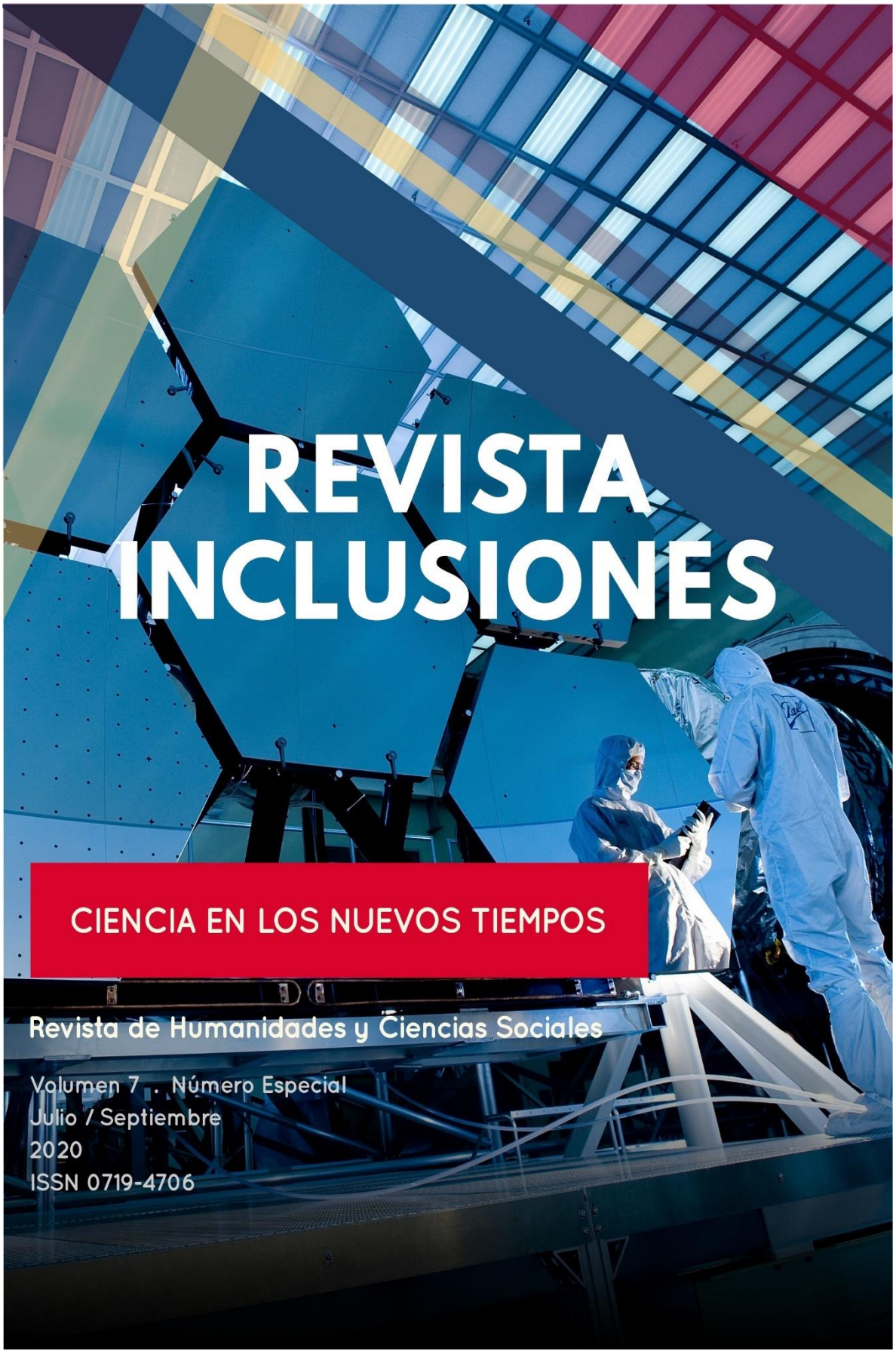

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PROSPECTS FOR USING THE RESULTS OF GENETIC TESTING IN INSURANCE

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Abstract

The prospects of using the results of genetic testing in the assessment of insurance risk when concluding an insurance contract are very relevant. When determining whether it is appropriate for insurers to use genetic information in assessing insurance risk in personal insurance, two main problems arise – the scientific reliability of genetic information and its actuarial significance. The purpose of the study is to determine the prospects for using the results of the genetic study to assess insurance risk in the field of personal insurance. The methodological basis of the research was made up of dialectical, teleological, axiological, logical, formal-legal and comparative-legal methods. The article gives the authors' definition of genetic information as the information related to various genetically determined states, which is obtained by the direct study of DNA. The study presents the conclusion that the most informative results to assess insurance risk in personal insurance are those of targeted sequencing to assess the relevance and demand of information resulting from the genetic study. For personal insurance, it is necessary to take into account several factors. Some of these factors are related to the characteristics of the insurance itself (a type of insurance, sales channels), while others concern the characteristics of the corresponding population, and still, others relate to the methods of genetic research used.

Keywords

Personal insurance – Underwriting – Targeted sequencing – Penetrance – Biobank

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Introduction

Determining the probability of an insured event is one of the key issues of interest to the insurer when entering into any insurance contract. While it is easy to get objective information in the field of property insurance, many questions arise in personal insurance about how to identify factors that affect the probability of an insured event, whether they can be taken into account when calculating the insurance rate, setting correction coefficients that take into account their presence or absence, and forming additional terms and conditions of the insurance contract. When entering into an insurance contract, insurers are increasingly raising the issue of expanding the sources of obtaining the necessary information, including