

Seeing the future? How genetic testing will impact life insurance



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Abstract

The cost of sequencing an individual's genome has fallen exponentially, so that genetics has started to become an integral part of clinical practice. This has provided physicians with a valuable diagnostic and in some cases a predictive pre-symptomatic tool, which they can use more effectively to manage patients' diseases and even take preventive actions.

The exponential fall in the price of genome analysis tools has also led to the robust growth of a direct-to-consumer market (DTC), allowing individuals to access quickly and cheaply their genetic profile. Insurers broadly welcome the increased clinical use of genetic services, as it can result in effective personalised treatments and preventive actions taken for patients.

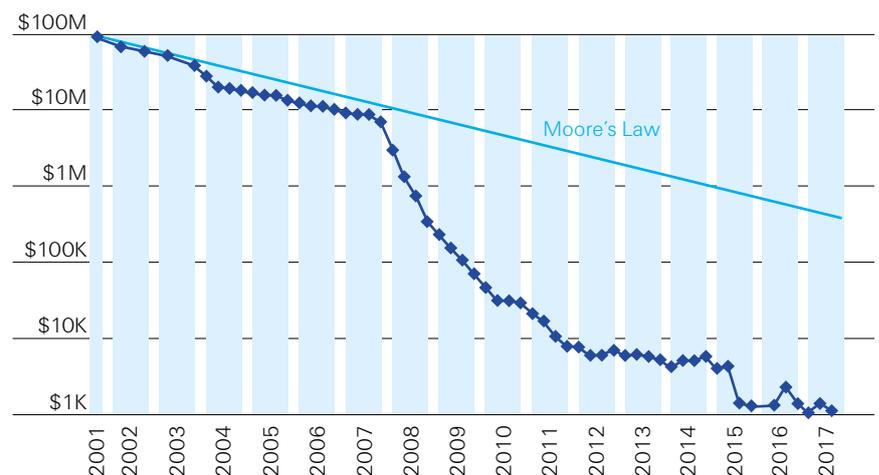
Insurers are, however, aware that there are some risks with the increased availability of genetic information. Most prominent of these is an information asymmetry. If individuals have access to genetic data that their insurer does not, it could be the basis of non-disclosure and anti-selection. Moreover, the effects of anti-selection could be amplified by different regulatory approaches to the use and disclosure of genetic tests for underwriting purposes.

This paper frames the concerns of the insurance industry, and how important the right approach and incentives will be in ensuring the effective use of genetic data in health and insurance contexts.

The evolution of genetic testing

The Human Genome Project was initiated in 1990. Thirteen years and USD 3 billion later, the project had successfully sequenced the human genome. It was one of the major scientific achievements of all time; and it became a robust and reliable technology platform to explore gene disease associations. The cost of genome sequencing subsequently plummeted. It still cost USD 10 million in 2006; by 2008 it was a tenth of that price. It was USD 6 000 in 2012, and currently stands at USD 1 000 (see figure 1) and can take as little as a few hours. At that fall in cost, demand is booming. Illumina, a global leader in the genome sequencing market, reported already over 220 000 people had their genomes sequenced alone in 2014 and suggests that the number will double about every 12 months¹. More optimistic experts even forecast the number to rise into the tens of millions in coming years.

Figure 1:
Cost per genome



Source: National Human Genome Research Institute
<https://www.genome.gov/sequencingcostsdata/>

While genome sequencing capabilities have significantly come down in costs, the most commonly used genetic tests are performed on microarray-based technology platforms. This stable and robust technology is able to analyse hundreds of thousands of genetic variants in a person's genome. Such variants are referred to as single nucleotide polymorphisms or SNPs and are used as markers for heritable events. SNPs are considered the most common variations within the DNA structure. Thus far, more than 10 million different SNPs have been discovered in the human genome². Currently most DTC genetic testing companies focus upon panels of selected SNPs derived from Genome-Wide Association (GWA) studies. GWA studies interrogate the complete genome of thousands of individuals, looking for associations between SNPs and traits such as common diseases. As of December 2017 over 3 200 human GWA studies have been published, detailing more than 55 000 SNPs associated with over 3 000 diseases and traits³. Once the genotype of a person is known, an individual's SNPs can be compared with the published literature to determine associations between these genetic variants and known diseases and therefore the likelihood of trait expression and disease risk.

