



## Patient-perceived risk associated with epilepsy and its medication treatment

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### ABSTRACT

Regardless of the expert advice of health care practitioners, it is ultimately the patient's decision how to best manage his or her condition. This decision can be influenced by the perceived risk of both the disease and its treatment. The objective of this study was to develop a survey to evaluate perceived risk associated with epilepsy and its medication treatment. Risk was evaluated in five domains: performance, financial, social, psychological, and physical. A 40-item patient-perceived risk questionnaire was developed and administered to patients at one university-affiliated epilepsy clinic. Pearson correlation and regression analysis was used to identify significant components of overall perceived risk. A total of 64 patients completed the survey. Performance and physical risk significantly explained 34% of the variance in overall perceived risk associated with epilepsy. The overall perceived risk associated with the treatment of epilepsy was explained by performance, physical, psychological, and social risks ( $r^2 = 0.386$ ). Thus, the treatment of epilepsy poses more challenges for patients to maintain their lifestyle than the disease itself.

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### 1. Introduction

Patients with epilepsy are prescribed medication to prevent seizures, yet they may choose not to take their medication as directed. It has been estimated that between 30 and 60% of patients with epilepsy do not take their medication as prescribed [1–3]. A patient's decision to not take his or her medication is influenced by concern over potential side effects, the perceived benefit of the medication [4,5], and social and psychological factors [6]. Patient-perceived risk can have a significant impact on her or his decision to manage the condition [7,8]. Perception of risks associated with disease conditions and their treatment requires attention so that health care practitioners may help their patients live a productive and satisfying life.

Risk perception is defined as “the individual judgment of the likelihood that a consequent loss could occur and the seriousness of its likely consequence” [9]. Jacoby and Kaplan demonstrated that perceived risk consists of five components: *financial risk*, *performance risk*, *physical risk*, *psychological risk*, and *social risk* [10]. *Financial risk* is the uncertainty of cost related to a decision. *Performance risk* is potential inability of achieving a patient need such as controlling symptoms. *Physical risk* is associated with potential danger to the well-being of the patient or relevant others. *Psychological risk* is the unknown impact or perceived likelihood that a disease condition may have on a person's self-image or

self-concept. The last Jacoby–Kaplan risk category is *social risk*, which is the perception of how others may see patients if they are taking a certain medication or if they are diagnosed with a condition. Each of these risks is unique and is hypothesized to contribute to overall perceived risk.

Given the importance of patient-perceived risk related to the medical condition, this study developed a survey to assess how patients with epilepsy perceive their condition and its medication treatment by using Jacoby and Kaplan's perceived risk framework. Specific issues that concern patients with epilepsy and are considered likely to occur were identified. According to Jacoby and Kaplan's framework, the risk-relevant issues identified by patients with epilepsy were expected to correlate and to explain overall perceived risk of epilepsy and its treatment on lifestyle.

The purpose of this project was to develop a survey to evaluate patient-perceived risks associated with epilepsy and its medication treatment.

### 2. Methods

The study was conducted in two parts. In-depth patient interviews with open-ended questions were used to identify relevant patient issues associated with epilepsy and its medication treatment in a small group of patients with epilepsy. From the information gained in the patient interviews, a questionnaire with closed-ended questions to assess perceived risk was developed and administered to patients at their clinic appointment.

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Part 1 was designed to develop a survey that assessed patient-perceived risk related to epilepsy and its medication treatment. As there were no previously published studies to provide guidance as to patients' perception of epilepsy and its medication treatment, in-depth patient interviews were conducted. The interview questions were:

1. When were you diagnosed with epilepsy?
2. What concerns you about your epilepsy?
3. How long have you been on your current medication or medications?
4. What are your concerns about your current medical treatment?

The transcripts from the interviews were reviewed by the researchers. Patients' responses were documented and common themes emerged from the interviews. The responses were used to develop the perceived risk assessment survey for patients with epilepsy in Part 2. The questionnaire consisted of 20 perceived risk items related to both the level of concern patients feel regarding the risk and the likelihood of that risk event occurring, resulting in a total of 40 questions. The level of concern was measured on a 5-point interval scale ranging from *not at all concerned* (1) to *extremely concerned* (5). The 5-point interval scale was used for measuring the likelihood of the event occurring to the patient, and ranged from *very unlikely* (1) to *very likely* (5). A "not applicable" option was provided for each item if the patient did not feel the item pertained to him or her. Sample questions are available in the [Appendix](#) of this article.