genetic information[1]. The desire of insurers to use genetic data for risk assessment comes across with reasonable concerns about genetic discrimination in insurance. Such discrimination is reflected in the legal regulation mechanism of several foreign countries and has led in some countries to the establishment of a moratorium on the use of genetic information, to the development of ethical guidelines, self-regulation, and industry ban on the use of genomic research results, as well as the recognition of genetic exclusivity[2], while in other countries, it has led to maintaining status quo that has become the subject of a particular analysis by the Geneva Association, which is an International Analytical Center in the field of insurance[3].

Literature review

Many experts and researchers deal with the problems of using the results of genetic testing in insurance. Thus, D. Vukchevich and Chen devoted their work to the study of life insurance through the prism of genetic research[4]. C.D. Zick et al. analyzed genetic testing for Alzheimer's disease and its impact on insurance purchasing behavior[5]. Oster E., I. Shoulson, K. Quaid, and E.R. Dorsey in their work presented data on the insurance of persons with genetically unfavorable diseases that have led to insurance risks[6].

Mossialos E. and A. Dixon argued in their research the need for genetic testing in life and health insurance of citizens[7]. Sandberg P. wrote about the impact of genetic information on life insurance and proposed the principles of European policy in this area[8]. Xepapadeas A., P. Ralli, E. Kougea, S. Spyrou, and A. Tsivelikasn assessed insurance services, which

[1] A. Sboner; X. J. Greenbaum; D. Auerbach y M. B. Gerstein, “The real cost of sequencing: higher than you think!”, Genome Biology Vol: 12 num 8 (2011).

[2] C. J. Saunders; N. A. Miller y S. E. Soden, “Rapid whole-genome sequencing for genetic disease diagnosis in neonatal intensive care units”, Science Translational Medicine Vol: 4 num 154 (2012).

[3] L. Liu; Y. Li; S. Li; N. Hu; Y. He; R. Pong; D. Lin; L. Lu y M. Law, “Comparison of next-generation sequencing systems”, Journal of Biomedicine and Biotechnology (2012): 1-11.

[4] D. Vukcevic y J. Chen, Thinking about life insurance through a genetic lens (Melbourne: Proceedings of the Actuaries Summit, 2017).

[5] C. D. Zick; Ch. J. Mathews; S. J. Roberts; R. Cook-Deegan; R. J. Pokorski y R. C. Green, “Genetic testing for Alzheimer’s disease and its impact on insurance purchasing behavior”, Health Affairs Vol: 24 num 2 (2005): 483-490.

