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Trends in gabapentin and baclofen exposures reported to U.S. poison centers

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ABSTRACT
\textbf{Context:} Prescriptions for nonopioid pharmacological therapies such as gabapentin and baclofen have been increasing. While gabapentin and baclofen are less likely than opioids to result in fatal overdose, they are each associated with dependence, misuse and adverse effects.

\textbf{Objective:} The objective of this study is to evaluate and describe trends in adult exposures to gabapentin and baclofen reported to U.S. Poison Centers.

\textbf{Methods:} This was a retrospective review of data collected by U.S. Poison Centers and entered in the National Poison Data System. We identified all cases of exposures to gabapentin (2013–2017) and baclofen (2014–2017) in patients aged 18 years and over. We then analyzed demographics, common co-ingestions, medical outcomes, and geographic distribution.

\textbf{Results:} During the five-year period (2013–2017), there were 74,175 gabapentin exposures. All gabapentin exposures increased by 72.3%; isolated exposures increased by 67.1%; and isolated abuse/misuse exposures increased by 119.9%. During the four-year period (2014–2017), there were 15,397 baclofen exposures. All baclofen exposures increased by 36.2%; isolated exposures increased by 35.0%; and isolated abuse/misuse exposures increased by 31.7%. Co-ingestions of sedatives and opioids were common for both medications. Admissions to a health care facility were required in 16.7% of isolated gabapentin exposures, and 52.1% of isolated baclofen exposures. Intentional suspected suicide attempts with isolated gabapentin exposures increased by 80.5% over a five-year period; and increased by 43% for isolated baclofen exposures over a four-year period. All states saw increases in gabapentin exposures and most states saw increases in baclofen exposures, gabapentin misuse/abuse, and baclofen misuse/abuse.

\textbf{Conclusion:} Gabapentin and baclofen misuse, toxicity, use in suicide attempts, and associated healthcare utilization among adults in the United States have significantly increased since 2013. Careful consideration and risk-benefit analysis should be employed when prescribing these medications.

Introduction

Drug overdose and misuse represent a significant public health concern in the United States. In 2017, there were 70,237 drug overdose deaths in the United States [1]. Opioids accounted for most fatalities. However, the most significant contribution to increasing overdose fatalities from 2015 to 2016 was illicit fentanyl and its analogues [2]. The number of opioids being prescribed decreased significantly between 2012 and 2017. In 2017, the opioid prescribing rate hit a 10-year low of 191 million prescriptions or 58.7 prescriptions per 100 persons in the United States [3]. At the same time, adequate pain management continues to represent an important need for many Americans. In 2016, approximately 50 million US adults (20% of U.S. adults) experienced chronic pain, and 20 million U.S. adults (8% of U.S. adults) experienced high impact chronic pain [4]. Some chronic pain conditions are associated with an increased risk of attempted suicide [5]. From 1999–2016, suicide rates in the United States have risen nearly 30% [6].

Prescribing guidelines from the Centers for Disease Control and Prevention recommend nonopioid pharmacological therapy and nonpharmacologic therapy, when available and appropriate, as the preferred treatment for patients with chronic pain [7]. The importance of patient-centered individualized multimodal, multidisciplinary pain management with emphasis on patient functional outcomes was further emphasized in the Pain Management Best Practices Inter-Agency Task Force Report [8].

Gabapentin, a gamma-aminobutyric acid (GABA) analog, was developed as an anticonvulsant and is commonly prescribed as an analgesic, primarily for neuropathic pain as well as multiple off label uses including: migraines, mental illness, and fibromyalgia [9]. Many providers have embraced gabapentin as a safer alternative to opioids for pain management. Gabapentin prescribing increased 64% from 39 million prescriptions in 2012 to 64 million by 2016 when it was the 10th most commonly prescribed medication in the United States [10]. Significant misuse and diversion of gabapentin have been well-documented [11–17]. Individuals have
reported euphoria, relaxation, improved sociability, a marijuana-like “high”, and a sense of calm following gabapentin use. Gabapentin overdose may be fatal, though far less commonly than opioids. Gabapentin is renally excreted so clearance will be prolonged in patients with impaired renal function [18]. There is no antidote for gabapentin and given the long half-life, overdose treatment may require prolonged, intensive management including hemodialysis [19,20].