Each of the perceived risk items comprised the level of concern the patient felt and the likelihood of that event occurring. The perceived risk item score was calculated by multiplying the level of concern rating by the likelihood of the event occurring rating, resulting in a potential range of 5 to 25. For example, if the patient scored a 4 (moderately high) on the concern scale for losing his or her job and a 2 (moderately low) on the likelihood scale, the perceived risk of losing his or her job would be 8 (moderately low overall perceived risk).

A separate question of overall perceived risk associated with epilepsy impacting the patient's lifestyle was measured on a 5-point interval scale ranging from *no risk at all* (1) to *extreme risk* (5). Similarly, overall perceived risk of medication for epilepsy impacting the patient's lifestyle was measured on the same 5-point interval scale. These two overall perceived risk measures were hypothesized to be dependent variables that are determined by item-specific risk measures. These measures could be classified as financial-, social-, psychological-, physical-, or performance-related risk measures.

The study population comprised patients with epilepsy seen at a tertiary care epilepsy clinic at a university-affiliated health system, located in a medium-sized Midwestern city. Patients older than 18 and able to complete the survey independently were selected. This instrument was administered to randomly select consenting patients.

Descriptive statistics were used to report the patient-perceived risk scores. A sample size of 66 patient responses was required to estimate perceived risk measured on a 5-point scale with  $\alpha = 0.05$  and a 0.1 level of precision. Pearson correlation was used to identify those individual perceived risk items that correlated with the overall perceived risk of epilepsy and its medication treatment on lifestyle. Multiple regression analysis was conducted with the overall risk measures as the dependent variables and the individual perceived risk items as the independent variables. Finally, univariate analysis was used to identify significant patient demographics related to the perceived risk measures. All statistics were tested at the 0.05 significance level using SPSS for Windows, Version 14.0.

### 3. Results

Biomedical institutional review board approval was obtained. Personal interviews were conducted with six patients with epilepsy in Part 1. The categorized issues that concerned the patients are listed in [Table 1](#). The patients expressed concerns about seizure control and the impact of their condition on the safety of their family and co-workers. Dependence on others to drive them to work and to social activities was a common issue expressed by the patients. This sense of dependence and control contributed to their feeling depressed about their condition. Patients stated that they tried to conceal their condition, because of their concern about other people viewing them negatively.

A total of 71 patients agreed to participate in the study, with 64 completing the survey (90%). The mean age was  $38 \pm 13$  years (mean  $\pm$  SD), and 58% of the participants were female. The average duration of epilepsy was  $16 \pm 14$  years (range: 0.1–51 years). The mean time since the patient's last seizure was  $78 \pm 243$  days (range: 0–1500 days). Respondents took an average of  $2.2 \pm 1.3$  antiepileptic drugs (AEDs) (range: 0–5). Twenty-seven percent were employed full-time, 14% were employed part-time (<32 hours/week), 20% were full-time homemakers, and 14% were disabled. The majority of the respondents (87%) had their epilepsy medication paid by private insurance or a government program. However, 13% of the respondents paid for all of their prescription medications out-of-pocket.

The demographic variables were compared with the overall perceived risk measures. There was no correlation between age, number of years since diagnosis, and overall perceived risk with the disease or its medication treatment ( $P > 0.05$ ). Also, overall perceived risk scores did not correlate with gender, education, employment status, or household income categories ( $P > 0.05$ ). Persons living alone or with others did not have a significant difference in their perceived risk score ( $P > 0.05$ ).

Each of the risk questions was analyzed to identify the risks relevant to the patient population ([Table 2](#)). Depending on others to drive the patient to work or to other places, losing control during a seizure, and becoming more restricted in life were risk measures with the highest scores. Almost half of the respondents felt that these events were very likely to occur. These patients were very concerned about side effects or other negative effects associated with their medication.

