

Measuring the Change in Use of Generic Oxcarbazepine (OXC) Versus Brand Names for Medicaid Enrollees Throughout the United States in 2018-2019

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Abstract

Background: There is a contentious debate on the efficacy and cost between the use of generic versus brand name anti-epileptic drugs (AEDs). Oxcarbazepine (OXC) is a common anti-epileptic drug available as generic oxcarbazepine and as brand names Trileptal and Oxtellar XR, which Medicaid covers for qualifying applicants through a system called Commonwealth of Pennsylvania Access to Social Services (COMPASS). This study analyzed the nationwide 2018 and 2019 Medicaid drug utilization datasets to compare the usage of generic oxcarbazepine and its brand names Trileptal and Oxtellar XR for persons throughout the United States. Medicaid has restrictive administrative policies such as prior authorization (PA), preferred drug lists (PDLs), and step therapy (ST) which create socioeconomic disparities in public care by restricting Medicaid patients' access to brand name alternatives. The hypothesis proposed that generic oxcarbazepine will be utilized significantly and constantly more in both years and therefore the change in generic and brand name use from 2018 to 2019 will not be significant.

Methods: A heat map for each drug and year was created per 100,000 Medicaid enrollees. A pie chart for each year was made to compare the prescribed amount of generic medication, oxcarbazepine, to the brand-name medications, Trileptal and Oxtellar XR. A bar graph was created to show which states had the most oxcarbazepine use, and a two tailed paired t-test was used to establish the significance of our data.

Results: The t-test revealed that there was not a significant change in use for generic oxcarbazepine ($p = 0.513$) and Oxtellar XR ($p = 0.953$). However, Trileptal ($p = 0.025$) had a significant change in use from 2018 to 2019.

Conclusion: Our hypothesis was confirmed. The change in use of generic oxcarbazepine and Oxtellar XR between the years 2018 to 2019 was insignificant, but the change in use of Trileptal was significant. Prescriptions for years 2018 and 2019 were largely generic oxcarbazepine with 94% and above. Future plans include exploring socioeconomic implications between generic oxcarbazepine and brand name drugs on individuals with Medicaid as well as the relationship between the prescription prices of generic oxcarbazepine, Oxtellar XR, and Trileptal and how it varies per state based on preference.

Introduction

There are approximately 3 million epileptic adults in the United States (U.S.) who use anti-epileptic drugs (AEDs). However, AED medications are also prescribed for diagnoses such as

bipolar I disorder, mania and others. As these drugs have biologically sensitive effects, a larger contentious discussion on the efficacy and access of generic and brand AEDs has ensued. This controversy affects patients who have Medicaid as some brand-name medications are not covered by Medicaid plans, leading patients to pay more for brand-name medications (1). Oxcarbazepine is a common anti-epileptic drug often prescribed to treat epilepsy and personality disorders and is available as generic OXC and as the brand-name alternatives Oxtellar XR and Trileptal. Both generic and brand-name AEDs vary slightly in chemical compounds due to different fillers that can lead to rare side effects in some patients (2). Table 1 denotes biochemical differences between generic OXC and its brand names. Although the drugs are meant to have similar clinical outcomes, patients and providers prefer to prescribe brand-name medication compared to generic medication, as they believe it treats illnesses and diseases more effectively (3).

The determination of generic drug efficacy of AEDs is important to establish, as it is central to maintaining ethical patient care and establishing pharmacological consistency in its effects. This requires AEDs, such as oxcarbazepine, which is often used in combination with other medicines, to be biologically effective, sensitive, and consistent with a patient's history. Since patients react differently to various pharmacological agents, it is critical that generic and brand names be readily available. However, restrictive Medicaid policies like prior authorization that require providers of each state's Medicaid agency in order to control and reduce Medicaid costs before prescribing a drug are enacted to hinder access for brand name drugs due to governmental costs (4).