Baclofen, another GABA A receptor agonist, is prescribed as a muscle relaxant and antispasmodic [21]. Baclofen is prescribed for muscle spasticity associated with: spinal cord diseases, central nervous system disorders including stroke and multiple sclerosis, and even chronic hiccups [22–24]. Baclofen is also prescribed for off-label use. Skeletal muscle relaxants, including baclofen, are frequently used to treat acute low back pain despite evidence of adverse effects without long term benefit [25].

Baclofen exposures reported to poison centers are rising [26]. Baclofen toxicity related to impaired renal clearance, recreational use, and intentional overdose has resulted in critical acute illness including respiratory depression, seizures, myoclonus, cardiac conduction abnormalities, and coma requiring mechanical ventilation and critical care utilization [27–30]. In addition to acute toxicity, regular exposure to baclofen induces tolerance, dependence, and a withdrawal syndrome that is characterized by seizures, agitation, confusion, and delirium [31].

Opioid prescribing has declined significantly since peaking in 2010–2012 [10]. Since 2012, gabapentin prescribing rates and reported baclofen exposures have risen significantly [26]. It is hypothesized that expanded utilization of and access to these medications are associated with greater potential for misuse, attempted suicide, and adverse clinical outcomes.

The purpose of this surveillance study was to characterize trends in adult (18 years or older) gabapentin and baclofen exposures reported to poison control centers (PCCs) between 2013–2017 (gabapentin) and 2014–2017 (baclofen). Background investigation revealed an overall increase in exposures to both agents reported in the National Poison Data System (NPDS) as well as significant associated toxicity.

Methods

Data for this surveillance study were drawn from gabapentin (2013–2017) and baclofen (2014–2017) exposures captured by the NPDS. Baclofen received its unique generic code in October 2013, which explains a four-year data collection period for this drug compared to five years of data for gabapentin. In this study, an adult population was examined as chronic pain management with these medications is unlikely to be utilized for pediatric patients outside of select populations with severe chronically painful illness. Each medication was assessed for the total number of exposures reported, reason for exposure, and co-incident xenobiotic exposures. For cases in which other substances were identified, the associated co-exposures were evaluated for frequency. Cases of isolated gabapentin/baclofen exposure were examined independent of cases with multiple substance exposure to determine the frequency of reported inpatient and/or critical care unit disposition as an indication of healthcare utilization attributable to the drug of interest alone. “All exposures” refer to exposures involving gabapentin or baclofen with or without co-exposure to other compounds. “Isolated exposures” refer to exposures only involving gabapentin or baclofen. Specific attention was given to exposures categorized as “intentional” and coded as attempted suicide, misuse, abuse, or unknown intent based upon NPDS definitions [26]. Intentional misuse is defined as “…exposure resulting from the intentional improper or incorrect use of a substance for reasons other than the pursuit of a psychotropic effect” [32]. Intentional abuse includes exposures “…resulting from the intentional improper or incorrect use of a substance where the patient was likely attempting to gain a high, euphoric effect or some other psychotropic effect, including recreational use of a substance for any effect” and intentional unknown includes exposures that are “…determined to be intentional, but where the specific motive is unknown” [32]. Intentional ingestions were divided by suicide attempts vs. non-suicidal intentional ingestions as the nonsuicidal categories of intentional ingestion may overlap and represent distinct motivation compared to self-harm.

