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Changes in pregabalin use and overdose after government interventions and media coverage: retrospective observational study

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ABSTRACT

OBJECTIVES

To evaluate trends in pregabalin use and overdose in Australia and examine temporal relationships with media coverage (December 2018), prescribing and dispensing restrictions (April 2020), and boxed warnings (February 2021).

DESIGN

Retrospective observational study of dispensing and overdose data, with changepoint, interrupted time series, and latent class analysis.

SETTING AND PARTICIPANTS

Pharmaceutical Benefits Scheme data (PBS; 10% random sample of people with drug subsidies) and overdose calls (self-harm, recreational use, and misuse) reported to Australia's largest Poisons Centre (50% national sample), 2016-24.

MAIN OUTCOME MEASURES

Population adjusted rates of dispensing and overdose, timing of breakpoints and rate ratios, proportion of people who use pregabalin at high risk of misuse.

RESULTS

227 864 people were dispensed 3 441 851 pregabalin prescriptions in the PBS 10% sample and 4871 pregabalin overdose calls were made to the Poisons Centre. Pregabalin use peaked in 2018 before plateauing and declining. Three breakpoints were found in dispensing data, with major decreases in level and slope: December 2018, May 2020, December 2021. The combined rate ratio for dispensing was 0.748 (95% confidence interval 0.700 to 0.800). Compared with the projected historical trend in the absence of interventions (counterfactual), approximately 118 390 (93 960 to 140 940) fewer pregabalin prescriptions were recorded nationally in December 2021, and an ongoing reduction of 0.7% (0.5% to 0.9%) was found each month. All breakpoints were associated with declines in overdose rates, with a combined rate ratio of 0.532 (95% CI 0.406 to 0.695). This reduction corresponded to approximately 41.3 (26.9 to 52.4) fewer pregabalin overdose calls in December 2021 and an ongoing reduction of 1.6% (1.0% to 2.3%) each month. Latent class analysis of 57 744 people dispensed pregabalin in the 12 months after the final breakpoint revealed four groups. The high risk group (7790, 13.5%) were more likely male, younger, dispensed more pregabalin, with shorter refill interval and high rates of opioids and benzodiazepine co-use (5120 (65.7%) and 2455 (31.5%), respectively).

CONCLUSIONS

Pregabalin use and overdose in Australia have declined in recent years. Major decreases in trend corresponded with media coverage (December 2018) and prescribing and dispensing restrictions (May 2020). The third breakpoint may be a delayed impact of boxed warnings (implemented February 2021). These findings suggest that regulatory and risk communication measures may contribute to reducing pregabalin related harm.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Pregabalin use and harms have been increasing rapidly worldwide

Many countries are attempting to curb use and misuse with restrictions and interventions

WHAT THIS STUDY ADDS

Pregabalin use and overdoses have plateaued and declined in Australia since 2018

Declines in trend are associated with high profile media coverage of harms, restrictions on prescriptions and supply, and new boxed warnings

Introduction

Gabapentinoids (pregabalin and gabapentin) were originally developed as antiseizure drugs. Subsequently licenced indications expanded to include neuropathic pain, fibromyalgia, and generalised anxiety disorder, depending on the country. Despite this relatively narrow range of approved indications, gabapentinoids are considered "blockbuster" drugs.[1] High income countries have the highest rates of gabapentinoid consumption, while low and middle income countries have had the highest consumption growth in recent years.[2 3] Most of this consumption is driven by off label use for non-registered indications.[4-6] Alongside rising use, there is mounting evidence of misuse, dependence, and harms from gabapentinoid use in Europe, the United States, Asia, and Australia.[7 8] In the UK, one third of substance use deaths involve a gabapentinoid, predominantly pregabalin,[9] and deaths involving gabapentinoids have more than doubled from 2018 to 2022.[10] Similar concerns have been reported elsewhere—misuse has increased in France, where over one quarter of falsified prescriptions involve pregabalin.[11] In Australia, pregabalin overdose increased by 54% year-on-year between 2005 and 2016, mirroring increased use after its government subsidy,[12 13] and around 15% of people dispensed pregabalin were at high risk of misuse.[12]

In Australia, several strategies have been implemented in response to concerns over pregabalin related harm. The Therapeutic Goods Administration

(Australia's drugs regulator) launched an investigation into pregabalin misuse in 2019,[14] resulting in alerts to healthcare professionals and updates to manufacturer product information in February 2021. The Therapeutic Goods Administration mandated a black box warning on pregabalin relating to its misuse potential, and highlighting risks of concomitant use with benzodiazepines and opioids,[15] consistent with action taken by other countries.[16] At a state level, in New South Wales (Australia's most populous state), pregabalin was upscheduled to schedule 4 appendix D (S4D, prescribed restricted substances), placing it under stricter controls that are consistent with benzodiazepines and weak opioids. This introduced requirements for secure storage in pharmacy safes and tighter regulation on possession and supply. Additionally, real time prescription monitoring was introduced in New South Wales from November 2021, becoming fully operational in May 2022.[17] Beyond regulatory measures, prescriber and consumer behaviour can also be influenced by media coverage.[18] Following research publications,[12 13] several high profile stories highlighted harms from pregabalin in the Australian press in late 2018,[19 20] resulting in national journalism awards.[21]

This study aims to provide an update on pregabalin use and misuse in Australia. We have focused on pregabalin because rates of gabapentin use and harms in Australia are low.[12] Specifically, we aimed to quantify trends in dispensing and poisoning over time, and examine temporal changes relating to key policy and media events described above; identify and characterise clusters of people who use pregabalin based on personal and drug use characteristics; and identify trends in clusters and prevalence of high risk use as defined by concomitant use of opioids and benzodiazepines, dose dispensed, dispensing interval, and number of prescribers.