Additionally, Medicaid programs operate a preferred drug list (PDL) that lists generic drug brands and requires healthcare providers to prescribe generic brands before brand-name alternatives. This process is called step therapy (ST) where in order to obtain brand-name drugs, Medicaid patients would need to perform poorly on the generic options — patients have to either experience worsening conditions or have no effect with the drug prescribed (5). However, ST varies across states through a mechanism called “step edits” which are “fail-first” policies that insurance companies enact to ensure generic medications are tried first to curb costs. For example, according to the Epilepsy Foundation, Pennsylvania is the only state that is a quadruple step edit state for AED access. The continued implementation of step edits prompts contentious debate, as controlling Medicaid costs through ST results in long-term ineffective treatment and harmful effects. In particular, there exists a disparity between usage of brand name of generic OXC,

causing Medicaid patients who require two or more AEDs to incur higher health care costs in states with restricted AED access.

This study examines the novel topic of measuring change in use of generic OXC compared to brand name drugs for persons enrolled in Medicaid throughout the U.S. in 2018 to 2019. Due to the administrative restrictions of Medicaid coverage, we hypothesize generic OXC to be prescribed more frequently over the brand names and that the change in use for the analyzed drugs is not significant from 2018 to 2019.

Methods

Data source

We used the United States 2018 and 2019 Medicaid drug utilization datasets for generic oxcarbazepine and its brand names, Trileptal and Oxtellar XR, for patients. Medicaid is a joint

federal and state health coverage program that assists low-income persons, disabled individuals, children, and the elderly with medical costs (6).

Participants

The proposed sample size consisted of patients that were enrolled in the United States Medicaid database in 2018 to 2019. The population type included patients from low-income families and the elderly. Patients must meet the required income eligibility for annual household income per household size. To meet eligibility criteria for our study sample, patients had to report use of either generic OXC, Trileptal, or Oxtellar XR for the Medicaid enrollment period of 2018 and 2019.

Data collection

Patients who require medical assistance must satisfy federal and state requirements regarding residency, immigration status, and documentation of citizenship. Eligibility also includes financial need requirements and considers disability-based circumstances.

Applications may be submitted electronically through COMPASS, via telephone call, or in paper form to any of the insurance contractors. According to COMPASS, applications require patient information such as household income from jobs, housing and utility expenses, birth dates, social security, and proof of citizenship and property. Applications may also be sent to a contractor as referrals from the CAO (County Assistant Office) or from the FFM (Federally Facilitated Marketplace). A family will be given a maximum 15-day period to supply any missing information. However, missing information will not delay the application submission beyond the 15-day window.

Medicaid obtains their primary source of statistical data from Medicaid Statistical Information System (MSIS), Medicaid Analytic extract (MAX) files, and the CMS-64 reports. MSIS serves as a source of data which factors in payments, utilization, and characteristics based on individuals who have submitted statewide eligibility within Medicaid. The Statistical Enrollment Data System (SEDS) collects enrollment data by states via the forms CMS-64ES, CMS-64.21E, and CMS-21E. Previously referred to as State Medicaid Research Files (SMRFs), the Medicaid Analytic eXtract (MAX) data are person-level data files taken from MSIS data regarding eligibility for Medicaid, service utilization, and payments. Figure 1 notes this information flow. These data records are developed to support research and policy analysis initiatives for populations of low-income and for Medicaid.