Various medical outcomes were also examined. In NPDS, there are 10 different coding options for medical outcomes including: minor, moderate, major and death. A minor effect is defined as “the patients exhibited some symptoms as a result of the exposure, but they were minimally bothersome to the patient” [32]. A moderate effect is defined as “the patient exhibited symptoms as a result of the exposure which were more pronounced, more prolonged or more of a systemic nature than minor symptoms” [32]. A major effect is defined as “the patient has exhibited symptoms as a result of the exposure which were life threatening or resulted in significant residual disability or disfigurement” [32].

Descriptive statistics were utilized to demonstrate outcomes of interest over time. State-specific population estimates for each year from the U.S. Census Bureau were used to calculate cases-per-million (CPM) of the state population. Heat maps comparing trends in gabapentin and baclofen exposures over time were tabulated using QGIS version 3.7 (QGIS, Johannesburg, South Africa).

Results

Demographics of patients with reported gabapentin exposures are summarized in Table 1. During 2013–2017, 74,175 gabapentin exposures with or without other substances were reported to PCCs. Among all cases reported to PCCs, 51,932 (70%) were intentional. The majority of intentional cases, 41,948 (81%), were attempted suicide, while 3537 (7%) were coded as abuse exposures, 3638 (7%) classified as misuse, and 2763 (5%) were deemed intentional exposures, but the reason was unknown.

Isolated exposures to only gabapentin accounted for 22,737 (30.65% of total) cases. Of the isolated exposures 1015 (4.46%) were intentional abuse exposures, 1709 (7.51%) were intentional misuse exposures, and 727 (3.19%) were
intentional-unknown exposures. 9387 (41.28%) were intentional suspected suicide attempts. The remainder of isolated exposures were unintentional.

During the five-year period (2013–2017) all exposures increased by 72.3%; all intentional abuse/misuse/unknown exposures increased by 104%, isolated exposures increased by 67.1%; isolated intentional abuse/misuse/unknown exposures increased by 119.9%; and suspected suicide attempts increased by 61.5% (Figure 1). The most frequently reported co-occurring substance exposures with gabapentin are included in Table 2.

All states saw an increase in gabapentin exposures from 2013 to 2017 (Figure 2). Annual rates of nonsuicidal exposure calls varied among states. Forty states saw an increase in isolated gabapentin intentional non-suicidal exposures from 2013 to 2017. Kentucky had the highest population-adjusted rate of isolated intentional non-suicidal exposures in both 2013 and 2017, followed by West Virginia in both 2013 and 2017. During this time, Kentucky had a relative rate increase of +182% for isolated gabapentin intentional nonsuicidal, and for West Virginia it was +141%. The highest relative rate increases in isolated intentional nonsuicidal exposure to gabapentin occurred in North Dakota (+762%), Iowa (+686%), and Maryland (+414%) (Figure 3).

Outcomes following exposure included hospital admission or death. Of the 22,737 isolated exposures reported between 2013 and 2017, 3806 (16.7%) resulted in admission to a health care facility; 2050 (53.9%) of these were to critical care units, and 1756 (46.1%) were to a non-critical care unit. Gabapentin was involved in 19 deaths during the study period (Table 3).

Demographics from patients with reported exposures to baclofen are demonstrated in Table 4. From 2014–2017, 15,397 baclofen exposures were reported to PCCs. Among all cases reported, 10,697 (69.47%) exposures were intentional. The majority of intentional cases, 8158 (76.26%), were attempted suicide, while 624 (5.83%) were coded as abuse exposures, 1022 (9.55%) classified as misuse, and 893 (8.34%) were deemed intentional exposures, but the reason was unknown.

