

Pharmaceutical Benefits Scheme

Post-market Review

Post-market Review of Medicines Used for Smoking Cessation

Report to PBAC

ToR 2: Utilisation of PBS-listed medicines for smoking cessation

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Abbreviations

Abbreviation	Full Name / Wording
ABS	Australian Bureau of Statistics
ATC	Anatomical Therapeutic Chemical Classification System
AUD	Australian Dollar
CI	Confidence Interval
N	Number
OTC	over-the-counter
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme

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Section 2: ToR 2

2.1 Key findings

This report provides an analysis of utilisation of PBS-listed medicines for smoking cessation.

2.1.1 Describe the overall trends in the utilisation and cost of smoking cessation medicines in Australia

In the financial year 2019/2020:

- There were 542,492 prescriptions dispensed for PBS subsidised smoking cessation therapies at a cost to the government of AUD 36 million (PBS benefits paid).
- Varenicline was the most utilised smoking cessation therapy with 303,681 PBS prescriptions dispensed (56% of total market) followed by Nicotine Replacement Therapy (NRT) with 233,544 PBS prescriptions (43% of total market) and bupropion with 5,267 PBS prescriptions.
- PBS use of NRT represented 7% of all NRT use in Australia during 2019, suggesting that the majority of NRT products are obtained over-the-counter (OTC). NRT patches accounted for 94% of all NRT products subsidised under the PBS, while the majority of NRT products sold OTC were nicotine gums.

2.1.2 Determine the prevalent and incident population treated with PBS listed medicines for smoking cessation.

- 1.2% of the Australian population (N=265,544) were supplied PBS smoking cessation therapy in 2019/2020.
- 0.3% of the Australian population (N=65,543) made their first ever attempt at quitting with PBS subsidised smoking cessation therapy in 2019/2020.

2.1.3 Provide the most recent statistics on the prevalence of smoking in Australia

The smoking rates differed widely between different sub-populations:

- In 2019, there were an estimated 2.9 million current smokers aged 18+ in Australia representing 14.7% from the overall population aged 18+ in Australia;
- In 2019, the rate of Aboriginal and Torres Strait Islander people aged 15+ who are current smokers was 41.4%, which was 2.8 times higher in comparison to the overall population aged 18+ in Australia;
- In 2018, at least 75% of non-Indigenous prison entrants aged 18-44 years were current smokers, and at least 79% of Aboriginal and Torres Strait Islander prison entrants aged 18-44 were current smokers;
- In 2018, 9.2% of women smoked in the first 20 weeks of pregnancy;
- People with self-reported mental illness (depression, anxiety disorder, schizophrenia, bipolar disorder, an eating disorder or other mental illness) were almost twice as likely to be current smokers compared to people without mental illness (24.2% vs 12.9% in 2019)

2.1.4 Prevalence of smoking cessation therapies under the PBS in specific populations

Of the 265,544 people who received PBS subsidised smoking cessation therapy in 2019:

- 40% also had mental illness, as measured by antipsychotic and antidepressant use
- 18% were women of child-bearing age (aged 15 to 44 years)
- 16% also had a smoking related illness, as measured by use of medicines for airways disease
- 10% were Aboriginal and Torres Strait Islander population, identified by the following criteria – a supply of prescriptions under the Closing the Gap Co-Payment Measure program, or utilisation of Indigenous-specific MBS items, or Voluntary Indigenous Identifier
- 1% were at risk of alcohol abuse, as measured by use of medicines for alcohol dependence.

2.1.5 Estimates of specific populations of interest with access to smoking cessation therapies under the PBS

In calendar year 2019, based on PBS utilisation and published literature, it is estimated that:

- 10% of all current smokers aged 18 years and over in Australia received smoking cessation therapies under the PBS;
- 1% of all Australian women of child-bearing age (aged 15 to 44 year) received smoking cessation therapies under the PBS;
- 6% of the Aboriginal and Torres Strait Islander population aged 18+ in Australia received smoking cessation therapies under the PBS.

2.1.6 Number of therapies and length of treatment with smoking cessation medicines

Based on an analysis of PBS data, there were 740,082 people who initiated a PBS subsidised smoking cessation therapy for the first time between 1/07/2010 and 30/06/2015. The following results are based on this initiating cohort who were followed for 5 years:

- The median duration of the first treatment episode was 28 days for bupropion and 42 days for NRT and varenicline;
- 60% of people in this cohort made only one attempt to quit smoking;
- Overall, people had on average 1.7 separate treatment episodes with smoking cessation therapies with an average break of 15 months between attempts.

2.1.7 Use of counselling services

According to the Australian Institute of Health and Welfare, National Drug Strategy Household Survey (2019), 1.8% of current smokers aged 14 years and over (i.e. approximately 52,000 people) contacted Quitline in 2019.

The survey suggests low uptake of counselling services compared to the population accessing PBS medicines for smoking cessation (265,544 people in 2019/2020).

2.1.8 Consistency with PBS restrictions

Among people supplied their first ever PBS subsidised smoking cessation therapy in financial year 2018/2019,

- 88% of NRT users complied with the PBS restriction in that they received a maximum of 12 weeks of PBS subsidised NRT per year. Analysis of all first ever NRT initiators in 2018/2019 showed that:
 - 60 % received only one prescription for NRT which covers 4 weeks of therapy,
 - 17% received 2 prescriptions for NRT which covers 8 weeks of therapy,
 - 12% received 3 prescriptions for NRT which covers 12 weeks of therapy.
- 98% of varenicline users complied with the PBS restriction requirement in that they received a maximum of 24 weeks supply of PBS subsidised varenicline per 12-month period. Analysis of the type of packs dispensed to first ever initiators to varenicline in 2018/2019 showed that:
 - 56% of initiators had only a starter pack (duration of 4 weeks),
 - 24% had a starter pack plus a continuation pack or a starter pack plus two completion packs (duration of 12 weeks)
 - 1% had a starter pack plus a continuation pack and three completion packs (duration of 24 weeks).
- 91% of bupropion users complied with the PBS restriction requirement in that they received a maximum of 9 weeks supply of PBS subsidised bupropion per year. Analysis of all first ever bupropion initiators in 2018/2019 showed that:
 - 45% of initiators had only a starter pack (duration of 2 weeks),
 - 20% of initiators completed up to 8 weeks of therapy.

There was no significant difference in duration of NRT therapy between Aboriginal and Torres Strait Islander people and non-Indigenous people who initiated NRT for the first time in 2018/2019. This is despite Aboriginal and Torres Strait Islander people being allowed an additional 12-week course per 12-month period (up to 24 weeks) of PBS subsidised NRT in the form of 25 mg/16 hour patch, 21 mg/24 hour patch, lozenges and gum. However, this does not include data on NRT therapies provided by Aboriginal Health Services that are participating in the Remote Area Aboriginal Health Services (RAAHS) program.

2.1.9 Stakeholder views (Forum and public consultations)

Stakeholders considered the cost of OTC NRT can be a significant barrier for many people, particularly those from populations with higher rates of smoking such as lower socioeconomic groups, Aboriginal and Torres Strait Islander people, and people with a mental illness. Stakeholders considered that financial cost was an important factor in treatment failures, particularly for non-PBS subsidised NRT therapies and when therapy was required for longer than is available on the PBS. Table B.2 provides indicative costs for OTC and PBS smoking cessation therapies (Background p. 13)

One stakeholder noted the 2018 evaluation of the Tackling Indigenous Smoking (TIS)¹ program found that the high cost of NRTs that are not available on the PBS was a significant barrier to NRT access for Aboriginal and Torres Strait Islander people.

Stakeholders also noted that lack of access to smoking cessation medicines is particularly important for people in regional and remote areas, including Aboriginal and Torres Strait Islander people.

Some clinicians noted that in their experience therapies are being used for longer than indicated to allow people additional time to abstain, and often in combination (short + long acting NRT combination, varenicline + NRT) to manage withdrawal and cravings.

2.2 Background

The Department of Health has engaged the services of [REDACTED] to undertake utilisation analysis of PBS-listed medicines for smoking cessation including but not limited to patient demographics, time on treatment, and the proportion using PBS subsidised combination treatment. Data from additional data sources from literature have been utilised. The findings of the research are collated into this report that may be considered by the PBAC and its Drug Utilisation Sub-committee (DUSC).

2.3 Methodology

2.3.1 Data source

The Department provided patient level PBS data for the time period of 1 July 2010 to 30 June 2020 for this research. The medicines for smoking cessation which are included in the analysis are listed in Table 1.

Table 1: Medicines included in the analysis

Medicine	ATC code	Category	Indication for use	Date of listing on the PBS
Varenicline	N07BA03	Drugs used in nicotine dependence	Varenicline is indicated as an aid for smoking cessation in adults [1]	1 Jan 2008
Nicotine Replacement Therapy (NRT)	N07BA01	Drugs used in nicotine dependence	NRT is indicated for treatment of nicotine dependence, as an aid to smoking cessation [2]	1 Dec 2008 (Aboriginal and Torres Strait Islander population) 1 Feb 2011 (general population)

¹ Tackling Indigenous Smoking Program Final Evaluation Report Prepared for the Australian Government Department of Health July 2018 <https://www.health.gov.au/sites/default/files/tackling-indigenous-smoking-program-final-evaluation-report.pdf>

Bupropion	N07BA	Antidepressant	Bupropion is indicated as a short-term adjunctive therapy for the treatment of nicotine dependence in those who are committed to quitting smoking [3]	August 2000
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2.3.2 Methods

1) Overall trends in utilisation and cost of smoking cessation medicines in Australia

Annual trends of all prescriptions dispensed and the government benefits paid for the specified medicines under the R/PBS in financial years 2010/2011 to 2019/2020 are reported. Consumer co-payments for the relevant time periods were used to estimate total PBS costs.

The cost of all NRT products sold OTC were extracted from Euromonitor International report on NRT Smoking cessation aids in Australia [4].

The proportion of the overall NRT market represented by the PBS was estimated based on the differences in costs between total PBS costs (including consumer co-payments) and the costs reported in the Euromonitor report.

2) Prevalent and incident population treated with PBS listed medicines for smoking cessation and population characteristics

Prevalent trends: the number of people in each financial year from 2010/2011 to 2019/2020 was determined by counting the number of people who received at least one supply for any smoking cessation medicine in the given year. The results were stratified by the type of medicine and by recipient gender.

Incident trends 1: the number of people who started smoking cessation therapy in each financial year from 2011/2012 to 2019/2020 was determined based on a one-year period with no use (financial year 2010/2011 was used as a baseline year).

Incidents trends 2: First ever users were determined in each financial year from 2010/2012 to 2019/2020 by counting the number of people who had not been supplied a prescription for any smoking cessation medicine under the PBS at any time from the beginning of the data. The results were stratified by the type of medicine at initiation, by age at initiation and by beneficiary status. The mean and median age and by gender was reported. Socio-economic status at initiation was determined based on a person's postcode and the Australian Bureau of Statistics index of socio-economic disadvantage.

3) Treatment rates at national level and state level based on PBS data

National, State and Territory treatment rates (people per 1000 population) of people initiating on and prevalent to smoking cessation medicines under the PBS were calculated as the number of initiating or prevalent people divided by population estimates provided by the Australian Bureau of Statistics (ABS) residential population estimates in Australia as at

30 June in the given year [5-13]. The rates were age-standardized to the age structure of the Australian national population at 30 June 2011.

4) Prevalence of smoking cessation therapies under the PBS in specific populations

For the prevalent population in each calendar year, estimates of use among specific populations of interest were presented as the proportion of people in the smoking cessation therapy population who are estimated to be in the population of interest (i.e. the smoking cessation population is the denominator).

Populations of interest were defined as:

- i) the population at risk of alcohol abuse (persons with at least one dispensing of a medicine subsidised for alcohol addiction, ATC code N07BB)
- ii) the population at risk of smoking related illness (a person with at least two dispensings of medicines for chronic respiratory disorders or chronic obstructive pulmonary disease (ATC code R03 excluding salbutamol, terbutaline, cromoglycate and nedocromil),
- iii) the population with mental illness (people who received at least one medicine for mental illness; ATC codes N05A (antipsychotics) or N06A (antidepressants)
- iv) the Aboriginal and Torres Strait Islander population based on the following criteria: supply of prescriptions under the Closing the Gap Co-Payment Measure program, or utilisation of Indigenous-specific MBS items, or Voluntary Indigenous Identifier
- v) women of child-bearing age were estimated based on women aged between 15 and 44 years at the time of PBS prescription.

We also reported the number of packs for all smoking cessation therapies provided through the Aboriginal Health Services and estimated the proportion from the number of smoking cessation therapies supplied through the PBS.

5) Prevalence of smoking in Australia in the general and specific populations

- The prevalence of current smokers in Australia was reported based on the Australian Institute of Health and Welfare, National Drug Strategy Household Survey 2019
- The prevalence of tobacco use among Aboriginal and Torres Strait Islander people - based on Tobacco in Australia: Facts and Issues
- The prevalence of smoking in the first 20 weeks of women who gave birth - based on the Australian Institute of Health and Welfare, Australia's mother and babies report
- The prevalence of current smokers among prison entrants - based on Australian Institute of Health and Welfare, The health of Australia's prisoners report 2018
- The prevalence of smoking in people with alcohol and drug problems or mental illness – based on the National Health Survey (2014-2015)

Based on these data and the data calculated in section 4 we estimated the proportion of specific populations of interest that access smoking cessation therapy under the PBS (the population of interest was the denominator). Due to data limitations, estimates are presented for 2013, 2016 and 2019 for the following populations of interest:

- Australian women of child-bearing age, aged 15 to 44 (based on Australian Bureau of Statistics demographics);
- Aboriginal and Torres Strait Islander population aged 18+ in Australia (based on Tobacco in Australia: Facts and Issues);

- All current smokers aged 18+ in Australia (based on Australian Institute of Health and Welfare, National Drug Strategy Household Survey 2019);
Data for overall population at risk of alcohol abuse, population with smoking related illness and population with mental illness was not available.

The use of various aids to assist smoking cessation including counselling services such as Quitline was reported based on the Australian Institute of Health and Welfare, National Drug Strategy Household Survey 2019 and any data provided by the Australian Government Department of Health, including data from the Quitline for 2019.

- Number of people contacting Quitline (per month by state)
- The proportion of people who call Quitline who are referred by a health professional/GP

6) Trajectories of care

Treatment pathways from initiation of smoking cessation medicine (first ever prescription) between 1 July 2010 and 30 June 2015 (the period from 1 Jan 2008 to 30 Jun 2010 was used as a baseline period) to the end of a follow-up of 5 years were presented, reporting restarts and switches in therapy to determine the most common switching, combinations of use and re-initiating patterns.

The results were aggregated to present patterns of clinical pathways for treatment episodes from first line to last line treatment, including gaps in therapy (a gap in refill for the current medicine of two times the length of the estimated prescription duration). The estimated prescription duration for each medicine was based on standard coverage days (SCD) calculated from the data for each medicine and reflecting the time period within which 75% of those who are prescribed that medicine have a repeat prescription dispensed. If multiple prescriptions of the same medication (but not the same strength) are supplied on the same day, it was assumed that these were used together and the treatment coverage period was not extended. If multiple prescriptions of the same medication and the same strength were supplied on the same day (for example original and repeat prescriptions were supplied under Regulation 24 (49) on the same day), then this was assumed to extend the coverage period (i.e. end of coverage period = supply date + number of prescriptions on the same day x SCD). Once medication episodes for each patient and each medicine were determined, then regimens of monotherapy and concurrent use were calculated. Short periods of overlap between two different regimens was considered a switch rather than co-administration (for example $A \rightarrow A+B \rightarrow B$ is considered as $A \rightarrow B$).

The results were stratified by type of index medicine.

7) Number of therapies and length of treatment with smoking cessation medicines

A cohort study was conducted to investigate duration of treatment in people who initiated (first ever) smoking cessation medicine between 1 July 2010 and 30 June 2015 (the period from 1 Jan 2008 to 30 Jun 2010 was used as a baseline period). The initiators were followed for five years.

Kaplan Meier survival analysis was conducted to estimate the duration of the first treatment episode. The study end point was the time to discontinuation of the first therapy due to

cessation, defined as a gap in refill based on the length of the estimated prescription duration which was calculated from the data and reflects the time period within which 75% of people returned for a repeat prescription. Gaps which were \geq two times the length of the estimated prescription duration were considered to represent cessation. Persons were followed up until cessation or end of follow-up (five years post index prescription). Persons who ceased therapy before the end of 5 years are reported as “event” persons. Death data was not available and accounted for.

The average number of separate episodes with PBS subsidised treatment per person from initiation to end of last treatment episode was reported. Separate episodes are episodes separated by gaps as defined above. The median duration of individual episodes was estimated using Kaplan Meier analysis to determine the median time of individual treatment episodes.

The average number of gaps per person (breaks from treatment) from initiation to end of last treatment episode were reported. The median duration of the individual gaps was estimated using Kaplan Meier analysis to determine the median time to restart of therapy.

8) Consistency with PBS restrictions

General and concessional beneficiaries are permitted up to 12 weeks’ supply of PBS subsidised NRT each year [14]. For varenicline, the PBS restrictions allow up to 24 weeks of treatment per 12-month period [15]. Up to 9 weeks of treatment per year is allowed under the PBS for bupropion [16].

To determine compliance with the maximum allowed restriction requirement, the number of people supplied their first ever PBS subsidised NRT, varenicline or bupropion therapy between 2015 and 2019 was determined. Then, the proportion in each year who received one, two, three or more prescriptions was determined. The weeks of coverage were then based on:

- For NRT all prescriptions correlate to four weeks coverage; there are no specific starter packs for NRT.
- Varenicline starter pack correlates to 4 weeks of coverage, continuation packs are for 8 weeks, and completion packs are for 4 weeks but with 2 repeats allowed.
- A starter pack for bupropion lasts for 2 weeks, while a completion pack lasts for 6 weeks.

People supplied smoking cessation medicines under the Closing the Gap Co-Payment Measure program were excluded as they are permitted more courses of treatment every twelve months. People with repatriation patient category were also excluded as there is no restriction on the number of courses permitted per year.

