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Black Box Warning by the United States Food and Drug Administration: The Impact on the Dispensing Rate of Benzodiazepines

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Abstract

Background/objectives: In 9/2020, the United States Food and Drug Administration (FDA) posted a black box warning for all benzodiazepines, addressing their association with serious risks of abuse, addiction, physical dependence, and withdrawal reactions. We evaluated changes in benzodiazepine dispensing rate trends after this warning. **Methods:** The dataset of Clalit Health Services (Israel's largest insurer, with 5 million members) was used to identify and collect benzodiazepine dispensing data for all patients who were dispensed these drugs at least once during the study period (1/2017–12/2021). The dispensing rate (number of patients who were dispensed benzodiazepines per month divided by the number of patients alive during that month) was calculated for each month in the study period. Linear regression and change point regression were used to review the change in trend before and after the black box warning. New users of benzodiazepines after the black box warning were analyzed by age. **Results:** A total of 639,515 patients using benzodiazepines were reviewed. The mean benzodiazepine dispensing rate per month was 0.21 and ranged from 0.17 (in 2/2017) to 0.24 (in 3/2020). No significant change in trend was observed before vs. after the black box warning (slopes of 0.00675 percentage points per month and 0.00001 percentage points per month, respectively; $p = 0.38$). The change point regression analysis identified a change point in 4/2019, which is prior to the black box warning. New users were younger after the black box warning compared to before this warning. **Conclusions:** The FDA black box warning did not affect the dispensing rate of benzodiazepines.

Keywords: benzodiazepines; regulation; safety

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1. Introduction

The US Food and Drug Administration (FDA) is responsible for drug approval before marketing after fully reviewing the data regarding safety and efficacy. Nevertheless, new information about drug safety is commonly discovered once a medication is FDA-approved and used by a large number of patients. The FDA's Office of Surveillance and Epidemiology conducts post-market safety evaluation, focusing on medication error prevention and risk management. If a safety concern emerges from clinical trial data or there are consistent

reports to the adverse event reporting system, the FDA decides whether to continue monitoring, require a box warning on the product labeling, or withdraw the drug from the market. A black box warning is a stringent warning that the FDA can add to the labeling of prescription drugs or drug products when there is reasonable evidence of an association of a serious hazard with the drug [1–4].

While the issue of a black box warning can indeed prompt changes in the treatment approaches and prescription practices of physicians, it is important to recognize that these warnings are not infallible and may sometimes go unnoticed or be subject to misunderstandings among prescribers. For example, within ambulatory care settings, it has been observed that patients have been prescribed at least one medication containing a black box warning, which could potentially apply to their treatment. Similarly, in another observational study, it was found that approximately 7 out of every 1000 patients received prescriptions that contravened a black box warning [5]. These findings underscore the persistent need for the development and implementation of a robust outreach strategy to effectively disseminate new drug safety information to healthcare professionals [6]. In Israel, black box warning information is disseminated to physicians by either a warning email with the new information or through a drug leaflet update that is provided and sent to physicians [7].

On 23 September 2020, the FDA issued a black box warning for all benzodiazepine medications to address the serious risks of abuse, addiction, physical dependence, and withdrawal reactions associated with them. The black box warning specifically indicated that "the current prescribing information for benzodiazepines does not provide adequate warnings about these serious risks and harms associated with these medicines so they may be prescribed and used inappropriately" [8]. Benzodiazepines have long been recognized as valuable therapeutic agents for the treatment of panic, anxiety, insomnia, seizures, alcohol use disorder, and other indications [9]. However, their extensive use and widespread availability have raised concerns regarding their potential effects on cognition, dependence, rebound anxiety, memory impairment, and discontinuation syndrome [10,11]. One primary concern associated with benzodiazepines is their addictive potential. Studies have shown that individuals who misuse or abuse benzodiazepines are at a higher risk of developing substance use disorders and experiencing withdrawal symptoms upon discontinuation [12,13]. Overall, the black box warning for benzodiazepines served as a call to action for healthcare professionals, regulatory bodies, and patients alike to prioritize the safe and appropriate use of these medications. Nevertheless, prior studies showed continued patterns of increased use of benzodiazepines, especially during the coronavirus disease 2019 (COVID-19) pandemic [12,14–17]. In this study, we aimed to evaluate the impact of the black box warning on dispensing rate patterns of benzodiazepines in Israel. While US legislation does not have direct legal implications outside of the US, directions and recommendations of the US FDA do impact the thinking of the wider scientific and medical community.

