Genetic Insurance Discrimination in Sudden Arrhythmia Death Syndromes
Empirical Evidence From a Cross-Sectional Survey in North America

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Background—There is virtually no information assessing the insurability of families affected with Sudden Arrhythmia Death Syndromes (SADS) for the determination of the nonclinical implications of genetic screening. It is important to identify the barriers and challenges faced by families as a result of genetic screening for SADS to enable equitable access to insurance coverage.

Methods and Results—To explore the insurance coverage experiences of SADS-affected families, we administered a cross-sectional online survey across North America from April 28, 2012 to November 13, 2013. Participants included individuals with a SADS diagnosis and their relatives who have applied for insurance (health, life, travel, and disability) or have existing insurance coverage. Of 202 participants, 92% had a SADS diagnosis (92%) as either a proband (50%) or an affected relative (42%); 8% of participants were unaffected family members of a proband; and genetic confirmation was reported by 73%. Of the 54% of SADS respondents who applied for insurance, 60% were rejected by insurers. The preexisting SADS diagnosis was the major reason reported for rejection (57%). Most respondents (80%) had insurance coverage through a spouse/parent plan at the time of diagnosis; 14% experienced a subsequent negative effect on coverage. Thirty-nine percent of affected SADS respondents reported an increase in insurance premium rates.

Conclusions—Increased genetic testing has negatively impacted insurability for SADS patients and affected family members. The challenges in obtaining life and health insurance are mainly because of the preexisting condition, even in the presence of protective laws in the United States. (Circ Cardiovasc Genet. 2017;10:00-00. DOI: 10.1161/CIRCGENETICS.116.001442.)

Key Words: genetic testing ■ genetics ■ insurance coverage ■ Long QT syndrome ■ syndrome
prognostic, and therapeutic) to assess family members at risk, identify the underlying cause of the condition, and guide treatment for channelopathies and cardiomyopathies is well documented in international consensus statements by the Heart Rhythm Society, the European Heart Rhythm Association, the American Heart Association,5,12 and the Canadian Cardiovascular Society/Canadian Heart Rhythm Society.13 However, genetic testing for inherited cardiac arrhythmias has resulted in the emergence of psychosocial and ethical issues for those given a diagnosis or determined to be an at-risk individual.14 These include stigma, privacy, insurability, and employment discrimination from the misuse of the genetic information.15,16 These nonclinical implications (ie, ethical, legal, and social implications) of genetic testing for inherited cardiac arrhythmias have not been addressed in North America.17

Insurers determine insurance eligibility on the basis of medical history and perceived risk of an individual experiencing a significant medical event (R. Chan, Clarity Group Financial Inc, personal communication, December 1, 2011) with little concern for risk stratification and based on limited knowledge of genotype–phenotype correlations of these conditions.18 There is evidence that individuals with genetic conditions have faced challenges in obtaining health and life insurance from the existing discriminatory practices of insurance companies, either because of the presence of a preexisting condition or having a genetic predisposition.19–21 However, there is a paucity of data describing the nonclinical ethical, legal, and social implications of genetic testing or implications of having the underlying inherited cardiac condition within the family, such as insurability, for affected individuals with inherited cardiac diseases or their family members. To address this knowledge gap, we elected to review the current experiences of Canadian and American individuals with a SADS diagnosis and their family members who have applied for insurance (health, life, travel, and disability insurance) and have existing insurance coverage.

Methods

Study Design
This cross-sectional study using an online survey instrument was performed with participants who met the following inclusion criteria: (1) living in Canada or the United States, (2) diagnosed with SADS and have applied for health insurance, life, travel, or disability insurance and have existing insurance coverage, and (3) family member of a SADS diagnosed individual who has applied for health, life, travel, or disability insurance and have existing insurance coverage. There were 202 eligible study participants who were administered the survey between April 28, 2012 and November 13, 2013. We sought to explore the experiences of families affected with SADS on accessibility to insurance and the impact on existing insurance coverage across North America. The recruitment phase remained open until the nonresponse duration >1 month was observed. The study was conducted according to the ICH-Good Clinical Practice guidelines and was approved by the University of British Columbia Children’s and Women’s Health Center’s Research Ethics Board, Vancouver, British Columbia (BC), Canada and participating centers. Written informed consent was obtained before the completion of the survey.

