Genetic Testing For Alzheimer's Disease And Its Impact On Insurance Purchasing Behavior

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ABSTRACT

New genetic tests for adult-onset diseases raise concerns about possible adverse selection in insurance markets. To test for this behavior, we followed 148 cognitively normal people participating in a randomized clinical trial of genetic testing for Alzheimer's disease for one year after risk assessment and Apolipoprotein E (APOE) genotype disclosure. Although no significant differences were found in health, life, or disability insurance purchases, those who tested positive were 5.76 times more likely to have altered their long-term care insurance than those who did not receive APOE genotype disclosure. If genetic testing for Alzheimer's risk assessment becomes common, it could trigger adverse selection in long-term care insurance. [PUBLICATION ABSTRACT]

FULL TEXT

Headnote

Widespread genetic testing for Alzheimer's susceptibility could present dilemmas for long-term care insurance. ABSTRACT: New genetic tests for adult-onset diseases raise concerns about possible adverse selection in insurance markets. To test for this behavior, we followed 148 cognitively normal people participating in a randomized clinical trial of genetic testing for Alzheimer's disease for one year after risk assessment and Apolipoprotein E (APOE) genotype disclosure. Although no significant differences were found in health, life, or disability insurance purchases, those who tested positive were 5.76 times more likely to have altered their longterm care insurance than those who did not receive APOE genotype disclosure. If genetic testing for Alzheimer's risk assessment becomes common, it could trigger adverse selection in long-term care insurance.

PROGRESS IN UNDERSTANDING the human genome and the recent development of genetic tests for susceptibility to adult-onset diseases have sparked debate in the public policy community regarding who should have access to genetic test results. Insurers argue that if they do not have access to such information, people who learn that their test results indicate an increased risk for serious adult-onset diseases would purchase more insurance coverage at prices that are below an actuarially fair rate. That is, genetic testing has the potential to create adverse selection in an insurance market.

The Actuarial Standards Board defines adverse selection as "the actions of individuals, acting for themselves or for others, who are motivated directly or indirectly to take financial advantage of the risk classification system."1 For example, if people know that they are at higher risk of dying from cancer at an early age, then they might be inclined to purchase life insurance to preserve wealth for surviving family members. If insurers are unaware of who might be engaging in this behavior, they would be unable to adjust their actuarial calculations and could face economic losses.2



Consumers and proponents of anti-genetic discrimination legislation argue that if genetic test results are shared with insurers, many consumers could be denied coverage or charged excessively high premiums. They note that distinctions made on the basis of genetic information are unfair because one's genetic makeup is immutable.3 In addition, researchers worry that the fear of discrimination may lead people to decline to participate in important genetic studies.4

These issues have moved policymakers to take action. At the federal level, the Health Insurance Portability and Accountability Act (HIPAA) of 1996 states that for the group health plans covered by the legislation, genetic information cannot be considered a preexisting condition in the absence of a diagnosis of the condition related to the genetic information.5 In October 2003 the U.S. Senate passed S. 1053, the Genetic Information Nondiscrimination Act, with unanimous support, and the House of Representatives is considering its version, H.R. 1910.6 Despite bipartisan support, immediate prospects for these bills to become law appear dim.7 Thirty-eight states have passed some form of legislation prohibiting the use of genetic information for risk selection and risk classification, but only seven prohibit genetic discrimination in life insurance without actuarial justification; only three extend their protections to disability and long-term care insurance.8 In sum, current public policy in this area is piecemeal at best.

Few empirical studies explore the validity of consumers' or insurers' claims. Studies of insurance discrimination have found mixed evidence on the question of insurance denial.9 Two studies that explore the question of how women's life insurance purchasing behavior changed after learning that they tested positive for the breast cancer (BRCAI) gene mutation have also yielded mixed results.10

Before developing further policies about who should have access to genetic test results, it is vital that we gain a better understanding of the extent to which genetic testing precipitates adverse selection or discrimination, or both, in insurance markets. This paper examines the potential for adverse selection in insurance markets in the context of testing for genetic susceptibility for Alzheimer's disease.