2.4 Results

2.4.1 Overall trends in utilisation and cost of smoking cessation medicines in Australia

Overall utilisation

Figure 1 presents the number of prescriptions supplied under the PBS and RPBS by quarter from July 2010 to June 2020. Varenicline was the most utilised smoking cessation therapy, followed by nicotine replacement therapy.

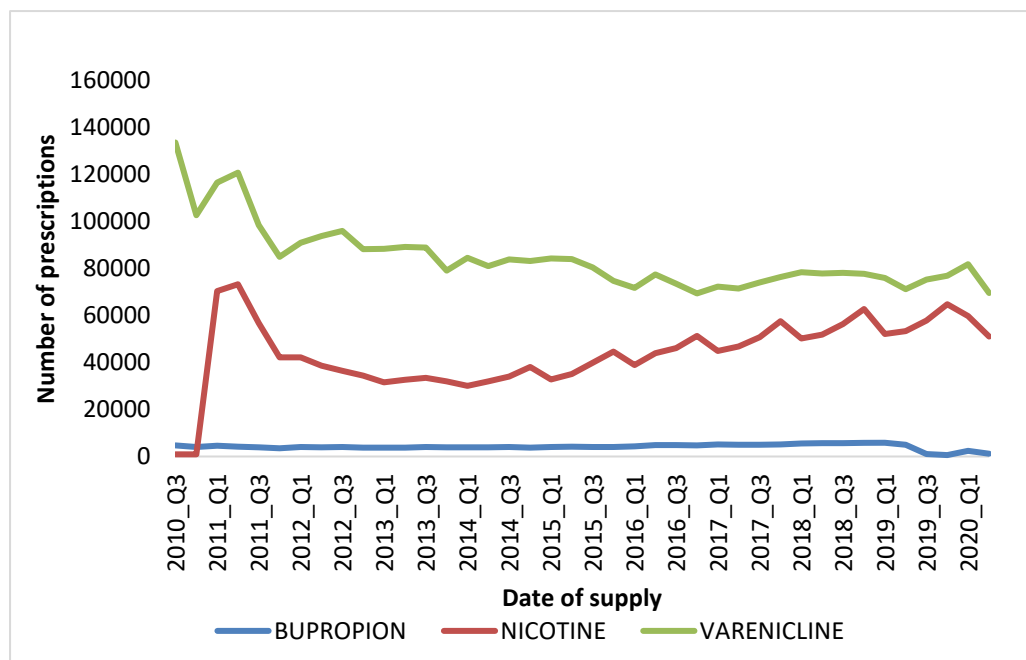


Figure 1. Drug utilisation for R/PBS listed smoking cessation therapy per quarter from Jul 2010 to Jun 2020

In 2019/2020, there were 542,492 prescriptions for smoking cessation therapies, which was down by 1.4% from 2018/2019 (N=550,103). In 2019/2020, 303,681 prescriptions were for varenicline (56% of market); 233,544 for NRT (43% of market) and 5,267 for bupropion (Figure 2 and Figure 2a).

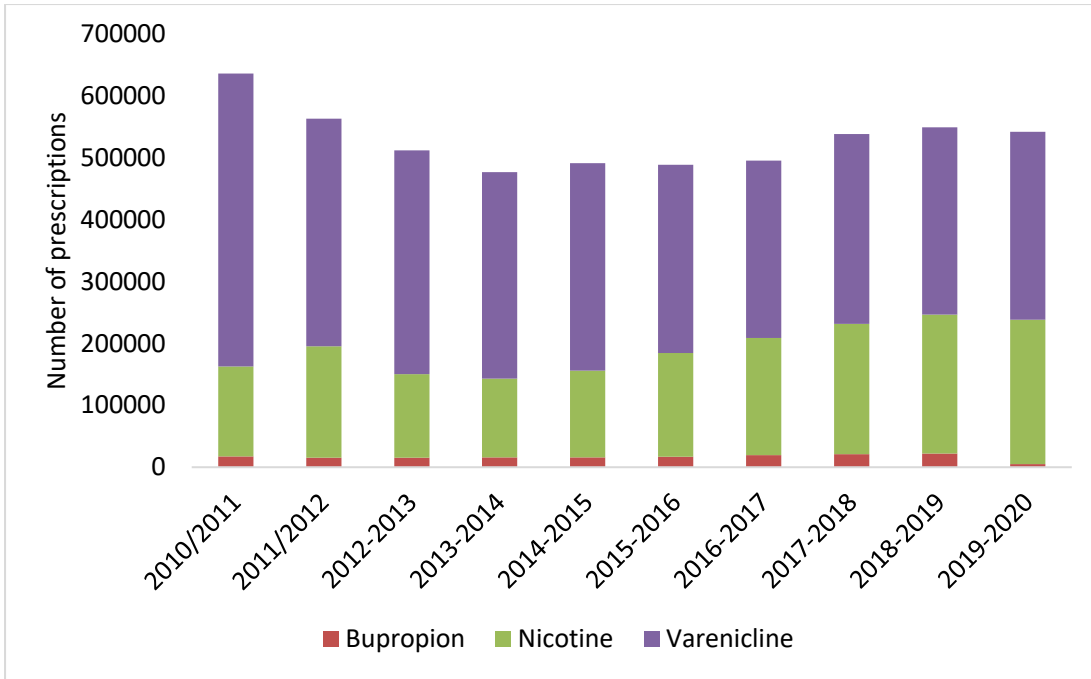


Figure 2. Number of R/PBS subsidised smoking cessation prescriptions supplied by financial year and type of medicine.

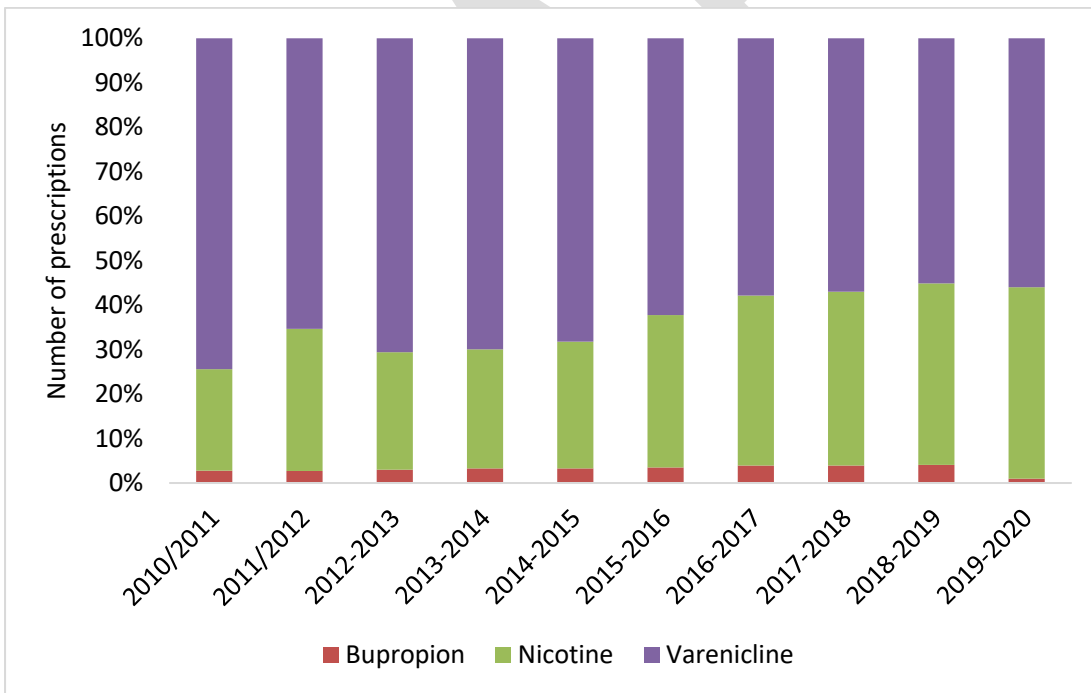


Figure 2a. Percent of R/PBS subsidised smoking cessation prescriptions supplied by financial year and type of medicine.

Figure 3 shows what the government paid under the PBS for smoking cessation products. In 2019/2020, the cost was AUD 35.6 million, down from 37.8 million in 2018/2019.

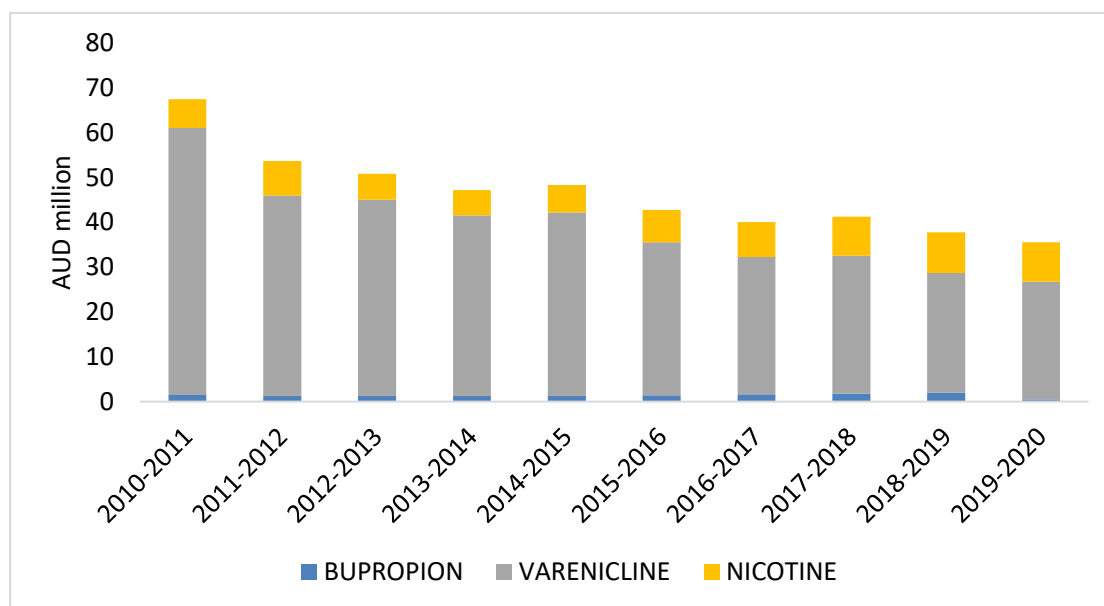


Figure 3. Government benefit paid (AUD millions) for smoking cessation therapies under the PBS by financial year and type of therapy

Figure 4 presents the total PBS cost of smoking cessation products based on the benefit paid by the government and consumer co-payment. In 2019/2020, the total cost was AUD 46.4 million, down from 48.6 million in 2018/2019. In 2019/2020, varenicline accounted for 73.3% of the total PBS expenditure, while nicotine replacement therapies accounted for 25.2% and bupropion for 1.5% (Figure 4).

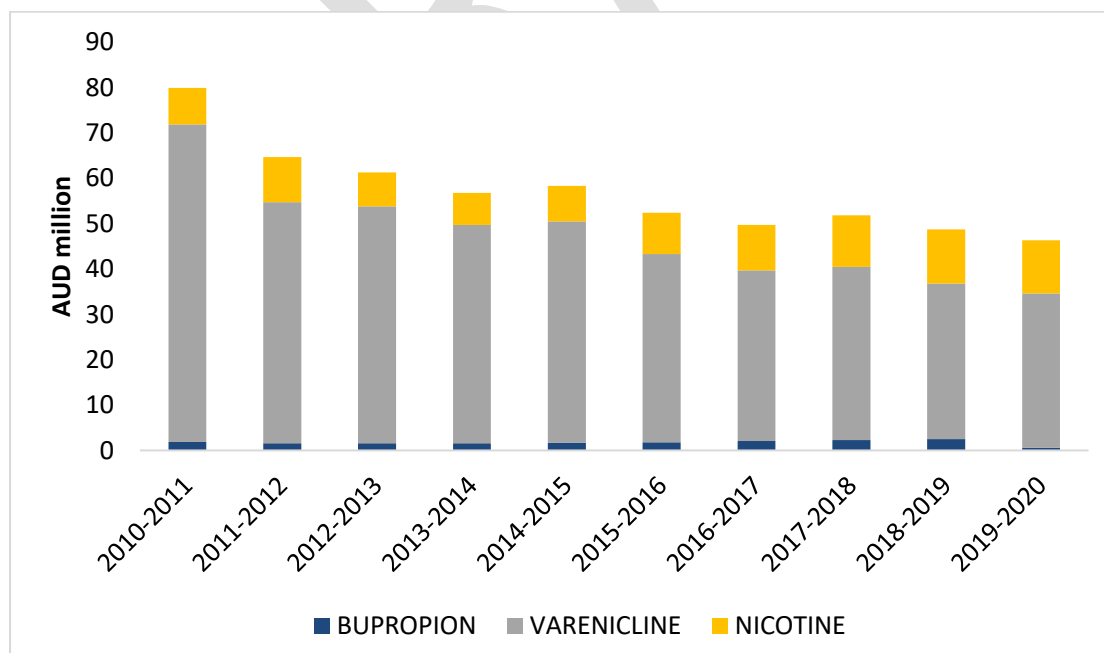


Figure 4. Total cost (AUD millions) of smoking cessation therapies under the PBS by financial year and type of therapy

NRT under the PBS scheme and over-the-counter

Before 1 February 2019, only NRT patches were subsidised under the PBS. NRT gums and lozenges were included on the PBS from 1 February 2019. In 2019/2020, NRT patches accounted for 94% of all NRT products subsidised under the PBS.

The volume and cost of all NRT products sold OTC from 2005 to 2019 was extracted from Euromonitor International report 2019 on NRT Smoking cessation aids in Australia [4].

There were 257.4 million NRT smoking cessation aids sold OTC in 2019 (Figure 5). The most commonly sold aid was NRT gum (194 million units in 2019), followed by NRT Lozenges (43.2 million units in 2019) and NRT patches (17.4 million units in 2019) – Figure 6.

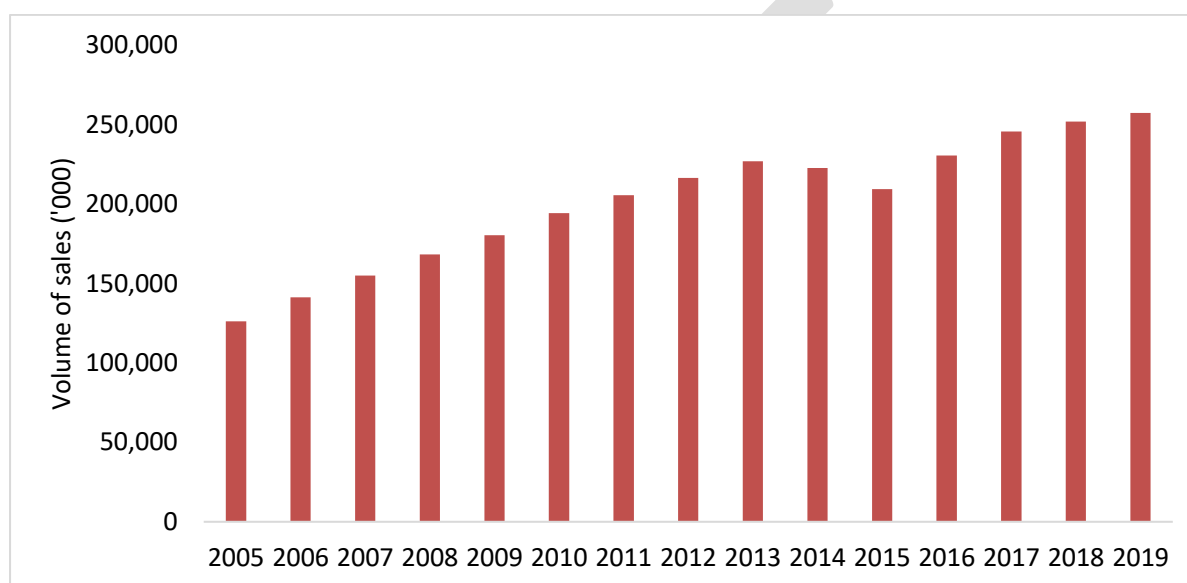


Figure 5. Total volume of all NRT smoking cessation aids sold over-the-counter

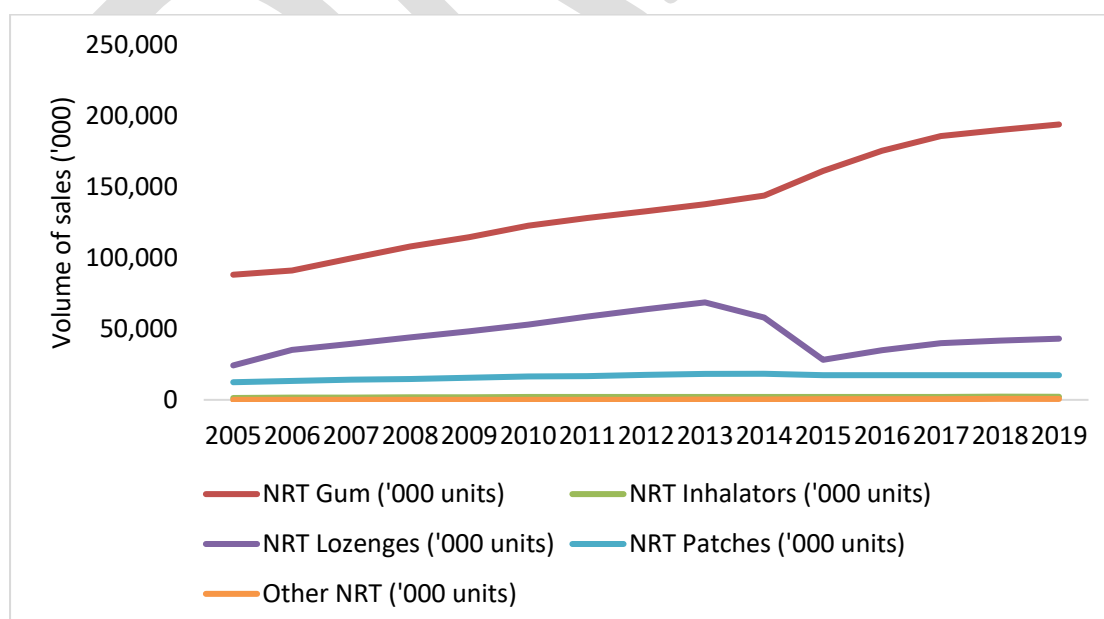


Figure 6. Volume of over-the-counter sales of NRT smoking cessation aids, by type of aid.

