Familial hypercholesterolemia screening in the Netherlands: psychological and social consequences
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Chapter 7

Getting insurance after genetic screening on familial hypercholesterolemia; the need to educate both insurers and the public to increase adherence to national guidelines in The Netherlands

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Keypoints

- In the Netherlands guidelines and legislation exist on the use of genetic test information.
- The present study shows that individuals still encounter insurance problems as a result of participating in a genetic screening program.
- It is not clear why these problems occur: whether insurance companies ask questions regarding genetic testing or questions that can be read as such, or that individuals themselves give more information than asked for.
- We conclude that guidelines and legislation on genetic information are but a prerequisite and that education of all involved is equally important.
Familial Hypercholesterolemia

Heterozygous Familial Hypercholesterolemia (FH) is a common autosomal dominant inherited metabolic disease with a prevalence of 1 in 500 in most Western countries. [1] [2] [3] Individuals with FH experience an increased risk for coronary artery disease (CAD) and excess mortality especially at a young age. [4] [5] Until recently the diagnosis of FH was based on clinical signs and symptoms alone. These included elevated cholesterol levels, in particular of LDL-cholesterol, in combination with the presence of tendon xanthoma, corneal arcus, xanthelasmas and a history of early (CAD). Frequently FH was diagnosed after a first cardiac event.

Genetic screening

The discovery of LDL receptor gene mutations in clinically diagnosed FH patients and the consequent development of DNA tests for these mutations, enabled the diagnosis of FH in pre-symptomatic patients. In principle, the availability of effective treatment for FH made screening of relatives of identified FH patients an attractive strategy to reduce the risk of CAD. In 1994, such a family-based genetic screening program for FH was implemented in the Netherlands. [6] [7] This program is targeted at at-risk relatives (over 16 years of age) of clinically diagnosed FH patients with a known mutation in the LDL-receptor gene, also called index patients. First degree relatives of index patients are offered genetic testing for the mutation found in the index patient. If these relatives carry the mutation, their first degree relatives are screened. Mutation carriers are back-referred to their general practitioner with the advice to have a further specialist examination at a lipid clinic.

Social consequences of genetic screening

Participating in such a genetic screening program may induce other effects than the aimed health benefit due to reduction of CAD risk. As a result of screening there may be negative social consequences, such as problems with regard to the access to insurance. In the Netherlands, as in most other countries, health insurance is compulsory. The health system in the Netherlands can be classified as a Sickness Insurance model. The Netherlands has developed a mixed health care system in which approximately 70% of the population is covered for their medical costs (except chronic residential care) through an income related social health insurance, and the remaining 30% through private health insurance. [8] Insurance companies do not always accept people who apply for insurance, but a special insurance arrangement is available for persons difficult to insure. If, however, a person has to leave the social health insurance plan as a result of a higher income, national rules enforce acceptance by a private insurer. The last decade has shown a rapid fusion from many sick funds and private health insurers into fewer large insurance-bank companies. These companies offer a wide array of work disability and life insurance packages, often in combination with mortgages.

Individuals who apply for insurance have to fill in a health questionnaire. Coverage of claims depends on true response to this assessment of prior risks. However, the information asked for is restricted with regard to information from genetic tests. In the Netherlands, a moratorium has been declared on the use of genetic test results. In this moratorium, insurance companies state that below an amount of 300,000 Dutch guilders (approximately 85,000 British pounds) for life
insurance and below an amount of 60.000 Dutch guilders for the first year and 40.000 Dutch guilders for the second and following years in work disability insurance, the results of genetic tests do not have to be supplied (including information with regard to the suffering or death of family members due to serious untreatable familiar disorders). The Act on Medical Examinations, which has come into force in 1998, contains the same conditions.

Many European countries have no legislation or guidelines on insurance and medical examinations with respect to genetic testing. [9] Other countries (e.g. France) have guidelines and have imposed a moratorium on the use of genetic tests. In the UK, guidelines on genetic testing are proposed by the insurance industry, rather than by the government.

The issue of this paper is whether such a moratorium on the use of genetic tests or legislation protects participants of a genetic screening program from experiencing problems in the access to insurance.

**Empirical study**

We conducted an empirical study among individuals screened for FH in the Netherlands by the program mentioned above, in a period in which the moratorium and/or the Act on Medical Examinations were into force. The following questions were addressed:

- to which extent do individuals screened for FH, run into problems when applying for insurance (dependent on the test result);
- which problems were the most prevalent, if any;
- how did problems relate to the medical condition: were they due to having a mutation for FH or to an elevated cholesterol level alone.

From about 1000 persons screened between 1st of January 1994 and 31st of December 1997, 350 individuals aged 20 to 60 years with known test results were selected from the registration. We aimed for an equal distribution of age and gender in the group with (n=175) and without (n=175) a mutation for FH. The age range was chosen for two reasons. Life insurance and mortgages are predominantly relevant for this age range, and cholesterol levels for those aged over 60 often exceed cut-off points used by insurance companies.

