

Publicly subsidised smoking cessation medicines in times of COVID-19 in Australia: An interrupted time series analysis

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Abstract

Introduction: In Australia, the available published literature demonstrated a spike in dispensed prescription medicines after the onset of the COVID-19 pandemic that subsequently returned to expected levels. Smoking cessation medicines may not follow this pattern because quit attempts are influenced by a range of factors. Knowledge of whether dispensing of these medicines has changed since the pandemic is lacking. We explored the change in dispensing of publicly subsidised smoking cessation medicines since the pandemic.

Methods: Australia's universal health-care system provides access to government-subsidised medicines via the Pharmaceutical Benefits Scheme and records of dispensed medicines are publicly available on a nationally aggregated level. We retrieved Pharmaceutical Benefits Scheme data from January 2016 to January 2021. We used interrupted time series modelling to quantify the impact of COVID-19 on dispensing of nicotine replacement therapy (NRT) patches, varenicline and all smoking cessation treatments combined separately.

Results: After an initial spike in medicines at the onset of the pandemic, the monthly rate of prescriptions dispensed for varenicline was predominantly within predicted ranges, while that of NRT patches was predominantly below predicted ranges.

Discussion and Conclusions: There has been a differential change in the number of subsidised smoking cessation medicines supplied in Australia since the COVID-19 pandemic, with varenicline prescriptions largely within, and NRT patches largely lower than, expected ranges. The reasons for the apparent change in dispensing of subsidised smoking cessation medicines are unclear.

KEYWORDS

COVID-19, nicotine replacement therapy, routinely collected health-care data, smoking cessation treatment, varenicline

1 | INTRODUCTION

The COVID-19 pandemic severely disrupted non-communicable disease prevention and treatment services [1] and created an unprecedented public health challenge [2]. The first confirmed case of COVID-19 in Australia occurred on 25 January 2020 [3] and large-scale changes to daily life (e.g., social distancing, work-from-home arrangements) were implemented by late March 2020. The COVID-19 pandemic also had an impact on the provision of medical services [4]. A range of policies were implemented at that time to protect Australian supplies of publicly subsidised prescription medicines after increased demand, indicative of panic buying, caused concern about potential medication shortages [5]. In the available published analyses, the total number of dispensed medicines, the 10 most commonly dispensed medicines and dispensed diabetes medicines experienced a temporary spike in March 2020 that returned to levels expected based on previous years' growth by June 2020 [4, 6, 7].

The use of subsidised smoking cessation medicines subsequent to COVID-19 may not follow the same pattern because the patient population is individuals who smoke and are motivated to make a quit attempt. Furthermore, quit attempts are influenced by a range of internal and external factors including concerns about the health impacts of smoking, advice from medical professionals, affordability of tobacco products and anti-smoking mass media advertising [8].

In Australia, subsidised prescription medicines are funded by the federal government and can be prescribed by approved healthcare providers across the country. By extension, evidence-based smoking cessation treatments (SCT) are also available nationally in the form of publicly subsidised prescription smoking cessation medicines. However, Australia lacks a multi-sectoral national tobacco dependence treatment strategy [9]. Quitlines, the principal means of providing behavioural counselling, are funded by individual states and territories, with variations in the services offered [9].

Some information on the impact of COVID-19 on smoking cessation behaviour in Australia is available. In the Australian component of the International Tobacco Control Four Country and Vaping Survey, respondents interviewed between April and June 2020 reported that, because of COVID-19, 37.6% had thought about quitting and 9.3% tried to quit or reduce their smoking [10]. However, whether use of subsidised SCT changed since the advent of the pandemic is unknown. Understanding changes in dispensing of prescription smoking cessation medicines during the pandemic is critical as this will help to plan for the provision of

appropriate care to treatment-seeking smokers and indicate possible proactive actions to take in the face of future similar events.

We aimed to explore and document the change in subsidised smoking cessation medicines dispensed since the emergence of the COVID-19 pandemic.

2 | METHODS

2.1 | Study design

This interrupted time series study used publicly available population-based administrative healthcare data. Because the data are publicly available and aggregated, ethics approval was not required.