The total retail cost of NRT smoking cessation aids sold over-the-counter in 2019 was \$152 million AUD (Figure 7). The cost of NRT gum and NRT patches accounted for \$56 million each in 2019 (Figure 8).

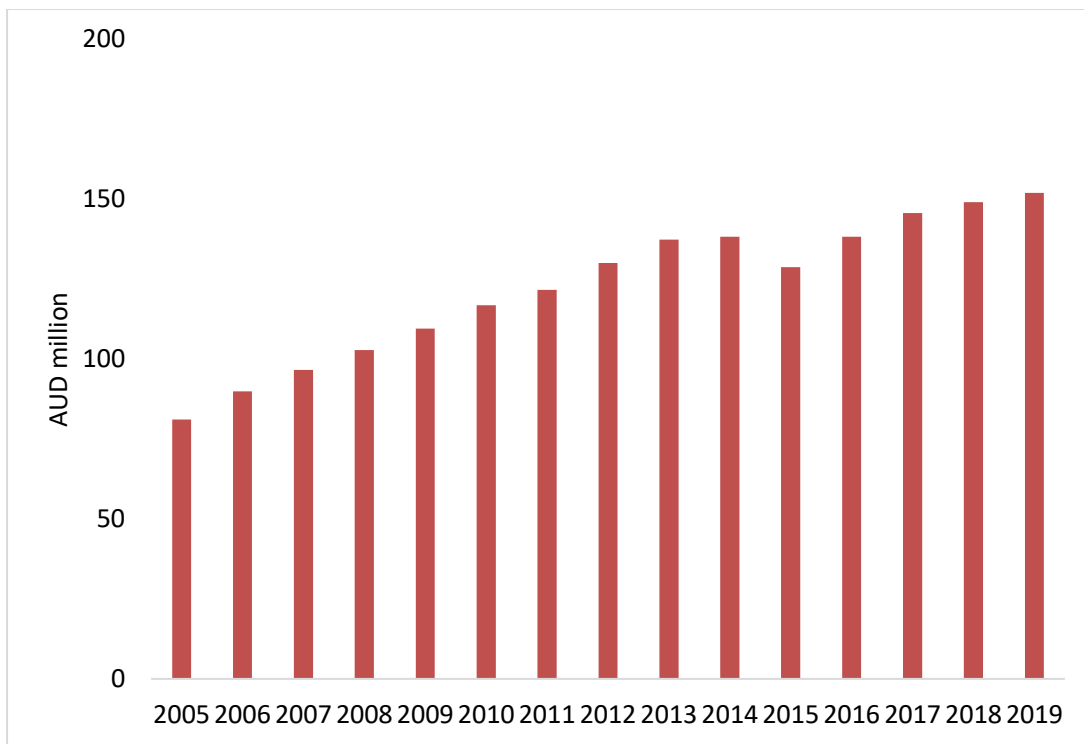


Figure 7. Total retail cost (AUD millions) of over-the-counter sales of NRT smoking cessation aids

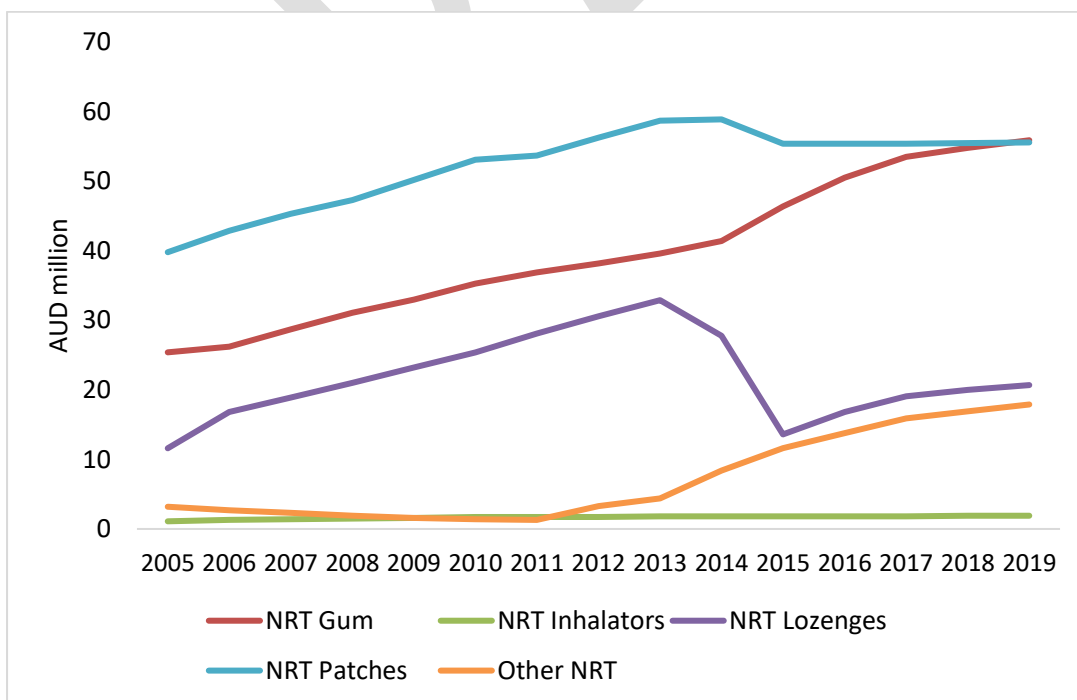


Figure 8. Retail cost (AUD millions) of over-the-counter sales of NRT smoking cessation aids, by type of aid

Figure 9 shows the NRT expenditure under the PBS and over-the-counter sales, with \$11.7 million spent under the PBS and \$152 million for OTC NRT aids in 2019. The NRT cost market under the PBS was 7.1% from the overall NRT market in 2019 (Figure 10). The results in figure 9 and 10 are reported for calendar years to allow comparison with Euromonitor International report 2019 on NRT Smoking cessation aids in Australia.

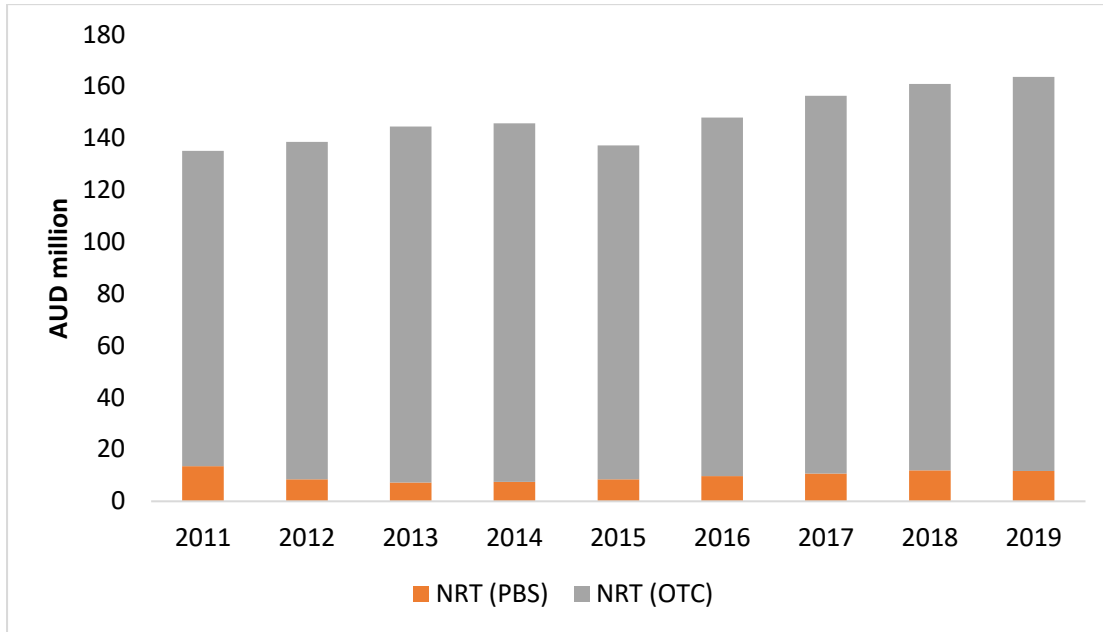


Figure 9. NRT cost under the PBS scheme and over-the-counter

Note: The cost under the PBS was for calendar years to allow comparison with Euromonitor International report 2019 on NRT Smoking cessation aids in Australia [4].

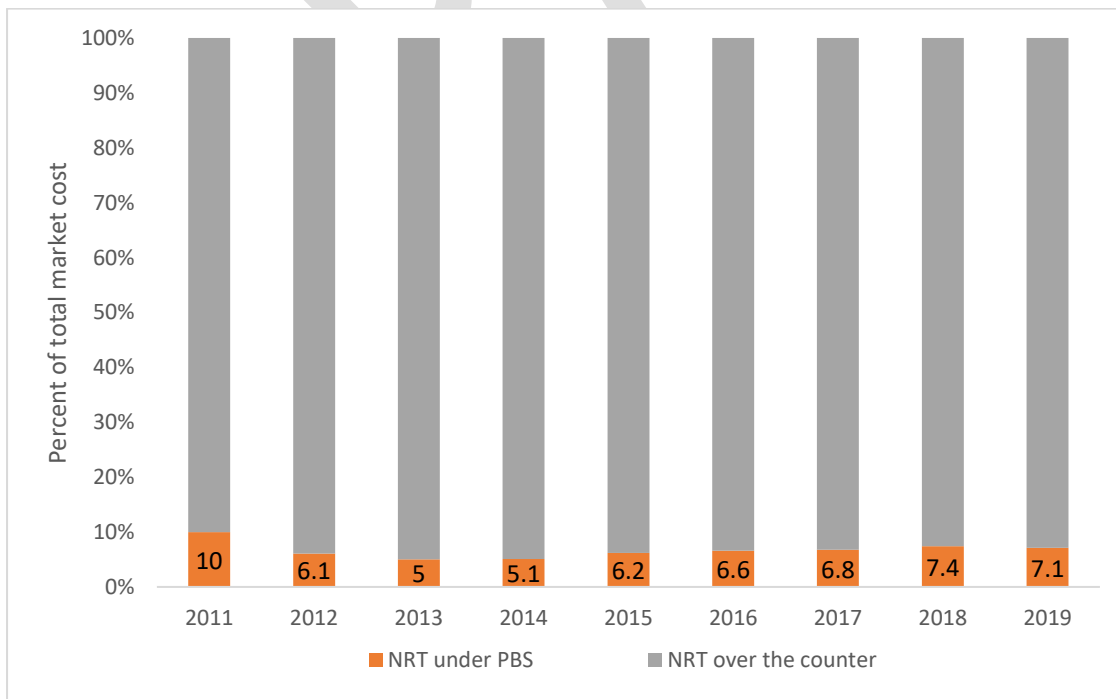


Figure 10. NRT cost market under the PBS from the overall NRT cost market

2.4.2 Prevalent and incident population treated with PBS listed medicines for smoking cessation

Prevalent population and characteristics

Figure 11 shows for each financial year the number of people who received at least one supply for any smoking cessation medicine in the given year. The number of prevalent people decreased from 421,009 in 2010/2011 to 265,544 in 2019/2020.

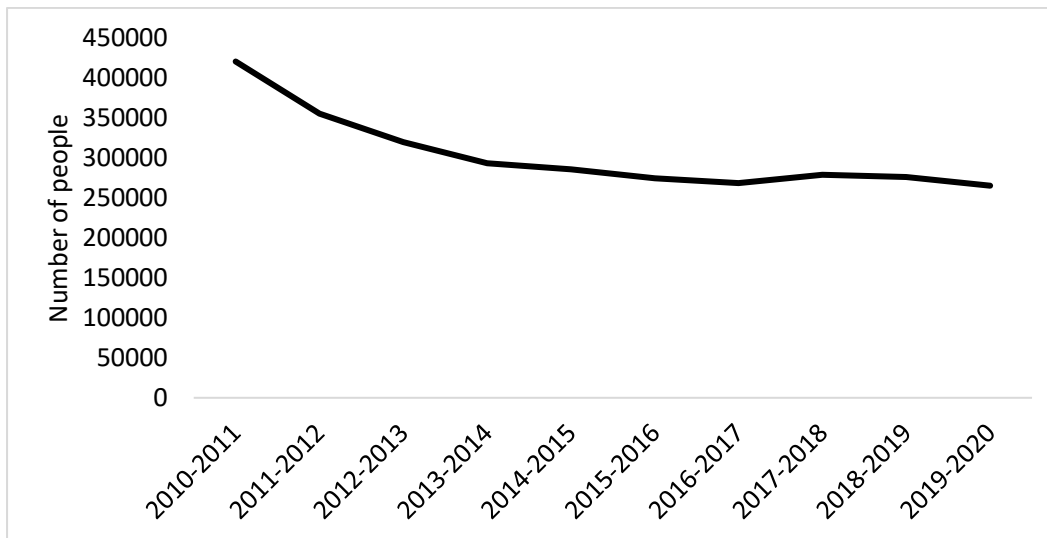


Figure 11. People prevalent to PBS-subsidised smoking cessation medicines

Varenicline continues to be the medicine most frequently supplied with 164,928 (60%) people supplied with it at least once in 2019/2020, followed by 107,537 (40%) people who received at least one nicotine replacement therapy (Figure 12).

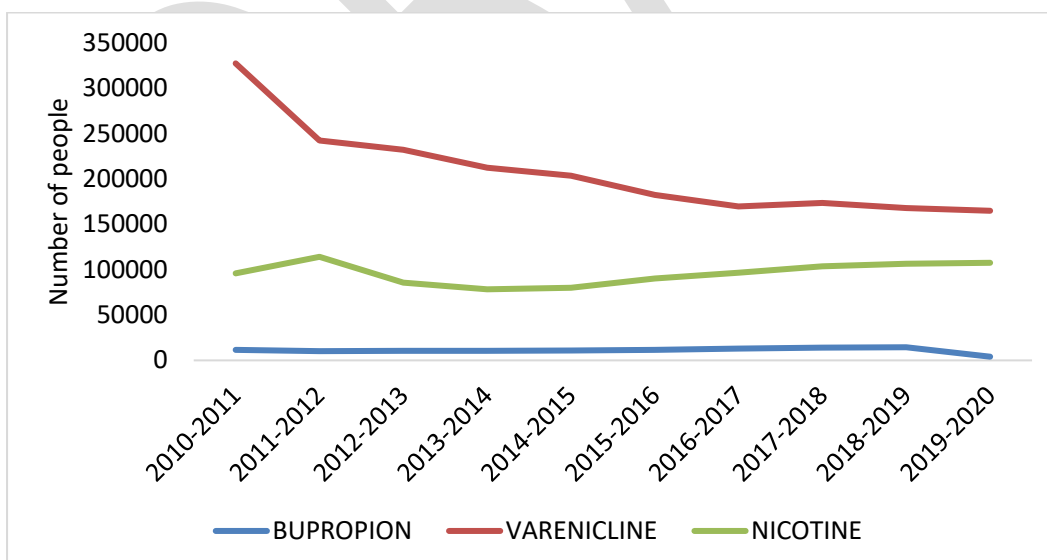


Figure 12. People prevalent to smoking cessation therapy, by type of therapy

More men (52.5%) than women (47.5%) were supplied with smoking cessation medicines across all years (Figure 13).

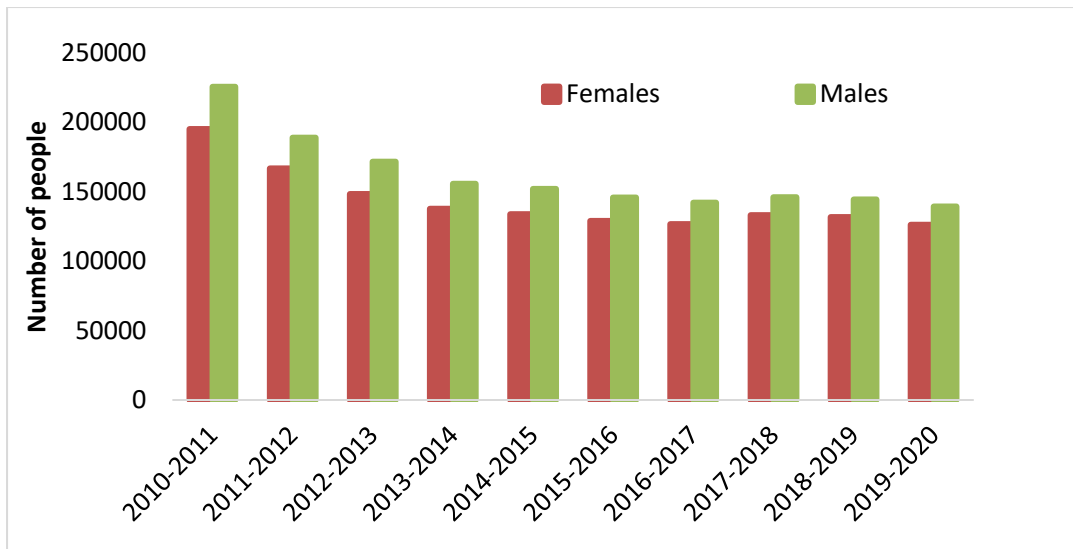


Figure 13. People prevalent to PBS-subsidised smoking cessation therapy by year and gender

Incident populations and their characteristics

Figure 14 shows for each financial year the number of people who initiated smoking cessation therapy after a one year period with no use (allowing for re-initiation) and the number of people who initiated therapy for the first time since the start of the data (1 Jan 2008); there were 64,543 (25%) people who initiated smoking cessation therapy for the first time ever, compared to 191,076 (75%) people who started therapy after a period of at least one year of no use.