[6] E. Oster; I. Shoulson; K. Quaid y E. R. Dorsey, “Genetic adverse selection: Evidence from long-term care insurance and Huntington disease”, Journal of Public Economics Vol: 94 num 11–12 (2010): 1041-1050.

[7] E. Mossialos y A. Dixon, “Genetic testing and insurance: Opportunities and challenges for society”, Trends in Molecular Medicine Vol: 7 num 71 (2001): 323-324.

[8] P. Sandberg, “Genetic information and life insurance: A proposal for ethical European policy”, Social Science and Medicine Vol: 40 num 11 (1995) 1549-1559.

were rendered in Greece taking into account the genetics[9]. Many other experts researched the field of using the results of genetic testing in insurance.

Methods

General description (basic principles and methods, description and characteristics)

The objectives of the present research have led to the need to study the methods of genetic testing offered by contemporary medicine, information about their cost, which is generally recognized as one of the limiting factors for their widespread use, as well as the proposed actuarial models and underwriting approaches, built taking into account various circumstances, conditioned primarily due to existing restrictions on access to the results of genetic research by insurers.

The methodological basis of the research included dialectical, teleological, axiological, logical, formal-legal and comparative-legal methods.

Algorithm

The implementation of the dialectical method of cognition, which is universal, allowed identifying certain patterns in solving the issue concerning using genetic information for personal insurance purposes. Through the use of teleological method related to the interpretation and study of problematic issues through the prism of goal setting and accounting for goals and strategies of developing public relations, the possible regimes of legal regulation of relations related to genomic research and the use of their results in the insurance business were analyzed.

Taking into account the fact that the acquisition and use of genetic information inevitably affect the human right to privacy, the axiological method, which involves the analysis of the above-mentioned public relations from the standpoint of moral, ethical, and social values, was of particular importance in conducting the present study.

The application of the logical method allowed correlating the conceptual apparatus used in the field of medicine with the categories that were significant for insurance activities and jurisprudence. It was supplemented with a formal legal method that led to the implementation of such a system of processing and analysis of existing legal norms and existing legal practice, which allowed assessing the legal concepts and structures that were legally approved, identifying the features of legal phenomena and prospects for their normative regulation. This predetermined the use of various methods of interpretation of the legal norms, as well as the study of factors and conditions that determined the development of a legal mechanism for the use of human genome data.

Flow chart

The study was conducted using certain research algorithms, which allowed obtaining the results. The research algorithm is presented in Figure 1.

[9] A. Xepapadeas; P. Ralli; E. Kougea; S. Spyrou; N. Stavropoulos; V. Tsiaoussi y A. Tsivelikas, “Valuing insurance services emerging from a gene bank: The case of the Greek Gene Bank”, Ecological Economics num 97 (2014): 140–149.

