ASISA GUIDELINES ON GENETIC TESTING

Effective from 25 March 2021

ASISA recommends the following guidelines to all its members. It is recognized that the policy will not be static but will be subject to periodic review to incorporate advances in technology and changes in knowledge. In the light of this, risk classification must be free to evolve and reflect the continual development of medical knowledge surrounding both the genetic information and the impact on future health risks. Evidence based underwriting standards will be utilised to evaluate the risks to the insurer and offer fair terms to the applicant.

CONTENTS

1. Introduction
2. Principles of Insurance
3. Genetic tests
4. Genetic tests and risk classification
5. The individuals Rights and obligations
6. Role of the Insurer
7. The Chief Medical Officer
8. The Underwriter
9. The Intermediary
10. Role of ASISA

1. INTRODUCTION

The aim of the human genome project was to map the entire genetic code. This was an international research effort that took many years to complete.

The detailed genetic information that has become available through this project has substantial implications for both society and individuals. There is also an important implication for the insurance industry worldwide.

Various consumer groups have expressed concern about the implications of genetic testing and the availability of life and health insurance. Attention has been drawn to what they perceive as potential misuse of genetic information by insurance companies. This is given as a reason why companies should either not have access to or be able to use these results.

ASISA believes it is necessary that consideration of genetic testing issues should recognize the balance that is required between the legitimate interests of policyholders and insurance companies. It is thus important that there is an understanding of how voluntary insurance operates in order to maintain a balance between all these interests.

Life insurance safeguards the financial security of millions of people by a process of risk pooling. The industry must act in such a way that there are safeguards for its policyholders' funds and its ability to pay claims in the future. For life insurance to remain viable, it is necessary that the majority of the population have access to insurance at normal premium rates. In South Africa, approximately 90% of the population receives life cover at normal or standard premium rates. It is the stated policy of ASISA that life insurance should remain available to as many people as possible at standard premium rates. This also holds true in the genetic testing era.

2. THE PRINCIPLES OF LIFE INSURANCE

The purpose of life insurance is to provide financial protection against illness or accidents leading to death or disability. Policyholders pay a relatively small, affordable amount into a common fund and the proceeds are distributed to the beneficiaries of those who die. In this way, the financial losses associated with unexpected death can be mitigated although the event cannot be prevented.

The likelihood and magnitude of losses that can be faced by the insurance company vary. There are many aspects that the company takes into account. These include age, the sum assured, occupations and avocations that modify the likelihood of unexpected death, health enhancing activities such as exercise, proper diet, and avoidance of tobacco products are also taken into account.

The insurance company evaluates these factors through a process known as 'risk selection and classification'. Risk selection is the determination of individual risks acceptable to the company. Risk classification is the separation of insurance risks into standard and degrees of substandard categories. The more common term for this process is 'underwriting'. By means of this process, the insurance company determines the appropriate contribution to the common fund by an individual policyholder.

A fundamental principle of private life insurance is equity: policyholders with the same or similar risk of death are charged the same amount. The higher the risk, the higher the premium; the lower the risk, the lower the premium. It would be unfair to existing policy holders if new applicants for insurance withheld information that would, if disclosed in the normal manner, lead to a higher premium being paid or the application being rejected.

During underwriting, risk classifications are created that recognize meaningful differences among individuals in order to place applicants into groups (pools) with comparable expected mortality rates. A premium commensurate with the predicted future cost of claims for that group is charged. The risk presented by any single individual cannot be determined with absolute precision. However, if people are assigned to groups with reasonable accuracy and the total number of people in these groups is large, then the estimate of the risk of the entire group is likely to be accurate.

The primary basis for risk classification is age. Yet, within each age group, the probability of death is greater for some than for others. Because of the broad variation in life expectancy, not all individuals within an age group can be offered insurance on the same terms. To accommodate for this variation, insurers use different mortality classifications: standard for average or lower than average risks, substandard for risks greater than those accepted on a standard basis, and "decline" for risks so great that the company cannot issue insurance coverage.

Despite the introduction of innumerable screening and diagnostic technologies during the last century, the percentage of applicants who have been able to obtain life insurance has remained stable or increased. No significant changes in these percentages are anticipated with the advent of genetic testing.