The Pearson correlation analysis comparing the individual perceived risk items and overall perceived risk impact on lifestyle is detailed in [Table 3](#). Losing control during a seizure, experiencing unexpected seizures, having a seizure alone, and experiencing side effects or other negative effects correlated to the overall perceived risk associated with epilepsy and medication used to manage epilepsy. Perceived risk associated with medication was also correlated with other psychological risk factors (i.e., feeling depressed, feeling bad about yourself) and social risk factors (i.e., others viewing you negatively, your family feeling bad about you). The significantly correlated risk factors were included in an overall perceived risk regression model.

The overall perceived risk associated with epilepsy on the patient's lifestyle was regressed with the independent variables perceived risk of losing control during a seizure, experiencing unexpected seizures, having a seizure alone, and experiencing side effects or other negative effects of the medication. The perceived risk of losing control during a seizure was the only significant independent variable. The regression model was significant ( $P = 0.00$ ) with an adjusted  $R^2$  of 0.34. The standardized  $\beta$  coefficient was 0.32, indicating that a 1-point increase in the perceived risk of losing control during a seizure will result in a 0.32-point increase in the overall perceived risk associated with the condition.

**Table 1**

Categorized issues concerning patients with epilepsy identified during personal interviews in Part 1

Financial	Performance	Physical	Social	Psychological
Job loss	Seizure control	Safety of others on the job	Dependency on others for transportation	Feeling depressed
Not obtaining desired job	Unexpected seizure	Safety of children under care of person with epilepsy	Burden on others	Feeling alienated
Affordability of care		Safety of unborn child		

**Table 2**Perceived risks identified by patients with epilepsy ( $n = 64$ )

Specific risk measure	Perceived risk score <sup>a</sup>	Very likely <sup>b</sup> (%)	Very concerned <sup>c</sup> (%)
You will become dependent upon others to drive you to work and to other places.	13.6 (10.7)	55	47
You will lose control during your seizure.	12.3 (9.3)	52	46
You will experience unexpected seizures.	11.2 (9.3)	50	41
You will have a seizure when alone.	10.9 (8.9)	53	33
Your life will become restricted.	12.2 (9.6)	43	47
You will experience side effects or other negative effects of your medication.	11.7 (8.0)	37	47
You will feel depressed.	11.1 (8.4)	45	38
You will feel bad about yourself.	9.4 (8.3)	31	30
You will lose money.	9.0 (9.7)	26	36
You will not work in your desired job.	8.7 (9.1)	31	30
Your family will feel bad about your epilepsy.	8.3 (8.2)	30	34
Others will view you negatively.	8.3 (7.1)	24	22
Your condition will worsen.	8.2 (7.2)	8	5
The children in your life will be frightened.	7.3 (7.6)	22	22
You will not be able to maintain the correct level of medication in your body.	6.9 (6.5)	20	37
There will be danger to others at work or at home.	6.0 (7.2)	11	33
You will miss taking medication on time.	6.0 (6.3)	14	33
You will lose your current job.	4.8 (6.9)	11	11
You will pass on epilepsy to your children.	5.1 (5.9)	3	18
There will be danger to an unborn child.	3.4 (4.5)	8	5

<sup>a</sup> Perceived risk is the product of the likelihood of the event and the level of concern of the event, ranging from 1 to 25. Data are presented as means (SD).

<sup>b</sup> Score of 4 or 5 on Likert scale (1 through 5, very unlikely to very likely).

<sup>c</sup> Score of 4 or 5 on Likert scale (1 through 5, very unconcerned to very concerned).