2.2 | Study population

As part of Australia's universal health-care system, individuals have access to government-subsidised medicines via the Pharmaceutical Benefits Scheme (PBS) and the Repatriation Pharmaceutical Benefits Scheme (RPBS) [11]. RPBS benefits are available to veterans and eligible dependents. Hereafter, and for simplicity, PBS medicines will refer to those subsidised by the PBS or RPBS. Patients pay a co-payment towards the cost of each PBS medicine with a lower co-payment required for those eligible for a concession (e.g., people in a variety of circumstances such as those receiving income support payments from the government) [12].

Three PBS-subsidised smoking cessation medicines are available: bupropion, varenicline and some forms of nicotine replacement therapy (NRT) when prescribed by medical practitioners and nurse practitioners in community settings. There are separate arrangements for PBS prescriptions in certain public hospitals for discharged or non-admitted patients [13]. Prescriptions provided to a patient must be presented to an approved supplier, mainly pharmacists, who dispense the medicine, collect a co-payment from the patient (if appropriate) and submit the supply record to the PBS system [14, 15].

2.3 | Data source and study sample

Records of the number of all dispensed PBS medicines (including those subsidised via the RPBS) are collected and are publicly available on an aggregated national level by month of supply [16]. Medicines are coded by PBS item codes [17]. We retrieved and combined PBS supply reports

for the period from January 2016 to January 2021 for all PBS item codes corresponding to Anatomical Therapeutic Chemical codes for nicotine dependence treatments (N07BA) [18] and all patient beneficiary categories. This study focuses on NRT patches and varenicline because bupropion accounts for less than 1% of smoking cessation medicine prescriptions dispensed [19, 20] and NRT gum and lozenges were first dispensed via the PBS in February 2019. Twelve PBS codes for NRT patches were collapsed to a single group. Similarly, three PBS codes for varenicline (initiation, continuation and completion packs) were collapsed to form a single group. Finally, all nicotine dependence treatments (NRT patches, NRT gum and lozenges, varenicline and bupropion) were combined and are referred to as the group of all SCT.

The estimated resident population of Australia was sourced from the Australian Bureau of Statistics [21]. Data were available quarterly therefore linear interpolation was used to estimate the population for inter-quarter months. Using the number of prescriptions dispensed each month, and the number of residents for each month, the rate of prescriptions dispensed per 100,000 population was estimated. Thus, the study sample is comprised of the observed rate of all PBS dispensed SCT in Australia for the study period.

2.4 | Statistical analysis

We quantified the impact of COVID-19 on dispensing of NRT patches, varenicline and all SCT separately using univariate interrupted time series modelling. We analysed observed data (i.e., observed rates of dispensed medicines per 100,000 population) from January 2016 to December 2019. Multiplicative and additive Holt-Winters models, which includes smoothing for both trend and seasonality, were performed and compared for fit using root mean square error and the mean absolute percentage error (MAPE). In all models, the multiplicative and additive models were not significantly different in fit. We sought to provide an estimate of the rate of prescriptions dispensed, by month, we would have expected from January 2020 to January 2021 based on the rates and trends observed over the previous 4 years. Therefore, we forecasted the monthly rate of prescriptions dispensed between January 2020 and January 2021 with 95% confidence intervals. Observed and forecasted data were then compared with values lying outside the 95% confidence interval taken to be significantly different.

All data analyses were conducted using Stata statistical software [22].

3 | RESULTS

For all models, the MAPE was 3.2% or less suggesting that the time series models were a good fit for the observed rate. The model for NRT patches had the best fit; the mean absolute percent error between the pre-COVID rate predicted by the model and the actual rate was 2.5%. For varenicline, the MAPE was 3.2% and for all SCT, the MAPE was 2.6%.