Medication Name	Oxcarbazepine (OXC)	Trileptal	Oxtellar XR
Half-Life (in hours)	Parent: ~2 hours MHD is approximately 9 hours (MHD is responsible for the majority of anti-epileptic activity)	Parent: ~2 hours MHD is approximately 9 hours (MHD is responsible for the majority of anti-epileptic activity)	Parent: 7-11 hours. The half-life of MHD was between 9-11 hours (MHD is responsible for the majority of the anti-epileptic activity).
Bioavailability	Most effective absorption of extended-release tablet if taken under fasting conditions	Oral tablet administration-100% absorption. No difference if taken with or without food.	Oral tablet administration-100% absorption. Extensively metabolized to its active 10-monohydroxy metabolite Single dose administration of 600 mg Oxtellar XR® following a high fat meal (800 – 1000 calories) produced MHD exposure (AUC) equivalent to that produced under fasting conditions. Peak MHD concentration (C _{max}) was about 60% higher and occurred 2 hours earlier under fed conditions than under fasting conditions.
Mechanism	The exposures of the active metabolite, 10-monohydroxy derivative (MHD), which is primarily responsible for pharmacological effect, and the parent compound, oxcarbazepine (OXC), after multiple dose administration of 1200 mg of OXC ER were not bioequivalent to those after administration	The pharmacological activity of Trileptal is exerted primarily through the 10-monohydroxy metabolite of oxcarbazepine, however, the exact mechanism by which oxcarbazepine and the monohydroxy metabolite (MHD) exert their anti-epilepsy effect is unknown. In vitro electrophysiological studies do show that they produce a blockade of voltage-sensitive sodium channels, which results in the stabilization of hyper-excited neural membranes, inhibition of repetitive neuronal firing, and diminution of propagation of synaptic impulses.	*Refer to mechanism for Oxcarbazepine
Epidemiology	Most used in children 4 years of age to 17 years of age, and adults 18-64 years of age	Most commonly used in children 4 years of age and older, as well as adults 18-82 years of age	No studies using Oxtellar XR in elderly adults have been conducted Most commonly used in children 6 to less than 17 years of age, as well as in adults 18-32 years of age

Table 1. Generic OXC and Brand Name Drugs Fact Sheet. The table shows half-life (in hours), bioavailability, mechanism, and epidemiology for both generic OXC and brand-name drugs (23, 24, 25).

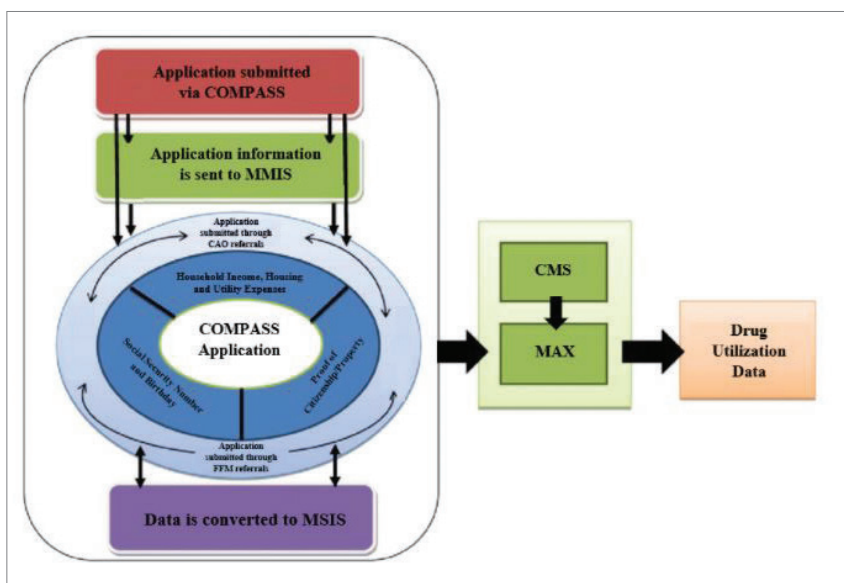


Figure 1. Conceptual model of data collection plan. Conceptual model depicts the relationships between integral administrative entities to produce Medicaid statistical databases. It includes patient application requirements and steps used to collect application information such as household income and other factors through FFM and CAO referrals. This model also details MSIS data collection factors such as payments and utilization. These factors get filtered into CMS and MAX which summarizes the Drug Utilization Data.

Data from the nationwide Medicaid "Drug Utilization 2018–2019" spreadsheet was examined to compare the use of generic and brand name OXC from Data.Medicaid.gov for low-income persons, disabled individuals, children, and the elderly. This study will utilize secondary data analysis, which will be completed on Excel.