The overall perceived risk associated with the epilepsy medication on the patient's lifestyle was regressed with the independent variables perceived risk of losing control during a seizure, experiencing unexpected seizures, having a seizure alone, experiencing side effects or other negative effects with the medication, experiencing a more restricted life, feeling depressed, not working in a desired job, family feeling bad about one's condition, others viewing one negatively, and becoming a danger at work. The average overall perceived risk of the disease and the medication impacting the patient's lifestyle was 2.84 (SD = 1.16) and 2.66 (SD = 1.20) on a 5-point scale, respectively. The regression model revealed that the perceived risk of losing control during

a seizure and feeling bad about oneself significantly explained the overall perceived risk associated with medications. The adjusted  $R^2$  for the regression model was 0.386. The standardized  $\beta$  coefficient for the perceived risk of losing control during a seizure was 0.515, and the standardized  $\beta$  coefficient for the risk of feeling bad about oneself was 0.768. The risk of feeling bad about oneself has a greater impact on the overall perceived risk associated with medication for epilepsy than the perceived risk of losing control, although both are important risk factors. Psychological risk factors had the most significant impact on the overall perceived risk of taking medications for epilepsy on the patient's lifestyle.

**Table 3**Comparison of specific perceived risk measures with overall perceived risk associated with disease and medication treatment impacting patient lifestyle (Pearson correlation statistic with significance level)<sup>a</sup>

Specific perceived risk measure	Perceived risk with disease	Perceived risk with medication
You will lose control during your seizure.	0.57 (0.009)	0.57 (0.007)
You will experience unexpected seizures.	0.46 (0.032)	0.50 (0.015)
You will have a seizure when alone.	0.47 (0.028)	0.50 (0.015)
Your life will become restricted.	NS	0.46 (0.029)
You will experience side effects or other negative effects of your medication.	0.45 (0.034)	0.72 (0.00)
You will feel depressed.	NS	0.65 (0.001)
You will feel bad about yourself.	NS	0.62 (0.002)
You will not work in your desired job.	NS	0.56 (0.038)
Your family will feel bad about your epilepsy.	NS	0.49 (0.024)
Others will view you negatively.	NS	0.64 (0.002)
There will be danger to others at work or at home.	NS	0.63 (0.005)

<sup>a</sup> Data are presented as means (SD). NS, not significant.

#### 4. Discussion

Patient noncompliance with medication is the manifestation of a mismatch between patients' and physicians' perceived risk of the disease and its therapy. Although a patient's decision to disregard recommended AED therapy may appear irrational to others (especially the prescribing health care provider), it is only the result of a risk-versus-benefit calculation where the perceived medication treatment risk outweighs the perceived disease risk. This study provides the first glimpse into how patients actually perceive the risks of epilepsy and its medication treatment.

Under Jacoby and Kaplan's perceived risk framework, a patient survey instrument was developed to assess social, psychological, financial, physical, and performance risks in patients with epilepsy. The results demonstrated that losing control during a seizure (performance risk) significantly impacts the overall perceived risk associated with the disease and its treatment on lifestyle. The perceived risk of patients feeling bad about themselves is also a significant factor in the overall perceived risk of medications for epilepsy. If it can be assumed that patients with epilepsy are risk avoiders, then reducing the level of perceived risks such as losing control during a seizure can reduce the overall perceived risk associated with disease and its treatment. Future studies exploring the relationship between perceived risk and the provider-patient relationship could shed new light in this area of research.

We found that the perceived risk associated with the disease impacting the patient's lifestyle is related to performance and safety issues. Having unexpected seizures, having them alone, losing control during a seizure, and experiencing side effects from the medication were correlated with patients' overall perceived risk of the disease impacting their lifestyle. The perceived risk of the medication impacting their lifestyle was correlated with the same performance and physical issues, plus social and psychological issues. The overall perceived risk of taking medication for epilepsy was related to their concern over losing a job, feeling depressed, and seeing changes in how others may perceive them. However, when considering the multiple factors that concern the patient, the loss of control during a seizure is the most significant determinant of overall perceived risk with the disease and with medication. More than half of the respondents felt it was very likely that they would lose control during a seizure and almost half of the respondents were very concerned.

Patients' feeling bad about themselves was a significant predictor of overall perceived risk associated with taking medication for epilepsy. Approximately one-third of the respondents indicated that it was very likely they would feel this way and they were very concerned. This finding is intriguing as it was not found in the regression model for overall perceived risk associated with epilepsy. What are the unique aspects of medication taking that may explain this? Do patients feel a sense of diminished independence or importance because they rely on medication to help them achieve their desired quality of life? Self-efficacy, or the patient's perception that he or she is able to perform a behavior and achieve a desired goal, has been shown to impact self-care behavior [11–13] and, specifically, medication-taking behavior [14]. It could be that a patient's feeling toward her- or himself may impact self-efficacy, thus impacting her or his decision to comply with the prescribed medication regimen.