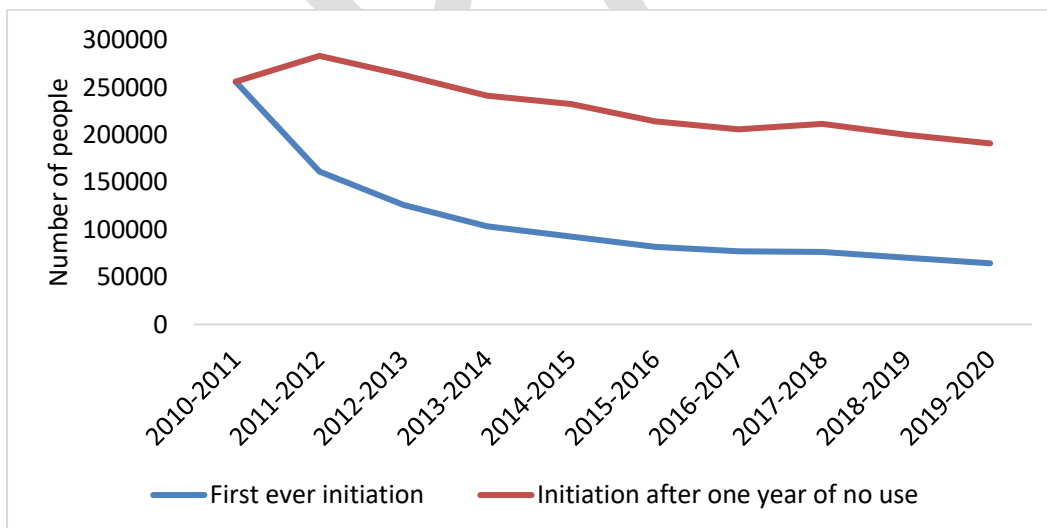


Figure 14. People initiating on smoking cessation therapies

Note: The result for 2010/2011 is based on a baseline period between 1 Jan 2008 and 30 Jun 2010

In 2019/2020, 37,151 people initiated varenicline for the first time followed by 26,784 people who initiated NRT and 608 people who initiated bupropion for the first time (Figure 15)

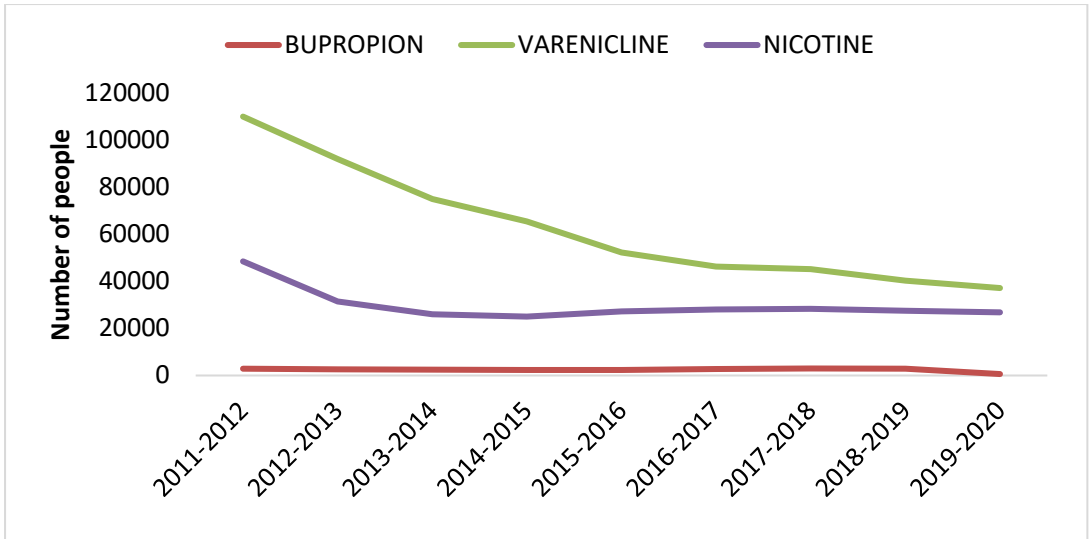


Figure 15. People initiating smoking cessation therapy for the first time ever, by type of therapy

Figure 15a shows that people aged 35 to 54 accounted for most of the first ever initiators across the years (Figure 15a), with 4 people per 1000 Australian in this age bracket initiating smoking cessation therapy for the first time ever in 2019/2020 (Figure 15b). In 2019/2020, in any age bracket between 18 and 64, over half of the initiators were general beneficiaries (Figure 15c).

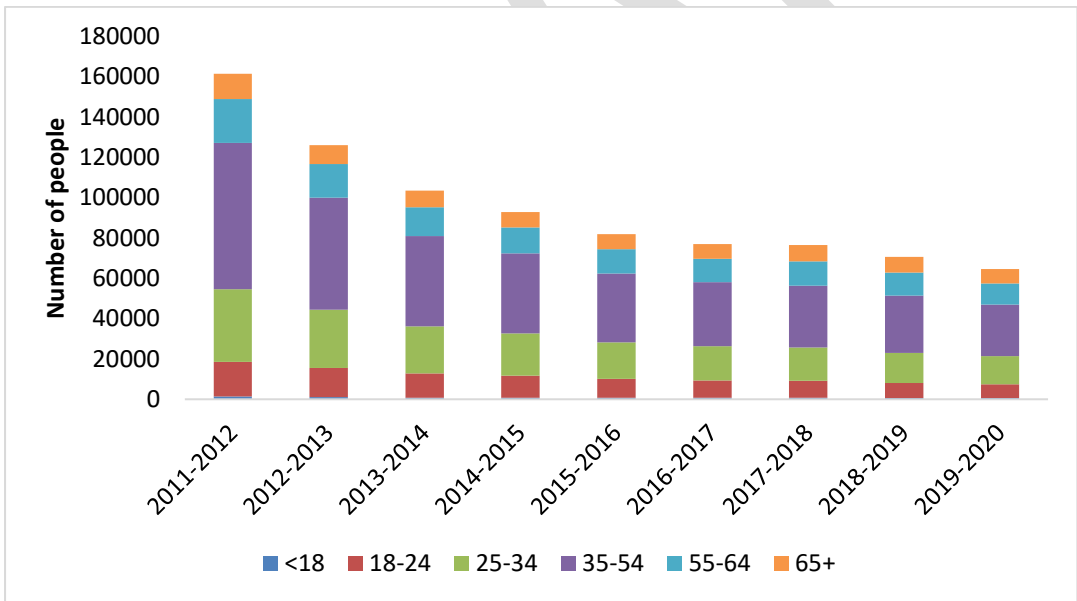


Figure 15a. People initiating smoking cessation therapy for the first time ever, by age at initiation

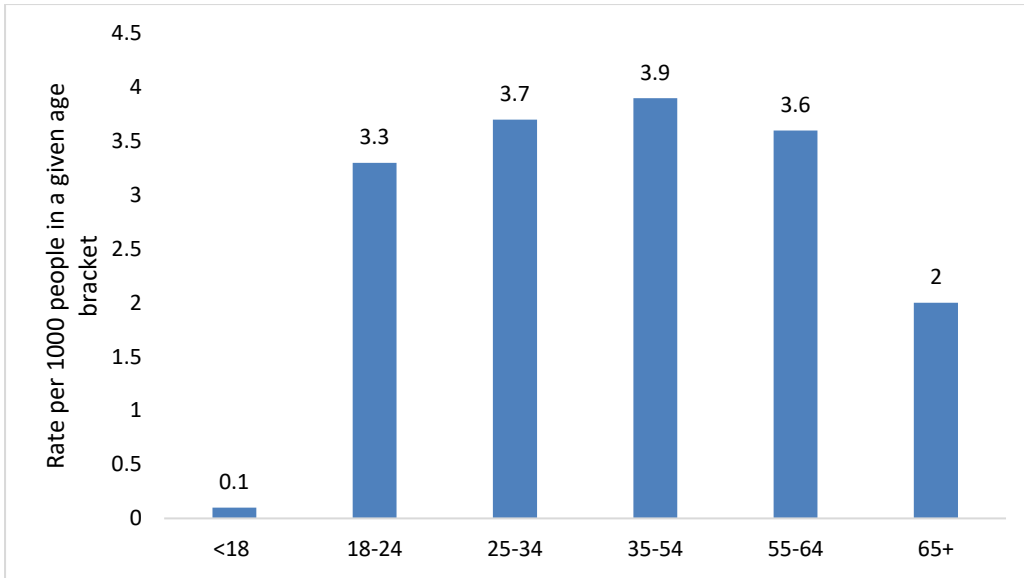


Figure 15b. Population rate per 1000 of first ever initiators of smoking cessation therapy in 2019/2020, by age at initiation

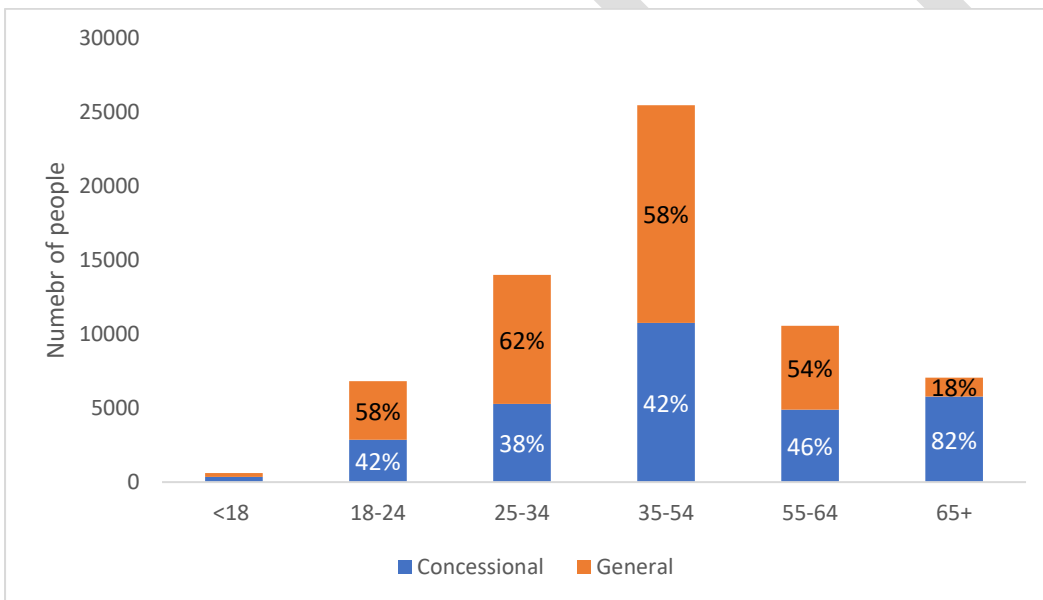


Figure 15c. People initiating smoking cessation therapy for the first time ever in 2019/2020, by age at initiation and beneficiary status

Table 2 presents the mean and median age at the time of first ever initiation to smoking cessation therapy stratified by gender and year, while table 2a present the proportions by the index of socio-economic disadvantage. The mean and median age was similar between women and men and relatively consistent across the years. The proportions in different categories of socio-economic disadvantage index were consistent across the years and showed that above 72% of smokers were with the highest index range.

Table 2. Age (years) at initiation to smoking cessation therapy by gender and year

Year		2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Women	Mean	42	42	42	42	43	43	43	44	44
Women	Median	42	42	42	42	43	43	43	44	44
Men	Mean	41	41	42	42	42	42	43	43	43
Men	Median	41	40	41	41	41	42	42	43	43

Table 2a. Index of socio-economic disadvantage at initiation to smoking cessation therapy by year

	Index range*	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020
Lowest	500-650	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%	0.2%
	651-800	1.5%	1.5%	1.5%	1.6%	1.7%	1.8%	1.6%	1.7%	1.6%
	801-950	24.6%	24.2%	24.9%	25.6%	26.2%	25.6%	25.9%	25.8%	25.6%
Highest	951-1174	73.9%	74.2%	73.6%	72.7%	72.1%	72.5%	72.3%	72.3%	72.5%

Note: *The Index of socio-economic disadvantage is based on person's postcode and the Australia Bureau of Statistics index of socio-economic disadvantage; the index ranges from 500 (lowest) to 1174 (highest)

2.4.3 Treatment rates at national and state level based on PBS data

Figure 16 presents the treatment rates at the national level reported per 1,000 of the Australian population. Only the age-adjusted rates are shown as the crude rates were identical. The age-adjusted rates are based on the Australian age distribution of the ABS estimated residential population at 30 Jun 2011.

There were 21 people per 1,000 population (2.1%) on smoking cessation treatment in 2010/2011 declining to 12 people per 1,000 population (1.2%) in 2019/2020 (Figure 16). Three people per 1,000 (0.3%) initiated smoking cessation medicines for the first time in 2019/2020, and 8 people per 1,000 (0.8%) initiated after one year of no use (Figure 16).

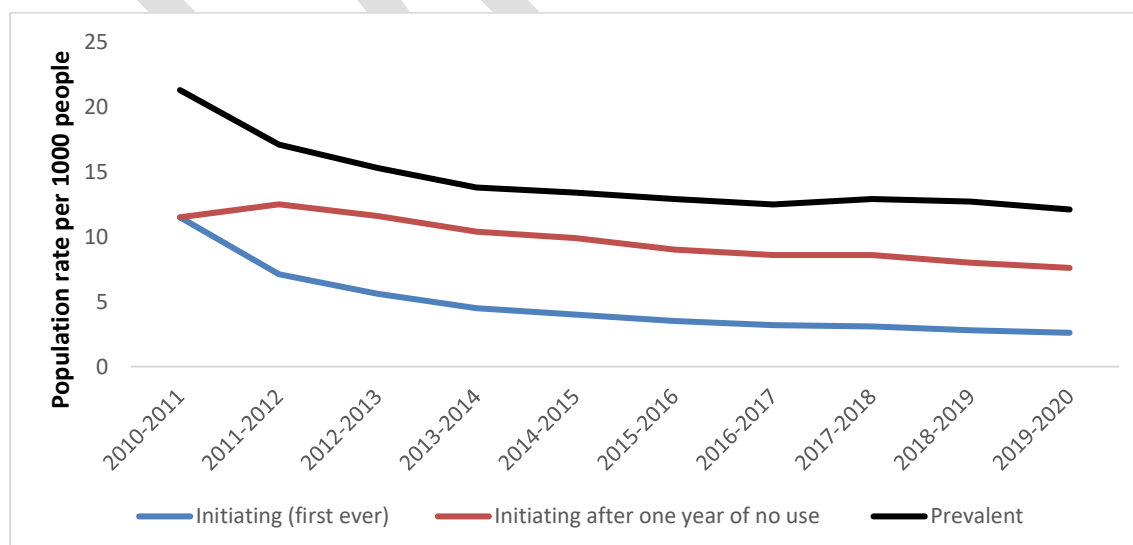


Figure 16. Age-adjusted treatment rates per 1,000 population, national level

Figure 17 - 19 present the treatment rates at state level reported per 1,000 Australian population.

There were 24 people per 1,000 population (2.4%) on smoking cessation treatment in 2019/2020 in Tasmania, followed by 17 people per 1,000 population in QLD (Figure 17). The lowest number was in Victoria and ACT (11 people per 1,000).

First ever initiation of smoking cessation therapy was slightly higher in Tasmania with 5 people per 1,000 population initiating treatment in 2019/2020 compared to 2 to 3 people per 1,000 in other states (Figure 18).

Initiation after one year of no use was highest in Tasmania with 13 people per 1,000 population in 2019/2020 compared to 6 to 10 people per 1,000 in other states (Figure 19).

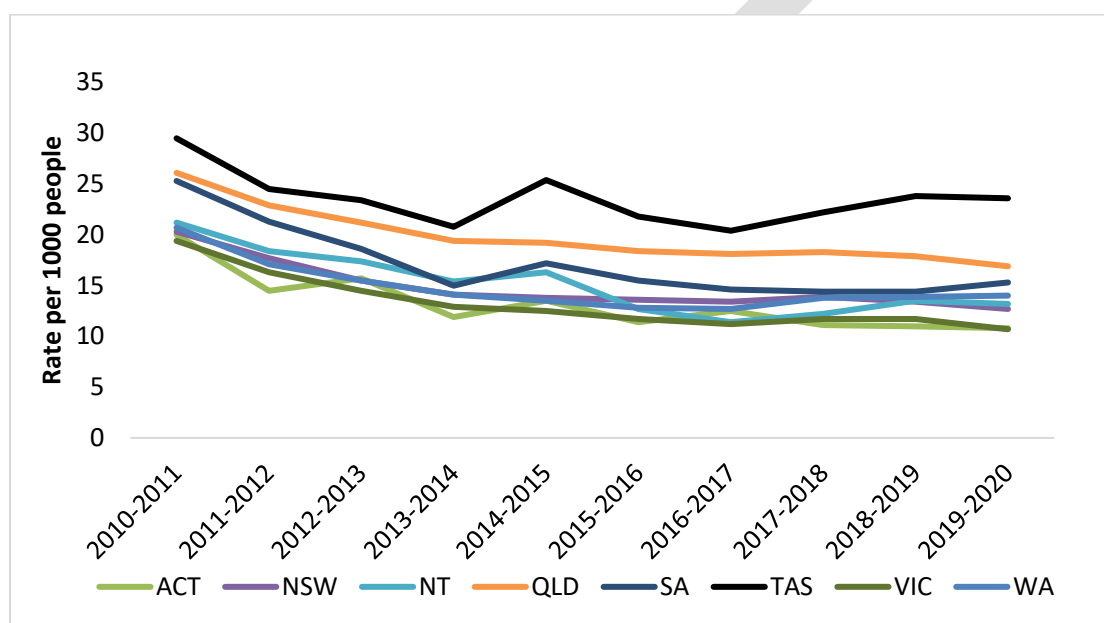


Figure 17. Age-adjusted prevalent rates per 1,000 population – by state

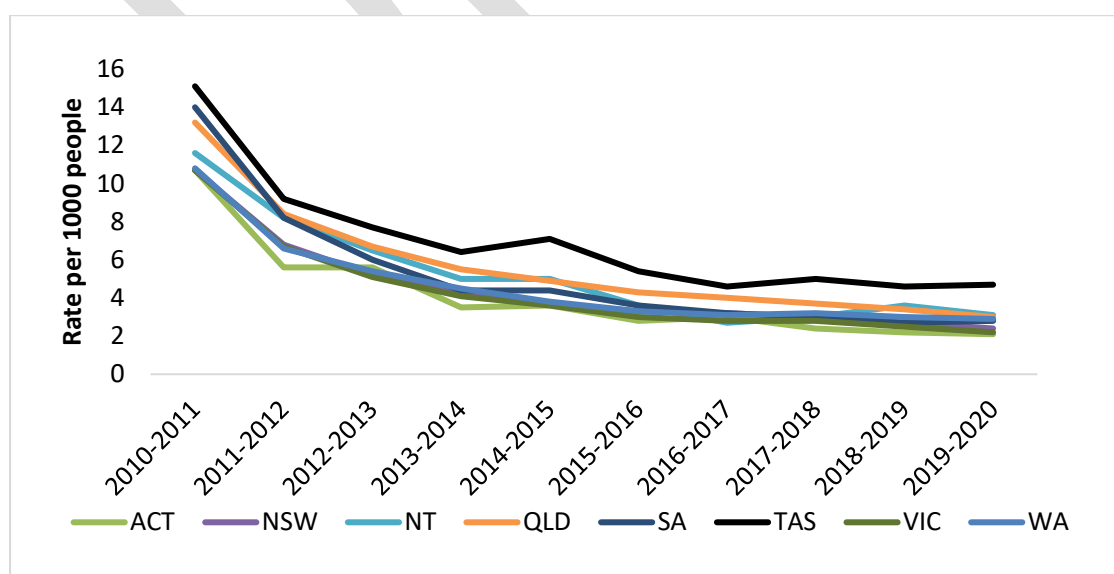


Figure 18. Age-adjusted incident rates (first ever initiation) per 1,000 population – by state