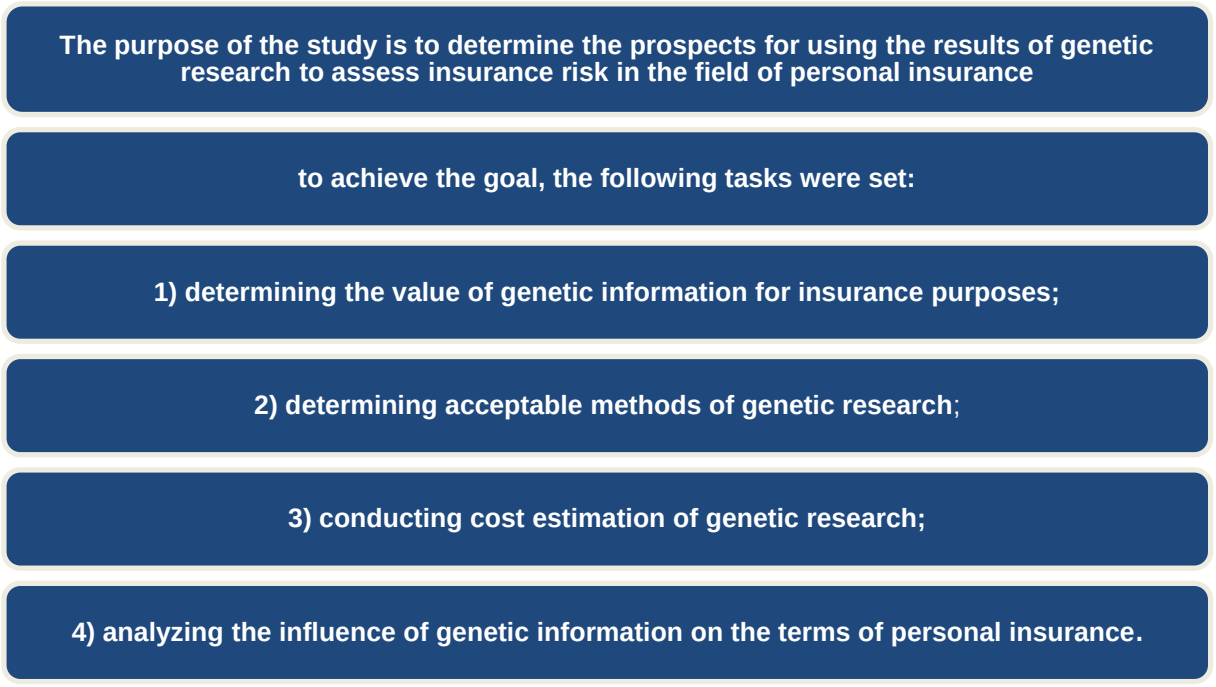

Figure 1
The research algorithm

Results

The conducted study resulted in the definition of the concept of genetic information. In a broad sense, this concept refers to any information related to various genetically determined conditions. It is not accidental that the main argument of those supporting the use of genetic information for insurance purposes is that it has long been deduced from the family history of the insured person, while the increased availability and reduced cost of genetic testing mean that its results will simply make greater contribution to the assessment of the risk of an insured event that is significant for the protection of the insurer's interests. In a narrow sense, it will only cover information obtained by direct DNA research.

Genetic research methods are constantly being improved, which contributes to a significant reduction in their cost. The turning point was the practice of using platforms of the Next-Generation Sequencing (NGS), which has replaced the Sanger method. The fundamental difference between these methods is the amount of sequence data obtained: while the Sanger method sequences just one DNA fragment at a time, NGS reveals sequences of hundreds to thousands of genes or gene regions at a time[10].

Currently, several methods of genetic studies are being used. The subsequent reduction of costs for their implementation and increasing the reliability of results are associated with third-generation technologies, which include true Single Molecule Sequencing (tSMS) technology.

[10] C. D. Zick; Ch. J. Mathews; S. J. Roberts; R. Cook-Deegan; R. J. Pokorski y R. C. Green, "Genetic testing for Alzheimer's disease and its impact on insurance purchasing behavior", Health Affairs Vol: 24 num 2 (2005): 483-490.

The SMRT technology, which consists in determining the DNA sequence during real-time monitoring of the single DNA polymerase molecule, allows obtaining very long DNA sequences, providing high sensitivity and specificity. This method is characterized by a relatively high error rate.

The most informative is Whole Genome Shotgun (WGS), which, using next-generation sequencing technologies (NGS), has the potential for simultaneous, comprehensive, differential diagnostic testing of probable monogenic diseases, which speeds up molecular diagnostics[11]. This method affects areas that usually fall out of sight of specialists. That is why in some types of diseases there is no full-fledged alternative to this method. The main disadvantage of this technology is its cost, which consists of the cost of conducting research and clinical interpretation of obtained results that is very time-consuming and often very long. At that, the percentage of successful diagnosis in complicated cases is stated at the level of 40-60%[12].

An alternative to WGS is Whole Exome Sequencing (WES) which is a study that reads the encoding sequence of all genes followed by selective analysis concerning a specific set of genes determined by the verifiable diagnosis.

Because of this, in clinical practice, priority is given to the targeted sequencing, which allows reducing the cost of research per sample while increasing multiplication of their number. For this purpose, several technologies can be applied, such as gene panel sequencing, RNA sequencing, etc., either of which has its advantages and disadvantages[13].