Methods

Data sources and study design

This is a retrospective study of pregabalin dispensing and overdose data from January 2016 to December 2024 (inclusive). We quantified medicine use based on Pharmaceutical Benefits Scheme (PBS) dispensing claims. Australia has a universal healthcare system where citizens and permanent residents are permitted to access subsidised drugs through the PBS. The PBS 10% sample is a national dataset containing a random 10% sample of any Australian ever dispensed a PBS drug and their dispensing history. People in the PBS dataset receive a randomly assigned unique identifier and the 10% sample is selected based on the last digit of each person's unique identifier. There are two categories of beneficiaries: general beneficiaries who pay a higher copayment than their concessional beneficiary counterparts. People entitled to concessional benefits are generally aged 65 years and older, on low incomes, unemployed, or with disabilities. This dataset is described in detail elsewhere.[22] These nationwide, person level dispensing data allowed us to classify people who use pregabalin into clusters based on demographic and drug use characteristics (eg, dose, dispensing interval, number of prescribers, and use with other drugs). We included all pregabalin dispensings in the PBS 10% sample using PBS codes 2348N (25 mg capsules), 2335X (75 mg capsules), 2355Y (150 mg capsules), and 2363J (300 mg capsules); all are available in a standard pack size of 56 capsules.

We quantified pregabalin overdose using data from the New South Wales (NSW) Poisons Information Centre. The NSW Poisons Information Centre is Australia's largest poisons centre, taking approximately 50% of Australia's 240 000 poisoning calls, 65% of which originate from the state of NSW. The Poisons Information Centre provides poisoning management advice to healthcare professionals and members of the public. The NSW Poisons Information Centre codes drug use with a substance dropdown list and there is a specific code for pregabalin. We included intentional pregabalin poisonings (which includes recreational use, self-harm overdose, and other forms of intentional non-medical use). Unique overdose calls were included, with follow-up calls about the same person excluded from counts.

Because of several possible impacts on pregabalin use (described above), our primary analysis was a changepoint analysis using monthly population adjusted dispensing rates. The changepoint analysis is a data driven approach investigating when there were any abrupt changes (level shifts) or changes in slope in a time series, if any. We then examined whether the changes identified in drug use translated to harms from poisoning. We hypothesised that pregabalin overdoses rise and fall in tandem with pregabalin use and availability in the community, as observed previously.[12] Once we had determined optimal breakpoints based on dispensing data, we performed interrupted time series analysis using the poisoning data with the identified optimal breakpoint in dispensing as the intervention date. Interrupted time series analysis is one of the strongest quasi-experimental designs for evaluating the effectiveness of population level health interventions.

Statistical analysis

A full description of our methods is provided in the supplementary methods. Summary statistics were presented as frequencies and percentages for categorical variables, and medians with interquartile ranges for continuous variables owing to non-normal distributions. Rate ratios were used to quantify level and slope changes. Level change rate ratios compare the rate immediately after an intervention with the expected rate immediately before the intervention and therefore represent an immediate and sustained change in the outcome rate. In contrast, slope change rate ratios compare the monthly trend after intervention with the monthly trend in the preceding segment, and therefore represent a change in the rate of increase or decrease over time. For multiple interventions or

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breakpoints, estimated rate ratios were calculated relative to the preceding segment and so account for the effects of earlier interventions.

Dispensing data

For our changepoint analysis, we fitted time series models accounting for autocorrelation as necessary and seasonality by including dummy variables for the months and Fourier terms (pairs of sine and cosine functions) in our models. We chose the most parsimonious model based on fit statistics (ie, Akaike information criterion and bayesian information criterion). We applied multiple structural change modelling[23] to the model chosen by the Akaike information criterion or bayesian information criterion, and computed the optimal breakpoints and their 95% confidence intervals (CIs). The changepoint analysis estimates the breakpoint and its variance, which quantifies uncertainty in the estimated breakpoint. The null hypothesis was no change or a break in the series. We allowed for the number of breakpoints to be more than one.

Changepoint analysis is presented as the estimated time of changepoint (month with 95% CI), and changes in slope and level (reported as rate ratios). Effect estimates were also calculated as percentage differences between observed and counterfactual estimates, where the counterfactual estimate represented the projected outcome had the preintervention trend continued in the absence of the intervention. We evaluated the validity of the counterfactual compared with the observed values before the intervention using the median absolute difference.

Overdose data

After identifying changepoints in dispensing data, our main analysis of overdose data was an interrupted time series analysis to measure any associated changes in overdose. Our outcome variable, the monthly number of overdose calls, follows a Poisson distribution. We analysed the data using segmented Poisson regression, or segmented negative binomial regression to account for overdispersion as necessary. Regression models included a time variable, an indicator variable for each post-breakpoint status and an interaction term between time and each indicator variable for post-breakpoint status. The time variable indicates a gradual monthly trend in overdose before the first breakpoint. The indicator for post-breakpoint status estimates a change in level indicating an immediate and sustained change in overdoses after the breakpoint. The interaction between time and the indicator variable estimates a change in slope indicating a gradual monthly change in overdoses after the breakpoint. We added the Australian Bureau of Statistics mid-year estimates of the population as an offset to the models to adjust for population growth over time. (We used 50% of the population estimate to account for the fact that the NSW Poisons Information Centre takes 50% of Australia's poisoning calls.) To account for autocorrelation, we used a Newey-West estimator as necessary based on Durbin-Watson statistics, in addition to checking residual plots, autocorrelation function plots, and partial autocorrelation function plots. We accounted for seasonality as necessary, according to the two approaches described above. Two tailed P values of less than 0.05 were considered to indicate statistical significance. We estimated the rate ratios and their 95% CIs. Effect estimates were calculated as percentage differences between observed and counterfactual estimates. We evaluated the validity of the counterfactual compared with the observed values before intervention using the median absolute difference.