Alzheimer's is a common, late-onset disorder characterized by a progressive decline in cognition and functional abilities over eight to twenty years.11 At least 4.5 million Americans now have Alzheimer's disease, and the direct medical costs of caring for Alzheimer's patients are estimated to be as much as \$100 billion per year. Costs are expected to rise in the future, as it is estimated that 13.2 million people will have the disease by 2050.12

The three most important Alzheimer's risk factors are increasing age, a family history of the disease, and the presence of a specific allele of the Apolipoprotein E (APOE) gene. Every person has one maternally and one paternally inherited APOE allele of type 2, 3, or 4. The 4 allele confers increased susceptibility to the development of Alzheimer's but is neither necessary nor sufficient to cause the disease. The presence of one 4 allele increases the risk of developing the disease two- to threefold, while having two 4 alleles increases the risk to fifteenfold or higher in Caucasian populations. The 4 allele is found in approximately 15 percent of the population and more than half of clinically diagnosed Alzheimer's patients.13

Study Data And Methods

* Study design. The Risk Evaluation and Education for Alzheimer's Disease (REVEAL) Study is a recently completed randomized controlled trial (RCT) evaluating the impact of a genetic education and counseling program for adult children of Alzheimer's patients.14 As the largest study of its kind, it provides a rare opportunity to gain initial insights into die relationship between genetic testing for Alzheimer's disease and insurance purchasing behavior.



Participants in the REVEAL Study were either self-referred or systematically ascertained through their family's membership in existing Alzheimer's research registries in Boston, Cleveland, or New York City. Recruitment began in August 2000, and the last of the follow-up respondent surveys was completed in October 2003. A total of 162 participants were randomized into the clinical trial.15 All study participants were at higher-than-average risk for developing Alzheimer's because the protocol required all participants to have at least one parent affected by the disease.

In the control arm of the REVEAL Study, participants were informed of their risk of developing Alzheimer's based on sex and family history alone, with lifetime risk estimates ranging from 18 percent to 29 percent. Meanwhile, intervention-group participants learned their APOE genotype and were informed of their risk on the basis of sex, family history, and genotype, with lifetime risk estimates ranging from 13 percent to 57 percent.16

Of the 162 people in the study, 148 were included in the analyses that follow. The remaining fourteen were excluded because they had missing data on one or more of the covariates. Among the 148 subjects, 46 were in the arm of the study where there was no APOE disclosure, 54 learned that they were 4 negative, and the remaining 48 learned that they were 4 positive (that is, had one or two 4 alleles).17

* Participants' characteristics. Participants' sociodemographic information illustrates that the REVEAL sample, like all research volunteer samples, is not a representative sample of the population (Exhibit 1). People in this study were more likely to be white, female, and well educated than members of the general population. Participants were also typically older than the general population, since participants had to be an adult child of a diagnosed Alzheimer's patient. Before intervention, it was ascertained that 97 percent of the sample had health insurance, 78 percent had life insurance, 40 percent had disability insurance, and 19.8 percent had longterm care insurance.18 These high rates of insurance coverage likely reflect the age, education, and ethnic composition of the sample.

* Approval and confidentiality protocols. The REVEAL Study was approved by the institutional review boards for human research protection at each participating institution and was monitored by an ethics advisory board. Participants gave informed consent and were assured the protection of their genetic information through standard research confidentiality protocols as well as by a National Institutes of Health (NIH) Certificate of Confidentiality.19 Genetic counselors presented semi-scripted education sessions that described APOE testing and the REVEAL Study research protocol. The possibility of genetic discrimination was mentioned by the counselors and in the study consent form, but in neither case was it described in detail. Educational sessions also focused on the possible benefits, risks, and limitations of genetic susceptibility testing, including the current lack of preventive options for Alzheimer's. All counseling was nondirective. Counseling did not explicitly focus on insurance issues.

* Outcome measures. Primary outcome measures in the REVEAL Study focused on determining the social and psychological impact of learning one's genotype. Additional study measures evaluated changes that participants reported making, or planned to make, in health, life, disability, and long-term care insurance following risk disclosure. These questions were asked in interviews that occurred six weeks, six months, and one year after risk disclosure. We used responses from all three questionnaires to construct variables that measured whether or not a respondent ever changed or thought about changing insurance coverage during the first year following risk assessment and disclosure.20

Given that participants knew their test results but insurance companies did not, proponents of the adverse selection theory would predict that those who tested positive for the 4 allele would be more likely to increase their



insurance coverage than those who tested negative or who did not receive APOE disclosure. We tested this hypothesis using a multivariate logit model that examined the impact of testing status on insurance changes controlling for possible confounding factors (such as marital status, age, sex, and education).21

Study Results

* Bivariate analysis. In the case of health, life, and disability insurance, we found no significant differences in reported insurance changes by disclosure status (Exhibit 2). When respondents were asked if they were "thinking about" making changes, we found no significant differences between the groups in the health and disability insurance categories. Those who tested positive for the 4 allele, however, were moderately more likely to be thinking about changing their life insurance coverage (p <.10). Long-term care insurance was the one domain where people who tested positive for the 4 allele reported having made more changes (p <.05) and to have been thinking about making changes (p <.05).