Gene panel sequencing involves its development for a specific inherited disease or group of them, which makes it possible to analyze certain genes without distraction to read other parts of the exome. This provides better coverage of the studied genes and reduces the cost of analysis compared to exome sequencing while maintaining the quality of the results being obtained.

The use of DNA-biochips is a promising research method with many modifications that allow carrying out simultaneous multiparametric analysis of a significant number of genes, using a relatively small amount of source material. The cost of such studies is several times lower than the cost of whole-genome and whole-exome sequencing, which gives reason to state about the possibility of their mass implementation. This will allow not only significantly increasing the speed and accuracy of the analysis, but also expanding the ability to assess numerous factors that cause a predisposition to several multifactor diseases.

However, this approach will not solve all the problems, especially in cases where genetic diseases are caused by de novo mutations that represent inherited defects.

It should be noted that the emergence of new methods of genetic research does not exclude the use of old proven technologies. In particular, Sanger sequencing, which has

[11] E. Oster; I. Shoulson; K. Quaid y E. R. Dorsey, “Genetic adverse selection: Evidence from long-term care insurance and Huntington disease”, Journal of Public Economics Vol: 94 num 11–12 (2010): 1041-1050.
[12] E. Mossialos y A. Dixon, “Genetic testing and insurance: Opportunities and challenges for society”, Trends in Molecular Medicine Vol: 7 num 71 (2001): 323-324.
[13] V. Njegomir y B. Marović, “Contemporary trends in the global insurance industry”, Procedia - Social and Behavioral Sciences (2012): 134-142.

been a leading technique for several decades, can still be very effective in analyzing a small portion of DNA. Its distinct advantage is the low cost provided by full automation of all processes.

When evaluating the prospects for using the genetic research results, it should be borne in mind that the choice of the appropriate method depends on a variety of factors, the main of which is the amount and nature of genetic information.

The cost of research also plays an important role. Given that whole-exome sequencing increases the detection of pathogenic mutations by 24% compared to the analysis of individual genes, while whole genome sequencing adds another 16% compared to whole-exome sequencing, at first glance, in terms of price-performance ratio, the whole-exome sequencing is the most optimal.

Discussion

The problem of assessing insurance risk in personal insurance consists in the need to take into account the fact of heterogeneity of the population due to the genetic characteristics of its representatives. The solution to this problem obviously requires taking into account several circumstances.

First of all, it is necessary to take into account the type of insurance. In cases where the legislator, implementing the social policy of the state, establishes the mechanisms of mandatory medical insurance, genetic research is not supposed to differentiate its conditions, since it is considered as a special form of state protection of citizens. Accordingly, the issue of whether it is permissible to use the results of genetic research is discussed exclusively concerning voluntary insurance.

Sales channels for insurance products are also very important. In the case of group insurance and electronic insurance, consideration of the individual characteristics of insured persons is not required[14]. The situation is different when selling individual products for investment and universal life insurance, as well as insurance against accidents and diseases for large insurance proceeds. Such insurance contracts can be entered into by insurers either directly or through insurance agents and brokers, but the sale process often involves individual underwriting, involving disclosure and analysis of the health information of the intended insured person.

Accordingly, different levels of underwriting should be distinguished. The primary underwriting is carried out by representatives of the insurer who apply standard procedures and rules, which allows obtaining information about genetic diseases through a survey of the policyholder in one form or another. Specialized underwriting to take into account individual risks can theoretically be focused on the results of genetic research corresponding to the specifics of the insurance product if the current legislation does not prohibit their implementation for this purpose. In terms of the various legislative restrictions, the insurers tend to calculate the possible risks. At that, attention is drawn to the need to take into account the type of insurance product. In particular, in the case of critical illness insurance, the insurer's interest in obtaining information about the insured person's genetic predisposition

[14] E. A. Kirillova; A. V. Pavlyuk y A. A. Mikheyev, “Online contractual process: Status and technology”, International Journal of Recent Technology and Engineering Vol: 8 num 1 (2019): 2234-2240.

to the particular disease is significantly higher than in the case of life and health insurance in general.