Post hoc analysis

We conducted a post hoc analysis to estimate the cumulative effect of all identified breakpoints. For this analysis, the periods between the breakpoints were treated as washout periods to allow intervention effects to accumulate. Outcomes after the final breakpoint were compared with those expected had the trend before the first breakpoint continued to provide an estimate of the overall effect of all interventions.

Sensitivity analyses

We also conducted several sensitivity analyses.

1. *Alternative outcome metric*: we performed an interrupted time series analysis of overdose calls per dispensing (rather than per population), using dispensing derived breakpoints.
2. *Prespecified intervention dates*: we conducted an interrupted time series analysis using prespecified intervention dates of April 2020 (S4D in NSW) and February 2021 (boxed warnings and changes to information leaflets).
3. *Covid-19 period as a breakpoint*: we included the covid-19 pandemic period, from March 2020 to November 2021, as a time varying confounder. (This date range has been used previously to describe Australia's covid-19 period.[24] Australia's interstate and international borders reopened in December 2021 and many public health measures were relaxed at this time.)
4. *Changepoint analysis of overdose data*: to determine data driven breakpoints in overdose, independent of dispensing derived breakpoints.
5. *Shifted changepoint analyses*: to model potential lagging and anticipatory changes, we conducted additional post hoc analyses of overdose calls per population where we shifted each breakpoint by one, two, and three timepoints (months) before and after the externally defined intervention date identified in dispensing data. We fitted all combinations of shifted breakpoints (343 models in total, including the original specification), using the Akaike information criterion and bayesian information criterion.

Comparison with gabapentin

Although our focus was on the use of pregabalin, to detect possible switching or substitution, we also plotted rates of gabapentin dispensing (PBS item

codes: 04591P, 01834M, 01835N, 04594T, 04595W) and overdose from 2016 to 2024.

Latent class analysis

To identify different clusters of pregabalin users, and potential misuse, we applied latent class analysis to identify different subgroups or clusters of people who use pregabalin within a one year period (from December 2021 to November 2022, corresponding to the year after the final breakpoint identified). We used the same methodology as described in our original paper on pregabalin.[12] Briefly, we used the following indicators that have been established as possible indicators of high risk use:[12] early refill (mean time between dispensings <20 days), number of pregabalin prescribers, total defined daily doses of pregabalin dispensed (1 defined daily dose=300 mg), mean tablet strength dispensed, dispensing of opioids or benzodiazepines within 30 days of pregabalin dispensing. We chose the optimal number of latent classes by comparing fit statistics and considering clinical relevance and class prevalence. Each person's most likely class membership was determined using conditional prior probabilities. We also investigated the association between class membership and several covariates using logistic regression. Covariates included were age group, sex, and PBS concessional status.

The PBS and NSW Poisons Information Centre datasets have a variable called "sex"; however, this variable may contain information on both sex and gender. We are unable to report on sex and gender as distinct constructs.

All analyses were performed in R version 4.3.1. We used the *strucchange* R package for changepoint analysis and the poLCA R package for latent class analysis. For more details on the statistical analyses, see supplementary methods.

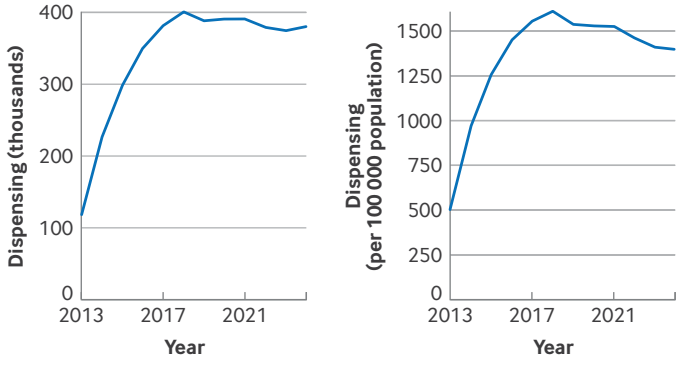

Fig 1 | Yearly pregabalin dispensing in Australia, 2013-24, showing counts (left panel) and population adjusted rates (right panel), using Pharmaceutical Benefits Scheme data (10% random sample of people with drug subsidies). Counts can be multiplied by 10 to obtain estimates of national dispensing counts. Data from 2013-16 have been published previously.[12] These data were included in this figure for reference but not included in other analyses in this paper

Handling of missing data

The poisons centre data contained some missing values for age and sex; missingness is reported where summary statistics are presented. The PBS data had no missing values for age and sex. Analyses of monthly dispensing and overdose rates relied on population adjusted rates and were not stratified by age or sex. Therefore, missing data in these variables did not affect the analysis and no imputation or other handling was required.

Patient and public involvement

During the development of this programme of work, we engaged with two people with lived experience of intentional poisoning and psychotropic medicine use (via a Roses in the Ocean, an Australian lived experience organisation) to prioritise the research approach. They emphasised the importance of studying psychotropic drugs that are disproportionately involved in poisoning related harms, including pregabalin.

Results

Trends in pregabalin dispensing

Pregabalin dispensings peaked in 2018 at 401 580 in the PBS 10% sample (extrapolated to 4 015 800 nationally). Annual dispensing rates have since declined, with 380 975 in 2024 (fig 1).