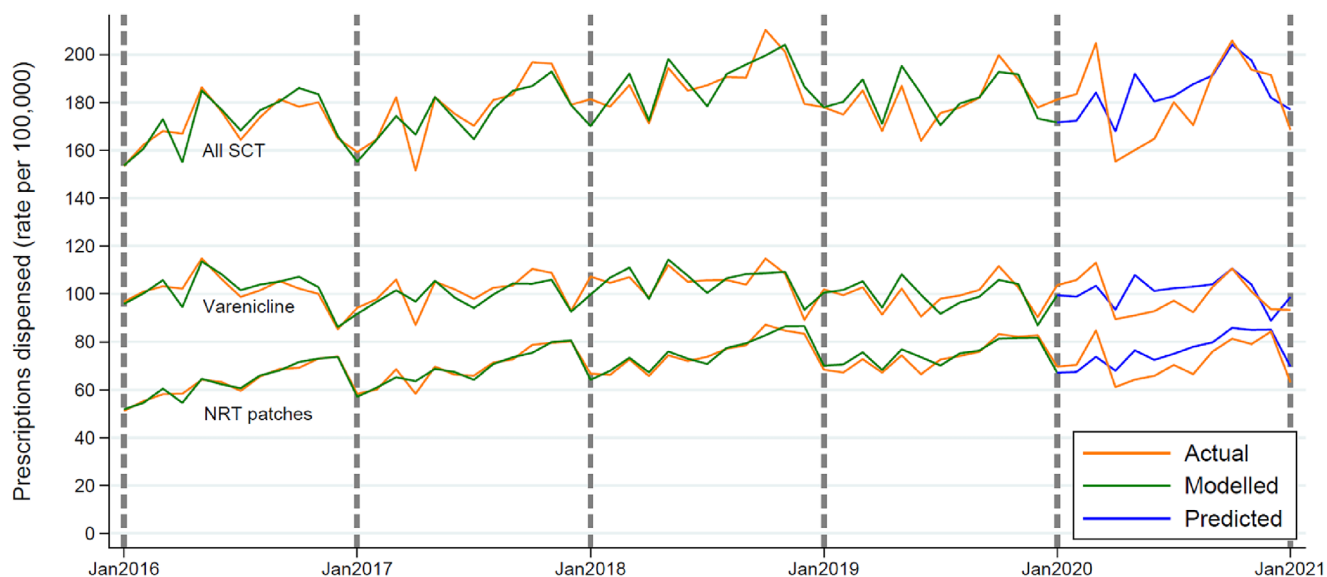
The time series pattern of NRT patches and varenicline were visually similar (i.e., roughly proportional), excepting December each year. The observed rate of PBS-subsidised smoking cessation medicines dispensed in March 2020 were statistically significantly greater than predicted. NRT patches, varenicline and all SCT declined precipitously in April 2020, but the observed rate of prescriptions dispensed was not statistically significantly lower than predicted for varenicline (Figure 1, Table 1). Thereafter, the rate of varenicline prescriptions dispensed was statistically significantly lower than predicted in May, June and August 2020, but was within predicted ranges in July 2020 and from August 2020 to January 2021 inclusive. In contrast, the observed rate of PBS-subsidised NRT patch prescriptions dispensed remained statistically significantly below predicted levels for 8 of the 10 subsequent months. The number of observed prescriptions and predicted prescriptions, along with 95% confidence intervals, are presented in Table 1.

4 | DISCUSSION

In this ecological study, we assessed the observed versus predicted dispensing of subsidised NRT patches, varenicline and all SCT after the onset of the COVID-19 pandemic. After an initial spike observed across all groups at the onset of the pandemic, the rate of prescriptions dispensed for NRT patches was predominantly below predicted ranges, while the rate of prescriptions dispensed for varenicline, and all SCT, was predominantly within predicted ranges. The peak in prescription smoking cessation medicines dispensed in March 2020 is in line with that observed for other medicines [4, 6, 7]. For varenicline and all SCT, as was observed for other medicines, the peak was followed by dispensing that returned to normal ranges over the subsequent months. For NRT patches, however, our analyses show a persistent decrease in dispensed use.