Administrative data were made available by the organisation responsible for the screening programme (the StOEH-foundation). To protect privacy, the StOEH, rather than the investigators, invited selected persons to participate by means of a postal questionnaire. Questionnaires could be returned to the StOEH. One reminder was sent two weeks after the first questionnaire. The study was approved by the Medical Ethical committee of the Academic Medical Center.

Of the 350 addresses, 327 apparently were valid. Of the 327 individuals who received the questionnaire, 202 returned the questionnaire (61% response). More women than men returned the questionnaire (116 versus 86). Of the 202 respondents, 46 individuals applied for insurance in the period between being screened and the present study (23%). Of those 46 individuals who tried to get insurance, 17 encountered problems (37%; see table 1).

The type of problem most often encountered was the requirement to pay a higher premium, the requirement to undergo additional medical tests, the requirement to let the insurance company scrutinise medical records, and complete rejection of the application for insurance. If stated, the argument of the insurance companies to support their policy was the fact that the applicant had FH. Surprisingly, most (13 out of 17) individuals who encountered problems applied for a life insurance well below the cut-off points stated in the moratorium and the Act on Medical
Examinations, which implies that the applicants were not obliged to provide the insurance company with information on genetic testing.

The question remains whether the problems individuals encountered were due to having a genetic mutation for FH or to the elevated cholesterol level. The table shows the relation of the clinical risk data among the 46 respondents who applied for insurance.

| Table 1 Problems with insurance related to Clinical Risk: Mutation and Cholesterol level |
|-----------------------------------------------|---------------------|------------------|
| Clinical Risk                                 | Problems            |                  |
| Mutation                                      | Cholesterol level   | No               |
| No                                            | ≤ 6.5 mmol/l        | 11               |
|                                               | > 6.5 mmol/l        | 1                |
| Yes                                           | ≤ 6.5 mmol/l        | 7                |
|                                               | > 6.5 mmol/l        | 10               |
| Total                                         |                     | 29               |
| Problems                                      | Yes                 |                  |
| No                                            |                      | 0                |
|                                               |                      | 1                |
| Yes                                           |                      | 3                |
|                                               |                      | 14               |
| Total                                         |                      | 17               |
| Total                                         |                      | 46               |

We apply a 6.5 mmol/l cut-off in cholesterol level since insurance companies consider individuals with a cholesterol level above this cut-off point to be at increased risk of death. We used loglinear analysis with having problems as the dependent variable and the mutation and cholesterol level as independents. Correlation between the independent variables was assumed. We looked for the most economic model that would fit the data, meaning the model with the fewest interactions. The model in which only the mutation is associated with having problems fitted the data (Likelihood Ratio Chi Square = 2.32, df=2, p=0.31), while the model in which only the cholesterol level is associated with having problems did not. Therefore, from this analysis it seems that encountered problems primarily relate to the FH mutation. This policy is at discrepancy with the current scientific state of the art which acknowledges the cholesterol (level) to be the transmitter or carrier of the higher mortality risk associated with FH. However, given the small sample sizes of the different subgroups, a definite conclusion regarding this issue cannot be drawn.

Discussion

This empirical study has shown that in the Netherlands, which combines relevant guidelines and legal arrangements on the use of genetic testing in insurance affairs, individuals encounter unanticipated insurance problems as a result of participating in a genetic screening program. Although the number of individuals exposed to an insurance procedure is small (46) due to the limited follow-up time of tested persons, the proportion of those encountering problems (a third) is worrisome, even if one accounts for some selective response. Moreover, others reported similar data [10].

Even more disturbing was the presence of problems in cases where the Act on Medical Examinations explicitly rules out a role for genetic test information. From our study it is not clear why these problems occur, i.e. whether insurance companies ask questions regarding genetic testing or questions that can be read as such, or that individuals themselves give this information without being asked for it. The latter may be particularly true for the relatively uneducated. If asked for, only 14% of the individuals knew about the Act on Medical Examinations or the moratorium. The line of questioning or the repeated statement in questionnaires that insurance coverage is lost if the information supplied is incorrect may induce over-response by the
applicant. Furthermore, compared to questionnaires designed for scientific purposes (e.g. health risk measurement in surveys), the existing insurance questionnaires frequently appear ambiguous, providing the applicant no clues as how to interpret questions.

Our main conclusion is that implementation of the Act on Medical Examinations requires more control on its procedural execution. Moreover, the participants of a genetic screening programme, the public in general, but also those engaged in the insurance acceptance process should be educated about the existing guidelines regarding genetic testing. At this stage responsibilities are ill-defined. Recently, the screening organisation included explicit information on the issue prior to the testing procedure. Our case study demonstrates that the presence of national guidelines and regulations on the (mis)use of genetic information is but a prerequisite for appropriate use of genetic information in the context of insurance. Education of all involved, including the screenee/patient is equally important.

References


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Conflicts: None