* Multivariate analysis. Exhibit 3 shows the estimated odds ratios for the long-term care insurance logits. These estimates control for testing status and covariates that may also be associated with long-term care insurance changes. Participants who learned that they had tested positive for the 4 allele were more likely than those who did not receive disclosure information to have reported making changes in long-term care insurance (p = .0511) even after marital status, age, sex, education, concern about developing Alzheimer's, past/present experience as an Alzheimer's caregiver, and whether or not the respondent had any long-term care insurance at baseline were controlled for. In contrast, the bivariate relationship between APOE disclosure and thinking about changing long-term care insurance disappeared when we controlled for these covariates.

Given the modest sample size, sensitivity tests were run to determine if the estimated relationship between testing positive for the 4 allele and making changes in long-term care insurance was robust. Bootstrap estimates of the long-term care insurance change equation presented in Exhibit 3 reveal that our results are only suggestive.22 Definitive confirmation of our result must await larger, more sociodemographically diverse samples.

Discussion And Policy Implications

This is one of only three empirical investigations of the extent to which genetic testing for adult-onset diseases contributes to adverse selection in insurance markets. Of these, it is the only study to employ an RCT methodology. It adds to the small but growing literature on genetic testing and adverse selection and offers the following policy implications.

* Adverse selection. First, there was little evidence of adverse selection in the health, life, and disability insurance markets despite the fact that the sample consisted of highly motivated people (that is, all had a family history of Alzheimer's disease and were highly educated) who were participating in a closed research trial where confidentiality of genetic information was guaranteed. This finding might be expected, however, given the ages of the participants, the relatively short period of follow-up (one year), people's typical insurance buying patterns, and the unique attributes of various insurance products.23

* Long-term care insurance. Second, the one insurance domain where we found suggestive evidence of adverse selection is long-term care. Almost 17 percent of those who tested positive subsequently changed their long-term care insurance coverage in the year after APOE disclosure, compared with approximately 2 percent of those who tested negative and 4 percent of those who did not receive APOE disclosure.24 The overall percentage with long-term care insurance rose from 19.8 percent at baseline to 27 percent just one year later.25 Roughly three-quarters



of this increase is attributable to study participants' having learned that they had tested positive for the 4 allele. Controlling for other insurance-related covariates, we found that participants who tested positive were 5.76 times more likely to change their long-term care insurance coverage during the subsequent year than were those who did not receive APOE disclosure (although this finding is not reinforced by the sensitivity analyses).

* Potential for adverse selection. Policymakers who are attempting to balance consumers' concerns regarding potential genetic discrimination against insurers' concerns that the withholding of genetic test results would make insurance markets unprofitable should proceed with caution. Our findings imply that the potential for adverse selection may vary considerably by insurance market, thus making it difficult to design a public policy that works well in all instances.26

It may be that the natural history of Alzheimer's disease combines with APOE testing and the characteristics of the mostly private long-term care insurance market to create the "perfect storm" with regard to adverse selection. That is, (1) Alzheimer's is a condition that has a high probability of requiring formal, long-term care services; (2) APOE testing gives significant, albeit incomplete, predictive information for the at-risk population; and (3) long-term care insurance is generally a private insurance market where an information asymmetry can have serious consequences. Taken in combination, these conditions create a situation where adverse selection may occur and where its consequences for insurers and consumers may be significant. This premise is consistent with the fact that we observe a positive relationship between testing positive and changing one's long-term care insurance coverage even in our relatively small sample.

APOE genotyping for risk assessment is not now recommended in asymptomatic people, but the field of Alzheimer's research is moving toward risk profiling and preventive treatments, so this could change.27 With 15 percent of the population carrying the 4 allele, would widespread APOE testing affect the viability of the long-term care insurance market? Long-term care insurance pricing for Alzheimer's depends on factors such as population incidence, claims experience, and estimates of the degree of adverse selection. A definitive estimate of the degree of potential adverse selection in this market cannot be ascertained until more empirical work is done with samples that include socioeconomically and demographically diverse segments of the population. But we do know that Alzheimer's is responsible for the longest, most common, and most costly long-term care insurance claims.28

* Impact on insurance costs. Major increases in higher-risk policyholders would be accompanied by increases in long-term care insurance costs. How these increased costs would be shared among policyholders at higher or lower risk of Alzheimer's, and whether prices would reach a level that is unattractive to most buyers, would depend on business and public policy decisions that are beyond the scope of this study.