From SNP disease association to full genome analysis

SNP arrays focus on shared genetic variants that are common to many individuals within a wider population. Hence, they only analyse a small proportion of the genome. In contrast, whole genome sequencing (WGS) allows the genome to be fully analysed. Up to now, this process requires more time and expense. The more cost effective approach is to sequence the protein coding regions within the genome, ie the exome (also known as whole exome sequencing or WES), which is roughly 1–2% of the genome. It is estimated that 85% of the disease-causing mutations are located in these protein coding and functional regions of the genome⁴. These genome-sequencing approaches allow simultaneous detection of all genetic variants with different pathogenic effects within an individual’s genome. This will help to better understand underlying mechanisms of many diseases and will ultimately improve disease diagnosis and aid in guiding personalised treatment and prevention plans.

As WGS provides a full genome analysis, unexpected results that are unrelated to the original reason or indication for sequencing will likely be identified. On this basis, the American College of Medical Genetics and Genomics (ACMG) released recommendations for reporting of such incidental findings in clinical WGS/WES sequencing back to the ordering physician and the patient⁵. The statement contains a defined set of pathogenic variants in 56 carefully chosen genes related to 24 mainly high penetrant disorders. Early intervention is available to all these disorders and is likely to reduce or prevent serious morbidity or early mortality if managed proactively. Many of these diseases are late onset, for which individuals might not experience symptoms until adulthood. Between 1–2% of patients completing full genomic sequencing are estimated to have an incidental finding for which these recommendations will apply. The list is expected to evolve over time as ongoing research links more variants to more diseases and evidence accrues on the penetrance of these variants.

Table 1:
Genetic testing methodologies

Technology	Rare diseases	Common diseases	# of genes tested	Turn-around time	Approx. cost
SNP microarrays	Moderate	Poor	Thousands	Days to weeks	\$100s
Single-gene sequencing	Good	Poor	One	Weeks	\$100s – \$1000s
Panel sequencing	Moderate	Good	Few – Hundreds	Weeks to months	\$100s – \$1000s
Full genome sequencing	Good	Good	All	Weeks to months	\$1000s

There are four main platforms of genetic testing services available: SNP microarrays, single gene sequencing, panel sequencing, and full genome sequencing. SNP microarrays typically run on high throughput platforms and have been the genetic testing service most frequently offered in the DTC market. Single gene sequencing has been to date the main choice to analyse certain known disease causing genes. Disease-targeted (eg breast cancer) gene panels use next generation sequencing technology to simultaneously assess variations in multiple well-defined disease-causative genes and have become commercially available. The recent exponential fall in costs for new sequencing technologies, coupled with enhanced bioinformatic capabilities, have made full genome sequencing both technically and economically feasible. This service has the potential to capture all classes of genetic variation and is going to change current clinical and public health practice. Categorical assignments for validity and utility in the columns are subjective and vary according to context of the tests being ordered. The ‘poor’, ‘moderate’ and ‘good’ categories are presented to simplify and to compare platforms generally.

Source: Swiss Re

Clinical genetic testing

SNP and more latterly WGS/WES techniques are expanding rapidly to become an integral part in diagnosis, treatment and prevention of disease. By the end of December 2017, the National Institutes of Health's (NIH) Genetic Testing Registry (GTR) included more than 54 000 tests related to over 10 000 medical conditions and 5 000 genes compared with about 10 000 tests as of August 2013⁶.

This increase in genetic testing has led to a range of tests being offered. Depending on a patient's individual medical issue, different types of genetic tests are now available in clinical practice. The most common include:

- **Prenatal testing** to detect changes in a foetus's genes or chromosomes before birth.
- **Newborn screening** to identify highly penetrant genetic disorders that can be treated early in life.
- **Diagnostic or confirmatory genetic testing** to identify or confirm a specific genetic condition in a symptomatic individual.
- **Carrier screening** to identify unaffected individuals as carriers for a specific autosomal recessive disease.
- **Predictive and pre-symptomatic testing** for estimating the risk of developing adult-onset disease or predicting future disease onset.
- **Pharmacogenetic testing** to guide individual drug dosage, selection and response.
- **Preimplantation genetic testing** to reduce the risk of having a child with a particular genetic or chromosomal disorder.
- **Nutrigenetic testing** to study the effect of genetic variations on the interaction between diet and health or on nutrient requirements.