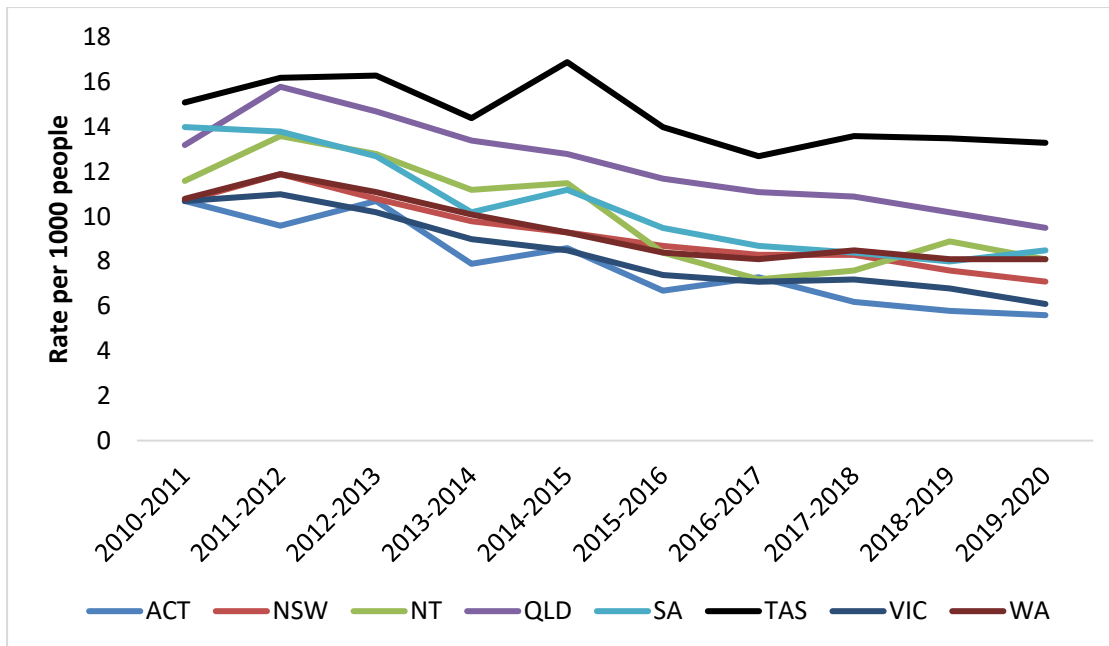


Figure 19. Age-adjusted incident rates (initiation after one year of no use) per 1,000 population – by state

2.4.4 Prevalence of smoking cessation therapies under the PBS in specific populations

For the prevalent population in each calendar year, estimates of use among specific populations of interest are presented as the proportion of people in the smoking cessation therapy population who are estimated to be in the population of interest (i.e. the smoking cessation population is the denominator).

Figure 20 shows that from people receiving smoking cessation therapy in 2019:

- 40% also had medicines for mental illness, as measured by antipsychotic and antidepressant use
- 18% were women of child-bearing age (aged 15 to 44 years)
- 16% also had smoking related illness (medicines for chronic respiratory disorders or chronic obstructive pulmonary disease)
- 10% were Aboriginal and Torres Strait Islander persons, identified by following criteria – a supply of prescriptions under the Closing the Gap Co-Payment Measure program, or utilisation of Indigenous-specific MBS items, or Voluntary Indigenous Identifier
- 1% were at risk of alcohol abuse, as measured by medicines for alcohol dependence

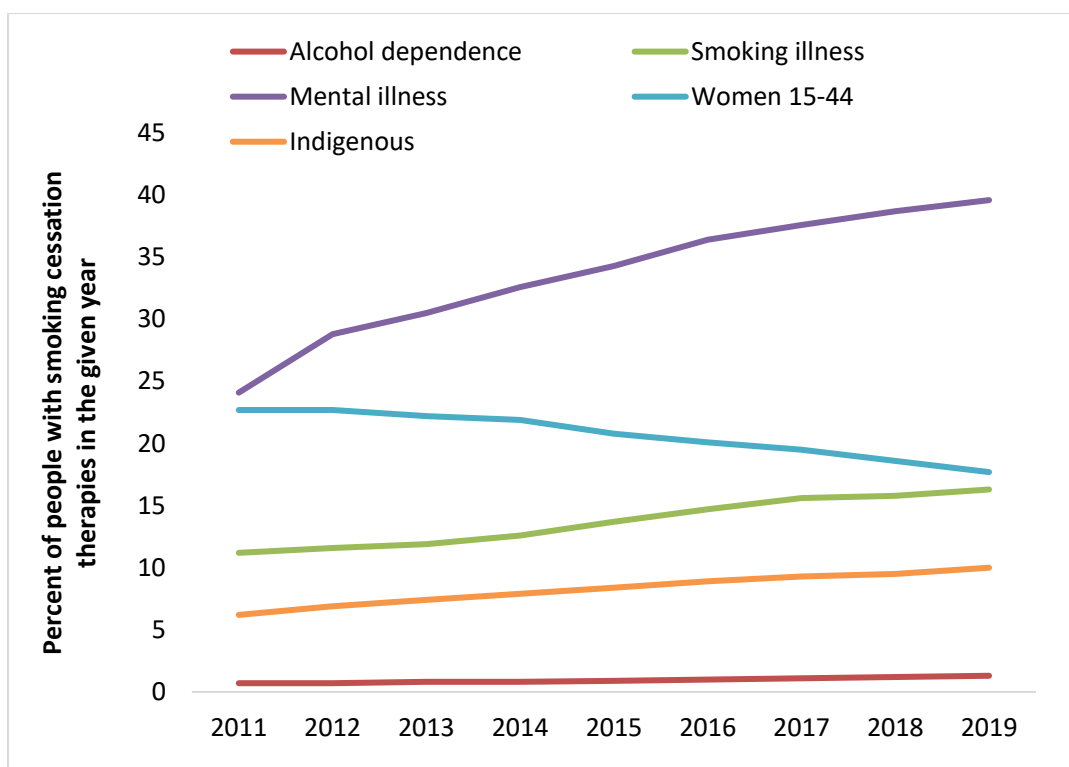


Figure 20. Proportion of people who received smoking cessation therapies who are estimated to be in the population of interest.

Table 3 presents the number of smoking cessation therapy packs provided by Aboriginal Health Services (AHS). The total number of packs for all smoking cessation therapy through AHS in 2019 was 5639, which is 1.04% of the number of smoking cessation therapies supplied under the PBS in the same calendar year (N=540,122).

Table 3. Number of packs of smoking cessation therapy provided by Aboriginal Health Services

Year	Bupropion	NRT	Varenicline	Total
2011	154	2030	1831	4015
2012	129	2682	1915	4726
2013	97	2797	1869	4763
2014	87	3342	1807	5236
2015	49	2071	1176	3296
2016	42	3091	1520	4653
2017	112	3130	1893	5135
2018	68	3808	1994	5870
2019	68	3943	1628	5639

2.4.5 Prevalence of smoking in Australia in the general and specific populations

Prevalence of current smokers in Australia

The Australian Institute of Health and Welfare, National Drug Strategy Household Survey 2019 [17] reports the number of people aged 14 years and over who are current smokers. People who smoke daily or less often are considered current smokers. Figure 21 shows that the number of current smokers aged 14 years and over decreased from 3.6 million in 2001 to 2.9 million in 2019. Men are more likely to be current smokers than women with the numbers being 1.6 million and 1.3 million in 2019, respectively.

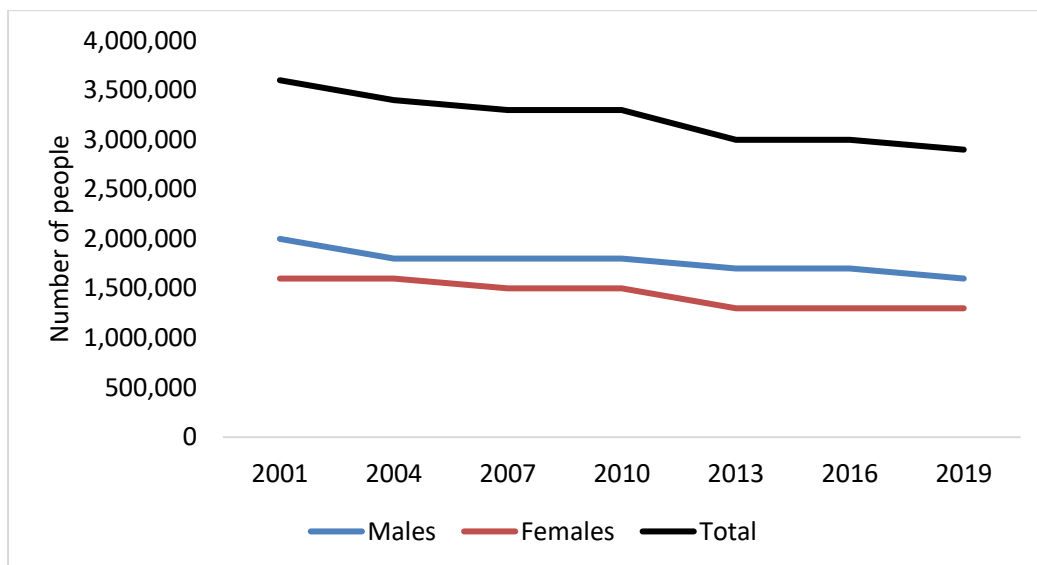


Figure 21. Number of current smokers aged 14+, total number and by gender

Figure 22 presents the rates of current smokers who are aged 18 years and over from the overall population aged 18+ in Australia based on the National Drug Strategy Household survey 2019 [17]. The overall rate declined from 23.8% in 2001 to 14.7% in 2019. The rates for both men and women declined across the years, with 16.6% of all men and 12.8% of all women aged 18+ being current smokers in 2019.

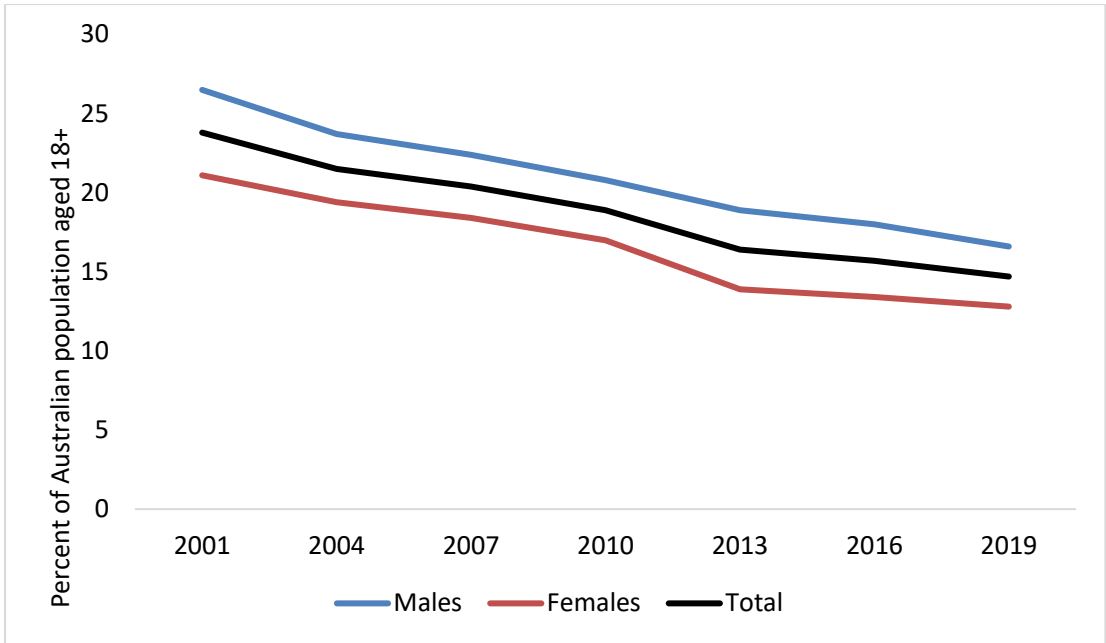


Figure 22. Prevalence of current smokers in Australia aged 18+ from all Australians aged 18+ and by gender

Figure 23 shows the rates of current smokers aged 14+ in 2019 by state and territory. The rates were highest in Northern Territory and lowest in ACT. The reported rates are based on the National Drug Strategy Household survey 2019 [17].

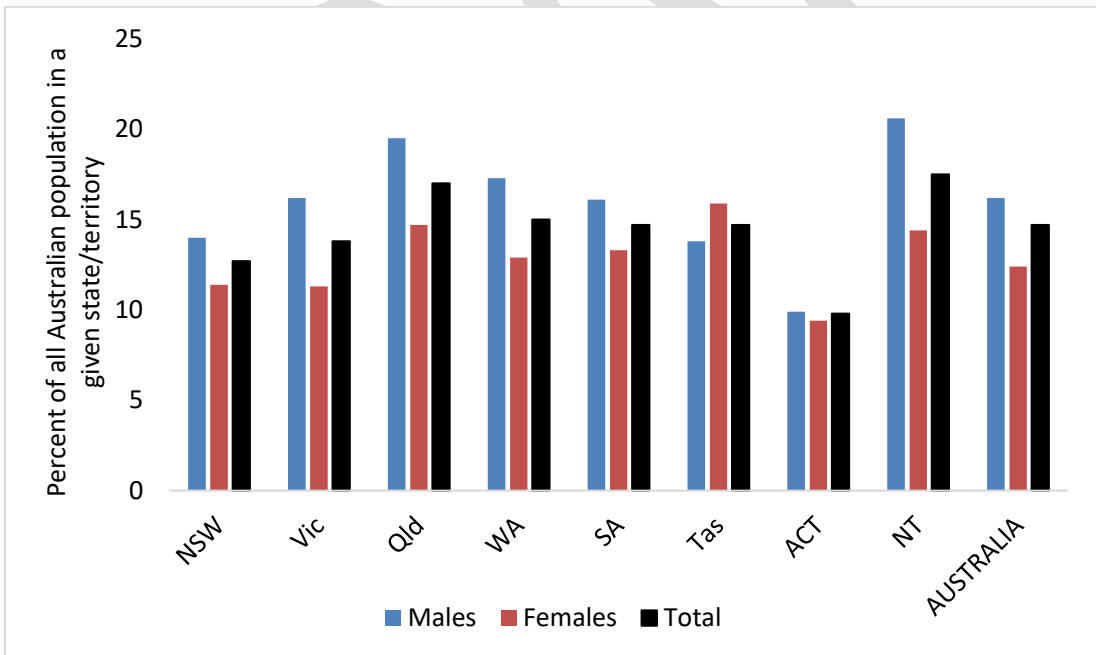


Figure 23. Prevalence of current smokers aged 14+ in 2019, by state and territory

Prevalence of tobacco use among Aboriginal and Torres Islander people

Data from the National Aboriginal and Torres Strait Islander Social Survey 2014-2015 [18] and the National Aboriginal and Torres Strait Islander Health Survey 2018-2019 [19] are used to estimate the prevalence of current people aged 15+ who are smokers by Aboriginal and Torres Strait Islander status (Figure 24). The rate of Aboriginal and Torres Strait Islander people who are current smokers declined from 53% in 2001 to 41% in 2019. However, the rates are 2.8 times higher in comparison to the overall Australian population.

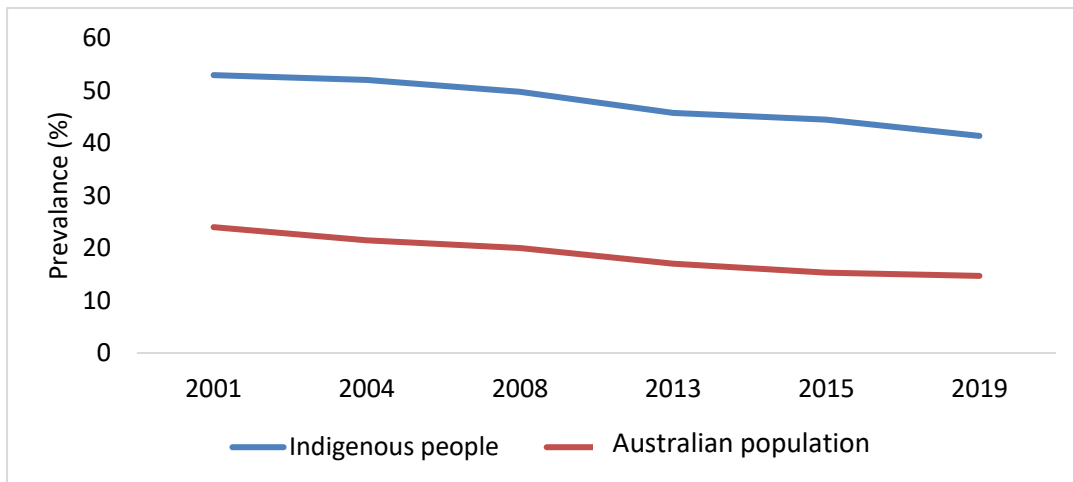


Figure 24. Prevalence of current smokers aged 15+ among Aboriginal and Torres Strait Islander and non-Indigenous persons.