In summary, careful underwriting of individual proposals and appropriate risk classification is essential to maintain a viable voluntary life assurance industry. Each individual is charged a premium that reflects the cost of providing cover. To give favourable treatment to one group would mean sharing the cost unfairly among all other policyholders.

3. GENETIC TESTS

For the purposes of these guidelines, genetic testing is defined as follows:

"The direct analysis of DNA, RNA, genes or chromosomes for the purposes of determining inherited predisposition to a particular disease or group of diseases."

There will eventually be several broad categories of genetic information.

The first will identify genes for specific diseases that are transmitted either by a single dominant gene or a pair of recessive genes. This information will enable prediction with a high degree of probability whether an individual will develop a particular disease. There are tests already available for some specific diseases e.g. Huntington's Disease, Cystic Fibrosis, Duchenne's Muscular Dystrophy, and Haemochromatosis. It is likely that many more will become available over the next decade. The predictive value of these tests is also likely to improve as the sophistication of knowledge grows.

The second category will be genetic information that predicts a predisposition to a disease or group of diseases e.g. a predisposition to coronary artery disease or cancer. The risk will often be

determined by multiple genes. The development of many or even most diseases is influenced to some extent by behavioural and environmental factors. This category of genetic information will not predict with certainty whether a disease will develop but rather gives the probability that an event may occur.

The third category will identify the genes that influence the course of various diseases that themselves are not genetic in nature e.g. the gene that influences the progression of HIV infection to AIDS.

It is likely that genetic testing will become common in future to enable those who are most at risk to pursue preventative strategies.

At present very few genetic tests are conducted and those that are, are for the most part, for relatively rare conditions. It is probable that in many instances genetic tests will become available for common medical conditions.

4. GENETIC TESTING AND RISK CLASSIFICATION

ASISA believes that guidelines are needed to deal with issues raised by the new genetic technology. The most important issue will be the ability of insurance companies to access results of genetic tests that have been performed prior to the application for insurance.

The second major issue is whether it will be appropriate for insurance companies to request or coerce an applicant to undergo genetic testing as a part of the risk classification.

These guidelines are applicable to all medically underwritten life insurance products.

4.1 Access to existing test results

Access to information relevant to the risk is a basic tenet of insurance and the foundation of underwriting. In the interests of equity and financial viability it is of fundamental importance that insurance companies have access to all existing information that is relevant to the risk. ASISA therefore believes that the results of genetic tests performed prior to the application for insurance should be underwritten no differently to any other information relevant to the risk.

4.2 Insurance companies requesting genetic tests

Genetic tests may give an indication of the future risk of developing a disorder or the course a particular disease may follow. The psychological effects of an unfavorable result may be devastating for some people. It is known that many individuals would prefer not to know their risk especially if the disease in question has no prospect of prevention or cure. The insurer should not request an applicant to undergo a genetic test to support an application for insurance whether this is in order to obtain a lower than standard premium rate (for preferred risk underwriting) or to indicate the presence or absence of a suspected genetic condition.
A request for a genetic test should be a clinical decision based on clinical information and a risk assessment of the patient, with informed consent, pre-test counselling, post-test counselling and follow-up.

5. THE INDIVIDUAL'S RIGHTS AND OBLIGATIONS

5.1 The applicant is obliged to answer all the insurer's questions comprehensively and honestly, including the results of genetic tests where applicable.

5.2 The applicant is not under any obligation to consent to information being disclosed to any other party, not involved in the underwriting of the application.

5.3 The applicant has the right to expect the insurer to assess the proposal fairly, based only on relevant information.

5.4 The applicant has the right to request the insurer to inform a personal medical attendant of any reasons for an adverse underwriting decision and whether genetic information was used in the decision-making process.

5.5 An applicant may choose to submit a predictive genetic test result that is in their favour in order to over-ride family history information.

5.6 Once the insurer has issued a contract in good faith, the applicant need not reveal the results of future genetic tests to that insurer.

5.7 As in the case of all medical information the applicant needs to give prior consent before the company may request any details of genetic tests results from the personal medical attendant. This consent is generally included in the application form.

5.8 Any genetic test result declared by the applicant will not be used to assess the applications of any other person e.g. family members.