These clinical genetic tests usually meet the highest standards of analytical and clinical validity (test sensitivity and specificity) and therefore accuracy of diagnosis or risk prediction. Another measure of the quality of a genetic test is its usefulness, or clinical utility. Clinical utility refers to whether the genetic test can provide information about future preventative and/or therapeutic interventions that will be helpful to tested people.

In addition, clinical genetic testing is accompanied by comprehensive pre- and post-test counselling from specialised health professionals to assess a patient's risk perception, expectations and explaining the implications of testing. Results from testing are interpreted together with personal health, medical and family history. Finally, trained professionals assist tested individuals to make informed decisions about preventive steps or follow-up clinical procedures if available.

The DTC genetic testing market

Alongside the clinical use of genetic tests, there has been rapid growth in the direct-to-consumer (DTC) genetic testing market. These companies operate in an undefined space between health (most specifically heritable diseases), wellness (personalised nutrition and fitness advice), pharmacology (suitability and efficacy of a particular drug), and genealogy. Insights into personal genetic information may promote awareness of genetic diseases allowing consumers to take a more proactive role in their healthcare. Information from such testing could encourage consumers to opt for earlier or more frequent medical screenings or adopt lifestyle changes to avoid specific diseases.

The International Society of Genetic Genealogy (ISOGG) lists about 45 personal genomics companies providing DTC genetic tests for health, traits, nutrition and pharmacogenetics⁷. The largest and best-known DTC genetic test provider is California-based company 23andMe. It states that its mission is: *"To help people access, understand and benefit from the human genome."* Backed by Google, the company offers saliva-based personalised genetic health, trait, drug response and ancestry reports, with the commercial stress largely being on ancestry. As of February 2016, the company had genotyped approximately 1.2 million customers⁸.

Regulation of DTC genetic testing services

The booming DTC genetic testing industry has caught the attention of regulatory agencies due to the rising public health concerns behind the validity, safety, and clinical utility of these genetic tests. Yet most DTC genetic tests are not regulated, partly as their specific purpose is not exclusively medical (as distinct from wellness); partly because of a belief that the individual has a right to be curious and learn about their DNA; and partly because authorities generally play catch-up to technology. In consequence, there is a chance that most DTC genetic tests go to market without any independent verification of the health claim made by the service provider.

In November 2013, the U.S. Food and Drug Administration (FDA) banned 23andMe from marketing its health-related genetic screening service in the US⁹. According to the FDA, 23andMe failed to meet the agency's regulatory requirements for medical devices. This resulted in concerns about the potential health consequences of customers receiving inaccurate health advice. 23andMe continued to sell personal genome tests for ancestry analysis to US clients until October 2015, when the company announced a revised product, including a limited number of carrier status reports that now meet FDA standards¹⁰. Over this period, 23andMe began offering various levels of ancestry, health-risk and carrier status reports in Canada and a number of European markets (UK, Denmark, Finland, Ireland, Sweden, and the Netherlands).

An adequate regulatory framework for genetic testing in the US has yet to be developed. In Europe, legislation governing DTC genetic services currently varies from country to country. In France, Germany, Portugal and Switzerland only a healthcare professional can order and undertake genetic tests. No such legislation exists in the UK, Belgium or the Netherlands. However, even in countries with legislation in place, it is difficult to prevent consumers accessing mail-order DTC services from companies based abroad.

Accuracy of DTC genetic test results

Although most DTC genetic testing services are based on a robust and accurate SNP microarray platform to screen for genetic variants associated with disease, the results can be difficult to interpret and understand. The majority of DTC genetic test panels and arrays focus on common complex disorders such as heart disease, cancer or diabetes and screen for multiple SNPs identified by GWA studies. Most of these variations, however, only account for a small fraction of the genetic variance in such common diseases. Often a complex interplay and combination of environmental factors and many different low-risk genetic variants are the cause of a disease (see table 2). Therefore, most SNPs are ‘modifiers’ rather than significant drivers for a disease. Hence, any medical benefit or clinical utility gained through a DTC service is modest at best (see table1).