Figure 25 present the rates of current smokers among Aboriginal and Torres Strait Islander people aged 18+ in 2019 by state and territories. Rates vary from 25% in ACT to 58% in NT.

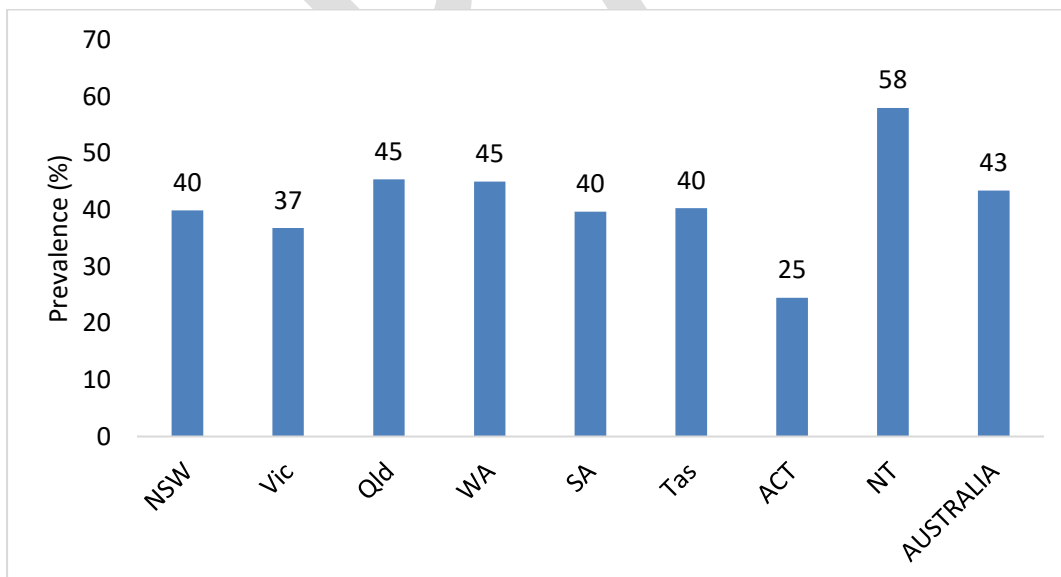


Figure 25. Prevalence of current smokers aged 18+ among Aboriginal and Torres Strait Islander people, by state and territory, 2019

Prevalence of smoking in the first 20 weeks of pregnancy among women who gave birth

Data from the Australian Institute of Health and Welfare reports on Australia's mothers and babies key statistics and trends [20, 21] and shows that the percent of women who smoked in the first 20 weeks of pregnancy declined from 12.9% in 2011 to 9.2% in 2018 (Figure 26)

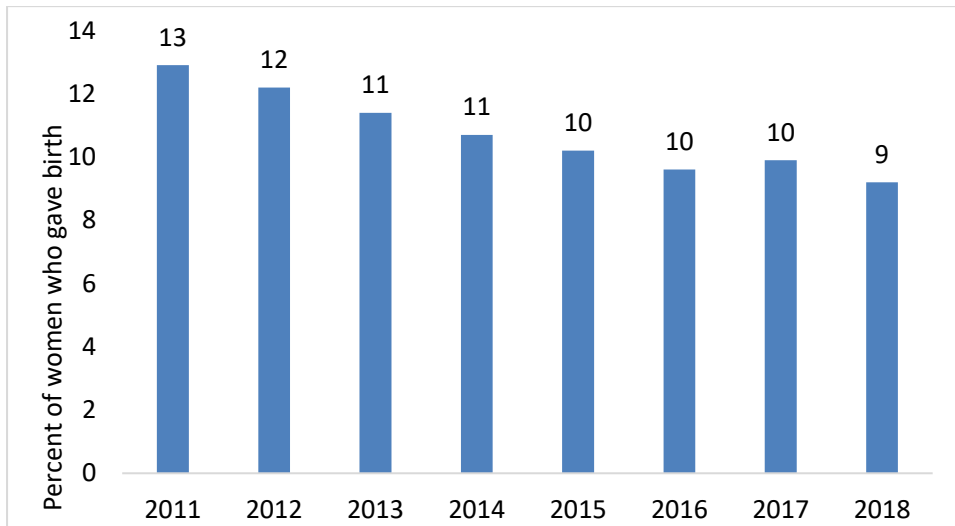


Figure 26. Smoking in the first 20 weeks of pregnancy among all women who gave birth

Figure 27 shows that in 2018, the rates of pregnant women who smoked in the first 20 weeks was highest in NT (21%) and lowest in ACT (6%).

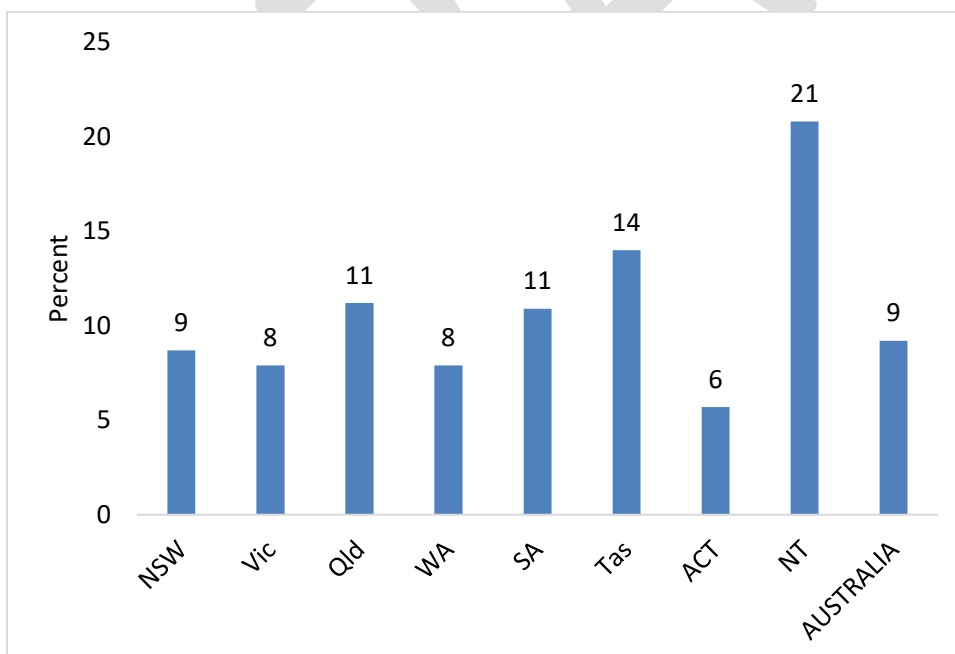


Figure 27. Smoking in the first 20 weeks of pregnancy among all women who gave birth, by state and territory, 2018

Prevalence of current smokers among prison entrants

The Australian Institute of Health and Welfare report on the health of Australia’s prisoners [22] shows that in 2018, at least 75% of non-Indigenous prison entrants aged 18-44 years were current smokers, and at least 79% of Aboriginal and Torres Strait Islander prison entrants aged 18-44 were current smokers. The rates were similar across age groups and between Aboriginal and Torres Strait Islander and non-Indigenous groups (Figure 28).

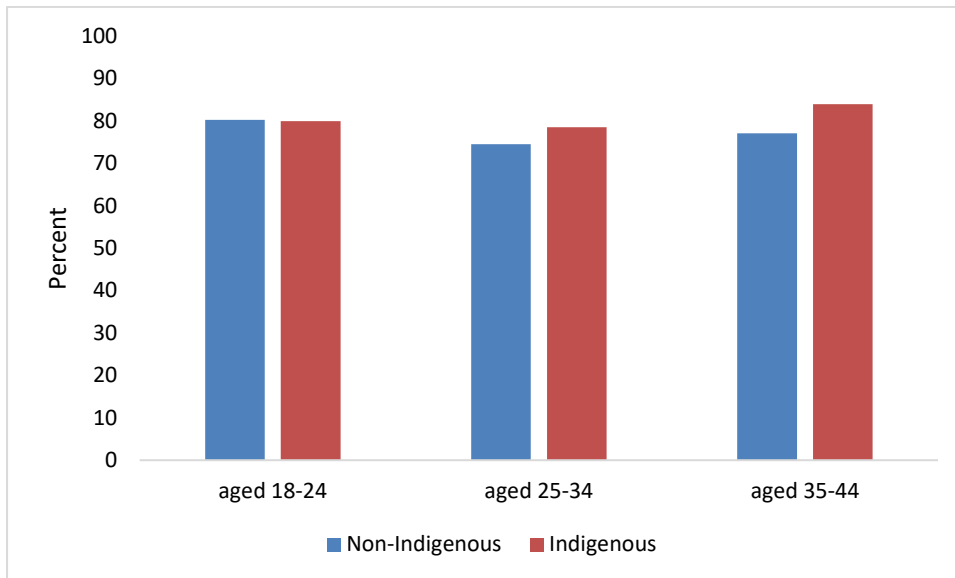


Figure 28. Current smokers among prison entrants, by age group and Aboriginal and Torres Strait Islander status, 2018

Prevalence of smoking in people with alcohol and drug problems or mental illness

Data from the National Drug Strategy Household Survey 2019 [17] show that people with self-reported mental illness (depression, anxiety disorder, schizophrenia, bipolar disorder, an eating disorder and other) are almost twice as likely to be current smokers compared to people without mental illness (Figure 29).

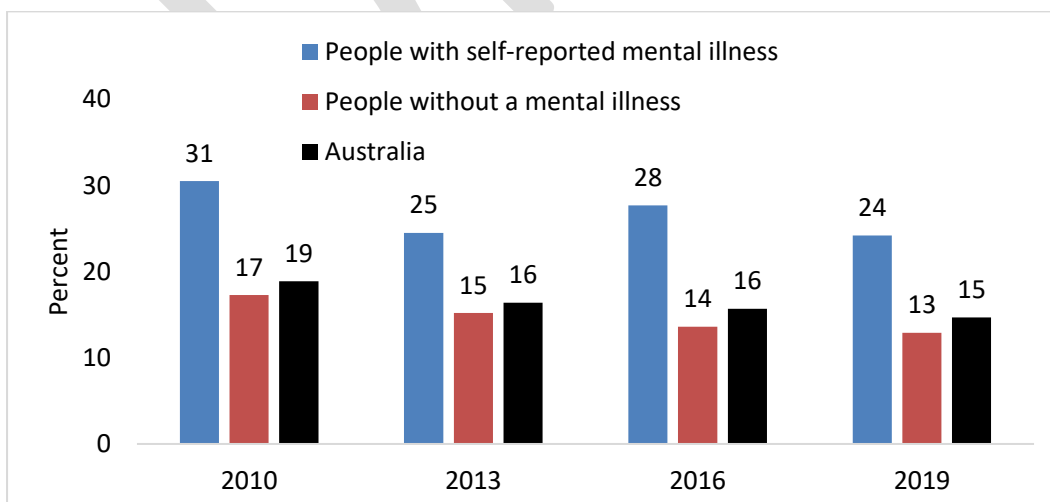


Figure 29. Current smoking rates in people aged 18+, by mental health status

Greenhalgh et al [23] aggregated data from the National Health Survey 2014-2015 to report the prevalence of daily smoking by the type of mental disorders. Figure 30 shows high prevalence of smoking among those with harmful use or dependence on drugs (74%) and alcohol (50%). Almost half of the people with schizophrenia were daily smokers, followed by 38% of people with panic disorders.

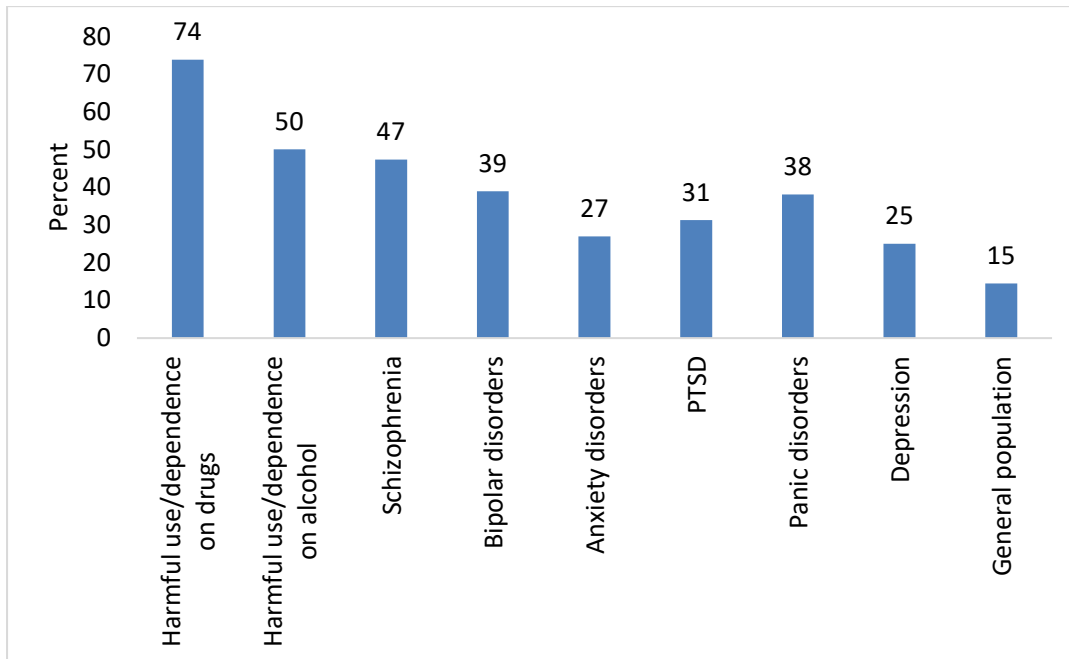


Figure 30. Prevalence of daily smoking by type of mental disorder in people aged 18+, 2014-2015.

Estimates of specific populations of interest with access to smoking cessation therapies under the PBS

Based on availability of data, estimates of use of smoking cessation therapies among current smokers aged 18+ in Australia are presented in Figure 31a and Figure 31b. Figure 31a shows that in the calendar year 2019, from the 2.9 million people who were current smokers, approximately 267,000 had at least one smoking cessation medicine dispensed under the PBS. Figure 31b presents the same results per 1000 population aged 18 years and over in Australia. It shows that in 2019, the rate of current smokers aged 18 years and over was 147 per 1000 people in Australia, while 14 per 1000 people aged 18 years and over received at least one smoking cessation medicine under the PBS.

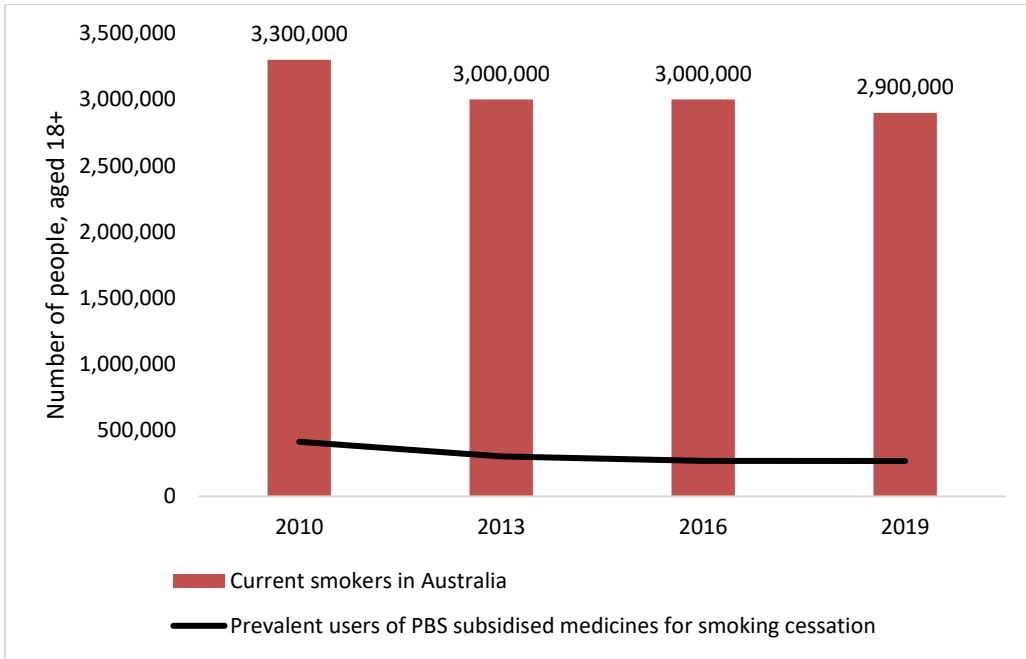


Figure 31a. Number of current smokers in Australia and prevalent users of PBS subsidised medicines for smoking cessation, aged 18 years and over.

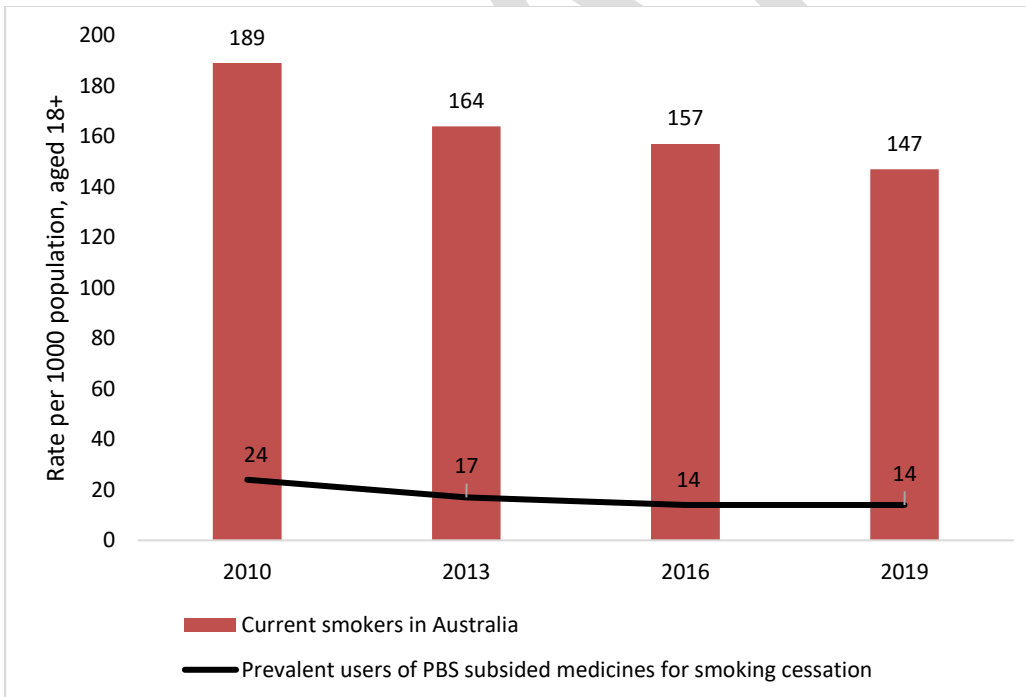


Figure 31b. Rate of current smokers and prevalent users of PBS subsidised medicines for smoking cessation, per 1000 residents in Australia, aged 18 years and over.