Survey Instrument
The survey incorporated the feedback from the SADS Foundations of Canada and the United States and select SADS families to determine the survey items. The survey instrument items consisted of (1) citizenship, (2) SADS diagnosis, (3) clinical history, (4) insurance application (health, travel, disability, and life), and (5) insurance coverage under a spouse/parent plan. The design captured the various scenarios that classify individuals affected with SADS: (1) proband (gene positive and phenotype positive), the first individual in their family with a SADS diagnosis, (2) affected relative (gene positive and phenotype positive) with a SADS diagnosis and not a proband, (3) unaffected relative (gene negative and phenotype negative), and (4) asymptomatic, concealed carriers (ie, gene positive and phenotype negative). The survey took ≈15 minutes to complete, asking a set of multiple choice, closed-ended and open-ended questions specific to those diagnosed with SADS, on experiences applying for insurance (ie, health, life, travel, and disability), and on experiences with existing insurance coverage with a spousal or parental plan. The survey was prepared originally in English and then translated into French and Spanish by a certified translator. The electronic version of the survey was set up using the Research Electronic Data Capture.22 Research Electronic Data Capture is a secure, password-protected, and encrypted electronic data capturing system maintained at the Child and Family Research Institute at BC Children’s Hospital in Vancouver, BC.

Study Enrollment
The survey was advertised to eligible participants with the cooperation of the SADS Foundations of Canada and the United States. These groups promoted the survey by posting the survey link on their website and in e-newsletters to recruit affected SADS families to complete the survey. Because these family support groups provide access to educational resources to patients and families with SADS conditions, we felt this recruitment strategy would be most effective to capture the study population of interest across North America. The cover page of the survey described the request for consent to voluntarily complete the survey and its anonymity for the assurance of confidentiality and privacy of the information collected. There was no collection of any identifying information such as name, personal health information, or date of birth.

Statistical Analysis
Data stored in Research Electronic Data Capture were exported to a statistical software program (SAS version 9.3; SAS Institute, Cary, NC). Descriptive analysis of the data was performed to summarize the data. Rejection rate in the group of respondents with an implantable cardioverter–defibrillator (ICD) was compared with the rate in those without an ICD using a χ² test with significance level P<0.05. Frequency tables were generated for all categorical variables, and values were reported as a percentage or proportion.

Results

Survey Respondents
A total of 202 participants completed the survey over a 1.5-year study period. The majority of respondents were American (91%). Most respondents had a SADS diagnosis (92%) as either a proband (50%) or an affected relative (42%). Unaffected family members of a proband constituted 8% of all survey respondents completing the entire survey. There were no respondents who could be classified as concealed carriers.

The clinical characteristics of affected SADS respondents, either a proband or an affected relative, are illustrated in Table 1. Genetic testing supported the SADS diagnosis as reported by 71% of probands and 79% of affected relatives. A majority of affected respondents (proband and affected relatives) reported a diagnosis of LQTS, 85% and 90%, respectively. Other reported SADS diagnoses included catecholaminergic polymorphic ventricular tachycardia, Brugada Syndrome, arrhythmogenic right ventricular cardiomyopathy, and Short QT syndrome (Table 1).
symptoms related to their SADS diagnosis were reported by all affected relatives and 73% of probands. The symptom most experienced was palpitations reported by 60% of probands and 38% of affected relatives. Other reported symptoms included syncope (fainting), presyncope (feeling faint), cardiac arrest, ICD shocks, and seizure. Most affected respondents were on medical treatment for their SADS diagnosis (proband, 84% versus affected relative, 93%), most frequently β-blockers; only 7% of probands reported taking other antiarrhythmic agents. A total of 50% of affected SADS respondents had an ICD.

Insurability Experiences

Applying for Insurance

The insurability experiences of all survey respondents (who completed this section) are summarized in Table 2. Fifty-four percent of all respondents had applied for insurance, after a diagnosis of SADS in the family, including health, life, travel, or disability. Application rejections were reported by affected relatives (64%), probands (59%), and unaffected relatives (25%) who applied for insurance. Most rejections were for life insurance as reported by 67% of probands, 67% of affected relatives, and 50% of unaffected relatives. Health insurance was also denied by insurance companies as experienced by 50% of unaffected relatives, 44% of affected relatives, and 24% of probands. On conducting a similar analysis on the subgroup of LQTS diagnosed individuals, the results were found to be similar on insurance application rejections and factors affecting insurance coverage; 55% of all respondents with LQTS faced application insurance rejections. Over half of all LQTS respondents on medical treatment or with an ICD who applied for insurance also experienced rejections (59% versus 67%, respectively). In the group of affected respondents with an ICD who applied for insurance (n=35), 23 experienced rejection; 16 out of 32 affected respondents without an ICD experienced rejection when they applied for insurance. There was no statistically significant difference in the rates of rejection between these 2 groups (P=0.19).