Table 2:

Genes implicated in the inheritance of common cancers

Cancer site	Relative risk ≥ 5.0	Relative risk ≥ 1.5 and < 5.0	Relative risk ≥ 1.01 and < 1.5
Lung	RB1, TP53		
Breast	BRCA1, BRCA2, TP53, PTEN, SK11, CHDH1	CHEK2, ATM, PALB2, BRIP1	CASP8, FGFR2, MAP3K1, TOX3, LSP1
Colon and rectum	APC, MLH1, MSH2, MSH6, PMS2	APC, BLM	MUTYH, CASP8, CRAC1, SMAD7
Prostate	BRCA2		NBS1, EHP1, TVD2, CTBP2, JAZF1, MSMB, LMTK2, KLK3, SLC22A3
Pancreas	BRCA2, CDKN2A, STK11, TP53, PRSS1, SPINK1	BRCA1, MSH1, MLH1	

Table 2 provides an overview of a set of genes that can be clustered into three groups carrying various degrees of relative risks for cancer: high-risk genes with relative risks above 5.0; moderate-penetrance genes with a relative risk between 1.5 and 5.0; and low-risk genes with relative risk between 1.01 and 1.5. It is important to note that some mutations contribute to several cancers with different relative risks. Overall, the real risk to an individual is complex to establish.

Source: Foulkes W (2008); N Engl J Med; 359:2143-2153

Lack of professional genetic counselling for DTC genetic testing

The DTC provision model of genetic testing has been criticised for its absence of any medical or healthcare supervision. Many DTC genetic test providers sell their products without the involvement of health professionals and do not offer pre- or post-test counselling. Other genetic and environmental factors, lifestyle choices, and family medical history also affect a person’s risk of developing a specific disease. As many reports from DTC genetic testing services do not take these important factors into account when estimating disease risks, there is potential for consumers to be misled. Without the intervention of a professional intermediary, customers may make uninformed decisions that adversely affects their health, such as inappropriate treatment decisions, continuing an unhealthy lifestyle or failing to take preventive measures.

Moreover, predictions of disease risk from different DTC genetic testing companies can vary significantly. In 2013, a study published in Nature simulated genotype data for 100 000 people and predicted the risks of six diseases based on the methods of three DTC genetic testing providers¹¹. The researchers found substantial differences among predicted risks owing to diverging estimates and the way that each company determined average risk. This has added to concerns regarding the limitations of DTC genetic testing as a clinical tool. It further highlights the limited predictive value, clinical validity and utility of many DTC genetic tests that are currently available.

Insurance and genetic testing

If present in an applicant's medical record, diagnostic genetic tests, that confirm disease in a symptomatic individual, are routinely assessed in life insurance underwriting. However, the legislative approach towards the request and use of existing predictive genetic testing information, in pre-symptomatic patients, is far from uniform. Accurate predictive genetic tests could significantly alter the dynamics between the life insurer and policyholder should the information not be accessible to insurers.

It is common insurance best practice not to request that insurance applicants should undergo predictive genetic testing. However, countries apply different approaches ranging from voluntary moratorium to strict legislation when a consumer has produced results from a predictive genetic test at the time of application (see table 3). Dependent on legislation, life insurers may, or may not, take these results into account when underwriting.

Table 3:

Main regulatory approach towards private insurers' access and use of genetic data in selected markets (as of December 2017; subject to change)