Owing to the nature of the aggregated publicly available data upon which our analyses are based, what the decrease represents is not certain. PBS data refer to instances of dispensed medicines and not treatment episodes or individuals. In the case of smoking cessation

(a) Actual and modelled, 2016-2019; actual and predicted, January 2020 – January 2021



(b) Actual and modelled, 2019; actual and predicted (with 95% confidence intervals), January 2020 – January 2021

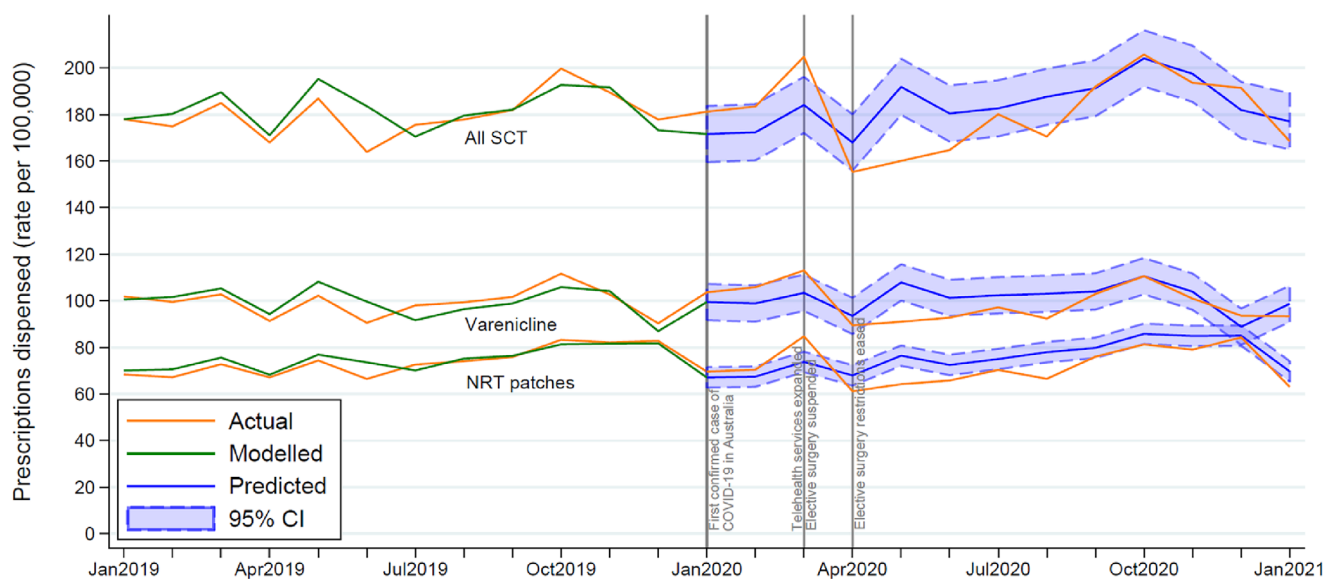


FIGURE 1 Rate of pharmaceutical benefits scheme-subsidised nicotine replacement therapy patch, varenicline and all smoking cessation treatment prescriptions per 100,000 population dispensed in Australia. CI, confidence interval. (A) Actual and modelled, 2016–2019; actual and predicted, January 2020–January 2021. (B) Actual and modelled, 2019; actual and predicted (with 95% confidence intervals), January 2020–January 2021.

medicines, each prescription dispensed represents only part of a full treatment episode. For example, NRT patches are most commonly dispensed in boxes of 28 (a 4-week supply) and, with repeats, patients may receive up to 12 weeks of PBS-subsidised NRT per 12-month period. The initial spike observed in March 2020 may reflect people who already held prescriptions filling their repeats early. This explanation aligns with

the policies implemented at that time to protect Australian pharmaceutical supplies from shortages due to panic buying. If this explanation is true, then the initial spike need not reflect any change in the rate of treatment episodes. Similarly, observed decreases in the rate of NRT patches dispensed could reflect a change in new prescriptions dispensed or a change in repeat prescriptions dispensed. Either of these possible explanations

TABLE 1 Observed and predicted rate per 100,000 population, and 95% confidence interval, of pharmaceutical benefits scheme-subsidised nicotine replacement therapy patch, varenicline and all smoking cessation treatment prescriptions dispensed in Australia, by month