Data analysis

The data from the Medicaid database for the years of 2018 and 2019 was utilized to compare the use of generic OXC and brand names in Medicaid patients nationwide. The data was downloaded from the Medicaid database and put into an Excel spreadsheet for further analysis, focusing on three specific drugs, generic OXC, Trileptal, and Oxtellar XR based on the year and number of prescriptions per 100,000 Medicaid enrollees. Heat maps were generated through summation of the number of prescriptions and dividing by the total number of state Medicaid enrollees per 100,000 for each state. Pie charts were formulated through summation of the number of prescriptions for each drug and divided by total value of the three drugs together. Bar graphs used the average value of the number of prescriptions for each drug per state. To analyze the trends of drug use nationwide, pie charts, bar graphs, and heat maps were formulated through Prism. The statistical test used to analyze the significance of change for each drug was a two tailed paired T-Test via Excel. The test used a significance level of $\alpha = 0.05$. The categorical values for 2018 and 2019 that were inputted were the sums of the number of prescriptions for each state. In the Oxtellar XR 2018 dataset, North Dakota (ND) had one value of 3,573 prescriptions which is an extremely high outlier. This led to the 2018 Oxtellar XR heatmap not being representative of the data. To simplify data depiction, ND data was substituted with the next highest value of Oxtellar XR which

was shown in Alabama (AL) with a value of 235.53. For data analysis purposes, the Washington, D.C., dataset was not used due to lack of data. Additionally, Vermont (VT) was removed for Oxtellar XR t-testing due to unavailable 2019 information.

Results

Figure 2A shows usage of OXC at 94.76%, Oxtellar XR with 2.70%, and Trileptal with 2.55% during the year of 2018. The total amount of prescriptions is 1.7435E+06. Figure 2B shows usage of OXC with 95.34%, Oxtellar XR with 2.87%, and Trileptal with 1.79% during the year of 2019. The total number of prescriptions is 1.76589E+06. Our findings showed that generic OXC was used at a significantly greater percentage than its brand names Oxtellar XR and Trileptal. This confirmed our hypothesis that patients would be using more generic OXC through Medicaid compared to brand names due to Medicaid's usage of ST that required patients to use and fail generic drugs before prescribing brand-name drugs.

Figure 3 shows the average usage of generic oxcarbazepine and brand-name drugs per 100,000 Medicaid enrollees in each state from years 2018 to 2019. Texas prescribed more AEDs as a whole compared to other states in both years. Also, the usage of generic OXC in all states exceeds the amounts of brand name Trileptal and Oxtellar XR drugs. This confirmed our hypothesis that generic OXC would be more commonly used for patients under Medicaid.

Figure 4 depicts heat maps for the usage of generic OXC and brand-name drugs per 100,000 Medicaid enrollees per state. Figure 4A shows that for the year 2018, oxcarbazepine depicted the highest number of prescriptions coming from Louisiana with 4,610.36, and West Virginia with 4,341.49. The lowest number of prescriptions is from Vermont, with 743.85. Figure 4B shows that the highest number of prescriptions for Oxtellar XR in 2018 comes from Texas with 224.08 and Alabama with 235.53. There are no prescriptions for Oxtellar XR in Arkansas, Minnesota, Alaska, New Hampshire, South Dakota, Vermont, and Wyoming for the year of 2018. Figure 4C shows that the highest number of prescriptions of Trileptal in 2018 comes from Wyoming with 357.89, North Dakota with 228.34, and South Dakota with 178.86. The lowest number of prescriptions for Trileptal in 2018 are in California, with 1.74 and New York with 3.19. Figure 4D shows the highest numbers of prescriptions of oxcarbazepine for the year 2019 come from Louisiana, with 5,234.34, West Virginia with 4,720.94, and Montana with 4,435.40. The lowest number of oxcarbazepine prescriptions in 2019 is from Vermont, with 735.80. Figure 4E shows that for the year 2019, the highest numbers of Oxtellar XR prescriptions come from Oklahoma with 444.45 and Texas with 220.39. There are no prescriptions in states Arkansas, New Hampshire, North Dakota, South Dakota, Vermont, and Wyoming for the year of 2019. Lastly, Figure 4F shows the highest numbers of prescriptions for Trileptal in 2019 come from North Carolina with 158.6, Texas with 130.83, and Maine with 111.85.