2. Results

A total of 641,674 patients who were dispensed at least one package of benzodiazepines during the study period were included in the cohort. Patients who died during the first 3 months of the study (n = 2147) and those whose birth date was not applicable (n = 12) were excluded. The final study cohort included 639,515 patients. Their characteristics are shown in Table 1. Among the 639,515 patients, 60% were women, 30% were of low (<5) socioeconomic status, and 36% were aged 65 and older.

Table 1. Baseline characteristics.

Baseline Characteristics	N (%)
Gender	
Man	254,355 (39.8)
Woman	385,149 (60.2)
Unknown	11 (0.0)
Age, years [1]	
21–24	17,873 (2.8)
25–29	29,855 (4.7)
30–34	36,679 (5.7)
35–39	41,370 (6.5)
40–44	43,339 (6.8)
45–49	41,171 (6.4)
50–54	43,130 (6.7)
55–59	50,626 (7.9)
60–64	58,963 (9.2)
65–69	65,452 (10.2)
70–74	56,753 (8.9)
75–79	50,542 (7.9)
80–84	46,897 (7.3)
≥85	56,865 (8.9)
Socioeconomic score (0, low; 10, high)	
0	24,196 (3.8)
1	2980 (0.5)
2	16,230 (2.5)
3	69,803 (10.9)
4	80,782 (12.6)
5	97,873 (15.3)
6	108,757 (17.0)
7	93,385 (14.6)
8	78,089 (12.2)
9	53,818 (8.4)
10	13,602 (2.1)
Country of Birth	
Israel	344,253 (53.8)
Not Israel	295,262 (46.2)
Ethnic and Religious Distribution	
General	525,978 (82.2)
Arab	76,336 (11.9)
Ultra-orthodox	26,518 (4.1)
Unknown	10,683 (1.7)

[1] Age was defined as of 1 January 2017.

The monthly benzodiazepine dispensing rate, calculated as the total number of patients dispensed benzodiazepines divided by the number of patients alive during that month, demonstrated a consistent monthly range of 0.17 to 0.24 packages per month per cohort member throughout the study period (Figure 1). The highest observed point occurred in March 2020 at 0.24, coinciding with the peak of the COVID-19 pandemic. In contrast, the lowest point was noted in February 2017 at 0.17. The mean dispensing rate over the entire study duration was 0.22 packages per month per cohort member. Age was calculated as of 1 January 2017, for all patients.

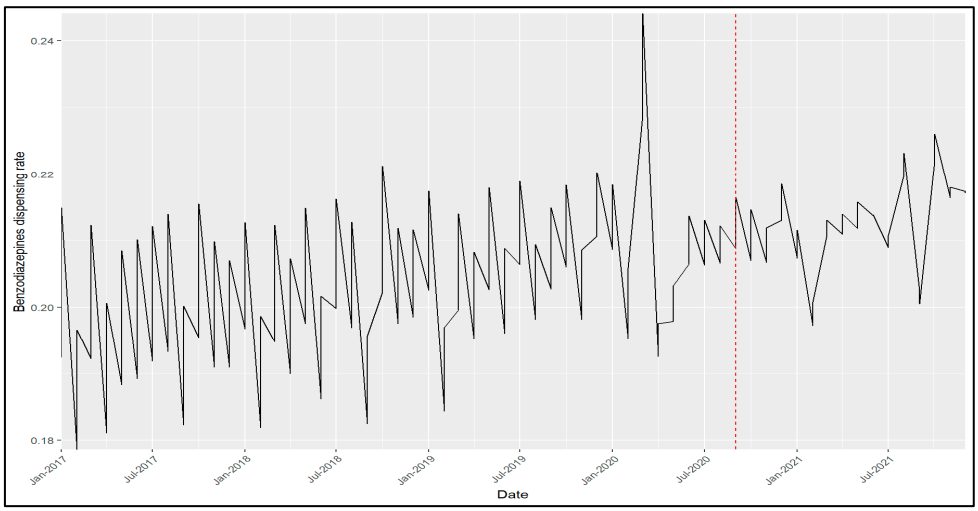


Figure 1. Benzodiazepine dispensing rate. The dotted red line represents the FDA black box warning date. The resolution is with 2 weekly data points.

Further stratifying the benzodiazepine dispensing rate by age groups revealed consistent trends over the years, with the elderly population (≥85) exhibiting the highest rates and the younger population demonstrating the lowest rates (Figure 2). This age-related variation persisted across the study period, highlighting potential age-dependent patterns in benzodiazepine dispensing rates.