IF GENETIC TESTING for Alzheimer's disease becomes more commonplace, it would likely precipitate the call for further policy action in the area of genetic testing and insurance. Those making policy choices would be faced with the dilemma of whether to handle genetic risk in insurance through market stratification driven by an absence of policy rules or by imposing rules (for example, nondiscrimination laws, mandatory universal coverage, or mandatory disclosure of genetic test results to insurance companies in the case of large policies). In making these choices, policymakers would need to balance considerations regarding consumers' rights to protect themselves from uncontrollable health risks with the insurance industry's adverse selection concerns that could affect product affordability.

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Footnote

NOTES

1. Actuarial Standards Board, Actuarial Standard of Practice no. 12 Concerning Risk Classification, section

2.1,1989, www.actuarialstandardsboard .org/pdf/asops/asop012_014.pdf (14 December 2004).

2. RJ. Pokorski, "Insurance Underwriting in the Genetic Era," American Journal of Human Genetics 60, no. 1 (1997): 205-216.

3. RR. Billings, "Discrimination as a Consequence of Genetic Testing," American journal of Human Genetics 50, no. 3 (1992): 476-482.

4. National Human Genome Research Institute, "Genetic Discrimination in Health Insurance," June 2004, www.genome.gov/10002328#1 (28 September 2004).

5. Centers for Medicare and Medicaid Services, "The Health Insurance Portability and Accountability Act of 1996 (HIPAA)," 16 September 2004, www.cms.hhs.gov/hipaa (28 September 2004).

6. For details, see the Library of Congress Web site, thomas.loc.gov.

7. House Committee on Education and the Workforce, "Hearings by Subcommittee on Employer-Employee Relations: 108th Congress," edwork force.house.gov/hearings/108th/eer/eerhearings .htm (14 December 2004).

8. See National Conference of State Legislatures, "Genetics and Health Insurance: State AntiDiscrimination Laws," www.ncsl.org/programs/ health/genetics/ndishlth.htm (14 December 2004); and "Genetics and Life, Disability, and Long-Term Care Insurance," October 2003, www.ncsl.org/programs/health/genetics/ ndislife.htm (14 December 2004).

E.V. Lapham, C. Kozma, and J.O. Weiss, "Genetic Discrimination: Perspectives of Consumers," Science 274, no. 5287 (1996): 621-624; EJ. Steinbart et al., "Impact of DNA Testing for Early-Onset Familial Alzheimer Disease and Frontotemporal Dementia," Archives of Neurology 58, no. 11 (2001): 1828-1831; and KJ. Wingrove et al., "Experiences and Attitudes Concerning Genetic Testing and Insurance in a Colorado Population: A Survey of Families Diagnosed with Fragile X Syndrome," American Journal of Medical Genetics 64, no. 2 (1996): 378-381.
K. Armstrong et al., "Life Insurance and Breast Cancer Risk Assessment: Adverse Selection, Genetic Testing Decisions, and Discrimination," American Journal of Medical Genetics Pan A 120, no. 3 (2003): 359-364; and C.D. Zick et al., "Genetic Testing, Adverse Selection, and the Demand for Life Insurance," American Journal of Medical Genetics 93, no. 1 (2000): 29-39.

11. R.C. Green, Diagnosis and Management of Alzheimer's Disease and Other Dementias, 2d ed. (Caddo, Okla.: Professional Communications Inc., 2005).

12. L.E. Hebert et al., "Alzheimer Disease in the U.S. Population: Prevalence Estimates using the 2000 Census," Archives of Neurology 60, no. 8 (2003): 1119-1122.

13. A.D. Roses, "Apoliopoprotein E Affects the Rate of Alzheimer Disease Expression: Beta-Amyloid Burden Is a secondary Consequence Dependant on APOE Genotype and Duration of Disease," Journal of Neuropathology and Experimental Neurology 53, no. 5 (1994): 429-437; and LA. Farrer et al., "Effects of Age, Sex, and Ethnicity on the Association between Apolipoprotein E Genotype and Alzheimer Disease: A Meta-Analysis," Journal of the American



Medical Association 278, no. 16 (1997): 1349-1356.