Country	Self-regulation	Limitation by law	Legal Ban	Comment relating to private insurance
Australia	X			No specific genetic test law has been enacted. Life insurers comply with FSC Genetic Testing Standard No. 11 (operational since 2002), which allows insurers to use existing genetic test results. With regard to family history, life insurers comply with FSC Family Medical History Standard No. 16 (effective 2005) which states that only first degree relatives will be used for underwriting purposes. Standard 11 & 16 are being reviewed by an FSC Working Group during 2016 to ensure alignment with a Life Insurance Code of Conduct which is also currently being developed by the FSC.
Canada			X	The Canadian Insurance Code on Genetic Testing does not allow insurers to ask applicants to undergo genetic testing. In May 2017, Bill S-201, also known as the Genetic Non-Discrimination Act, passed into law which makes it illegal for insurance companies or employers to request genetic testing or ask for results for the purpose of insurance risk selection.
China	X			No specific genetic test law has been enacted. Genetic information is considered as private and protected by laws. There are no restrictions for insurance companies asking for genetic tests or results. However, since genetic testing is highly regulated and expensive, no insurance company has yet been required to use it. Use of family history is allowed and is widely used.
Germany		X		According to the law of genetic engineering predictive testing information is permitted only to be requested and used where the sum assured exceeds the amount of EUR 300 000 (life insurance) or an annuity exceeds EUR 30 000 p.a. (occupational disability insurance, general disability insurance and care pension insurance). No restrictions apply to diagnostic genetic tests. The data protection authorities permit the use of family history under usual standard.
Japan	X			No specific genetic test law has been enacted. Life insurers impose self-restrictions with regard to access and use of genetic data. Life insurers also impose self-restriction as to collecting family history on all products. The Ministry of International Trade and Industry (MITI) established a guideline in 2004 on how to deal with genetic data, where MITI requests economic operators to utilise the anonymised data which could not identify an individual.

Country	Self-regulation	Limitation by law	Legal Ban	Comment relating to private insurance
Hong Kong	X			In 2000, the HKFI issued a Code of Practice. Genetics Testing & Insurance based primarily on the code issued by the ABI. The Equal Opportunities Commission suggests that insurers in Hong Kong who wish to rely on genetic information should exercise care. Discriminatory decisions based on such information may be unlawful, unless reasonably based on actuarial or other data or justifiable under the Disability Discrimination Ordinance. Family history questions are widely used.
India	X			There is no regulation in India regarding the use of genetic test findings for the purpose of insurance risk selection. There is increasing debate on the subject. Genetic tests or reports are not requested as part of the risk selection in insurance. Family history data as disclosed by the applicant can be used for risk categorisation. The family history question is both a part of the application form and the medical examination.
Netherlands		X		The moratorium (1990/1995) was linked to the protocol on medical examination in 2004, as a result of the evaluation of the Medical Examination Act (1998). Insurers must not ask for, or use, results of predictive genetic tests or family history where the total amount assured is below EUR 250 000 for life insurance, and below EUR 36 249 for the annual benefits in the first year (A-Rente, DI cover) and below EUR 24 267 for the annual benefits in the following years (B-Rente, DI cover). No restrictions apply to diagnostic genetic tests.
Poland			X	According to the new insurance act from Sept 2015 insurers are not allowed to request any genetic test results for insurance (Ustawa o dzialalnosci ubezpieczeniowej z 2015 r., art. 37.1 and 38.1). This regulation is a copy of the previous insurance act from 2003. Genetic testing is also mentioned in other acts. Although the Constitution does not refer to genetic testing directly, it states that any form of discrimination is not allowed. According to the Data Protection Act processing of personal data revealing genetic code is prohibited. According to the Medical Ethics Code (Kodeks Etyki Lekarskiej) medical professionals must keep all genetic information (in the meaning of genetic test results) of their patients confidential. However, family history is not considered "genetic information" in Poland and is broadly underwritten by Polish insurers.
Portugal			X	The Genetic Information Act (2005) prohibits insurers from obtaining, requesting, accepting or in any other way making use of genetic data (including family history data) on their policyholders or insurance applicants.
Singapore	X			In May 2007, the Bioethics Advisory Committee called on insurers not to use genetic test results to calculate the risks and premiums of applicants for now. The Life Insurance Association (LIA) which represents 16 life insurers, including nine that offer health insurance agreed to this moratorium. Life insurers here do not require the applicant to declare whether any genetic test has been done, nor request for its result. Moratorium remains, with family history questions an integral part of the application form.
South Africa	X			There is a number of areas in legislation that reference genetics, although non-specific and unrelated to insurance. Certain issues are expressly addressed and others not. The insurance regulatory body (ASISA) has published a practice note recommending that insurers not require genetic testing to be done for insurance applications but do recognise insurers' right to disclosure by applicants of 'genetic information' (including family history) where known.