Figure 31c shows estimates of use of smoking cessation therapies in specific populations in 2013, 2016 and 2019. In 2019,

- 10% of all current smokers aged 18+ in Australia received smoking cessation therapies under the PBS;
- 1% of all Australian women in child-bearing age (aged 15 to 44) received smoking cessation therapies under the PBS;
- 6% of all Aboriginal and Torres Strait Islander population aged 18+ in Australia received smoking cessation therapies under the PBS.

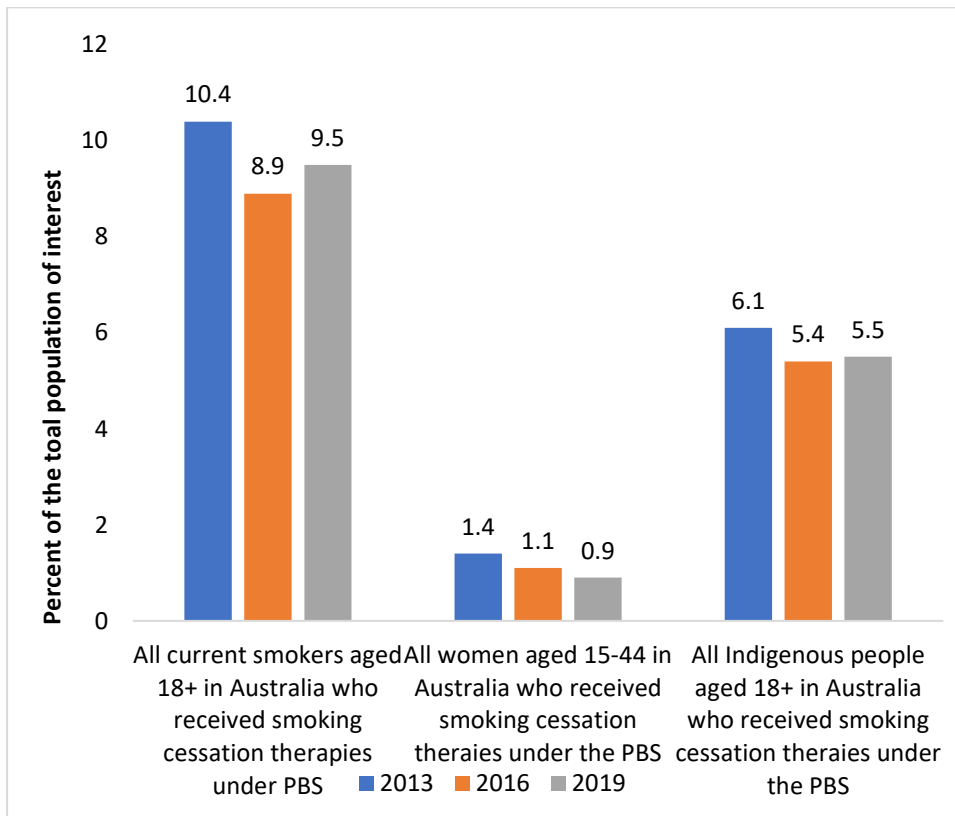


Figure 31c. Proportion of people that received smoking cessation therapies under the PBS from total Australian population of interest

Use of various aids to assist smoking cessation

The use of various aids to assist smoking cessation including use of counselling services such as Quitline was based on the Australian Institute of Health and Welfare, National Drug Strategy Household Survey 2019 [17]. Figure 32 shows that most current smokers reported using nicotine gum, patch, inhaler or spray as an aid to quit smoking (17% in 2019).

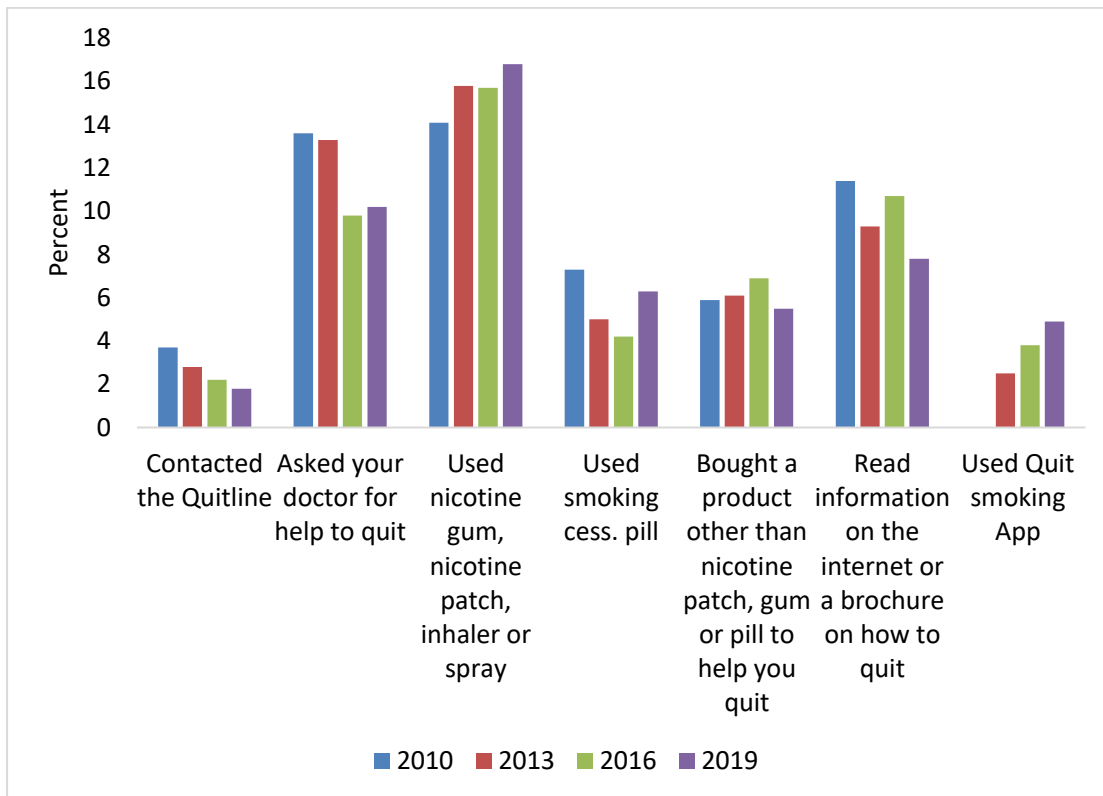


Figure 32. Activities undertaken by current smokers aged 14+ to help quit smoking

Use of Quitline as a counselling service

Quitline data was provided to the Department of Health for this review, including data from the Victorian, Queensland and NSW Quitline for 2019.

Number of people contacting Quitline

Figure 33 presents the number of people contacting the Quitline across the three states; each state received between 300 to 750 calls a month. On average, Queensland received a higher number of calls compared to the NSW and Victoria Quitline. During 2019 Queensland Quitline provided an 'intensive quit support program' which provided 12 weeks of free NRT combination therapy and 4 outbound Quitline calls to clients.



Figure 33. Number of inbound calls to Quitline, by state, 2019

Proportion of people who call Quitline who are referred by a health professional/ GP

In NSW, 13% of Quitline callers had a referral by GP and a further 6% came from hospitals.

In Victoria, 5% of Quitline callers had a referral from primary and community health, and a further 2% came from hospitals or a health service.

There was no data available for QLD.

2.4.6 Trajectory of care

All people who initiated smoking cessation therapy (first ever prescription) between 1 July 2010 and 30 June 2015 were identified.

NRT was available on the PBS as patches only before 1 Feb 2019 (gums and lozenges were subsidised under the PBS after 1 Feb 2019) and analysis of dual use of different NRT formulations between 1 Feb 2019 and 30 Jun 2020 showed dual use of patch and gum to be

0.5%, while dual use of patch and lozenge to be 0.3% of overall NRT use in the period– thus because dual use was not common it is not reported separately in the results below.

The number of people initiating to smoking cessation products by medicine at initiation is presented in Table 4. Varenicline was the most commonly initiated medicine and the top 15 sequences of care after its initiation are shown in Table 5. These 15 sequences present therapies including gaps in therapy and account for 98.7% of all trajectories of care after varenicline initiation. 62% of people made only one attempt to quit with varenicline in the five year follow-up.

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Table 4. Initiation of smoking cessation medicine between 2010 and 2015 – by type of medicine.

Medicine at initiation	Number of people	Percent of all smoking cessation therapies initiations
Varenicline	541,077	73.1
NRT	184,537	24.9
Bupropion	14,468	2.0
Total	740,082	100

Table 5. Top 15 sequences after initiation of varenicline (N=541,077)

Top 15 sequences after varenicline initiation	Number of people	Percent	Cumulative percent
Vare	332899	61.5	61.5
Vare --> Gap --> Vare	97174	18	79.5
Vare --> Gap --> Vare --> Gap --> Vare	50262	9.3	88.8
Vare --> Gap --> Nico	23488	4.3	93.1
Vare --> Gap --> Nico --> Gap --> Nico	9055	1.7	94.8
Vare --> Gap --> Vare --> Gap --> Nico	5960	1.1	95.9
Vare --> Gap --> Nico --> Gap --> Vare	5492	1	96.9
Vare --> Gap --> Bupr	3817	0.7	97.6
Vare --> Gap --> Bupr --> Gap --> Vare	1183	0.2	97.8
Vare --> Nico	910	0.2	98
Vare --> Gap --> Bupr --> Gap --> Bupr	894	0.2	98.2
Vare --> Gap --> Vare --> Gap --> Bupr	842	0.2	98.4
Vare --> Nico+Vare --> Nico	708	0.1	98.5
Vare --> Gap --> Vare --> Gap --> Bupr	591	0.1	98.6
Vare --> Nico --> Gap --> Nico	295	0.1	98.7

Legend: "+" denotes concurrent use of medicines;

"-->" denotes transition from one therapy to another

Vare = Varenicline; NRT = Nicotine Replacement Therapy; Bupr = Bupropion; Gap – gap in therapy

Table 6 shows the top 15 sequences after NRT initiation which account for 97.2% of all trajectories. 55% of people made only one attempt with NRT over 5 years.

Table 6. Top 15 sequences after initiation of NRT (N=184,537)

Top 15 sequences after NRT initiation	Number of people	Percent	Cumulative percent
Nico	102186	55.4	55.4
Nico --> Gap --> Nico	28375	15.4	70.8
Nico --> Gap --> Nico --> Gap --> Nico	18265	9.9	80.7
Nico --> Gap --> Vare	14668	7.9	88.6
Nico --> Gap --> Vare --> Gap --> Vare	5436	2.9	91.5
Nico --> Gap --> Nico --> Gap --> Vare	4442	2.4	93.9
Nico --> Gap --> Vare --> Gap --> Nico	3233	1.8	95.7
Nico --> Vare	729	0.4	96.1
Nico --> Nico+Vare --> Vare	549	0.3	96.4
Nico --> Gap --> Bupr	465	0.3	96.7
Nico --> Nico+Vare --> Vare --> Gap --> Vare	224	0.1	96.8
Nico --> Vare --> Gap --> Vare	213	0.1	96.9
Nico --> Gap --> Nico --> Nico+Vare --> Vare	183	0.1	97
Nico --> Vare --> Gap --> Vare --> Gap --> Vare	180	0.1	97.1
Nico --> Gap --> Nico --> Gap --> Nico --> Vare	178	0.1	97.2

Legend: "+" denotes concurrent use of medicines;

"-->" denotes transition from one therapy to another

Vare = Varenicline; NRT = Nicotine Replacement Therapy; Bupr = Bupropion; Gap – gap in therapy

Table 7 presents the top 15 sequences after bupropion initiation which account for 96.6% of all trajectories. 58% of people attempted to quit with bupropion only once over 5 years.

Table 7. Top 15 sequences after initiation of bupropion (N=14,468)

Top 15 sequences after bupropion initiation	Number of people	Percent	Cumulative percent
Bupr	8383	58	58
Bupr --> Gap --> Vare	1458	10.1	68.1
Bupr --> Gap --> Bupr	1252	8.7	76.8
Bupr --> Gap --> Nico	542	3.7	80.5
Bupr --> Gap --> Vare --> Gap --> Vare	627	4.3	84.8
Bupr --> Gap --> Bupr --> Gap --> Bupr	616	4.3	89.1
Bupr --> Gap --> Nico --> Gap --> Nico	281	1.9	91
Bupr --> Gap --> Bupr --> Gap --> Vare	255	1.8	92.8
Bupr --> Gap --> Vare --> Gap --> Bupr	156	1.1	93.9
Bupr --> Gap --> Vare --> Gap --> Nico	129	0.9	94.8
Bupr --> Gap --> Nico --> Gap --> Vare	114	0.8	95.6
Bupr --> Gap --> Bupr --> Gap --> Nico	56	0.4	96
Bupr --> Vare	36	0.2	96.2
Bupr --> Nico	34	0.2	96.4
Bupr --> Bupr+Vare --> Vare	32	0.2	96.6

Legend: "+" denotes concurrent use of medicines;

"-->" denotes transition from one therapy to another

Vare = Varenicline; NRT = Nicotine Replacement Therapy; Bupr = Bupropion; Gap – gap in therapy

2.4.7 Number of therapies and length of treatment with smoking cessation medicines

Duration of first treatment episode to cessation or end of follow-up

There were 740,082 people who initiated smoking cessation medicine (first ever prescription) between 1 July 2010 and 30 June 2015. The mean age at initiation was 43 years (SD=14.6), with 56% being males (Table 8). The cohort demographics by type of index therapy show that NRT initiators were older with more females compared to varenicline and bupropion initiators (Table 8).

Table 8. Cohort demographics

Medicine at initiation	Number of people	Mean age (SD)	Gender
Varenicline	541,077	41 (13.9)	58% males 42% females
NRT	184,537	48 (15.6)	49% males 51% females
Bupropion	14,468	42 (13.5)	52% males 48% females
Total	740,082	43 (14.6)	56% males 44% females

Kaplan Meier survival analysis was conducted to estimate the duration of the first episode with index medicine for smoking cessation. The study end point of the first episode was the time to cessation. Figure 34 shows median duration of 42 days (6 weeks) of the first treatment episode. Figure 35 is stratified by the type of index medicine and shows median duration of 28 days for bupropion and 42 days (6 weeks) for both NRT and varenicline.

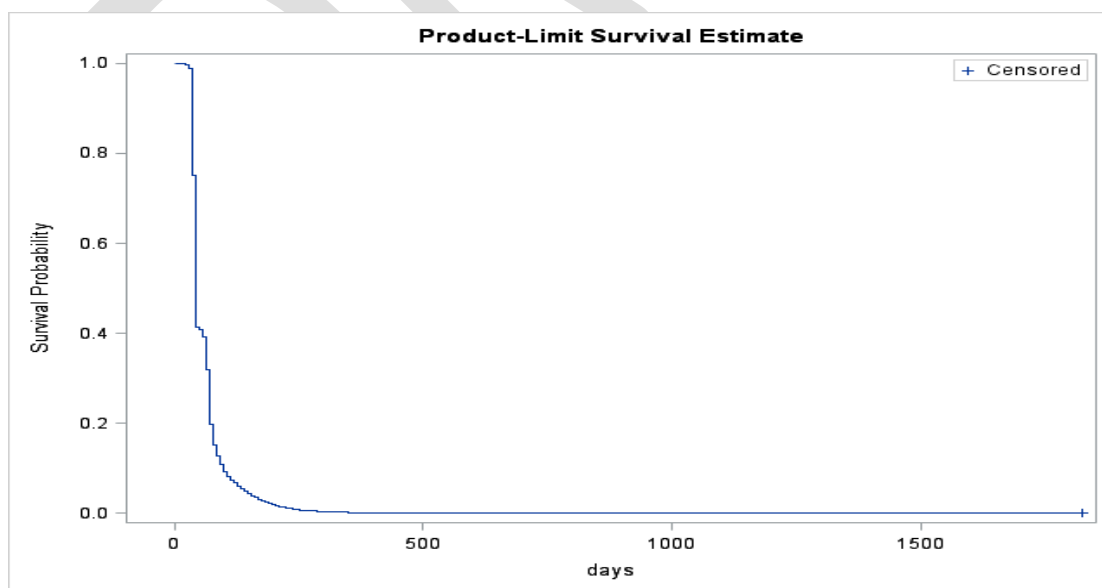


Figure 34. Kaplan-Meier estimate for time to treatment discontinuation of the first episode with any smoking cessation medicine.