	NRT patches				Varenicline				All SCT			
	Observed number	Predicted number	Predicted 95% CI	Observed number	Predicted number	Predicted 95% CI	Observed number	Predicted number	Predicted 95% CI	Observed number	Predicted number	Predicted 95% CI
January 2020	69.6	67.1	(62.7–71.4)	103.7	99.5	(91.6–107.2)	181.2	171.6	(159.5–183.6)			
February 2020	70.4	67.5	(63.0–71.8)	105.9	98.9	(91.0–106.6)	183.5	172.4	(160.3–184.4)			
March 2020	84.8	73.8	(69.3–78.1)	113.1	103.5	(95.6–111.2)	204.8	184.1	(172.0–196.1)			
April 2020	61.2	68.0	(63.5–72.3)	89.5	93.5	(85.7–101.3)	155.3	168.0	(155.9–180.0)			
May 2020	64.2	76.5	(72.0–80.8)	91.0	107.9	(100.1–115.7)	160.1	191.9	(179.8–203.9)			
June 2020	65.8	72.5	(68.0–76.8)	92.8	101.3	(93.4–109.0)	164.8	180.4	(168.3–192.5)			
July 2020	70.3	75.0	(70.6–79.4)	97.2	102.4	(94.6–110.1)	180.1	182.7	(170.5–194.7)			
August 2020	66.5	78.0	(73.5–82.3)	92.4	103.1	(95.2–110.8)	170.5	187.6	(175.5–199.7)			
September 2020	76.0	79.8	(75.4–84.2)	103.0	104.1	(96.2–111.8)	192.0	191.3	(179.2–203.4)			
October 2020	81.3	85.8	(81.4–90.2)	110.6	110.6	(102.8–118.3)	205.8	204.1	(192.0–216.1)			
November 2020	79.1	84.9	(80.5–89.3)	101.0	104.0	(96.1–111.7)	193.6	197.5	(185.4–209.5)			
December 2020	84.3	85.1	(80.6–89.4)	93.7	88.9	(81.0–96.6)	191.5	181.9	(169.8–194.0)			
January 2021	63.1	69.7	(65.3–74.0)	93.4	98.7	(90.9–106.5)	168.5	177.1	(164.9–189.1)			

Note: Bold indicates observed number outside bounds of 95% confidence interval (CI). Abbreviations: NRT, nicotine replacement therapy; SCT, smoking cessation treatments.

(decreased new prescriptions dispensed or decreased repeat prescriptions dispensed) are potentially concerning if viewed in isolation.

However, they ought not to be viewed in isolation because individuals may have shifted from one subsidised smoking cessation medicine to another, or continued to use NRT patches, or indeed other cessation supports, outside the PBS subsidised system. To understand how these two possibilities would be visible in the PBS data, it is important to highlight the cost structure of PBS services from the patients' perspective and the availability of over-the-counter medicines.

In Australia, under the PBS, patient contributions (i.e., co-payments) to the costs of medicines are controlled and are the same for all medicines but do vary by patient category. Concession patients are those eligible for a discounted co-payment while general patients receive no discount [12]. In 2021, for example, the maximum cost for a prescription medicine was AU\$6.60 for concession patients and AU\$41.30 for general patients. NRT patches can be obtained by prescription, which would be recorded in the PBS data, or purchased over the counter, which would not be recorded in the PBS data. Furthermore, the cost of NRT patches at discount pharmacies is only marginally higher than the PBS co-payment for general patients. The savings realised by using PBS-subsidised NRT patches, which also includes the inconvenience of (and in some cases a co-payment for) a medical consult, instead of retail NRT patches may not be a strong incentive for many general patients. It is concession patients, however, who receive the bulk of PBS-subsidised NRT patches (i.e., since 2016, patches were dispensed to concession patients at 3–4 times the rate of general patients) [16]. Varenicline (and bupropion) can only be obtained by prescription and therefore are fully captured in the PBS data. Thus, it is possible that the observed decrease in NRT patches reflect a decrease in use of NRT patches overall, a decrease in dispensing of subsidised NRT patches, or a shift to another SCT. The observed rebound in dispensing of all SCT could support this last possibility. Unfortunately, the publicly available PBS data, being aggregated, do not shed light on individuals shifting treatment. And sales data from pharmaceutical manufacturers is not freely and publicly available to determine if NRT patch sales have changed. Lastly, it must be acknowledged that greater numbers of individuals may have tried vaping as a cessation aid or opted for other quit smoking strategies. These too would not be captured in the PBS data.