In our study we showed that patients have a complex set of issues that they relate to their overall perceived risk of their disease or medication treatment impacting their lifestyle. Similarly, Marland and Cash interviewed 61 patients with epilepsy, asthma, or schizophrenia and found that patients either directly or indirectly seek to optimize their quality of life, balancing the concerns about medication side effects with the fear of potential relapse of their disease [6]. Harden and colleagues found that worry about seizures (future seizures, apprehension over future injury resulting from seizures, concern about medication side effects, and social embarrassment from having seizures in public) and the impact of epilepsy on their independence (social activities, driving and work limitations) impacted quality of life for patients with epilepsy [15]. Clinicians should recognize the multidimensional issues that patients have relative to epilepsy treatment. Patients must cope with living with their disease. Adding medication can add complexity to the coping process. Our study showed that performance, physical, social, and psychological issues are related to patients' perception of the perceived risk of medication impacting their lifestyle. Additional studies are needed to learn more about these issues and potential coping processes that can help patients.

It is interesting that epilepsy duration, age, socioeconomic status, number of AEDs, educational level, and duration of epilepsy did not correlate with the perceived risk measures. Demographics, therefore, do not play a useful role in identifying patients with significant risk perceptions. Although gender differences in the perceived risk associated with epilepsy medication were not found in this study, the issue of potential adverse effects of AEDs on developing babies did come up during the patient interviews and 8% of the surveyed patients indicated they were very concerned. Though we did not specifically ask a question about teratogenesis influencing a women's perceived risk of AED therapy in our sample, it could have played a role. A future study could be designed to more fully elucidate the impact of a pregnancy on perceived risk of AED therapy. Thoughtful interview by the health care providers is required to understand individual patients' concerns about their disease and its medication treatment.

Our study is not without limitations. This was a cross-sectional study. Additionally, the results of this study are limited to the type of patients seen at a university-affiliated epilepsy clinic in a midsized Midwestern city. A larger sample size is warranted to validate the survey. Once validated in a larger study, this survey can be a useful tool to identify perceived risks associated with epilepsy and its treatment. The survey can also be used in studies testing the impact of clinical programs designed to improve patient care. The effects of clinical programs designed to improve patients' understanding of their condition can thus be directly measured by our survey designed to measure patient-perceived risk related to epilepsy and its treatment impacting the patient's lifestyle.

In summary, this study provided the first glimpse into the risk assessments patients make about their disease and its treatment. Patient risk perceptions can be used to craft better strategies to help patients comply with optimal treatment regimens. The results indicate that by specifically addressing concerns patients have about losing control during a seizure and how they feel about themselves (psychological factors), the health care provider may reduce the overall perceived risk associated with the disease and with the AED impacting the patient's lifestyle.

## Appendix. Sample survey questions

*Instructions:* Answer the following questions as they apply to YOU. Circle the number on the scale which best describes how YOU feel. Check “not applicable” if the item does not apply to you or if you don’t know.

1. What is the LIKELIHOOD of the following happening to YOU because of your epilepsy (circle one response per line)?

	Very unlikely				Very likely	Not applicable
You will experience unexpected seizures	1	2	3	4	5	[ ]
You will not work in your desired job	1	2	3	4	5	[ ]
You will lose control during your seizure	1	2	3	4	5	[ ]
Others will view you negatively	1	2	3	4	5	[ ]

2. How concerned are YOU about the following as it relates to YOUR epilepsy (circle one response per line)?

	Very unconcerned				Very concerned	Not applicable
You will experience unexpected seizures	1	2	3	4	5	[ ]
You will not work in your desired job	1	2	3	4	5	[ ]
You will lose control during your seizure	1	2	3	4	5	[ ]
Others will view you negatively	1	2	3	4	5	[ ]

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