Primary analysis: pregabalin dispensing

Our primary analysis of dispensing data was a data driven breakpoint analysis. Three breakpoints were observed when pregabalin dispensing decreased significantly. In December 2018 (corresponding to high profile media coverage in the lay press), an abrupt decrease in pregabalin dispensing occurred (rate ratio 0.935, 95% CI 0.911 to 0.960; table 1, fig 2). Breakpoint 2 was identified in May 2020 (the month after S4D rescheduling) when a further abrupt decrease in pregabalin dispensing (0.955, 0.919 to 0.993) and a slight slope decrease occurred (table 1). In December 2021 (breakpoint 3, following boxed warnings and gradual introduction of real time prescription monitoring), a decrease in level was detected (0.930, 0.886 to 0.976), and a decrease in slope (table 1).

We compared the observed and counterfactual trends in December 2021 (fig 2; counterfactual is what would have happened if trends before 2019 continued; see supplementary figure 1 for counterfactuals from other breakpoints). Preintervention model validation showed close agreement between observed and counterfactual values, with a median absolute difference of 9.321 dispensings per 100 000 population, where the baseline median rate was 256 per 100 000 population. We observed a decrease in pregabalin dispensing rate (rate ratio 0.748, 95% CI 0.700 to 0.800; table 2). Compared with the counterfactual estimate for December 2021, this was equivalent to a reduction of 25.2% (95% CI 20.0% to 30.0%) in dispensing rate or approximately 11 839 (95% CI 9396 to 14 094) fewer prescriptions in December 2021 in the PBS 10% sample, extrapolated to 118 390 fewer prescriptions

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Table 1 | Changepoint analysis with Poisson segmented regression to investigate breakpoints in monthly pregabalin dispensing and corresponding changes in pregabalin overdose calls

Breakpoint (95% CI)	Change in level, rate ratio (95% CI*)	Change in slope, rate ratio (95% CI)
Pregabalin dispensing per population		
Dec 2018 (Nov 2018 and Jan 2019)	0.935 (0.911 to 0.96)†	0.993 (0.991 to 0.995)†
May 2020 (Feb 2020 and Aug 2020)	0.955 (0.919 to 0.993)†	0.994 (0.993 to 0.996)†
Dec 2021 (Sep 2021 and Feb 2022)	0.93 (0.886 to 0.976)†	0.993 (0.992 to 0.995)†
Overdose calls per population		
Dec 2018 (Nov 2018 and Jan 2019)	0.968 (0.884 to 1.06)	0.99 (0.984 to 0.997)†
May 2020 (Feb 2020 and Aug 2020)	0.984 (0.882 to 1.097)	0.979 (0.974 to 0.984)†
Dec 2021 (Sep 2021 and Feb 2022)	0.92 (0.822 to 1.029)	0.984 (0.979 to 0.988)†

*95% confidence interval (CI) estimated with heteroskedasticity and autocorrelation consistent covariance matrix using Newey-West standard error as appropriate.
†95% confidence interval excludes 1.

nationally where the counterfactual absolute number of prescriptions would be approximately 469 812 nationally. Prescriptions continued to decline after this breakpoint at a rate ratio of 0.993 per month (95% CI 0.991 to 0.995), equivalent to an ongoing gradual reduction of 0.7% (95% CI 0.5% to 0.9%) in dispensing per month. Basic personal characteristics (age and sex) were similar before and after each breakpoint identified (supplementary table 1).

Trends in pregabalin overdose

A total of 4871 intentional pregabalin overdoses (encompassing self-harm, recreational use, and non-medical use) were reported to the NSW Poisons Information Centre between 2016 and 2024. Overdoses were increasing rapidly before they peaked in 2020 at 642, then fell to 569 in 2024 (fig 3). Forty six per cent (2250) of these overdoses occurred in men and 53% (2561) in women (sex not recorded in the remainder). The median age was 39 years (interquartile range 26-50).

Primary analysis: pregabalin overdose

Our primary analysis of overdose data was to determine whether changes identified in dispensing were associated with changes in overdose. Figure 4 shows monthly trends in population adjusted pregabalin overdose. We used interrupted time series analysis to quantify trends in overdose using the optimal breakpoints found for dispensing data. This analysis showed no statistically significant abrupt shifts, but significant decreases in slope corresponding to all three breakpoints (table 1, fig 4, supplementary figure 2).

We analysed overdose trends with the time between breakpoints 1 and 3 used as a washout period. Preintervention model validation showed close agreement between observed and counterfactual values, with a median absolute difference of 0.0479 overdoses per 100 000 population, where the baseline median rate was 0.285 overdoses per 100 000 population. We compared trends before December 2018 and after December 2021 and found a level shift, rate ratio 0.532 (95% CI 0.406 to 0.695) and a decrease in slope (0.984, 0.977 to 0.990; table 2, counterfactual line in fig 4). These data correspond to 41.3 (95% CI 26.9 to 52.4) fewer overdose calls to the NSW Poisons Information Centre in December 2021 (compared with the observed 58 calls) and a continued reduction of 1.6% (95% CI 1.0% to 2.3%) overdoses per month. Given the NSW Poisons Information Centre takes 50% of Australia's poisoning calls, we estimate approximately 83 fewer monthly overdose calls nationally in December 2021 compared with counterfactual values.