14. R.C. Green, "Risk Assessment for Alzheimer's Disease with Genetic Susceptibility Testing: Has the Moment Arrived?" Alzheimer's Care Quarterly 3, no. 3 (2002): 208-214; JS. Roberts et al., "Reasons for Seeking Genetic Susceptibility Testing among First-Degree Relatives of People with Alzheimer Disease," Alzheimer Disease and Associated Disorders 17, no. 2 (2003): 86-93; and J.S. Roberts et al., "Who Seeks Genetic Susceptibility Testing for Alzheimer's Disease? Findings from a Multisite, Randomized Clinical Trial," Genetics in Medicine 6, no. 4 (2004): 197-203.

15. Initially, 179 people were self-referred to the study through the media and memory clinics. Another 169 were contacted through an Alzheimer's research registry, for a total of 348. Of these 348,206 attended a prestudy Alzheimer's education session. Of the 206,162 agreed to participate in the blood draw and counseling session and followed through with the study.

16. See Farrer et al., "Effects of Age, Sex, and Ethnicity"; R.C. Green et al., "Risk of Dementia among White and African American Relatives of Patients with Alzheimer Disease," Journal of the American Medical Association 287, no. 3 (2002): 329-336; and L.A. Cupples et al., "Estimating Risk Curves for First-Degree Relatives of Patients with Alzheimer's Disease: The REVEAL Study," Genetics in Medicine 6, no. 4 (2004): 192-196.

17. Having two 4 alleles raises the risk of developing AD more than having one 4 allele. There were only three people in the 4 positive group who had two 4 alleles. Their small numbers precluded undertaking analyses comparing the insurance behavior of those having two 4 alleles with that of other study participants.

18. Nationally, only 7 percent of people age sixty-five and older carry long-term care insurance. M. Niefield et al., "Long-Term Care: Medicaid's Role and Challenges" (Washington: Kaiser Commission on Medicaid and the Uninsured, November 1999). The fact that our respondents' initial holdings were almost three times the national average reinforces our contention that the sample is not representative of the general population.

19. This certificate allows "the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding whether at the federal or state or local level." National Institutes of Health Office of Extramural Research, "Certificates of Confidentiality Kiosk," grantsl.nih.gov/ grants/policy/coc/index.htm (14 December 2004).
20. People were included in the analysis if they responded to any of the insurance change questions and if they did not have missing data on any of the covariates. If a person's insurance responses were missing at either the sixmonth or one-year interview, his/her response from the preceding interview was used to measure insurance change.

21. A logit estimating routine is used because of the qualitative nature of the dependent variable (that is, 1 = yes, 0 = no). See W.H. Greene, Econometric Analysis (New York: Macmillan, 1993).

22. Using bootstrap estimation with 10,000 replications, we obtained an odds ratio estimate associated with testing positive for the 4 allele of 1.75. The bias-corrected (BC) 95 percent confidence interval estimation for this estimate was -1.42 to 19.8. Since this interval includes zero, we must be cautious in our interpretation of the logit regression results.

23. Health insurance is typically obtained through an employer with no underwriting, and disability insurance would typically play a very small role in providing coverage for a late-onset progressive disease such as Alzheimer's. The need for additional life insurance also would likely be minimal, given that in most instances, children would have been raised and the mortgage would have been paid off by the time this late-onset disease struck. In contrast, long-term care insurance is designed specifically to protect financial assets and to minimize caregiving burdens of close family members late in one's life. For all of these reasons, those in our sample who had the 4 allele of the APOE gene are not likely to see any economic need to alter health, disability, or life insurance coverage.

24. A careful review of the open-ended responses to the insurance questions found no instances where participants who were e4-negative decreased their insurance coverage during the year.

25. Because a genetic test result is permanent, it is quite possible that these percentages would increase over



time. In particular, people who learned their genetic test results at a relatively young age (before age fifty) may believe that they need not change their long-term care insurance holdings in the short term.

26. The potential may also vary by the genetic test in question, although we could not investigate this. 27. See, for example, H. Brodaty et al., "Consensus Statement on Predictive Testing for Alzheimer Disease," Alzheimer Disease and Associated Disorders 9, no. 4 (1995): 182-187; L.A. Farrer et al., "Statement on Use of Apolipoprotein E Testing for Alzheimer Disease," journal of the American Medical Association 274, no. 20 (1995): 1627-1629; and LM. McConnell et al., "Genetic Testing and Alzheimer Disease: Has the Time Come?" Nature Medicine 4, no. 7 (1998): 757-759.

28. Society of Actuaries, Long Term Care Experience Committee Intercompany Study, 1984-1999 (Schaumberg, Ill.: SOA, September 2002).

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DETAILS

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