Only a small proportion of affected SADS respondents (6% probands and 7% affected relatives) reported other significant health issues that may have affected their insurability. Approximately 18% of affected SADS respondents reported that they were forced to pay higher than standard premium rates because of a SADS diagnosis in the family.

Insurance Coverage From a Spousal or Parental Plan

Insurance coverage through a spousal or parental plan was reported by 93% of unaffected relatives, 81% of probands, and 79% of affected relatives (Table 2). Insurance coverage was affected as a result of the SADS diagnosis for affected relatives (23%), unaffected relatives (14%), and probands (11%).

Reasons for Insurance Application Rejections

An explanation for insurance application rejection was provided by insurers to 67% of all affected SADS respondents (who reported the reasons given as illustrated in Figure 1). The major reason for rejections was because of the preexisting SADS condition (57%) followed by the perception of the high-risk nature of the SADS condition (32%). Eleven percent of all affected SADS respondents disclosed that their applications were rejected because of having an ICD, whereas 4% reported reasons such as having a cardiac arrest and factors unrelated to the SADS condition.

Factors Affecting Insurance Coverage

Ninety-three percent of affected SADS respondents reported factors influencing their insurance coverage through a spousal or parental plan. Insurance coverage was primarily affected by an increase in premium rates as reported by 39% of respondents (Figure 2). Other factors reported include the cancellation or loss of coverage (23%), partial or lack of coverage for SADS-related events (15%), rejected claims (8%), and no coverage for genetic testing (8%).

<table>
<thead>
<tr>
<th>Table 1. Clinical Profile of Affected SADS Respondents*</th>
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</thead>
<tbody>
<tr>
<td><strong>Descriptive Variables</strong></td>
</tr>
<tr>
<td>SADS diagnosis</td>
</tr>
<tr>
<td>LQTS</td>
</tr>
<tr>
<td>CPVT</td>
</tr>
<tr>
<td>Brugada Syndrome</td>
</tr>
<tr>
<td>ARVC</td>
</tr>
<tr>
<td>Other cardiac arrhythmias</td>
</tr>
<tr>
<td>SQTS</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
<tr>
<td>Genetic testing (to confirm SADS diagnosis)</td>
</tr>
<tr>
<td>Symptoms related to the SADS diagnosis</td>
</tr>
<tr>
<td>Type of symptoms</td>
</tr>
<tr>
<td>Palpitations</td>
</tr>
<tr>
<td>Syncope (fainting)</td>
</tr>
<tr>
<td>Presyncope (feeling faint)</td>
</tr>
<tr>
<td>Cardiac arrest</td>
</tr>
<tr>
<td>ICD shocks</td>
</tr>
<tr>
<td>Seizure</td>
</tr>
<tr>
<td>Medical treatment for SADS diagnosis</td>
</tr>
<tr>
<td>Medication type</td>
</tr>
<tr>
<td>β-blockers</td>
</tr>
<tr>
<td>Antiarrhythmic agents</td>
</tr>
<tr>
<td>Have an ICD for the SADS diagnosis</td>
</tr>
</tbody>
</table>

*Values reported as a percentage (proportion).
†Proband as defined as the first member of the family diagnosed with SADS.
‡Affected relative defined as an SADS diagnosed family member of a proband.

ARVC indicates arrhythmogenic right ventricular cardiomyopathy; CPVT, catecholaminergic polymorphic ventricular tachycardia; ICD, implantable cardioverter-defibrillator; LQTS, Long QT syndrome; SADS, Sudden Arrhythmic Death Syndromes; and SQTS, Short QT syndrome.

SADS diagnosis 53% (53/100) 41% (12/29)

Factors affecting insurance coverage; 55% of all respondents with LQTS faced application insurance rejections. Over half of all LQTS respondents on medical treatment or with an ICD who applied for insurance also experienced rejections (59% versus 67%, respectively). In the group of affected respondents with an ICD who applied for insurance (n=35), 23 experienced rejection; 16 out of 32 affected respondents without an ICD experienced rejection when they applied for insurance. There was no statistically significant difference in the rates of rejection between these 2 groups (P=0.19).

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To our knowledge, this is the first study to explore the insurability experiences of affected SADS families, largely from the United States, and shows evidence of the nonclinical implications of the genetic diagnosis of SADS, that is, genetic discrimination. Genetic discrimination is a negative social consequence of genetic screening for inherited disorders and exists even when an individual who receives a genetic diagnosis remains asymptomatic. Within the context of insurability, genetic discrimination manifests as a result of an individual’s preexisting genetic condition or a genetic predisposition for the denial of insurance or increased costs for insurance coverage, especially for health and life insurance. There have been many published studies on genetic discrimination and life insurance for genetic conditions, and our study adds to the literature, being the first North American study relevant to this topic.