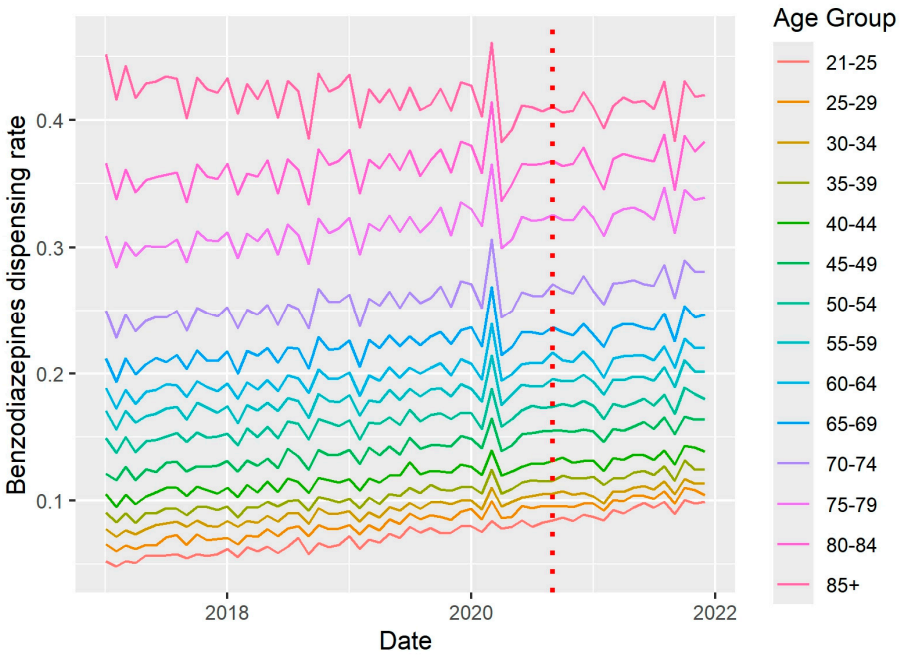


Figure 2. Benzodiazepine dispensing rate by age group. The dotted red line represents the FDA black box warning date. The resolution is with monthly data points.

Linear regression analysis evaluating dispensing rate trends before and after the FDA black box warning date revealed distinct trends in the dataset (Figure 3). Prior to the black box warning, the regression model demonstrated an upward slope of 0.0675, indicating a positive association between benzodiazepine dispensing rate and time. Following the FDA black box warning, the slope decreased to 0.00001. The difference in slopes before and after the FDA black box warning was not statistically significant ($p = 0.38$, t-test), suggesting no substantial alteration in the association between benzodiazepine dispensing rate and time after the FDA black box warning.

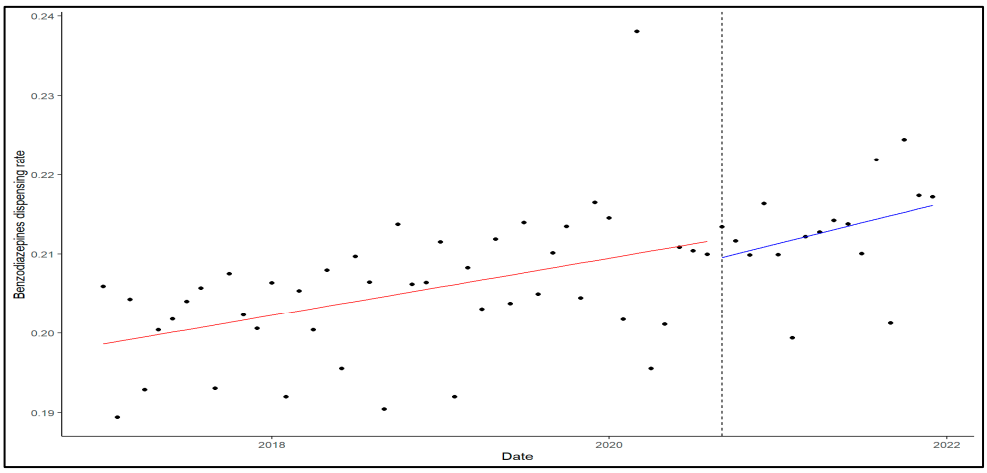


Figure 3. Linear regression before and after the FDA black box warning date (23 September 2020). The dotted line represents the FDA black box warning date. The slopes of the regression lines before and after the black box warning date were not statistically significantly different (p = 0.38, t-test).