Isolated exposures to only baclofen accounted for 6169 (40% of total) cases. Of the isolated exposures, 250 (4%) were intentional abuse exposures, 558 (9%) were intentional misuse exposures, and 381 (6.17%) were intentional unknown exposures. 2837 (45.98%) were intentional suspected suicide

### Table 1. Demographic and substance-related information obtained at exposure calls (Adults, Gabapentin 2013–2017).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Isolated Intentional Suspected Suicide n = 9387</th>
<th>Isolated Intentional, Nonsuicidal n = 3451</th>
<th>Isolated Exposures n = 22,737</th>
<th>All Intentional Suspected Suicide n = 41,948</th>
<th>All Intentional, Nonsuicidal n = 9938</th>
<th>All Exposures n = 74,175</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years, mean (Range)</td>
<td>39.1 (18–98)</td>
<td>39.8 (18–92)</td>
<td>45.0 (18–99)</td>
<td>40.5 (18–102)</td>
<td>39.8 (18–99)</td>
<td>44.6 (18–102)</td>
</tr>
<tr>
<td>Gender (n, %)</td>
<td>Male 3858 (41)</td>
<td>1699 (49.2)</td>
<td>9044 (39.8)</td>
<td>16,714 (39.8)</td>
<td>4869 (48.9)</td>
<td>29,805 (40.2)</td>
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<tr>
<td></td>
<td>Female 5515 (58.7)</td>
<td>1750 (50.7)</td>
<td>13,670 (60.1)</td>
<td>25,200 (60)</td>
<td>5064 (50.9)</td>
<td>44,316 (59.7)</td>
</tr>
<tr>
<td></td>
<td>Missing 14 (0.14)</td>
<td>2 (0.1)</td>
<td>23 (0.1)</td>
<td>34 (0.8)</td>
<td>5 (0.5)</td>
<td>54 (0.1)</td>
</tr>
</tbody>
</table>

Figure 1. Number of calls by year (Adults, Gabapentin 2013–2017).

Table 2. Top 13 co-ingested substances for all adult gabapentin exposures 2013–2017.

<table>
<thead>
<tr>
<th>Co-Ingested Substances</th>
<th>Reported (n = 165,514)</th>
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<tbody>
<tr>
<td>Sedative-hypnotic</td>
<td>37,973 (22.94%)</td>
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<td>Sympathomimetic</td>
<td>4420 (2.67%)</td>
</tr>
<tr>
<td>Hallucinogenic Compounds</td>
<td>2509 (1.52%)</td>
</tr>
<tr>
<td>Anticonvulsant</td>
<td>2251 (1.36%)</td>
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<tr>
<td>Cough/Cold</td>
<td>970 (0.59%)</td>
</tr>
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Table 3. Demographic and substance-related information obtained at exposure calls (Adults, Gabapentin 2013–2017).

### Table 4. Top 13 co-ingested substances for all adult baclofen exposures 2014–2017.

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attempts. The remainder of isolated exposures were unintentional.

During the four-year period (2014–2017), all exposures increased by 36.2%; all intentional non-suicidal exposures increased by 42.1%; suicide attempts increased by 40.2%; isolated exposures increased by 35.0%; and isolated intentional non-suicidal exposures increased by 31.7% (Figure 4). The most frequently reported co-ingestions with baclofen are listed in Table 5.

Forty-three states saw an increase in all baclofen exposures from 2014 to 2017 (Figure 5). Thirty-three states saw an increase in isolated baclofen intentional nonsuicidal exposures from 2014 to 2017. Some similar patterns emerged across states as with gabapentin exposures. Kentucky had the highest rate of isolated intentional nonsuicidal cases in both 2014 and 2017; however, during this time, they had a relative decrease of −6% cases per million of population. The highest relative rate increases in isolated intentional nonsuicidal baclofen exposures occurred in Wisconsin (+297%), Virginia (+293%), and Missouri (+231%) (Figure 6).

Admission to a health care facility was required in 3218 (52.2%) of the isolated baclofen exposures; 2366 (73.5%) of these required admission to critical care, and 852 (26.5%) of
isolated exposures admitted to a healthcare facility were to a noncritical care unit. Death resulted in 18 identified exposures (Table 6).