Our data suggest that insurance application rejections at 56% for the whole cohort and 60% for probands and affected relatives (mutation carriers) are both higher than the 33% reported in a cross-sectional Dutch survey involving hypertrophic cardiomyopathy mutation carriers who experienced rejections when applying for insurance. This difference is not surprising as the Netherlands has a law in place, the Medical Examination Act, to protect individuals from being denied pension, life, or disability insurance by insurance companies on the basis of DNA test results or genetic information; the federal laws in the United States do not provide protection against

**Table 2. Insurability Experiences of Affected SADS Individuals and Family Members**

<table>
<thead>
<tr>
<th>Descriptive Variables</th>
<th>Proband†</th>
<th>Affected Relative‡</th>
<th>Unaffected Relative§</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insurance application</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Applied for insurance (since the SADS diagnosis)</td>
<td>56% (56/100)</td>
<td>48% (14/29)</td>
<td>53% (8/15)</td>
<td>54% (78/144)</td>
</tr>
<tr>
<td>Insurance application rejection</td>
<td>59% (33/56)</td>
<td>64% (9/14)</td>
<td>25% (2/8)</td>
<td>56% (44/78)</td>
</tr>
<tr>
<td>Life insurance</td>
<td>67% (22/33)</td>
<td>67% (6/9)</td>
<td>50% (1/2)</td>
<td>66% (29/44)</td>
</tr>
<tr>
<td>Health insurance</td>
<td>24% (8/33)</td>
<td>44% (4/9)</td>
<td>50% (1/2)</td>
<td>30% (13/44)</td>
</tr>
<tr>
<td>Disability insurance</td>
<td>6% (2/33)</td>
<td>0% (0/9)</td>
<td>0% (0/2)</td>
<td>5% (2/44)</td>
</tr>
<tr>
<td>Travel insurance</td>
<td>3% (1/33)</td>
<td>0% (0/9)</td>
<td>0% (0/2)</td>
<td>2% (1/44)</td>
</tr>
<tr>
<td>Significant health issues that may affect insurability (other than the SADS diagnosis)</td>
<td>6% (6/100)</td>
<td>7% (2/29)</td>
<td>0% (0/15)</td>
<td>6% (8/144)</td>
</tr>
<tr>
<td>Assessed to pay higher than standard premiums because of an SADS condition in the family</td>
<td>17% (17/99)</td>
<td>21% (6/29)</td>
<td>0% (0/15)</td>
<td>16% (23/143)</td>
</tr>
</tbody>
</table>

**Figure 1.** Reasons provided by insurers to affected Sudden Arrhythmia Death Syndromes (SADS) respondents for application rejections. Description of reported reasons for insurance application rejections given by insurance companies. The high-risk nature of the SADS condition categorizes responses that referenced perceived risk on behalf of the insurers. ICD indicates implantable cardioverter–defibrillator.
Some initiatives undertaken to protect against genetic discrimination have been implemented. In particular, the Affordable Care Act should alleviate some concerns and social implications of genetic discrimination as discovered in our affected SADS study population will be reduced; the Affordable Care Act complemented the Genetic Information Nondiscrimination Act (2008) and the recently implemented Patient and Protection Affordable Care Act of 2010. Genetic Information Nondiscrimination Act was implemented to remove a perceived barrier to clinical genetic testing. It prevents health insurance companies from discriminating against an individual based on genetic information to determine insurance eligibility or influence their delivery of insurance. The Affordable Care Act complements the Genetic Information Nondiscrimination Act law by providing further protection to prohibit health insurance companies to deny policy enrollment or claims based on an individual’s health status, including pre-existing conditions, and also provides a provision to prevent the use of medical histories to calculate premium rates.

Since these provisions from The Affordable Care Act came into full effect on January 1, 2014, we anticipate that the evidence of genetic discrimination as discovered in our affected SADS study population will be reduced; the Affordable Care Act should alleviate some concerns and social implications of genetic testing. In particular, the issue of higher premium rates should be addressed; this was the most frequently reported factor affecting our SADS cohort’s (80%) existing insurance coverage (39%).