Change point regression analysis was conducted to investigate temporal variations in the benzodiazepine dispensing rate per month between January 2017 and December 2021 (Figure 4). The analysis identified a significant change point in April 2019, indicating a shift in the trend of benzodiazepine dispensing rates. Notably, the identified change point, April 2019, precedes the black box warning date of 23 September 2020.

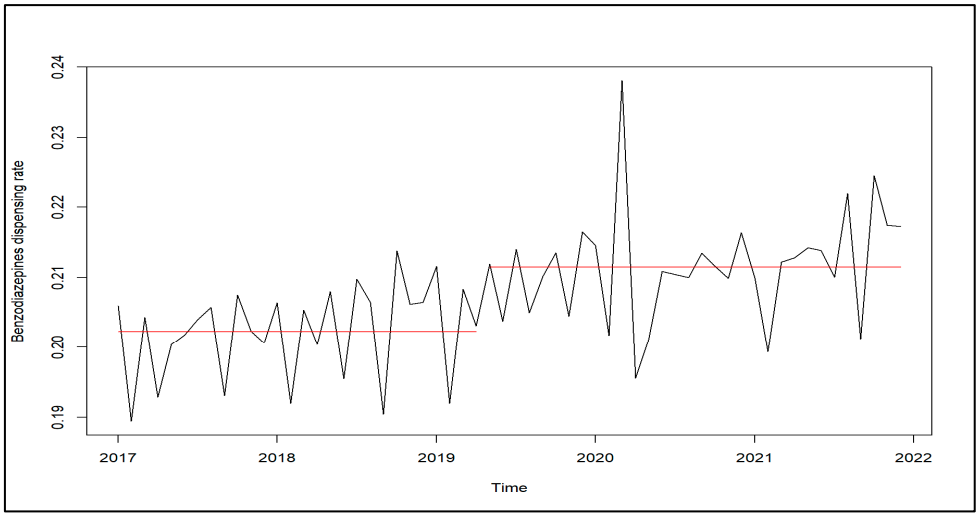


Figure 4. Change point regression. The red line represents the change point regression (April 2019).

The impact of the FDA black box warning on benzodiazepine dispensing rates was assessed by analyzing the number of patients taking benzodiazepines before and after the FDA black box warning date (Figure 5). The data were further segmented by age groups to discern potential demographic variations. We observed a noteworthy pattern in the post-black box warning period. Specifically, the number of new benzodiazepine users among younger age groups increased significantly compared to the pre-black box warning period.

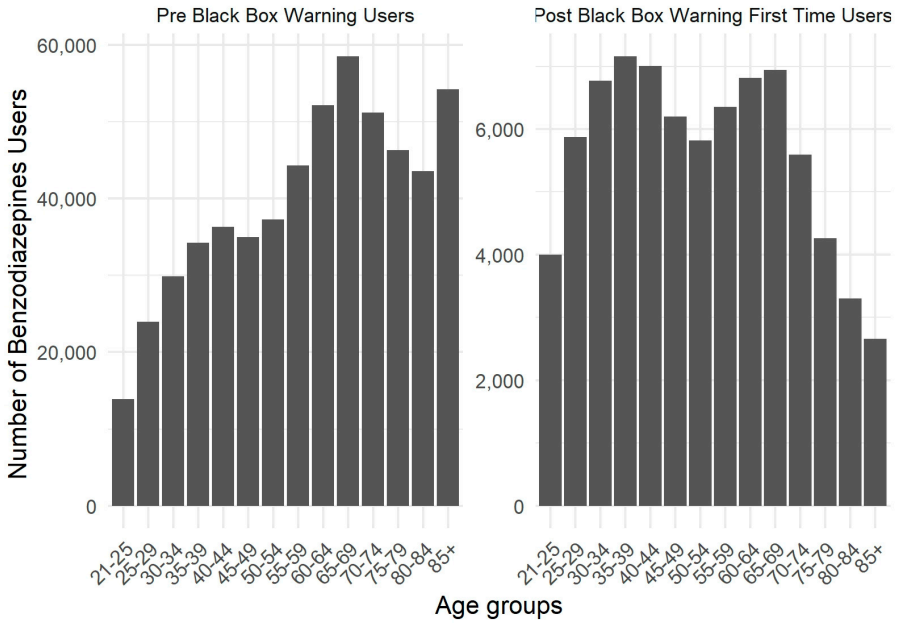


Figure 5. Number of benzodiazepine users before and new users after the FDA black box warning by age group.