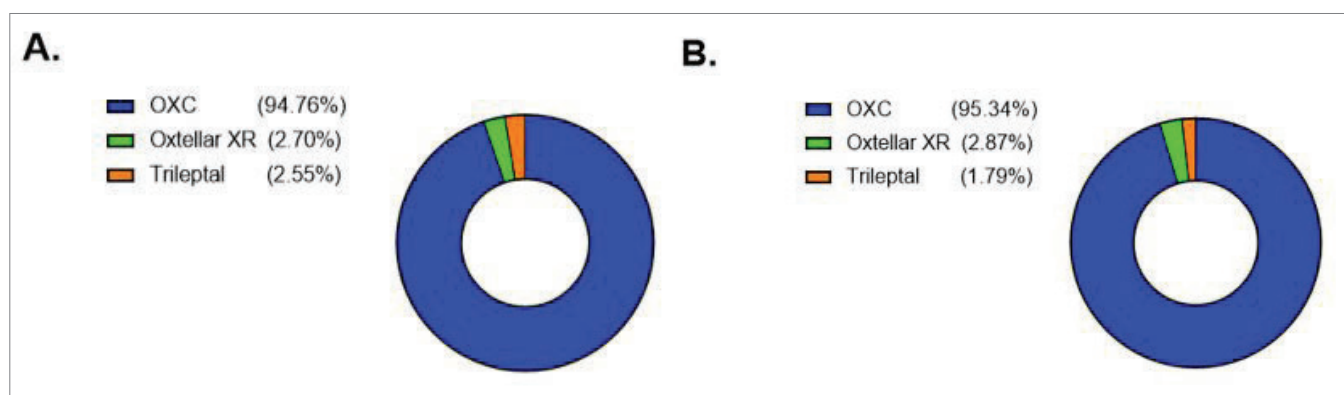


Figure 2. (A) Total number of prescriptions of OXC, Oxtellar XR, and Trileptal in 2018. (B) Total number of prescriptions of OXC, Oxtellar XR, and Trileptal in 2019.