The insurance application rejection rate because of the preexisting SADS condition of 58% from our study is higher than the 14% reported by the Committee on Energy and Commerce, Congress of the United States. This committee investigated the insurance practices by 4 of the largest US for-profit health insurance companies, during 2007 to 2009, who denied health insurance coverage based on a preexisting condition. These results illustrate that, even with the enactment of protective laws, genetic discrimination occurs for families affected with SADS who were denied insurance mainly because of the preexisting condition (58%) and perceiving the condition as high risk (32%). The perceived risk of the SADS condition on behalf of insurers is unjustified for several reasons. Most patients with SADS who receive treatment have a favorable outcome; symptomatic patients (with LQTS) left untreated are reported to have a high mortality rate of 21% within 1 year from first syncope; however, those receiving appropriate treatment have a mortality rate of 1% during a 15-year follow-up. Classifying all individuals with LQTS as high-risk individuals is unsubstantiated; risk stratification exists for LQTS and other channelopathies. It is unlikely that these are known or applied by the insurers. Finally, being a mutation carrier does not necessarily indicate risk for SADS because diagnosed cases are not always confirmed by genetic testing. The applicability of genetic testing results can be limited because of the genetic heterogeneity, variable expressivity, penetrance of the underlying disease, and ongoing gene discovery of inherited arrhythmias. This variability in the phenotype expressivity limits the ability to identify risk factors for inherited cardiac arrhythmias. For example, the sudden death of a relative does not necessarily identify a risk of sudden death for another relative with the condition. As a result, genetic test results should not be considered by insurers to provide black and white insight on risk, and risk stratification tools should be used, when available.

The potential benefits of genetic testing for inherited arrhythmias as it applies to clinical practice are effective in preventing serious events such as a sudden cardiac arrest and sudden death in affected families with a confirmed definitive diagnosis and identification of at-risk gene carriers who are asymptomatic.
Treatment in the presymptomatic phase of these conditions saves lives. However, these negative insurance experiences faced by affected families with SADS may offset these benefits and oppose the recommendations for genetic testing for inherited cardiac disease.53–55 The genetic discrimination faced by affected SADS individuals may prohibit genetic testing and prevent or delay diagnosis, which can have significant negative impacts on health.53–55 Because of the substantial nonclinical ethical, legal, and social implications a genetic diagnosis for SADS may carry, a genetic counselor with extra training in cardiovascular genetics should be aware of the protective laws and policies for proper pre- and post-test genetic counseling to address the risks of testing, such as insurability, among other issues.17,56,57

Limitations
There are a few study limitations to be noted. The study design did not allow for the calculation of the survey response rate. The recruitment method used through the online advertisements by the patient advocacy organizations was used to maximize the response rate across North America. As a result, we were not able to determine the number of eligible participants who were aware of the online survey but did not complete it.

The majority of our SADS study cohort of probands and affected relatives comprised LQTS diagnosed individuals (86%). However, because the diagnostic yield of genetic testing for LQTS is considered to be the highest (75% to 80%) among all other channelopathies,14 this percentage of patients with LQTS is not unusual and likely reflects a bias stemming from the population drawing from families who choose to interface with the SADS Foundations of the United States and Canada. Similarly, the high prevalence of ICDs in the LQTS cohort represents a selection bias in terms of respondents because most individuals with LQTS do not require ICDs.

The sample size served to be a limitation as well. Although the clinical manifestation of SADS conditions is heterogeneous and the survey was inclusive of the various scenarios of affected individuals and family members in this study, we were unable to capture respondents who were asymptomatic gene carriers or concealed carriers (ie, gene-positive and phenotype-negative relatives). Also, the affected and unaffected relative subgroups were under-represented. Although 85 affected relatives completed the questions on citizenship and the type of insurance in the United States, this study also emphasizes the need for future studies to validate these findings and conduct further exploratory studies in Canada. Because no protective laws exist in Canada,56 it might be useful to further investigate the experiences of Canadians who have genetic testing and subsequently apply for insurance, to determine how to best structure new protective laws. Even in the United States, where Genetic Information Nondiscrimination Act does exist, fear for insurance discrimination is still the second most common reason for individuals to decline genetic testing, and it has been found that those who may take comfort in the enactment of protective laws are unaware of their existence.58 With that in mind, protective laws may become more effective if we can work to make affected individuals more aware of them.

Conclusions
In summary, the survey findings identify the challenges in accessing health or life insurance faced by affected families, secondary to a SADS diagnosis. Proper education and genetic counseling before and after the test results are available and should be encouraged for individuals and family members undergoing genetic testing for SADS. The support of patient advocacy groups, genetic counselors, and clinicians is also needed, the importance of which is emphasized by the Canadian Cardiovascular Society and Canadian Heart Rhythm Society, as well as the Heart Rhythm Society.13,59 A follow-up quantitative study should be undertaken to conduct in-person interviews with affected SADS families and with genetic counselors to determine their knowledge of current laws and pre- and post-genetic counseling practices.

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Disclosures
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