Insurance and genetic testing

Country	Self-regulation	Limitation by law	Legal Ban	Comment relating to private insurance
Switzerland		X		The law regarding Genetic Investigations in Humans (2004) states that insurers are not allowed to request predictive genetic tests for insurance purposes. No restrictions apply to diagnostic genetic tests. Private life and disability insurers will be allowed to obtain and use existing test results where the total amount insured on all policies exceeds CHF 400 000 for life insurance or CHF 40 000 per annum for disability insurance, and the decision is actuarially justified. Information for family history is permitted.
United Kingdom	X			The Concordat and Moratorium of Genetics and Insurance states that private insurers should not require customers to disclose the results of predictive genetic tests for policies with a total amount assured of up to GBP 500 000 for life insurance or GBP 300 000 for critical illness insurance, or annual benefits of up to GBP 30 000 for income protection insurance. No restrictions apply to diagnostic genetic tests. This was introduced in 2001 and is due to run to at least 2019. There are no restrictions on the use of family history information.
United States		X		Genetic legislation in the United States focuses on the prohibition of genetic discrimination in employment and medical insurance. At a federal level medical insurance plans are prevented by law from using any genetic information (The Genetic Information Nondiscrimination Act, H.R. 493, 2008). Legislation varies at state level reflecting different approaches to the need for consent and actuarial justification. State laws exist, although they vary widely in scope, applicability and amount of protection provided. Approximately 1/3 of the states have some type of regulation(s) restricting the use of genetic information in determining coverage for life insurance albeit the approaches are very different.

The difference in regulatory requirements shown in the above table reflect concerns around data privacy and the maturity of private insurance within different insurance markets. Generally the regulator aims at protecting the freedom of the consumer not to know his or her propensity to disease and therefore does not allow insurers to ask applicants to undergo predictive genetic tests. Moreover, access to existing predictive genetic test results may be restricted. It should be noted that insurers do not want to insist on predictive tests but want access to the same information that applicants have, for so-called symmetry of information. However, there are few restrictions on the use of diagnostic genetic test results, or on the use of family health history information by life insurers.

Source: Swiss Re

Europe

Europe has more regulation governing genetic testing than any other markets. However, there is no uniformity in how genes and genetic information are even described. The lack of a generally approved definition of a genetic test makes the drafting of a consistent regulation demanding. Most legislations agree that genetic tests for pre-symptomatic patients, to identify a future disease, are considered different from other forms of predictive medical tests.

In the UK, the Association of British Insurers and the government have agreed on a voluntary moratorium, which has been in place for over a decade, and was recently extended to 2019, on the use of predictive genetic test results by life insurers. German law allows insurers to request predictive genetic test results for insurance above a defined sum insured. However, in many European countries (eg Austria, Belgium, Denmark, France, Norway and Portugal) any use of predictive genetic test results for insurance purposes is prohibited.

North America

In the United States, the Genetic Information Nondiscrimination Act (GINA) of 2008 prohibits discrimination on the basis of information derived from genetic tests for health insurance. The federal law does not apply to life, disability or long-term care insurance. However, some individual states reference life insurance in terms of a need for actuarial sound risk assessment and specific consent requirements.

Until May 2017 Canadian life insurers could request or use the results of an existing genetic test for the purposes of classifying risk. On May 4, 2017 Bill S-201, an "Act to prohibit and prevent genetic discrimination" became effective which now prohibits life insurance companies from accessing the results of genetic tests for the purpose of underwriting a potential insured. In December 2017 the Canadian Life and Health Insurance Association (CLHIA) is still seeking clarity from the Supreme Court of Canada on the constitutionality of the law.

Asia

India and China have a lower regulatory threshold with reference to genetics. South Korea prevents genetic discrimination in social activities such as education, promotion, employment or insurance. In Australia, life insurers comply with the FSC Genetic Testing Policy No.11 (2001/2005), which allows insurers to use existing genetic test results, where appropriate.

Family history data protection

The issue of whether insurers should have access to genetic data is further complicated by the argument that all diseases are influenced by our genetic make-up. Any medical test result that relates to a possible future health outcome will reveal information of a genetic nature¹².

