr. Haji Rohaizat bin Haji Yon
Deputy Director General of Health (Medical)

Y.Bhg. Dato' Dr. Hj. Azman bin Hj. Abu Bakar
Former Deputy Director General of Health Malaysia (Medical)

Y.Bhg. Dato' Dr. Hj. Bahari bin Dato' Tok Muda Hj. Che Awang Ngah
Director of Medical Development Division
Ministry of Health Malaysia

Members :

Dr. Keng Wee Teik
Paediatric Consultant (Clinical Genetics)
Department of Genetics
Hospital Kuala Lumpur

Dr. Ngu Lock Hock
Paediatric Consultant (Clinical Genetics)
Department of Genetics
Hospital Kuala Lumpur

Prof. Dr. Thong Meow Keong
Paediatric Consultant (Clinical Genetics)
Department of Paediatrics
Pusat Perubatan Universiti Malaya

Dr. Roziana Ariffin
Pathology Consultant (Genetic Pathology)
Department of Pathology
Hospital Kuala Lumpur

Prof. Dr. Zilfalil bin Alwi
Paediatric Consultant (Clinical Genetics)
Department of Paediatrics
Hospital Universiti Sains Malaysia

Dr. Japaraj Robert Peter
O&G Consultant (Maternal Fetal Medicine)
Department of Obstetrics & Gynaecology
Hospital Raja Permaisuri Bainun, Ipoh

Dr. Zabedah Md Yunus
Center Head
Special Diagnostic Center
Institute For Medical Research (IMR)
Ministry of Health Malaysia

Dr. Noor Aziah binti Zainal Abidin
Senior Principal Assistant Director
O&G and Paediatric Services Unit
Medical Development Division
Ministry of Health Malaysia

Dr. Jafanita binti Jamaludin
Senior Principal Assistant Director
O&G and Paediatric Services Unit
Medical Development Division
Ministry of Health Malaysia

Dr. Muhammad Aadiyat bin Abdul Hamid
Senior Principal Assistant Director
O&G and Paediatric Services Unit
Medical Development Division
Ministry of Health Malaysia

Contributors (meetings held from 2015-2019) :

Prof. Datuk Dr. A Rahman A Jamal
Director
UKM Molecular Biology Institute (UMBI)
Universiti Kebangsaan Malaysia

Dr. Chin Loi Kim
Pathology Consultant (Haematology)
Jabatan Genetik
Hospital Kuala Lumpur

Dr. Ravichandran a/l Jeganathan
O&G Consultant
Department of O&G
Hospital Sultanah Aminah, Johor Bahru

Dr. TP Baskaran
O&G Consultant
Department of O&G
Hospital Kuala Lumpur

Dato' Dr. Roshida Hassan
Director
National Blood Center
Ministry of Health Malaysia

Dr. Zubaidah Zakaria
Center Head
Cancer Research Center
Institute for Medical Research (IMR)
Ministry of Health Malaysia

Prof. Dr. Zarina Abdul Latif
Paediatric Consultant (Clinical Genetics)
Department of Paediatrics
Hospital Universiti Kebangsaan Malaysia

Prof. Dr. Rofina Yasmin Othman
Professor
Institute of Biological Sciences
Faculty of Science
University Malaya
(Representative of MOSTI)

Dr. Rowani Mohd Rawi
Paediatric Consultant (Clinical Genetics)
Department of Paediatrics
Hospital Universiti Sains Malaysia

Dr. Hishamshah bin Mohd. Ibrahim
Paediatric Consultant (Hemato-Oncology)
Institut Pediatrik
Hospital Kuala Lumpur

Dr. Winnie Ong Peitee
Paediatric Specialist (Clinical Genetics)
Department of Paediatrics
Hospital Kuala Lumpur

Datuk Dr. Mohamad Farouk bin Abdullah
O&G Consultant (Reproductive Medicine)
Department of O&G
Hospital Tengku Ampuan Rahimah, Klang

Dr. Nurliza bte Abdullah
Forensic Pathology Consultant
Department of Forensics
Hospital Kuala Lumpur

Norsiah Md Desa
Head of Molecular Pathology
Cancer Research Centre
Institute for Medical Research (IMR)
Ministry of Health Malaysia

Prof. Dr. Teo Soo Hwang
Chief Executive Officer
Cancer Research Initiatives Foundation
Cancer Research Malaysia
Sime Darby Medical Centre

Prof. Dr. Sufin Yap
Paediatric Consultant (Clinical Genetics)
Department of Paediatrics
Pusat Perubatan Universiti Malaya

Prof. Dr. Sheila Nathan
Professor
School of Bioscience and Technology
National University of Malaysia
(Representative of MOSTI)

Prof. Abdul Rashid Abdul Rahman
President
Islamic Medical Association of Malaysia

Dato' Hatijah Ayob
President
Malaysian Rare Disorders Society

Lee Yee Seng
President
Malaysia Lysosomal Storage Diseases Association

Juliana Lee
Coordinator
Malaysian Rare Disorders Society

Theng Lay Kee
Treasurer
Malaysia Metabolic Society

Dr. Maizura bt Musa
Senior Principal Assistant Director
Medical Practice Division
Ministry of Health Malaysia

Dr. Nik Nuratiqah bt Nik Abeed
Senior Assistant Director
Medical Practice Division
Ministry of Health Malaysia

Dr. Norhasliza bt Abu Bakar
Senior Assistant Director
Family Health Development Divison
Ministry of Health Malaysia

Sharifah Hascindie Syed Omar
Senior Federal Counsel
Legal Advisor Office
Ministry of Health Malaysia

Prof. Dato' Dr. Mahani Mansor Clyde
Chairman
National Bioethics Council of Malaysia

Supt. Lisa Tang
DNA Analysis Section
Makmal Forensik
Polis Diraja Malaysia (PDRM)

Shazelina Zainul Abidin
Principal Assistant Director
Human Rights and Humanitarian Division
Department of Multilateral Affairs
Ministry of Foreign Affairs Malaysia

Nurul Syaza Azlisha
Assistant Director
Human Rights and Humanitarian Division
Department of Multilateral Affairs
Ministry of Foreign Affairs Malaysia

Syamil Chehram Shah Abdullah
Principal Assistant Director
Immigration Department of Malaysia

Supiani Sibin
Principal Assistant Director
Immigration Department of Malaysia

ACKNOWLEDGEMENT

Medical Services Development Section would like to express our deepest gratitude and appreciation to the following individuals and groups towards the development of this Guidelines On Ethical Issues In The Provision Of Medical Genetics Services In Malaysia :-

Y.Bhg.Datuk Dr. Noor Hisham bin Abdullah,
Director General of Health Malaysia for his leadership and guidance;

Y.Bhg. Datuk Dr. Haji Rohaizat bin Haji Yon
Deputy Director General of Health (Medical)

Y.Bhg. Dato' Dr. Haji Azman bin Haji Abu Bakar,
Former Deputy Director General of Heath (Medical)

Y.Bhg. Dato' Dr. Hj. Bahari Bin Dato' Tok Muda Hj. Awang Ngah,
Director of Medical Development Division for their continuing support;

and,

Special gratitude to Members of the Drafting Committee for their constructive comments and last but not least to all those who provided valuable input and feedback to make this publication a success.

Thank you..

MINISTRY OF HEALTH MALAYSIA

MEDICAL DEVELOPMENT DIVISION
Block E1, Parcel E, Federal Government Administrative Centre,
62590 Putrajaya, Malaysia.
Tel : 603-8883 1047 Fax : 603-8883 1427
http://www.moh.gov.my

9 789670 769714