3. Discussion

In this study, we reviewed the effect of the black box warning on the benzodiazepine dispensing rate before and after the FDA black box warning date in September 2020. In 2017, the same health service system published a research report concluding higher rates for benzodiazepines in the older population in Israel [16]. As the majority of the users in that study were over 80 years of age, we hypothesized that the benzodiazepine dispensing rate would decrease after September 2020 due to the FDA black box warning and the known side effects, alongside the natural death of the older population chronically using benzodiazepines. Our hypothesis is not supported by the findings, as a decrease in the benzodiazepine dispensing rate was not observed; instead, a constant increase in use was detected, with a clear peak at the beginning of the COVID-19 pandemic in March 2020. To rule out the possibility that the constant increase in dispensing rates of benzodiazepines stems from the elderly population, we categorized the population by age. We found an age-dependent pattern—a higher dispensing rate among the older population, but also a notable dispensing rate among the younger age groups—that was consistent throughout the study period with variability corresponding to external events such as the COVID-19 pandemic. Indeed, the study showed clear evidence of an increasing dispensing rate amongst younger age groups between 2020 and 2022. This is definitely of concern, and one may hypothesize that this is linked to the outbreak of the COVID-19 pandemic.

No significant differences in the dispensing rate trend were observed after the black box warning. When regression analysis was used to identify the point in time where a change in the dispensing rate occurred, the identified date was April 2019 and not September 2020, suggesting that the black box warning had no major impact. This result of the change point analysis reinforces the interpretation that the shift in dispensing rate trends was not temporally linked to the FDA warning, but likely reflected earlier influences.

The increasing number of benzodiazepine users is consistent with the global trend of increased benzodiazepine use, especially during the COVID-19 pandemic [17–23]. This increased use is not only concerning due to the known withdrawal syndrome but also for the younger population added every year to the chronic users. While the age distribution of benzodiazepine users before the black box warning trended towards the older population,

the new users after the black box warning trended towards younger age groups, indicating that the total number of users is likely to increase in the coming years.

Although we did not observe a significant change in dispensing rate trends following the FDA black box warning, this may reflect broader clinical realities, such as limited awareness or implementation of regulatory guidance among prescribers. The continued use of benzodiazepines, particularly among younger adults, may also relate to pandemic-related stress and limited alternative treatment options. These factors, along with differences in national and international prescribing guidelines, warrant further exploration. Future studies using longitudinal models without pre/post grouping may help uncover more nuanced trends across specific subgroups. This study constitutes a case study for the adherence to black box warnings and the lack of change in dispensing rates despite a clear message from the FDA to exercise increased caution before starting a patient on benzodiazepines. The FDA, as mentioned on its podcast page, emphasized the necessity for ongoing safety updates to enhance the responsible use of benzodiazepines, even with the existing black box warning in place [8].

Our study has several limitations. The COVID-19 pandemic had a tremendous effect on mental health and anxiety [15,24,25], which might have impacted the adherence to the black box warning. Also, our study reviewed the change in the dispensing rate over 5 years, although it may take longer to observe the impact of the black box warning, due to the trickle-down effect and more gradual change in dispensing rate patterns. Our use of separate regressions to examine pre- and post-warning trends may not fully account for the temporal continuity between these periods. This is an opportunity for future analyses. We chose to group patients based on initiation of therapy at different times. An alternative way to analyze the data would be to simply analyze overall use with time, which may provide an opportunity to see the impact of external events on the cessation of therapy. This is an opportunity for further research. While our approach evaluated the general dispensing rate of benzodiazepines, a more nuanced approach may have evaluated different doses used. As there were multiple different medications evaluated within the benzodiazepine class, an appropriate analysis of dosing could not be performed. However, this is an opportunity for further research. While we did not perform interaction analyses, an opportunity for future research would be to understand deeper nuances in benzodiazepine dispensing rates amongst sub-populations of patients. This could include, for example, evaluating interactions between time of initiation and age group. The listing of all patient's ages was as of 1 January 2017. This introduced an age lag for users initiating therapy later in the study period.

The strengths of this study include its large sample size, and its use of a robust and expansive dataset to investigate benzodiazepine dispensing rate trends. Notably, all Israeli citizens are covered through the public health system, mitigating potential confounding factors associated with patients seeking care in private clinics and underscoring the unique strength of our dataset in providing a comprehensive understanding of benzodiazepine utilization patterns in a nationally representative context.