This brings into question the use of family history information by insurers. For more than 150 years, the life insurance industry has asked questions about the occurrence of disease in close family members. As such, the insurance industry has a long established good record of managing this data appropriately.

The insurance industry has faced challenges by making the questions asked of applicants more specific. An example of the Swiss Insurance Association addresses the family member health status as follows:

“Have your parents, siblings or grandparents had any diseases of the nervous system, cardiac diseases, strokes, diabetes, cancer or hereditary diseases before the age of 55?”

The question is specifically related to family members; reflects on those medical conditions of statistical relevance; and the group is sufficiently wide to be non-identifiable. Most countries accept that insurers ask for family history although not all; this long-recognised risk factor is particularly relevant for critical illness business. Some countries have regulated the way insurers are allowed to ask for the data, such as the Netherlands¹³ and Norway¹⁴, and insurers have responded by introducing criteria similar to those developed by the Swiss Insurance Association. However, others such as Portugal have taken a very strict approach and do not allow insurers to ask for family history information¹⁵.

Figure 2:

Restrictions on genetic data in insurance

Restrictions on genetic data in insurance

Over the last two decades, greater restrictions have been put on the use of genetic data by insurers. These measures include:

- (1) insurers are generally not allowed to ask applicants to undergo predictive genetic testing and where there is no legislation in place insurers have agreed not to ask for such tests;
- (2) insurers are limited in making use of already available predictive genetic information in the underwriting process by providing actuarial justification for any rating applied. In some European markets this data can only be used as above defined sums insured;
- (3) the use of diagnostic genetic information used to confirm the presence of a disease is generally allowed for underwriting purposes as long as actuarially justifiable;
- (4) family history information has, with a few exceptions, not been challenged and is key to limit the exposure to genetic anti-selection risk.

Health incentives for insurance clients

A key focus of DTC genetic testing companies has been the provision of personalised nutrition and health advice. Insurers in a number of markets are tying in insurance products to wellness and fitness goals. This has led to an interest in providing third-party genetic health analysis. These current offers are designed to be a value-added service to policyholders, as well as being a valuable marketing tool in the dry world of life insurance.

A pioneer of this good health approach has been Discovery Life. Almost two decades ago, it launched its Vitality programme, aimed at incentivising policyholders to improve health behaviour through a reward programme. It supports fitness tracking, nutrition guidance, and preventative health programmes.

During the second quarter of 2016, Discovery Life planned to offer a comprehensive WES analysis for only USD 300 to Vitality members in South Africa and the UK¹⁶. This is significantly more comprehensive and informative than SNP genotyping services offered by 23andMe and other DTC providers. Clients who choose to have DNA sequencing will receive a comprehensive report about their genome, including disease risks and potential strategies to improve their health. The vital part of the analysis and interpretation of genetic test advice has been outsourced to Human Longevity Inc (HLI), The San Diego-based genomic company, which was co-founded in 2013 by the US scientist Dr J Craig Venter, a primary force behind the private competitive project to the Human Genome Sequencing consortium. HLI will provide the testing reports to Discovery who will deliver the information to clients through their network of physicians to aid in the understanding and interpretation of each individual's genome report.

The insurance industry will closely watch the expansion of genetic testing, particularly WES/WGS services. As these services can reveal genetic predispositions that a tested person may never have wanted to know, it will be interesting to see to what extent and how this information is delivered to people tested. What would occur if a debilitating genetic condition was identified, for which no treatment or preventive measures exist? Will clients be asked to share this information with their insurer? Should they consider changing their sum insured or received benefits? And how may that information impact their current and future insurability?

Increasing anti-selection exposure

The goal of insurance underwriting is the fair and equitable assessment of mortality and morbidity risk. It assumes a 'level playing field' in which both the insurance company and the insurance applicant have access to the same health-related information. This ensures that the insurer can properly assess the applicant's risk, so that the premium reflects the degree of risk assumed. Genetic testing can reveal that an individual who is otherwise healthy has a higher risk of developing a disease in the future, being unable to work or requiring extensive medical care.