The issue of whether to resort to genetic research should be resolved with consideration for the possibility of risk assessment based on traditional methods. Among these methods, the analysis of family diseases is traditionally referred to as a counterpart, even if very imperfect. This method is currently used with some restrictions along with the assessment of medical and nonmedical risk factors, especially since a significant number of states have explicitly prohibited insurers from requiring genetic testing to assess predisposition to a particular disease.

It is also important to take into account the general concern about genetic discrimination, which can have various negative consequences. In particular, the need to inform the insurer of circumstances that may affect the occurrence of an insured event may force the postponement or even cancellation of planned genetic testing, which may be vital for the well-being of a person.

However, the reliability of the obtained data remains a key issue, as genetic tests can produce both false positive and false negative results[15]. The applicability of a genetic test in a specific situation, as a rule, depends on several factors: from analytical and clinical reliability to clinical usefulness, conditioned by both the quality of the conducted study and the specifics of a particular disease.

From the standpoint of analytical and clinical reliability, such studies have undoubted advantages, however, when applying targeted testing not covering all the DNA elements, false negative results are probable. Besides, the presence of genetic predisposition does not necessarily entail appropriate clinical manifestations, since the penetrance of the gene can vary significantly. In this sense, the greatest concern among specialists is caused by multifactorial diseases caused by the interaction of multiple gene mutations, for which the prognostic value of genetic tests is quite low, while the corresponding predisposition acts only as one of the risk factors, whose significance for assessing the probability of an insured event cannot be calculated unequivocally[16].

This circumstance significantly affects the potential use of predictive genetic tests for risk assessment in personal insurance, since a person's lifestyle often has a very significant impact on their health, which can balance the predicted genetic risk. In this sense, research conducted based on information obtained based on the analysis of data from currently actively created biobanks covering national cohorts in North America, Europe, and Asia, is noteworthy since it allows identifying certain statistical patterns that are significant from the viewpoint of insurance.

Special importance is attached to the UK Biobank, which is a national and international resource with unprecedented research capabilities, created to improve the prevention, diagnosis, and treatment of a wide range of serious and life-threatening diseases.

[15] P. Born, “Genetic testing in underwriting: Implications for life insurance markets”, Journal of Insurance Regulation Vol: 38 num 5 (2019).

[16] V. B. Borodulin; O. V. Shevchenko y A. A. Svistunov, “Tekhnologiya i primenenie DNK-biochipov”, Bulletin of the Higher Education Institutions, North Caucasus Region. Natural Science num 1 (2012): 69-73.

The main focus here, certainly, is on genetic research. The rich phenotypic coverage of these population groups allowed studying the correlation options of genotype and phenotype, identifying the pleiotropic effects of genes, establishing on this basis relatively reliable relationships between individual pathological conditions and the risk of developing a particular disease. Thus, the prerequisites were created for a generalized assessment of the significance of genetic and non-genetic risk factors for a particular disease.

It should be noted that the assessment of the impact of genetic research on insurance, being mainly speculative, is made by specialists concerning two aspects (Figure 2. Assessment of the impact of genetic research on insurance):

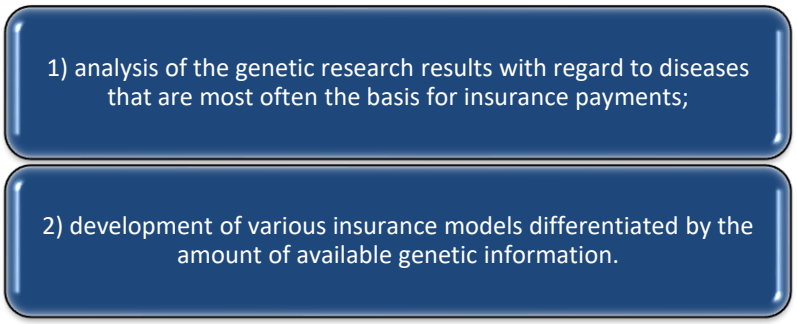

Figure 2
Assessment of the impact of genetic research on insurance

One cannot ignore the problems of interpretation of the data obtained in conducted studies, given that in contemporary genome-wide studies, the number of genotypes under consideration reaches several million. However, regardless of the context of testing, various results can be obtained, namely, from positive, which usually provide information about the diagnosis or risk, and negative, which exclude the tested diagnosis or reduce the risk assessment, to sometimes even uninformative results, which cannot be evaluated adequately. The fact is that the results of genetic tests, while unchanged, can be subject to different interpretations, which may change in the light of new developments in this field. For this reason, updated reports on possible risks may appear that entail updating forecast models.