In order to fully examine these possibilities, other sources of data are needed. Researchers can access the existing pharmaceutical sales data at a cost, but these data are ecological. To examine shifts in individual-level trajectories of SCTs, individual-level data is needed. PBS

data do exist at the individual patient level though only limited individual characteristics are available (e.g., age, gender, area of residence) and access does incur a cost. Individual-level survey data with rich measures of quit behaviours, linked to individual-level PBS data, are the ideal means by which to answer these research questions.

Understanding how societal disruptions, such as the current COVID-19 pandemic and future pandemics, may be associated with changes in the use of smoking cessation services is important because for Australians who smoke and are motivated to quit in the age of COVID-19, new strategies may be needed to connect them with evidence-based subsidised quit smoking support. For example, if the requirement to access a general practitioner or nurse practitioner is a barrier to accessing SCT, providing access via pharmacies (with referral to counselling), or access via Quitlines themselves, would remove many barriers [9]. Only one Australian Quitline (Queensland) provides pharmacotherapy (NRT) directly to clients. However, this service is limited to those who meet narrow eligibility criteria, such as pregnant women or Aboriginal and Torres Strait Islander peoples [23]. While public health responses to pandemics predictably focus on immediate and obvious consequences, less obvious components of pandemic planning are also needed such as interventions optimised to support those individuals making quit attempts [24].

4.1 | Limitations

This study has some limitations. First, PBS data do not capture prescription smoking cessation medicines supplied in hospitals, but this is likely to be small compared to community use. Second, PBS data do not capture dispensings of medicines by Remote Area Aboriginal Health Services. Third, the publicly available PBS supply data is aggregated by month and reported nationally and thus we are not able to describe state-specific nuances from these data, nor describe patterns in terms of age or sex. Our findings therefore refer to ecological level associations. We do not have individual-level data and do not incorporate measures such as smoking history or comorbidities that might confound an apparent individual-level association.

5 | CONCLUSIONS

There has been a differential change in the rate of subsidised quit-smoking medicines supplied in Australia since the onset of the COVID-19 pandemic, with varenicline

and all SCT prescriptions dispensed largely within, and NRT patches largely lower than, expected ranges. The reasons for this are unclear. Further research should use individual-level longitudinal PBS data, combined with survey data, to explore the impact of pandemic disruptions on smoking cessation trajectories and determine if targeted interventions are needed.

AUTHOR CONTRIBUTIONS

Each author certifies that their contribution to this work meets the standards of the International Committee of Medical Journal Editors.

ACKNOWLEDGEMENT

Open access publishing facilitated by The University of Queensland, as part of the Wiley - The University of Queensland agreement via the Council of Australian University Librarians.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The datasets underlying this article were derived from sources in the public domain and are available at <https://www.pbs.gov.au/info/statistics/dos-and-dop/dos-and-dop>.