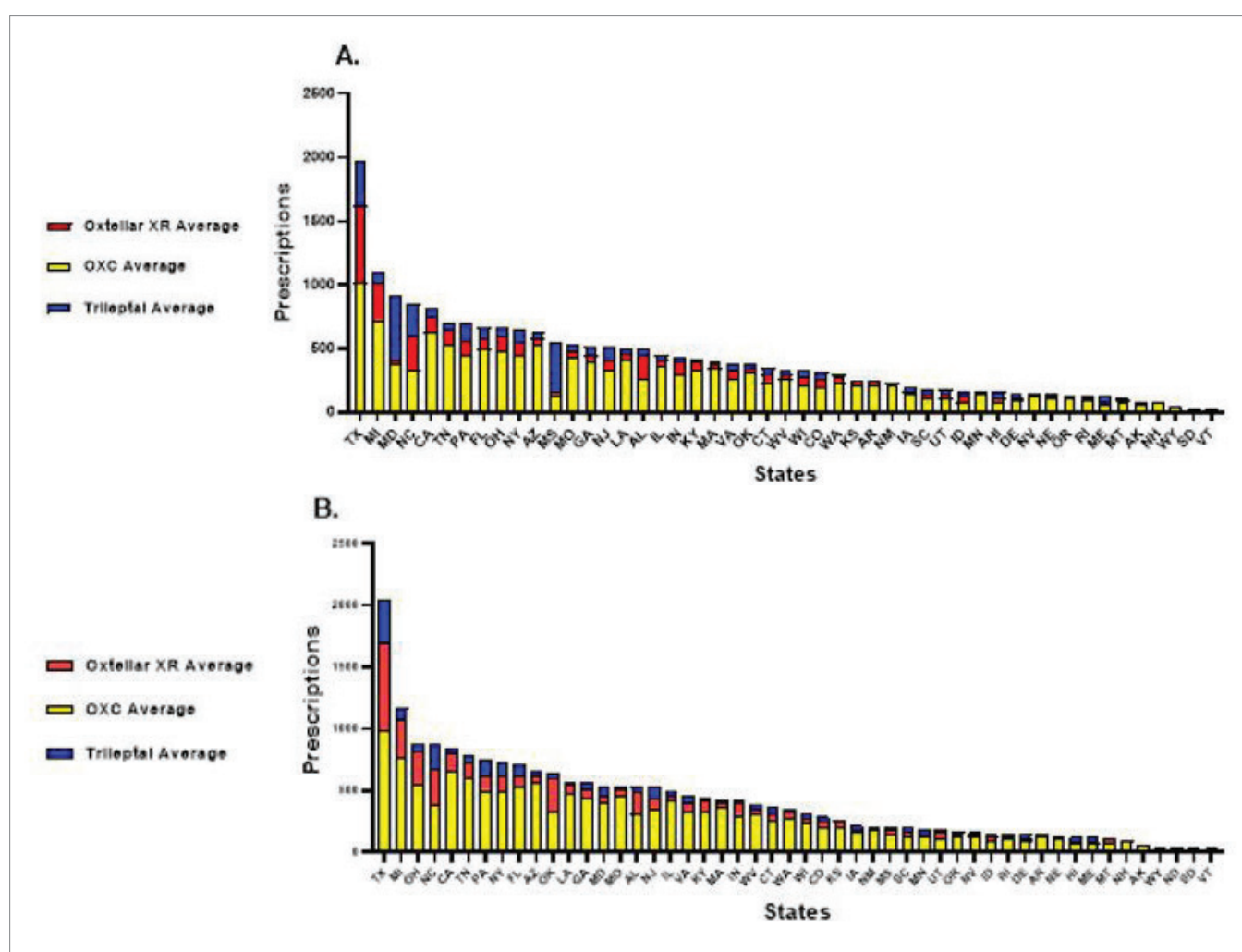


Figure 3. (A) Average generic OXC and brand-name usage per 100,000 Medicaid enrollees in 2018. (B) Average generic OXC and brand-name usage per 100,000 Medicaid enrollees in 2019.