A particular problem when using genetic research is obtaining side results in the form of data on gene mutations that are not associated with the alleged disease, which raises a complicated ethical problem about the need to inform the patient, and in some cases, their relatives, and if so, in what form. According to the American College of Medical Genetics and Genomics (ACMG), only known pathogenic mutations with high penetrance in 56 genes associated with diseases, whose early diagnosis is important for maintaining patient health, should be reported[17]. There is an opinion that the problem of genetic research in the insurance business has become less acute since there are a very limited number of diseases that manifest themselves later in life, although the frequency of such health problems is not so significant as to jeopardize the financial interests of the insurer[18].

[17] R. C. Green; J. S. Berg y W. W. Grody, “ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing”, Genetics in Medicine Vol: 15 num 7 (2013): 565-574.
[18] L. I. Shagam y V. Yu. Voinova, “Vozmozhnosti i ogranicheniya vysokoproizvoditel'nogo sekvenirovaniya v diagnostike monogennyh zabolevanij”, Russian Bulletin of Perinatology and Pediatrics num 2 (2016): 105-109.

The discussion about the feasibility of using the results of genetic tests for personal insurance purposes does not interfere with the discussion of possible underwriting models. Most of them are based on an assessment of the behavior demonstrated by clients depending on the degree of awareness of the risks identified by genetic testing. Special emphasis is placed on two risk groups, one of which is formed by persons who have a low probability of occurrence of an insured event, while the other one includes persons with a high risk of occurrence of an adverse event. It is obvious that the insurer, having no access to genetic information, is forced to calculate the insurance premium based on weighted average indicators. At that, the main issue for him is the question of under what circumstances the policyholders belonging to the first group, being sufficiently aware of their genome, will refuse insurance, which will indicate the adverse consequences of using such a method of selecting clients.

Some experts, in the context of legal restrictions on access to genetic information in the course of underwriting, suggest taking into account the possible proportion of the population who applied for polygenic testing. It is assumed that this proportion will increase as the cost decreases and the predictive ability of genetic tests increases[19]. This makes it more realistic to assume that the majority of the population will apply for insurance before receiving the results of genetic tests. It is obvious that the development of such a scenario is caused by various factors. On the one hand, the case is about the general awareness of citizens about the relevant research, as well as their financial capabilities, while on the other hand, this is due the practice of informing patients about the potential impact of the obtained results on the possibility of life insurance, which is common among doctors and genetic consultants, due to the universally recognized obligation of the insured to inform the insurer concerning the assessment of the probability of an insured event.

Canadian researchers calculated the actuarial consequences of a total ban on the use of genetic test results in insurance, taking insurance against critical diseases as basic. The key question still concerns the percentage of people, who, having information about a predisposition to illness, will seek to purchase insurance against critical illness, and what insurance coverage they will be focused on. Several factors are taken into account to calculate potential risks. One of them is the prevalence of the disease in the corresponding population. Another is the penetrance of a gene, which determines the likelihood of disease in individuals with a genetic predisposition to it[20]. At that, it is assumed that the effect of penetrance is a standard risk since a person will not know before the onset of the symptoms which risk group he belongs to (standard, where the predisposition will not manifest itself, or nonstandard, in which the disease will still develop). However, individuals who have received a positive test result will obviously show an increased interest in critical illness insurance. It is suggested that they can be identified in the course of underwriting based on family anamnesis or early symptoms of the disease, even if there is no access to the results of a genetic test, which is estimated at 25% of the total number of people, who received a positive result since family anamnesis limited to close relatives, not always is a complete source of information[21].