Studies have demonstrated that people armed with such results from genetic testing only occasionally share this information with their insurer. At the same time, such information has been shown to significantly affect decisions of customers regarding the purchase or later alterations of insurance cover^{17,18}. Recent studies from the Canadian Institute of Actuaries concluded that the financial impact from non-disclosure and/or restriction in access and use of existing predictive genetic information will be substantial to insurers offering term products^{19,20}. It would be more than insurance companies could be expected to absorb without an increase in premium rates. The effect on life insurance would be important, but critical illness products in particular would be at greatest risk for anti-selection.

Currently, results from DTC genetic testing services remain unreliable for risk assessment as the effects of most SNPs are difficult to interpret and are not necessarily clinically relevant. With the exception of a limited number of SNPs, most of the genetic variants used by DTC genetic testing companies offer modest predictive information and provide only incremental changes in a person's risk profile.

This is different from WES/WGS, where all pathogenic or likely pathogenic variants present in disease causing genes are revealed. The broad application of WES/WGS in basic research and clinical practice therefore can provide an increasing amount of complex 'at-risk' health information that can strongly correlate with occurrence, progression and prognosis of disease. The rapid developments in this field also hold significant potential for more accurate, future risk prediction of common, complex disorders such as heart disease, cancer, stroke and diabetes, caused by the effects of multiple genes in combination with lifestyle and environmental factors.

These late onset diseases are the leading causes of death and disability in developed countries and are particularly relevant to life, disability and the long-term care insurance lines. There is currently little information to underwrite late-onset disease risk, except for family history information, which has been an important surrogate for inherited impairments.

In the near future, the greater affordability and accessibility to genetic testing information for well-characterised high-risk, high penetrance variants and associated diseases may affect an individual's perception of the need to buy, or alter disclosures for life protection products. In addition, improved information from genetic testing will provide individuals with increasingly accurate estimations of their future health. This could drive lapse and re-entry rates, leading to increased anti-selection risk.

Conclusion

We have entered an age where genetic information is readily available at low cost. When the genome was first unlocked, many believed it would hold the key to understanding many inheritable conditions and diseases caused by acquired genetic mutations such as most cancers. In fact, the interplay between genes and various disease states has proved difficult to understand and outside of a few clearly defined conditions, has been of limited predictive quality. Our understanding of our genetic code will deepen; but at this point it is hard to conceive of genetic data becoming the dominant risk factor within insurance underwriting.

While genetic testing may not impact aggregate risk pools initially, it may evolve to become a game changer at an individual level. The growing availability of relevant, reliable and predictive health information from genetic testing will increase the threats of anti-selection to insurers. Insurance pools have to be constructed on the basis of trust. The same risk-relevant information must be available to insurers as well as to the insured. If an insured party has access to genetic information that their insurer does not, particularly in a product such as critical illness, then insurance pools will weaken and eventually collapse. Prohibiting insurance companies from accessing such information for the purpose of underwriting a potential insured would have a significant impact on insurers and the efficient operation of insurance markets.

The ethics around genetic testing and results are complex, particularly when tests reveal conditions that were not anticipated or expected. Moreover, the insurance industry is not requesting genetic tests as a prerequisite to insurance. Nonetheless, legal frameworks should be constructed around the basis of symmetry of knowledge. If insurers are denied relevant data that is easily available to insured parties, it will become increasingly unviable to underwrite certain products. That would not only be a game changer for the industry – if life insurance becomes less available, the wider implications for societies and economies could also be considerable.

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Additional reading

The genetic revolution and its wider implications for insurance

http://media.cgd.swissre.com/documents/6RDS_Longevity_genetic_revolution1.pdf

Fair risk assessment in life and health insurance

http://media.swissre.com/documents/pub_Life_Risk_Selection.pdf

Breast and colorectal cancer: Advances and developments in prevention, early detection and treatment

http://media.cgd.swissre.com/documents/CGD_Breastandcolorectalcancer_Aug12.pdf

Two decades after BRCA: Setting paradigms in personalized cancer care and prevention

http://media.swissre.com/documents/Medical_newsletter_2_2014.pdf

23andMe consumer genetic testing – a challenge to the insurance industry?

http://media.cgd.swissre.com/documents/23andMe_Genetic_2015.pdf

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