**Discussion**

Increasing rates of suicide attempts and nonsuicidal intentional exposures contributed substantially to a significant rise in toxic gabapentin and baclofen exposures reported to...
PCCs from 2013/2014–2017 as opioid prescribing rates declined. Implications on medication safety interventions, regulation, multimodal pain management strategies, patient and provider education, and mental health screening and treatment are significant.

Part of the response to the epidemic of prescription and illicit opioid-related overdose deaths has been a greater emphasis on reducing prescription opioid availability. Gabapentin and baclofen are two medications that have seen increased availability to patients as alternatives to opioid for the treatment of acute and chronic pain. With greater accessibility, poison center exposures have demonstrated a marked increase in toxic exposures to these two medications. The increases are especially notable as overall exposures reported to poison centers declined during the same time period [26]. As poison center data do not represent the totality of cases in the United States, the steep upward trends in reported exposures reflect a much larger problem than the raw numbers would suggest.

Intentional exposures represent ~70% of total reported exposures to gabapentin and baclofen. The prevalence of intentional exposures demonstrates the need for identification of risk factors associated with suicide and misuse when prescribing these medications in addition to patient safety, storage, and dosing education geared toward limiting unintentional exposures and toxicity. The overwhelming majority of intentional exposure cases were suicide attempts. It would be anticipated that patients who are prescribed gabapentin and/or baclofen would be more likely to be treated for mood disorders and pain as they are frequently comorbid and therapy overlaps significantly [33,34]. Additionally, nonsuicidal intentional use and misuse of these medications rose sharply in the short period of time from 2013/2014–2017. Gabapentin has specifically been recognized for its misuse and diversion potential, synergistic effect with opioid use, and contribution to use disorders [35]. Baclofen misuse has not been as frequently described but is anecdotally observed and associated with severe toxicity, physical dependence, and complicated withdrawal [13,31]. Baclofen exposures rose significantly and the nature of its utilization by prescribers and patients warrants further dedicated evaluation. Each medication has demonstrated potential for recreational misuse in isolation and in combination with other drugs. For both gabapentin and baclofen, the
most commonly associated substance involved in exposures represent psychoactive medications and recreational drugs with significant potential for addiction and/or toxicity. In particular, sedative-hypnotics, including benzodiazepines, and opioids are frequently identified as co-ingested agents with the expectation that effect and toxicity will be potentiated by the combined effects [36].

The findings further highlight the importance of patient and provider education as well as risk-benefit consideration when prescribing these medications with relatively weak evidence of benefit for a variety of off-label uses, particularly in the setting of polypharmacy and in patients at risk for depression and substance use disorder [9–17,25,37]. Gabapentin, specifically, is frequently identified as a contributing cause of overdose
death in postmortem toxicology reports [38]. Patients who are prescribed these medications should be screened for substance use disorders, mood disorders, and suicidal ideation utilizing validated screening tools and the prescription drug monitoring program.

While mortality from gabapentin and baclofen does not approach that of opioids, medical morbidity and healthcare costs associated with toxic exposures are not trivial. Admission to a health care facility was required in over 1 in 8 isolated gabapentin and more than half of isolated

Figure 6. Average frequency of all adult isolated Baclofen intentional nonsuicidal calls per million population by state. (A) Average frequency per million population 2014; (B) Average frequency per million population 2017.
baclofen exposures. Critical care admission was required in a majority of these cases, with nearly 3 out of every 4 admissions to a hospital for baclofen toxicity resulting in critical care disposition. Hospitalization, particularly critical care placement, comes at a considerable cost.