5.9 The applicant may ask the insurer to review any adverse underwriting decision based on a relevant predictive genetic test result.

6. ROLE OF THE INSURER

6.1 The insurer should not ask or coerce the applicant to undergo any genetic test in order to obtain insurance.

6.2 The insurer should ensure that existing test results are only obtained with the written consent of the tested individual as with other medical information.

6.3 A genetic test result declared by an applicant should not be used in the assessment of an application for insurance by another individual e.g. a relative of the life insured.

6.4 The insurer is required by legislation to ensure that confidentiality of medical information is maintained at all times.

6.5 The insurer should provide its employees with sufficient information and training so that they can understand the content and meaning of these guidelines as it relates to their specific responsibilities.

6.6 The insurer may ask the client questions regarding health issues including genetic tests.

6.7 The insurer should endeavour to offer alternative products (as may be actuarially justifiable) for those clients who are uninsurable because of a genetic abnormality.

6.8 As with all medical information all underwriting decisions involving a genetic test, whether or not the result was a significant factor in the decision should be thoroughly documented, so that adequate information can be provided to the applicant or his/her medical practitioner on request.

7. THE ROLE OF THE CHIEF MEDICAL OFFICER (CMO)

7.1 The CMO should keep the company informed of developments in genetic testing that may affect risk assessment.

7.2 If the CMO believes that the applicant does not know the result of a genetic test or does not understand the implication he should contact the applicant's medical advisor, after having obtained the necessary consent, to discuss the implications of the results.

7.3 The CMO should contribute to the company's underwriting philosophy regarding genetic testing.

7.4 The CMO should advise the chief executive regarding the company's confidentiality and security of information practices relating to genetic tests.

7.5 The CMO should provide the underwriting department with:

- Training regarding genetics
- Advice regarding complex cases.

7.6 The CMO should liaise with the medical profession regarding genetic testing and insurance.

7.7 If the insurer does not have a CMO, these functions should revert to the nominated Genetic Underwriter or to the reinsurer.

8. THE ROLE OF THE UNDERWRITER

8.1 The insurer should appoint a senior person in the underwriting department who will be responsible for all cases where there is a genetic test result.

8.2 The underwriter should consult the CMO on all cases where the decision will be influenced by a genetic test result. If the insurer does not have a CMO, the underwriter should approach their reinsurance partners for guidance in difficult cases.

8.3 The insurer should take into account the benefits of special medical surveillance, early medical intervention and possible successful treatment when assessing the risk as a normal part of underwriting.

8.4 The underwriter should only take those test results into consideration that have been confirmed to be relevant and valid. There should be sufficient evidence-based medical justification for the decisions taken by the underwriter.

8.5 The underwriter should record in detail the rationale behind his/her decision based on fact, medical and genetic opinion, and judgment.

8.6 The underwriter should have a sound grasp of these guidelines and keep up to date regarding genetic issues that may affect risk assessment.

8.8 In all cases where an adverse decision has been given as a result of a genetic abnormality, the underwriter may be requested to inform the applicant's doctor in writing of the reasons for the decision.

9. THE ROLE OF THE INTERMEDIARY

9.1 The intermediary is expected to be aware of and understand their role in terms of these guidelines should an applicant disclose a genetic condition. It is the insurer's responsibility to make them aware and inform them accordingly.

9.2 The intermediary should not suggest or coerce the applicant into undergoing genetic testing as part of an application for insurance.

9.3 The intermediary should not discuss the results of any genetic tests with the client, the client's doctor or the genetic underwriter. Any communication should be between the insurer and the treating doctor.

9.4 The intermediary should not request copies of test results from any person including medical practitioners, laboratories, or applicants, or hand test results over for delivery to the company.

10. THE ROLE OF ASISA

ASISA will maintain this guideline and will update the document as and when necessary. The Medical and Underwriting Standing Committee, which is under the auspices of the Life and Risk Board Committee, will be the custodian of this guideline.

HISTORY OF AMENDMENTS

Effective date	Amendments
25 March 2021	Review and Changes to the previous version which was titled "ASISA Standard on Genetic Testing"

Responsible Senior Policy Advisor: Anna Rosenberg