[19] E. N. Suspitsyn; V. I. Tyurin; E. N. Imyanitov y A. P. Sokolenko, “Polnoekzomnoe sekvenirovanie: principy i diagnosticheskie vozmozhnosti”, Pediatrician Vol: 7 num 4 (2016): 142-146.

[20] P. Bennett y S. J. Smith, “Genetics, insurance, and participation: How a citizens’ jury reached its verdict”, Social Science and Medicine Vol: 64 num 12 (2007): 2487-2498.

[21] P. Sandberg, “Genetic information and life insurance: A proposal for ethical European policy”, Social Science and Medicine Vol: 40 num 11 (1995) 1549-1559.

Special attention is paid to assessing the probability of refusal to renew the insurance contract since insured persons will more likely to refuse to continue insurance if there is no evidence of illness for several years. Moreover, this coefficient is proposed to be taken into account from 0.5% for the first insurance contracts, gradually increasing it to 4%, since it is initially not clear whether the insured person is included in the standard or nonstandard group[22].

The amount of insurance coverage is also important since in some countries exceeding the legally established limit gives the insurer the right to demand the results of genetic research. In the USA, the benchmark is more than $ 1 million, in the UK it depends on the type of insurance, and for life insurance, it is £500,000, while for critical illness insurance it is £300,000[23].

As a result of a comprehensive analysis, it was suggested that 75% of the holders of a positive result will apply for a $250,000 insurance contract[24]. Moreover, the extension of the legal ban on insurers' access to genetic information will lead to an increase in the corresponding quantitative indicators due to possible abuse of persons who are aware of the insurer's limited ability to obtain reliable information about the probability of an insured event. The natural response of the latter in this context will be to increase the average insurance premium rates by about 26% within the age range of 30-65 years in general, or by 16% for men and 41% for women (since some critical diseases are characteristic only for this part of the population)[25].

Coverage of between 2 and 5% of the population by genetic testing could be a critical point at which companies need to review their prices, products, and underwriting practices, that will put the sustainability of the industry at risk. In short, genetics has created a fundamental ethical contradiction between the desire to protect policyholders without discriminating them based on genetic information, especially when genetics is determined at birth, and the desire to protect the integrity of insurance companies' business models in the context of information asymmetry and potential adverse selection.

Conclusion

Genetic information is information related to various genetically determined conditions obtained by direct DNA studies.

To determine the relevance and demand for information resulted from a genetic study for personal insurance purposes, several factors must be considered. Some of these factors are related to the characteristics of the insurance itself (a type of insurance, sales channels), while others concern the characteristics of the corresponding population, and still, others relate to the methods of genetic research used. The proposed underwriting

[22] D. Vukcevic y J. Chen, Thinking about life insurance through a genetic lens (Melbourne: Proceedings of the Actuaries Summit, 2017).

[23] J. Lemaire y A. S. MacDonald, Genetics, Family History, and Insurance Underwriting: An Expensive Combination? 2003. Retrieved from https://www.actuaires.org/ASTIN/Colloquia/Berlin/Lemaire_MacDonald.pdf

[24] A. Xepapadeas; P. Ralli; E. Kougea; S. Spyrou; N. Stavropoulos; V. Tsiaoussi y A. Tsivelikas, “Valuing insurance services emerging from a gene bank: The case of the Greek Gene Bank”, Ecological Economics num 97 (2014): 140–149.

[25] A. V. Khera y S. Kathiresan, “Genetics of coronary artery disease: Discovery biology and clinical translation”, Nature Reviews Genetics Vol: 18 num 6 (2017): 331-344.

models are usually focused on the most common genetic diseases, and take into account factors, such as the prevalence of the disease in the relevant population, the gene penetrance that determines the probability of occurrence of the disease in individuals with a genetic predisposition to it, the degree of coverage of the population by genetic testing, etc. Particular importance should be attached to the creation of national biobanks as a source of depersonalized statistical information about the correlation options of the genotype and phenotype, as well as the pleiotropic effects of genes.

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