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REFERENCES

- World Health Organization. COVID-19 significantly impacts health services for noncommunicable diseases. Available from: <https://www.who.int/news/item/01-06-2020-covid-19-significantly-impacts-health-services-for-noncommunicable-diseases>.
- World Health Organization. Impact of COVID-19 on people's livelihoods, their health and our food systems. Available from: <https://www.who.int/news/item/13-10-2020-impact-of-covid-19-on-people's-livelihoods-their-health-and-our-food-systems>.
- Department of Health. First confirmed case of novel coronavirus in Australia. Available from: <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/first-confirmed-case-of-novel-coronavirus-in-australia>.
- Australian Institute of Health and Welfare. Impacts of COVID-19 on Medicare Benefits Scheme and Pharmaceutical Benefits Scheme service use. Available from: <https://www.aihw.gov.au/reports/health-care-quality-performance/covid-impacts-on-mbs-and-pbs/contents/impact-on-pbs-service-use>.
- Therapeutic Goods Administration. Limits on dispensing and sales of prescription and over-the-counter medicines. Available from: <https://www.tga.gov.au/media-release/limits-dispensing-and-sales-prescription-and-over-counter-medicines> 2020.
- Mian M, Sreedharan S, Giles S. Increased dispensing of prescription medications in Australia early in the COVID-19 pandemic. *Med J Aust.* 2021;214:428–9.
- Engstrom T, Baliunas DO, Sly BP, Russell AW, Donovan PJ, Krause HK, et al. Toilet paper, minced meat and diabetes medicines: Australian panic buying induced by COVID-19. *Int J Environ Res Public Health.* 2021;18:6954.
- Greenhalgh E, Jenkins S, Stillman S, Ford C. What finally prompts smokers to quit? In: Greenhalgh E, Scollo M, Winstanley M, editors. *Tobacco in Australia: facts and issues.* Melbourne: Cancer Council Victoria; 2020.
- White S, McCaffrey N, Scollo M. Tobacco dependence treatment in Australia – an untapped opportunity for reducing the smoking burden. *Public Health Res Pract.* 2020;30:3032020.
- Gravelly S, Craig LV, Cummings KM, Ouimet J, Loewen R, Martin N, et al. Smokers' cognitive and behavioural reactions during the early phase of the COVID-19 pandemic: findings from the 2020 ITC four country smoking and vaping survey. *PLoS One.* 2021;16:e0252427.
- Department of Health. About the PBS. Available from: <https://www.pbs.gov.au/info/about-the-pbs>.
- Services Australia. Concession and Health Care Cards. Available from: <https://www.servicesaustralia.gov.au/individuals/subjects/concession-and-health-care-cards>.
- Department of Health. Prescribing Medicines – Information for PBS Prescribers. Available from: https://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section_1_2_Explanatory_Notes.
- Department of Health. Supplying Medicines—What Pharmacists Need to Know. Available from: https://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section_1_3_Explanatory_Notes.
- Department of Health. How Pharmacists Claim Reimbursement: Information Required. Available from: https://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section_1_7_Explanatory_Notes.
- Department of Health. PBS and RPBS Section 85 Date of Supply Data. Available from: <https://www.pbs.gov.au/info/statistics/dos-and-dop/dos-and-dop>.
- Services Australia. Pharmaceutical Benefits Schedule Item Reports. Available from: http://medicarestatistics.humanservices.gov.au/statistics/pbs_item.jsp.
- Department of Health. PBS item drug map Data. Available from: <https://www.pbs.gov.au/info/statistics/dos-and-dop/dos-and-dop>.
- Department of Health. Smoking Cessation Therapy: PBS/RPBS utilisation. Drug utilisation sub-committee (DUSC). Available from: <https://www.pbs.gov.au/info/reviews/post-market-review-of-medicines-for-smoking-cessation>
- Department of Health. Draft Report to the Pharmaceutical Benefits Advisory Committee (PBAC) for the Post-market Review of medicines for smoking cessation. Available from: <https://www.pbs.gov.au/info/reviews/public-consultation-on-the-post-market-review-of-medicines>.

21. Australian Bureau of Statistics. National, state and territory population 2021.
22. Stata statistical software: release 16 [program]. College Station, TX: StataCorp LLC; 2019.
23. Queensland Government. Get help from quitline. Available from: <https://quithq.initiatives.qld.gov.au/quit-support/quitline/get-help-from-quitline/>.
24. Gendall P, Hoek J, Stanley J, Jenkins M, Every-Palmer S. Changes in tobacco use during the 2020 COVID-19 lockdown in New Zealand. *Nicotine Tob Res.* 2021;4:866–71.

How to cite this article: Baliunas D, Gartner C, Hollingworth SA, Sullivan C, Comans T, Pole JD. Publicly subsidised smoking cessation medicines in times of COVID-19 in Australia: An interrupted time series analysis. *Drug Alcohol Rev.* 2023;42(1): 225–32. <https://doi.org/10.1111/dar.13557>