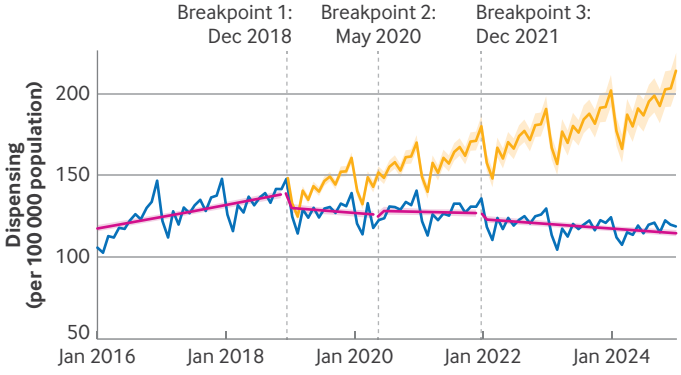

Fig 2 | Monthly dispensing per 100 000 population from January 2016 to December 2024 in blue. Dashed vertical lines show estimated optimal breakpoints in pregabalin dispensing trend (ie, December 2018, May 2020, and December 2021), with fitted straight lines (bounded by associated 95% confidence intervals) from segmented regression analyses in pink. Values predicted from segmented regression modelling in the absence of any breakpoints (counterfactual) are shown in orange and shaded area shows 95% confidence intervals

Sensitivity analysis: alternative outcome metric

When overdose calls were modelled per pregabalin prescriptions dispensed (rather than per population), we found no significant level shifts, but two significant slope changes (decreases) were observed, corresponding to the May 2020 and December 2021 breakpoints (supplementary table 2, supplementary figure 3).

Sensitivity analysis: prespecified intervention dates based on timing of legislation

We performed interrupted time series analysis with prespecified breakpoints of April 2020 (S4D rescheduling) and February 2021 (boxed warnings). This analysis showed a significant decrease in

Table 2 | Post hoc analysis: Poisson segmented regression to investigate changes in pregabalin related poisoning calls after December 2021, with December 2018 to November 2021 treated as washout period

Dispensing and poisoning	Previous trend, rate ratio (95% CI*)	Change in level, rate ratio (95% CI)	Change in slope, rate ratio (95% CI)
Dispensing per population	1.005 (1.004 to 1.006)†	0.748 (0.700 to 0.800)†	0.993 (0.991 to 0.995)†
Poisoning calls per population	1.015 (1.01 to 1.021)†	0.532 (0.406 to 0.695)†	0.984 (0.977 to 0.99)†

*95% confidence interval (CI) estimated with heteroskedasticity and autocorrelation consistent covariance matrix using Newey-West standard error as appropriate.
†95% confidence interval excludes 1.

level for dispensing and overdose after the April 2020 rescheduling (supplementary table 3). After the February 2021 boxed warning, we observed a significant decrease in level and slope for dispensing and overdose (supplementary table 3).

Sensitivity analysis: covid-19 as a breakpoint

When covid-19 was modelled as a time varying covariate, the same breakpoints were identified as the main analysis (supplementary table 4). The May 2020 breakpoint remained associated with a decrease in level and slope for dispensing, and a decrease in slope for overdoses, although with slightly wider 95% confidence intervals (supplementary tables 4 and 5).

Sensitivity analysis: breakpoint analysis of overdose data

Changepoint analysis of overdose data did not identify any statistically significant breakpoints.

Sensitivity analysis: shifted breakpoint analyses

Shifting each dispensing derived breakpoint by one, two, and three months before and after identified the best fitting model with breakpoints in March 2019, February 2020, and January 2022 (supplementary table 6).

Comparison with gabapentin dispensing and overdose

Australian rates of gabapentin use and overdose were much lower than for pregabalin. We observed an increase in use and overdose with gabapentin over the study period; however, this increase was not enough to account for the declines seen for pregabalin (supplementary figure 4).

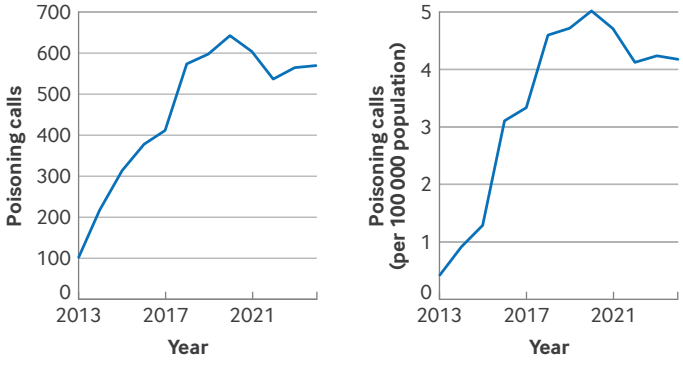

Fig 3 | Yearly pregabalin overdose calls to the New South Wales Poisons Information Centre, showing raw counts of unique exposure calls (left panel) and population adjusted rates (right panel). Data from 2013-16 have been published previously.[12] These data were included in this figure for reference but not included in other analyses in this paper

Characteristics of people using pregabalin and latent class analysis

In the 12 month period from December 2021 to November 2022, 57 744 people who were dispensed PBS subsidised pregabalin in the PBS 10% sample (extrapolated to approximately 577 440 people using pregabalin nationally or about 3% of Australia's adult population using pregabalin per month). Most people (56.9%, 32 867) were women (table 3) and the median age was 65 years (interquartile range 52-76). Half had concomitant opioid dispensing and almost one fifth had concomitant benzodiazepine dispensing (table 3).

Our latent class analysis found four distinct groups (table 3). The class 1 "high risk" group (13.5%, 7790) were more likely to be men compared with the other groups. Additionally, people in the high risk group were much younger compared with those in other groups, except compared with the "short course" group. People in the high risk group were also more likely to have concessional status, except compared with the "low dose, low volume" group (supplementary table 7). People in the high risk group were dispensed more pregabalin defined daily doses, higher tablet strengths, and had a shorter refill interval (table 3). Concomitant dispensing of opioids and benzodiazepines was frequent in those in the high risk group (65.7% (5120) and 31.5% (2455), respectively; table 3).

While our primary latent class analysis used the 12 month period from December 2021 to November 2022, we re-ran the analysis over the study period to examine distribution of classes by year to determine whether there were any changes with time. We used the 12 month period from March to February to be consistent with the paper using earlier data.[12] Class distribution was stable over the study period (supplementary table 8). Use with opioids and benzodiazepines has gradually declined over the study period (table 4). The reduction was particularly evident for concomitant use of pregabalin and opioids, dropping from 56.1% (34 089/60 780) in 2016-17 to 46.8% (27 255/58 271) in 2023-24.