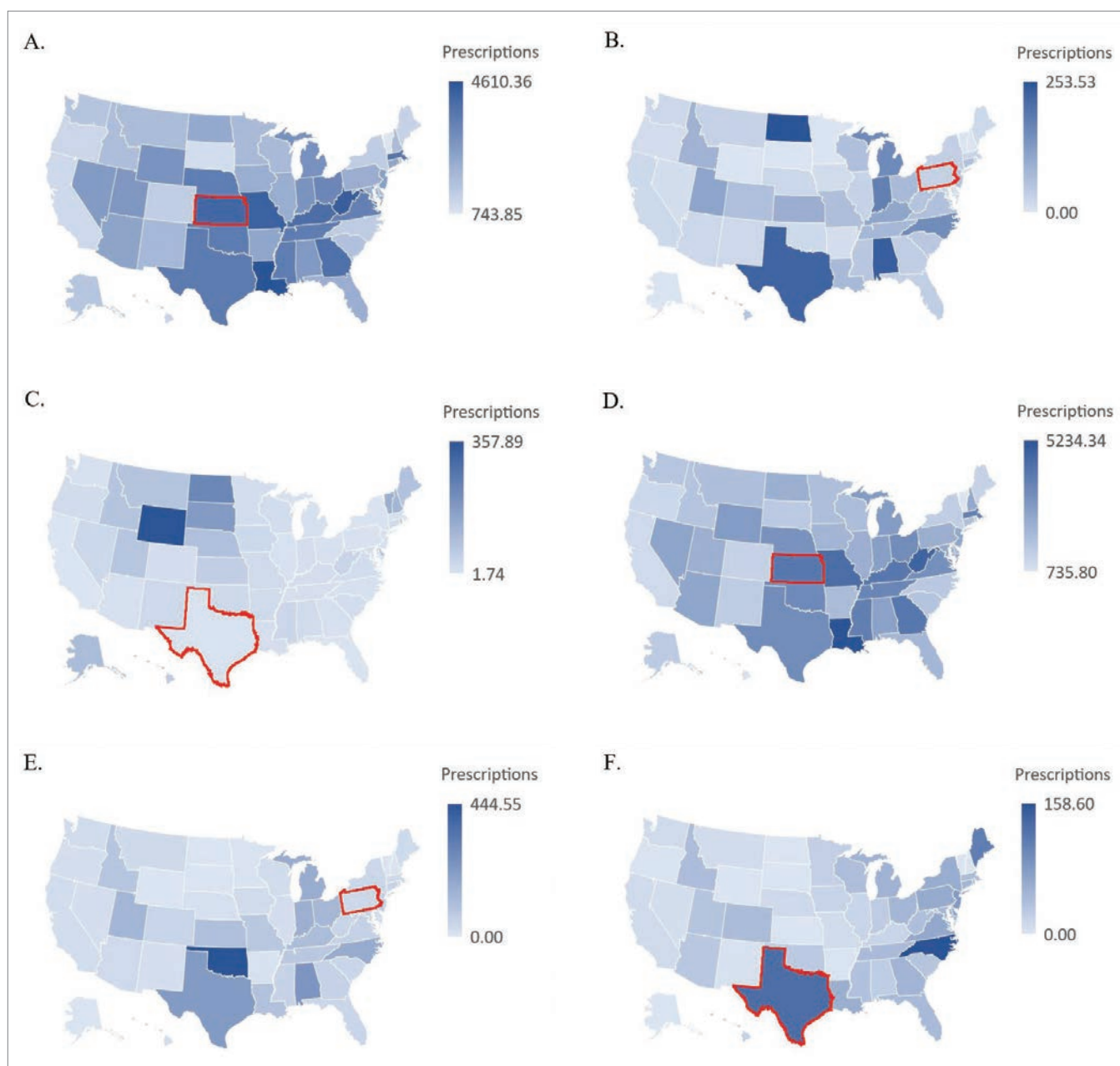


Figure 4. (A) Heat map of generic OXC usage per state among Medicaid patients in 2018 (dark blue: highest; light blue: lowest). (B) Heat map of Oxtellar usage per state among Medicaid patients in 2018 (dark blue: highest; light blue: lowest). (C) Heat map of Trileptal usage per state among Medicaid patients in 2018 (dark blue: highest; light blue: lowest). (D) Heat map of generic OXC usage per state among Medicaid patients in 2019 (dark blue: highest; light blue: lowest). (E) Heat map of Oxtellar usage per state among Medicaid patients in 2019 (dark blue: highest; light blue: lowest). (F) Heat map of Trileptal usage per state among Medicaid patients in 2019 (dark blue: highest; light blue: lowest).

There are no prescriptions in 2019 for Trileptal in the following states: Arkansas, Arizona, Kansas, New Hampshire, North Dakota, South Dakota, Vermont, and Wyoming.