Understanding that state-specific variation in practice patterns, access to care, and substance use could result in significant heterogeneity in impact and response, we broke exposure rates down by state for overall exposures and isolated exposures to identify areas in need of more focused response. Gabapentin and baclofen exposure trends were similar in many states, however, did not necessarily reflect overall reported overdose mortality. Rates of exposure were highest in states that also reported large numbers of overdose deaths in 2017 [39]. West Virginia and Kentucky each had large numbers of gabapentin and baclofen exposures as well as the highest and fourth highest rates of overdose deaths, respectively [39]. At the same time, North Dakota had relatively high rates of gabapentin and baclofen exposures by population while reporting the 3rd lowest overdose death rate in 2017 [39]. Further local evaluation of patient characteristics and prescribing habits are needed to determine factors that contribute to national variability is exposure rates. Due to growing concerns related to the misuse of gabapentin, Kentucky (2017), Tennessee (2018), and Michigan (2019) have re-classified the drug as a Schedule V controlled substance [40,41]. This introduces additional barriers to prescribing gabapentin in large quantities and for long durations as well as allowing criminal prosecution in cases of diversion [42]. Eight states (Massachusetts, Minnesota, Nebraska, North Dakota, Ohio, Virginia, West Virginia, and Wyoming) have mandated reporting of gabapentin prescriptions in a Prescription Drug Monitoring Program (PDMP) database. This enables easier detection of outliers in gabapentin prescribing [35]. These interventions took place in the final year or after our data collection period. Re-evaluation of prescribing and exposure trends in these states may provide insight into the effects of such programs.

Baclofen remains unscheduled throughout the country. The scheduling of these drugs may need to be further examined at the federal level or, at least, in the states most significantly affected by misuse and toxicity. However, restricting access to medications should be pursued carefully and with full consideration of potentially negative unintended patient impact.

Limitations to this study include reliance on voluntarily reported exposure cases to PCCs for inclusion in NPDS. Additional exposures may go unreported to PCCs. Thus, exposures described in this study may not represent the total incidence of national exposures [25]. Likewise, as toxicity from classes of drugs becomes more common, healthcare providers may be less likely to seek expert guidance on care and, therefore, less likely to contact a poison specialist for assistance leading to an appearance of a downward trend or a slowing rate of increase that is more a function of the reporting mechanism than true exposure incidence. Confirmatory testing for the presence of gabapentin, baclofen and/or additional co-ingestions was not consistently documented. Definitive verification of the causative substance cannot be determined using poison center data. While substances reported to PCCs represent the best available information, they can be inaccurate or incomplete introducing the potential for under or over reporting as well as difficulty in determining the relative contribution of each substance to the individual’s overall experience. We attempted to mitigate this error by evaluating all cases in which the substances of interest were involved as well as those in which each was the only reported substance thereby improving the likelihood that observed outcomes were specific to that medication. The reported dose of exposure is often not available or unreliable so a true dose-response assessment could not be determined for these medications or co-ingested substances. While poison center data does not provide a complete representation of all adverse effects and medication toxicity, it is the most comprehensive nationwide database available for the evaluation of non-fatal poisoning and drug toxicity that allows evaluation of year-to-year trends to estimate overall impact.

Conclusion

Harmful, costly exposures to gabapentin and baclofen related to intentional use have significantly increased in US adults since 2013. Increased exposures coincide with reductions in opioid prescribing and may represent an unintended consequence of the ongoing need for effective pain management and migration away from opioid use. While the risks of opioids have been widely publicized, medication alternatives to opioids also carry risks that need to be better understood, described, and disseminated so that providers and patients can make decisions regarding the role of these medications in their pain management based upon an evidence-informed risk-benefit analysis.

Acknowledgements

The American Association of Poison Control Centers (AAPCC) maintains the National Poison Data System, which houses de-identified case records of self-reported information collected from callers during exposure management and poison information calls managed by the country’s poison control centers (PCCs). NPDS data do not reflect the entire universe of exposures to a particular substance as additional exposures may go unreported to PCCs; accordingly, NPDS data should not be construed to represent the complete incidence of U.S. exposures to any substance(s). Exposures do not necessarily represent a poisoning or overdose and AAPCC is not able to completely verify the accuracy of every report. Findings based on NPDS data do not necessarily reflect the opinions of AAPCC.
Disclosure statement

No potential conflict of interest was reported by the authors.

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