Discussion

Principal findings

Pregabalin use and overdose have been on a steep upward trajectory since the subsidy started in 2013.

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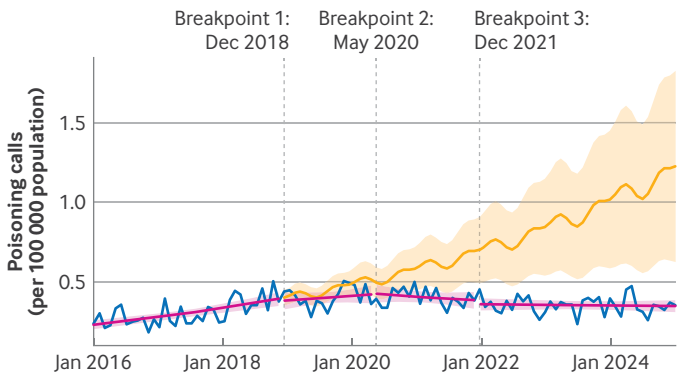

Fig 4 | Monthly pregabalin related poisoning calls per 100 000 population from January 2016 to December 2024 in blue. Dashed vertical lines show estimated optimal breakpoints in pregabalin dispensing trend (ie, December 2018, May 2020, and December 2021), with fitted straight lines (bounded by associated 95% confidence intervals) from segmented regression analyses in pink. Values predicted from segmented regression modelling in the absence of any breakpoints (counterfactual) are shown in orange and shaded area shows 95% confidence intervals

In this study, we observed a levelling off in 2018, and declining use and overdose to 2024. Media coverage and rescheduling (S4D) were associated with a major decrease in pregabalin use and overdose. A further drop in use and overdose was seen in December 2021, which may be a delayed impact of black box warnings or owing to other factors like real time prescription monitoring. These findings are promising because they represent a levelling off in trend, in contrast to the continued rise in pregabalin use globally.[3] However, prevalence of pregabalin use in Australia remains high and approximately 13% of use was classified as high risk (compared with 14.7% in our earlier analysis).[12]

Strengths and limitations of this study

The following strengths and limitations should be considered. The dispensing data provide individual drug use data from a large national sample; however, they capture subsidised dispensing only. Private prescriptions (when people pay the whole cost of the drug) are not captured and illicit supply is not considered. We expect the impact of private use to be small because available estimates indicate that private prescribing of pregabalin is rare (2.2%),[5] and no changes to subsidy rules were implemented over the study period. Poisons centre data are subject to reporting bias because calls are voluntary. We had data from the NSW Poisons Information Centre, which

Table 3 | Latent class analysis: age, sex, and concession status distribution for each dispensing class and characteristics of latent classes, December 2021 to November 2022

Characteristics	Class 1: high risk	Class 2: medium dose, longer term	Class 3: low dose, low volume	Class 4: short course	Overall
No of people	7790 (13.5)	21 472 (37.2)	8055 (13.9)	20 427 (35.4)	57 744 (100)
Age (years)					
<55	3090 (39.7)	5426 (25.3)	611 (7.6)	8125 (39.8)	17 252 (29.9)
55-64	1939 (24.9)	4579 (21.3)	902 (11.2)	4509 (22.1)	11 929 (20.7)
65-79	2234 (28.7)	7917 (36.9)	3271 (40.6)	5770 (28.2)	19 192 (33.2)
≥80	527 (6.8)	3550 (16.5)	3271 (40.6)	2023 (9.9)	9371 (16.2)
Sex					
Female	3772 (48.4)	12 253 (57.1)	5470 (67.9)	11 372 (55.7)	32 867 (56.9)
Male	4018 (51.6)	9219 (42.9)	2585 (32.1)	9055 (44.3)	24 877 (43.1)
Concession status					
General dispensing only	1490 (19.1)	5482 (25.5)	694 (8.6)	10 315 (50.5)	17 981 (31.1)
At least one concessional dispensing	6300 (80.9)	15 990 (74.5)	7361 (91.4)	10 112 (49.5)	39 763 (68.9)
Mean time between pregabalin dispensings					
Only one	113 (1.5)	0 (0)	0 (0)	14 705 (72.0)	14 818 (25.7)
<20 days	1754 (22.5)	2752 (12.8)	930 (11.5)	1624 (8.0)	7060 (12.2)
≥20 days	5923 (76.0)	18 720 (87.2)	7125 (88.5)	4098 (20.1)	35 866 (62.1)
No of pregabalin prescribers					
1-2	6022 (77.3)	18 597 (86.6)	7208 (89.5)	20 427 (100)	52 254 (90.5)
≥3	1768 (22.7)	2875 (13.4)	847 (10.5)	0 (0)	5490 (9.5)
Total defined daily doses dispensed					
<42	0 (0)	2 (0.0)	5082 (63.1)	20 427 (100)	25 511 (44.2)
42-329	890 (11.4)	21 470 (100.0)	2973 (36.9)	0 (0)	25 333 (43.9)
≥330	6900 (88.6)	0 (0)	0 (0)	0 (0)	6900 (11.9)
Concomitant dispensing of opioids					
No	2670 (34.3)	9958 (46.4)	3912 (48.6)	13 517 (66.2)	30 057 (52.1)
Yes	5120 (65.7)	11514 (53.6)	4143 (51.4)	6910 (33.8)	27687 (47.9)
Concomitant dispensing of benzodiazepines					
No	5335 (68.5)	16965 (79.0)	6306 (78.3)	18 540 (90.8)	47 146 (81.6)
Yes	2455 (31.5)	4507 (21.0)	1749 (21.7)	1887 (9.2)	10 598 (18.4)
Average tablet strength dispensed (mg)					
≤25	1 (0.0)	0 (0)	7701 (95.6)	9890 (48.4)	17 592 (30.5)
26-75	90 (1.2)	14182 (66.0)	354 (4.4)	9830 (48.1)	24 456 (42.4)
76-150	3528 (45.3)	7290 (34.0)	0 (0)	699 (3.4)	11 517 (19.9)
>150	4171 (53.5)	0 (0)	0 (0)	8 (0.0)	4179 (7.2)

Data presented as number (%).

