BACKGROUND
The risks of switching to generic AEDs have been studied extensively. The concept of drug equivalence is often emphasized, but safety, quality, and efficacy assumptions underlying the long-term benefit of switching are not systematically evaluated.

OBJECTIVES
To investigate clinical outcomes for patients treated with branded topiramate versus users of single-generic topiramate. The impact of generic substitution on time to first occurrence of hospitalization rates, longer hospital stays, and greater pharmacy utilization was compared.

METHODS
1. Study Population: To determine the impact of generic substitution of 1 versus multiple generic versions of topiramate, patients who used branded topiramate were included. The specific study period was from 01/2000-10/2007.

2. Study Design: Patients were classified into three groups: brand users, single-generic users, and multiple-generic users. Patients were monitored for an average of 665 days.

3. Study Measures: Outcomes used to measure resource utilization included: the number of diagnostic codes, number of prescriptions, and number of dispensings.

4. Multivariate Analysis: Generic switch and switchback rates were estimated using the Kaplan-Meier method. Multivariate Cox regressions were performed to estimate the risk factors for hospitalization and longer hospital stays.

RESULTS
1. Compared with brand use, multiple-generic use was associated with significantly higher risks of hospitalization, longer hospital stays, and greater pharmacy utilization but similar outpatient use of other drugs.

2. Higher risks associated with multiple-generic use were not statistically significant.

3. Multivariate analyses adjusted for the following variables: Charlson Comorbidity Index, mean (SD) 0.2 (0.7), age in years, mean (SD) 34.7 (17.1), gender, and treatment characteristics.

4. Conclusions: The risks of multiple-generic substitution of topiramate were significant and should be considered in clinical practice.

LIMITATIONS
1. No detailed clinical information regarding motives for drug switching or information on potentially relevant comorbidities and treatment characteristics was available.

2. Our findings on topiramate are consistent with previous research on the adverse consequences of generic substitution of other AEDs such as valproate and levetiracetam.

REFERENCES
6. PND46

ACKNOWLEDGMENTS
The study was sponsored by Ortho-McNeil Janssen Scientific Affairs, LLC, Titusville, New Jersey, USA.

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