A two tail paired samples t-test was conducted to compare the sums of prescribed oxcarbazepine, Oxtellar XR, and Trileptal per each state to determine the significance of change in use of each drug from 2018 to 2019 nationwide. There was not a significant difference in the use of generic oxcarbazepine for 2018 ($M = 33,041.2$, $SD = 33,151.4$) and 2019 ($M = 33,379.6$, $SD = 33,490.9$); $t(48) = 2.01$, $p = 0.513$. There was not a significant difference in the use of Oxtellar XR for 2018 ($M = 959.5$, $SD = 1,579.9$) and 2019 ($M = 955.3$, $SD = 1,534.2$); $t(47) = 2.01$, $p = 0.953$. There was a significant difference in the use of Trileptal for 2018 ($M = 888.5$, $SD = 1,393.6$) and 2019 ($M = 633$, $SD = 1,053.9$); $t(48) = 2.01$, $p = 0.025$. For Oxtellar XR statistical analysis, Vermont was excluded due to unavailable 2019 data.

Discussion

The main objective of our study was to analyze the change in use of generic OXC versus its brand names from 2018 to 2019. Although OXC is a multipurpose drug with numerous benefits, the accessibility for it varies per state according to their respective Medicaid policies. The generic drug is prescribed significantly more than its brand name alternatives (Figure 2). In particular, generic OXC use increased from 2018 to 2019, while Oxtellar XR use remained stagnant and Trileptal use significantly decreased. Consistent with past literature, state Medicaid programs curb prescription costs via restrictive formularies such as PA, ST and PDLs to encourage generic drug use.

To depict the national trends among states, geographical distribution of the data via heat mapping was used to determine the density of generic vs brand name OXC. As mentioned previously, Pennsylvania is the only state that is a quadruple state edit for AEDs. Implementing restrictive Medicaid policies is suggestive of mainly utilizing and/or having access to generic OXC before its brand names. Figures 3A and 3B were consistent in demonstrating that generic OXC was more likely to be used compared to its brand names secondary to the quadruple step edit process. The relationship between the use of Trileptal (Figure 4C and 4F) and Oxtellar XR (Figure 4B and E) versus the use of generic OXC (Figure 4A and 4D) also identified greater use in generic OXC than its brand names. Similarly, there were certain states such as Missouri, Kansas, and Louisiana that had very dense regions for the use of generic OXC. However, these states differed in their Medicaid AED access.

Consequently, Kansas included AEDs on their PDLs whereas Louisiana excluded AEDs from their PDLs. Additionally, the heat maps (Figure 4B and 4E) for Alabama and Texas showed similar findings of significant use of Oxtellar XR in 2018 followed by a significant decrease in the use of Oxtellar XR the following year. While Texas and Alabama utilize PDLs without AEDs, it is important to note that Alabama limits brand name usage up to 4 times per month. Specifically in Texas, it remains unknown whether it covers classes of drugs excluded from its PDL. In contrast, Oklahoma was the only state that significantly increased Oxtellar XR use from 2018 to 2019. While its Medicaid includes AEDs on PDLs, it requires prior authorization (PA) for some brand name AEDS (26).

Based on the results, Trileptal was the only AED noted to have a significant change in use from 2018 to 2019. Both Wyoming and North Carolina were among the denser regions for Trileptal use in 2018 and 2019, respectively. While Wyoming Medicaid requires PA for brand names, it covers AEDS, despite their exclusion from its PDL. Additionally, North Carolina Medicaid does not have a PDL. Consequently, these states allowed for facilitated administrative access to Trileptal. While our reference data states that it is unknown whether Texas Medicaid covers drugs outside of PDLs, Texas was consistently depicted to be a denser region compared to other states for both Oxtellar XR and Trileptal use (26).

Limitations were found while using the 2018 and 2019 dataset from Medicaid. The datasets were incomplete at the time we obtained the data, which was January 26, 2021. Therefore, many states either had no data entered or only had one value. The research that has been done mainly focuses on the difference of generic and brand name OXC; however, further studies could be implemented to explore this drug and its socioeconomic implications on individuals with Medicaid. The analysis of open access in 2018 and 2019 in Figure 2A and 2B showed that the use of Oxtellar XR is more than Trileptal. A potential future question to examine is whether there are differences in preference that exist between the two brand-name medications by analyzing the accessibility of state Medicaid programs per state.

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