Table 4 | Yearly trends in people dispensed pregabalin by number of prescribers and concomitant use of opioids and benzodiazepines

Year	No of people	Three or more pregabalin prescribers, n (%)	Concomitant dispensing of opioids, n (%)	Concomitant dispensing of benzodiazepines, n (%)
Year 1 (Mar 2016 to Feb 2017)	60 780	5095 (8.4)	34 089 (56.1)	13 611 (22.4)
Year 2 (Mar 2017 to Feb 2018)	63 221	5637 (8.9)	35 239 (55.7)	13 840 (21.9)
Year 3 (Mar 2018 to Feb 2019)	63 409	5892 (9.3)	35 277 (55.6)	13 487 (21.3)
Year 4 (Mar 2019 to Feb 2020)	60 622	5684 (9.4)	32 641 (53.8)	12 587 (20.8)
Year 5 (Mar 2020 to Feb 2021)	60 628	5323 (8.8)	30 901 (51)	11 855 (19.6)
Year 6 (Mar 2021 to Feb 2022)	59 757	5341 (8.9)	29 323 (49.1)	11 280 (18.9)
Year 7 (Mar 2022 to Feb 2023)	57 819	5398 (9.3)	27 736 (48)	10 540 (18.2)
Year 8 (Mar 2023 to Feb 2024)	58 271	5293 (9.1)	27 255 (46.8)	10 250 (17.6)

captures 50% of Australia's poisoning calls. Therefore, our data underestimate the true rate of pregabalin use and overdose. A key strength of poisons centre data is that they can accurately identify pregabalin overdose (unlike hospital admissions data coded with ICD-10 (international classification of diseases) codes because no specific code exists for pregabalin).

Owing to many factors that could plausibly affect pregabalin use and misuse, and because our study period included the covid-19 pandemic, we chose a changepoint analysis rather than relying solely on prespecified intervention timing. Across several sensitivity analyses, the main findings were largely robust to alternative model specifications, outcome definitions, and assumptions about timing of effects. However, changepoint analysis of overdose data did not identify major breakpoints. This apparent discrepancy reflects differences in analytical approaches rather than inconsistency in findings. Overdose is a rare clinical outcome with inherently volatile monthly rates, and policy driven behavioural changes often manifest as gradual, nonlinear deceleration rather than abrupt shifts. Compared with interrupted time series analyses, changepoint methods are more conservative and have reduced power to detect gradual or modest changes. Therefore, we presented an effect estimate with a counterfactual analysis aggregated across the entire period between the breakpoints, which confirmed a meaningful divergence from the historical trajectory. However, uncertainty increases over long time horizons, as reflected in the 95% CIs of the counterfactual estimates.

A key limitation in our approach is our limited capacity to measure unintended consequences of the various interventions. Potential unintended harms that were not possible to measure include reduced access to treatment for patients with neuropathic pain and epilepsy who may benefit from these drugs.[25] Negative media reporting and increased awareness of the pregabalin misuse potential could lead to stigma, which is a documented barrier for people with chronic pain.[26] Additionally, restrictions could lead to switching to other agents, including opioids and benzodiazepines; however, this seems unlikely—in Australia all opioids and benzodiazepines are at least as restricted as gabapentinoids, and all are monitored by real time prescription monitoring. Community opioid use in Australia has also declined over the study period.[3] Switching to other psychotropics without similar restrictions and warnings such as antidepressants and antipsychotics is also possible, but analysis of switching was outside the scope of this study. We observed increases in gabapentin use and overdose over the study period, however these increases were small in comparison to the decreases seen for pregabalin.

Meaning of the study

Lessons from the Australian experience may help inform and evaluate similar interventions elsewhere. In 2026, the UK Medicines and Healthcare Products Regulatory Agency announced strengthened warnings on gabapentinoid product information and packaging, alongside prescriber education and patient resources,[27] reflecting a comparable multifaceted regulatory approach that warrants prospective evaluation.

We found a changepoint (decreasing) associated with media coverage in the lay press. Media coverage of safety signals, legislative change, and health warnings have the potential to change health behaviour, including drug use. Media coverage critical of 3-hydroxy-3-methylglutaryl-coenzyme A reductase inhibitors (statins) resulted in an increase in statin discontinuation in Australia[18] and the UK.[28] Antidepressant use in the US decreased substantially after widely publicised warnings in 2003, which was associated with an increase in suicide attempts, indicating possible unintended consequences.[29] Media coverage of the association of aspirin and Reye's syndrome played a central role in reducing aspirin use in children and a decline in Reye's syndrome incidence.[30] This decline highlights the need for drug regulators to engage with the media to improve public dissemination of safety messages.

The reduction in concomitant dispensing of pregabalin with opioids and benzodiazepines may reflect prescriber education, boxed warnings, and real time prescription monitoring that generates alerts for these combinations. A course of gabapentinoids with other depressants (particularly opioids) increases the risk of overdose, respiratory depression, and death.[9 31] Pregabalin is frequently misused with other sedatives,[13 32] and pregabalin deaths almost always involve other substances, predominantly opioids, hypnosedatives, and antidepressants.[33] Many of these deaths are unintentional.[34] Despite these known risks,

approximately half of people using pregabalin in this study were also using opioids, indicating that further prescriber attention to this clinically significant drug-drug interaction is warranted.