4. Materials and Methods

4.1. Subjects and Data Source

Data for this study were obtained from the clinical and administrative data systems of Clalit Health Services, a not-for-profit integrated care delivery system serving over half of the Israeli population. The study included all Clalit patients who were $\geq$21 years old before 1 January 2017, and were dispensed benzodiazepines at least once during the study period (1 January 2017, to 30 December 2021). Patients who died within the first three months of

the study period were excluded to ensure a minimum follow-up window and to avoid distortions in the early-month dispensing rate estimates due to incomplete data.

For each patient in the cohort, every month in which benzodiazepines were dispensed between January 2017 and December 2021 was recorded. If patients were dispensed 3 packages of benzodiazepines for 3 months, it was considered as 3 consecutive monthly dispensations of the drug. The benzodiazepine's dispensing rate was computed for each month from January 2017 to December 2021, by summing up the number of patients to whom benzodiazepines were dispensed during a given month and dividing it by the total number of study patients during that month, as adjusted for their date of death as provided.

Standard demographic data including gender, country of birth, socioeconomic status score, and ethnic and religious status were recorded. Age was calculated as of 1 January 2017, and this definition was used consistently across all analyses, including for comparing pre- and post-black box warning users. Ages were grouped in 5-year increments from 21 to 24 years to $\geq$85 years.

Patients were categorized as "pre-black box warning users" or "post-black box warning new users". Post-black box warning new users were defined as those taking benzodiazepines for the first time in the study period after the FDA black box warning (September 2020). Pre-black box warning users were defined as patients taking benzodiazepines between the start of the study period and the date of the FDA black box warning. If a patient had never received benzodiazepines prior to the black box warning, they were considered to be a "post-black box warning new user".

The socioeconomic score was based on small statistical areas (SSAs) used in the 2008 Israeli census. The Israeli Central Bureau of Statistics (CBS) utilized demography, education, employment, housing conditions, and income to define the SSAs, and these were grouped into 20 categories. These data were updated by the POINTS Location Intelligence Company to improve the accuracy of the socioeconomic status score measure, using up-to-date sociodemographic, commercial, and housing data. The entire data population was grouped into 10 categories, ranging from 1 (lowest) to 10 (highest) [26–28].

4.2. Analyses

Two types of regression analyses were performed to assess the change in the benzodiazepine dispensing rate before and after the black box warning date (23 September 2020). These included linear regressions performed before and after the date of the black box warning, estimating the slope and intercept of the regression line. The difference in the slopes of the regression line was determined with a *t*-test. In addition, change point detection was used to identify the change point based on the variance and the means in a series of timepoints. The change point detection method identified a specific point or period in the months where a significant change occurred. It was used to find whether there was a distinct shift or change in the trend of benzodiazepine dispensing rate after the black box warning date or at other timepoints, to explore whether the timing of the trend change coincided with the FDA warning. Age distribution of the "pre-black box warning users" and the "post-black box warning new users" was compared. $p < 0.05$ was considered statistically significant.

4.3. Ethics

This research was approved by the Institutional Review Board/Helsinki Committee of Clalit Health Services. An informed consent waiver was granted as the study was retrospective, and all data were de-identified.

5. Conclusions

Our study sheds light on the evolving patterns of benzodiazepine dispensing rates post-FDA black box warning, emphasizing the imperative for continued vigilance and responsive regulatory measures to ensure the optimal and safe utilization of this drug class in clinical practice. Future studies are warranted to identify the gaps related to black box warning adherence and highlight the need for comprehensive strategies to improve dissemination of drug safety information to healthcare professionals.

Author Contributions: Formal analysis, N.S.L., K.F., J.G. and D.A.G.; methodology, N.S.L., J.G. and D.A.G.; writing—original draft, N.S.L., J.G. and D.A.G.; writing—review and editing, N.S.L., K.F., J.G. and D.A.G. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board of Clalit Health Services (COM2-0043-22 and 10 July 2022).

Informed Consent Statement: Patient consent was waived as the study was retrospective, and all data were de-identified.

Data Availability Statement: The dataset presented in this article is not readily available because it is subject to approval from the Clalit data extraction committee. Requests to access the dataset should be directed to the corresponding author.

Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

CBS	Central Bureau of Statistics
COVID-19	Coronavirus disease 2019
FDA	Food and Drug Administration
SSA	Small statistical area

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