The rescheduling of pregabalin to S4D in April 2020 coincided with a breakpoint, a decreasing level shift (in dispensing) and a slope change (decreasing, in dispensing and overdose). The effects of this intervention are hard to distinguish from any effects from the covid-19 pandemic; however, after adjusting for covid-19 in our sensitivity analyses, the same breakpoints were found. This legislation brought pregabalin in line with benzodiazepines and weak opioids, and resulted in additional rules around possession, supply, prescriptions, and storage. Other governments have taken similar steps to curb harms from gabapentinoids. In the UK, pregabalin and gabapentin were upscheduled to schedule 3 controlled substances in April 2019 (they are now subject to stricter prescription requirements and supply intervals).[35] However, in 2020, pregabalin prescriptions and deaths continued to climb in the UK.[9] The impact on prescribing has been modest.[36] In France, pregabalin was reclassified in 2021 to have restrictions similar to narcotics, including secured prescriptions and tightening of prescribing rules. This change was associated with a 23% drop in pregabalin dispensing and a decline in courses with opioids and benzodiazepines.[11]

We observed a decrease in pregabalin use and overdose after the December 2021 breakpoint. We could not identify one specific intervention that occurred at this time but speculate that this gradual change may be caused by a combination of factors. The new black box warnings were introduced in February 2021; it is conceivable that these would not result in an immediate change. Prescribers are unlikely to consult the product information each time they prescribe gabapentinoids. Real time prescription monitoring may also have had an impact; however, measuring this impact is not easy because it was adopted by each Australian jurisdiction differently in terms of implementation date, monitored substances, and mandated use. In New South Wales, real time prescription monitoring started in November 2021 and included pregabalin among the monitored drugs.[17] In the US, many states require gabapentinoids to be recorded in prescription drug monitoring programmes,[37] and in 2019 the Food and Drug Administration issued a drug safety communication and new mandatory warnings.[16] These measures were associated with a decrease in gabapentinoid poisonings between 2019 and 2022 in the US, from 76.5 to 68.5 poisonings per million US population.[38]

Unanswered questions and future research

Australian primary care data indicate that around half of people prescribed pregabalin had a neuropathic pain diagnosis, only 1% had an epilepsy diagnosis, and the remainder of use is off label.[5] Future studies could explore whether the decrease in pregabalin use disproportionately reduced high risk and off label use. Future studies could also examine treatment trajectories of people withdrawing from pregabalin, how fast they taper, what people switch to (if anything), and whether the breakpoints we identified were a result of increased discontinuation, reduced initiation, or both. Deprescribing of gabapentinoids has been identified as an important area of research,[39] with guidelines recently released.[40] Future studies could audit prescriber awareness and use of these guidelines, as well as provision of psychosocial support during tapering.

Non-medical use of gabapentinoids is associated with chronic pain, high psychological distress, and socioeconomic disadvantage.[41] Future qualitative research could explore the effects of the interventions described here on stigma, barriers to access, and impacts on pain and mental health from a patient perspective. Finally, although most pregabalin dispensing is captured by the PBS,[39] confirming our findings using sales data would be useful, which would also represent private dispensing.

Conclusions

After many years of escalating pregabalin use and overdose in Australia, rates appear to have plateaued and started to decline since 2018.[12 13] Although we cannot attribute causality, this decline was associated with widespread media coverage of harms in 2018, stricter scheduling in 2020, and boxed warnings in 2021. While our findings are positive, pregabalin use and overdose remain high, with dispensing rates still far outstripping what would be expected if pregabalin was prescribed for approved indications alone. Therefore, ongoing monitoring is needed and we should consider further interventions, including additional scheduling restrictions. The decrease in concomitant use of opioids and benzodiazepines (targeted by boxed warnings) is positive. However, almost half of people using pregabalin also use opioids, and further attention targeting this high risk drug interaction is warranted.

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Ethical approval: This study was approved with a waiver of consent by the Sydney Children's Hospitals Network Human Research Ethics Committee (2021/ETH00165, NSW Poisons Information Centre data), and Department of Human Services external request evaluation committee (RMS4432, PBS 10% sample).

Data sharing: The Pharmaceutical Benefits Scheme 10% sample was used under license and may not be shared without the express permission of approving ethics committees and data custodians. Interested parties may request access to the data by contacting the Australian Government Services Australia (https://www.servicesaustralia.gov.au/statistical-information-and-data). Data requests for the NSW Poisons Information Centre data can be made to the Australian Poisoning Surveillance Initiative (https://apsi-databank.sydney.edu.au/), all requests require data custodian approval and many require ethics committee approval. Monthly counts and rates used in the analysis will be shared on reasonable request. Statistical code is provided in the supplementary material.

Transparency: The lead author (RC, the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: We will disseminate our findings to key policy makers, including those whose interventions we have evaluated: the Australian Therapeutic Goods Administration, Pharmaceutical Benefits Advisory Committee, Advisory Committee on Medicines, and NSW Pharmaceutical Services. Findings will be shared with members of the Medicines Intelligence Centre for Research Excellence Consumer Advisory Group and more broadly through their networks. The findings of this study have been shared, and will continue to be shared, through presentations at conferences, clinical meetings, and policy advisory meetings. Results will be communicated through social media channels of the University of Sydney, the Medicines Intelligence Centre for Research Excellence, and the NSW Poisons Information Centre. A press release will be disseminated to lay and medical press.

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Supplementary file: Supplementary material