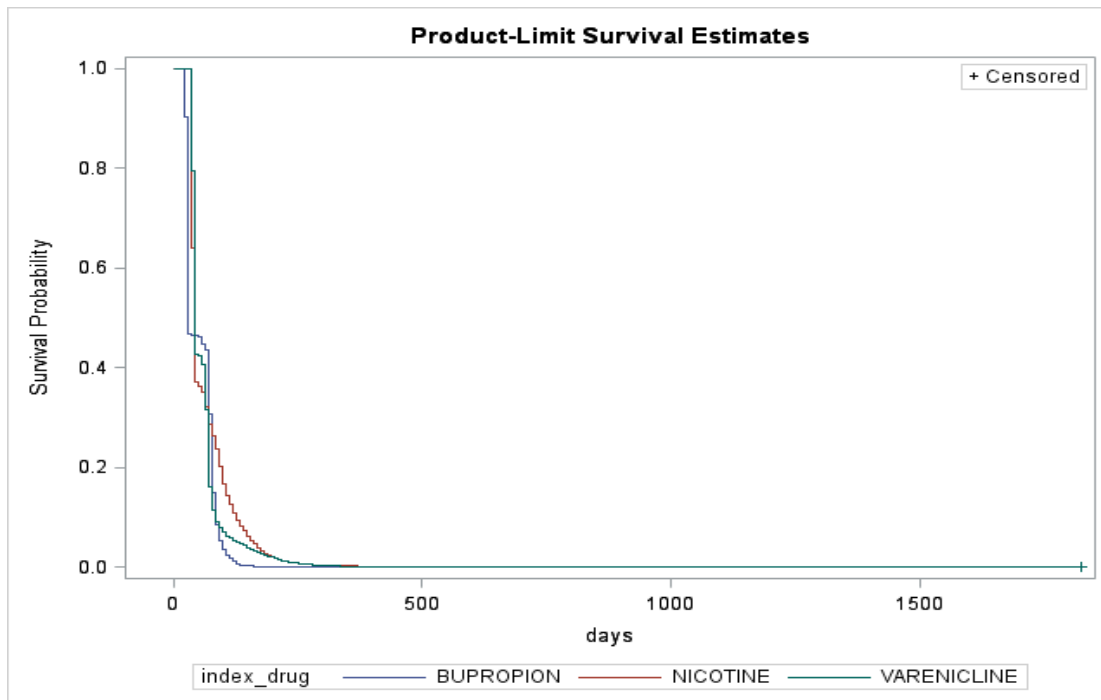


Figure 35. Kaplan-Meier estimate for time to treatment discontinuation of the first episode, by type of index medicine.

Duration of individual treatment episodes from initiation to end of treatment

The average number of separate episodes (episodes separated by gaps) with PBS subsidised treatment per person from initiation to end of last treatment episode was determined. Overall, 60% of people who initiated smoking cessation therapy between 1 July 2010 and 30 June 2015 had only one attempt (one treatment episode) in the five years of follow-up. They were included in the analysis below.

People who initiated smoking cessation products had on average 1.7 separate treatment episodes (SD=1.1) with a median duration of 41 days (6 weeks) (Figure 36).

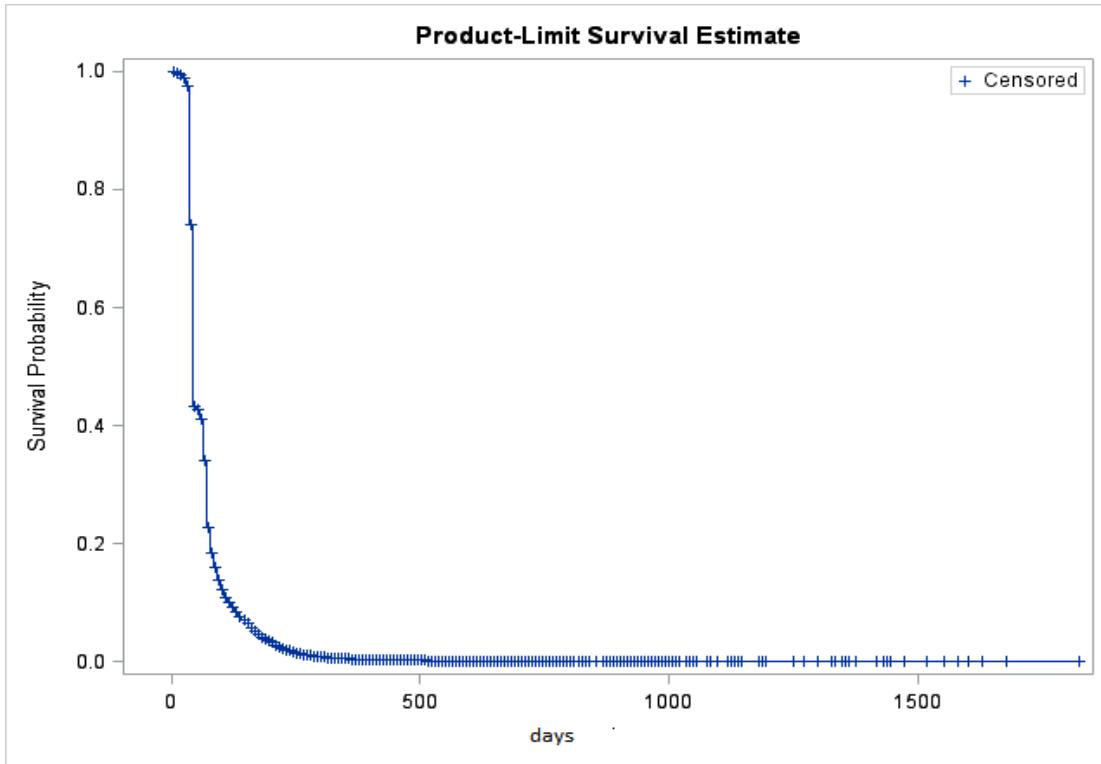


Figure 36. Kaplan-Meier estimate of duration of individual treatment episodes from initiation to end of treatment.

NRT initiators had on average 1.8 separate episodes (SD=1.2); varenicline initiators had 1.6 (SD=1), and bupropion initiators had 1.7 (SD=1.2). The median duration of separate episodes was 41 days for all three medicines (Figure 37).

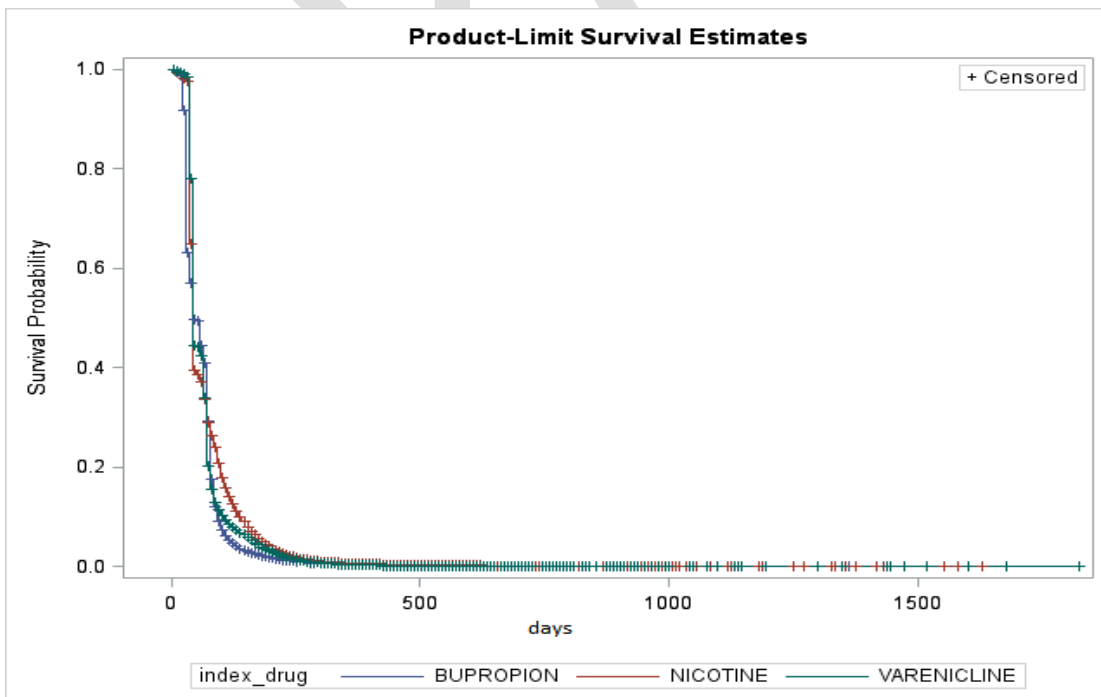


Figure 37. Kaplan-Meier estimate of duration of individual treatment episodes from initiation to end of treatment, by type of index medicine

Duration of individual gaps (breaks in therapy) from initiation to end of treatment

The average number of individual gaps per person from initiation to end of last treatment episode was determined. Only gaps between initiation and end of the last treatment episodes were included as separate entities. People who had no gaps were excluded from the analysis.

Overall, 40% of people who initiated smoking cessation products between 1 July 2010 and 30 June 2015 had breaks in therapy indicating multiple quit attempts – they had on average 1.7 treatment episodes with gap of 15 months (461 days, 95% CI 456; 467) (Figure 38).

NRT initiators had on average 1.8 treatment episodes with gaps of 13 months (377 days, 95% CI 370-377). Varenicline initiators had on average 1.6 treatment episodes with gap of 17 months (496 days, 95% CI 490-510). Bupropion initiators had on average 1.7 treatment episodes with gap of 14 months (433 days, 95% CI 426-447) (Figure 39).

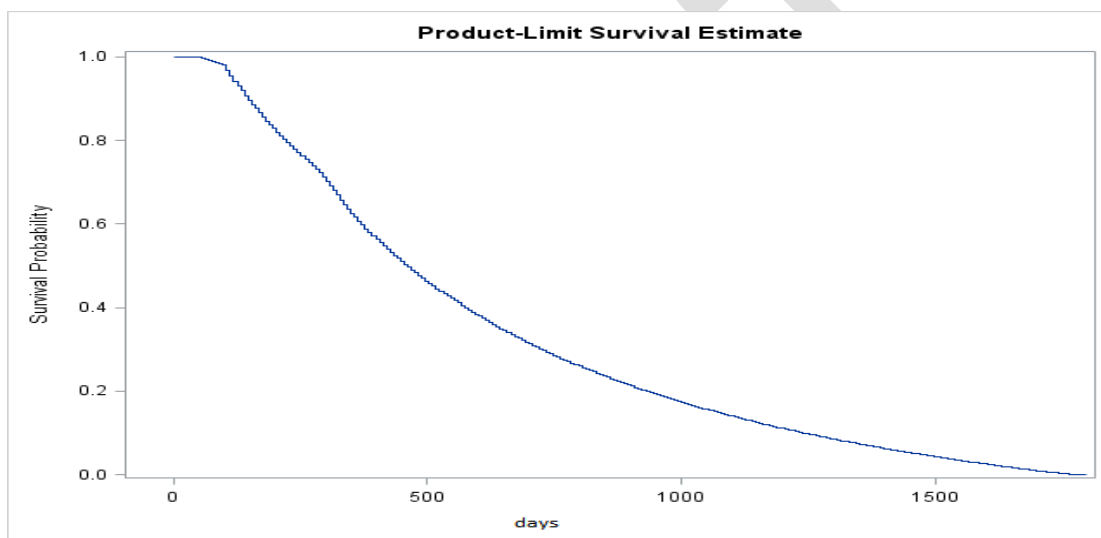


Figure 38. Kaplan-Meier estimate of duration of individual gaps from initiation to end of treatment.

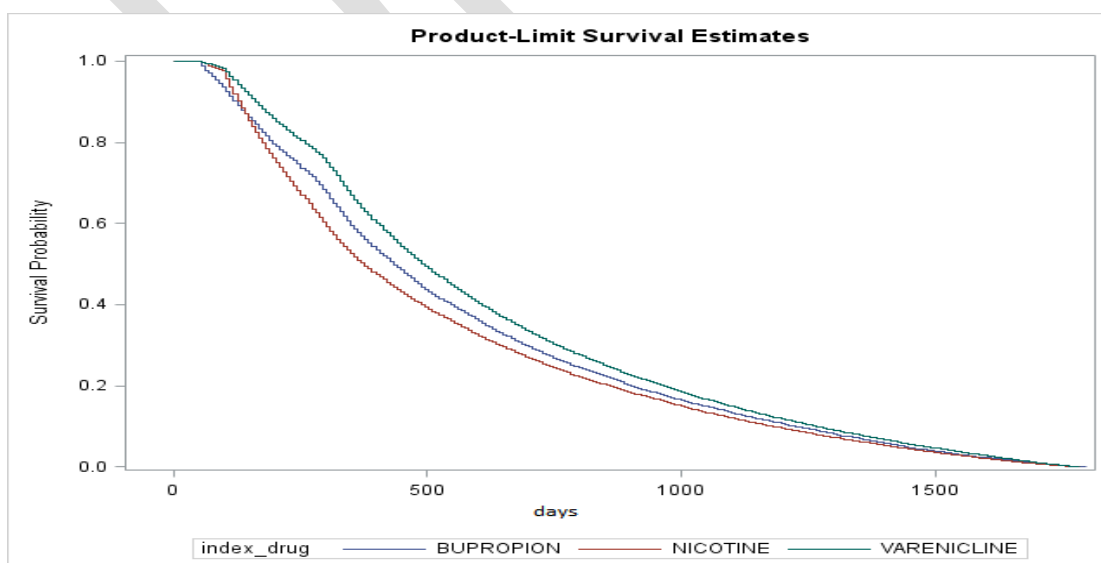


Figure 39. Kaplan-Meier estimate of duration of individual gaps from initiation to end of treatment, by type of index medicine

2.4.8 Consistency with PBS restrictions

General and concessional beneficiaries are permitted up to 12 weeks' supply of PBS subsidised NRT each year [14]. For varenicline, the PBS restrictions allow up to 24 weeks of treatment per 12-month period [15]. Up to 9 weeks of treatment per year is allowed under the PBS for bupropion [16].

To determine compliance with the maximum allowed restriction requirement, the number of people supplied their first ever PBS subsidised NRT, varenicline or bupropion therapy between financial 2014/2015 and 2018/2019 was determined. Then, the proportion from all initiators in each year who received one, two, three or more prescriptions was determined. The weeks of coverage were then based on:

- For NRT all prescriptions correlate to four weeks coverage, with 2 repeats allowed. There are no specific starter packs for NRT. Consumers may receive up to 12 weeks of therapy under the PBS.
- Varenicline starter pack correlates to 4 weeks of coverage; continuation packs are for 8 weeks, and completion packs are for 4 weeks with 2 repeats allowed. Consumers may receive up to 24 weeks of therapy under the PBS when receiving starter, continuation and completion scripts.
- A starter pack for bupropion lasts for slightly more than 2 weeks, while a completion pack lasts for slightly more than 6 weeks. Consumers may receive up to 9 weeks of therapy under the PBS when receiving the started and completion packs.

NRT therapy consistency with restrictions

Table 9 shows that 60% of all first ever NRT initiators in financial 2018/2019 received only one prescription for NRT which covers 4 weeks of therapy. The compliance with the restriction requirement of a maximum of 12 weeks supply of PBS subsidised NRT was 88.4% in 2019.

Table 9a shows no significant difference in duration of therapy between Aboriginal and Torres Strait Islander people and non-Indigenous people who initiated NRT for the first time ever in financial 2018/2019. However, this analysis does not include data on NRT therapies provided by Aboriginal Health Services that are participating in the Remote Area Aboriginal Health Services (RAAHS) program.

Table 9. Percentage of people receiving their first ever PBS subsidised therapy with NRT by year of initiation, and duration of therapy (people have been excluded if patient category was repatriation or closing the gap)

Weeks of coverage	2014/2015 %	2015/2016 %	2016/2017 %	2017/2018 %	2018/2019 %
4	57.3	57.8	59.6	59.4	59.7
8	18.3	17.6	17.2	17	17.1
12	16.3	14	12.4	12.2	11.6
16	3.3	3.8	3.9	3.9	3.8
20	1.7	2.1	2.1	2.2	2.4
24	1.5	1.9	1.9	2	2
28	0.4	0.8	0.9	0.9	0.9
32	0.4	0.5	0.5	0.6	0.6
36	0.4	0.5	0.5	0.6	0.5
40	0.2	0.3	0.3	0.3	0.3
Percentage of people compliant with restrictions	91.9	89.4	89.2	88.6	88.4

Note: all item codes for NRT under PBS are with duration of 4 weeks, 2 repeats are allowed for max treatment of 12 weeks; no specific PBS items are designated as starter packs.

Table 9a. Comparison of therapy between Aboriginal and Torres Strait Islander people and non-Indigenous people who initiated NRT for the first time ever in financial 2018/2019

Weeks of coverage	Non-Indigenous (%)	Aboriginal and Torres Strait Islander people (%)
4	59.7	61
8	17.1	18.7
12	11.6	11.8
16	3.8	3.5
20	2.4	1.6
24	2	1.5
28	0.9	0.7
32	0.6	0.4
36	0.5	0.4
40	0.3	0.3

Varenicline therapy consistency with restrictions

Table 10 shows that the compliance with the restriction requirement of a maximum of 24 weeks supply of PBS subsidised varenicline was 98% in financial 2018/2019. Analysis of the type of packs dispensed to first ever initiators to varenicline in 2018/2019 showed that:

- 56.4% of initiators had only a starter pack (duration of 4 weeks),
- 23.8% had a starter + a continuation pack or a starter + two completion packs (duration of 12 weeks)
- 1.4% had a starter + a continuation + three completion packs (duration of 24 weeks)

Table 10. Percentage of people receiving their first ever PBS therapy with varenicline by year of initiation and duration of therapy (people have been excluded if patient category was repatriation or closing the gap)

Weeks of coverage	2014/2015	2015/2016	2016/2017	2017/2018	2018/2019
4	53	53.7	53.9	54.4	54.8
8	2.7	4.1	5.1	8.5	9.4
12	35.3	32.7	30.6	24.7	23.2
16	3.8	4	4.3	5.5	5.3
20	1.7	1.8	2.4	2.9	3.1
24	2.8	2.9	2.7	2.4	2.2
28	0.3	0.4	0.5	0.7	0.9
32	0.1	0.1	0.3	0.3	0.4
36	0.2	0.2	0.1	0.2	0.3
40	0	0	0	0.1	0.1
Percentage of people compliant with restrictions	99.3	99.2	99	98.4	98

*Note: Varenicline starter pack is with coverage of 4 weeks, no repeats allowed;
Varenicline continuation pack is with coverage of 8 weeks, no repeats allowed;
Varenicline completion pack is with coverage of 4 weeks, 2 repeats allowed*

Bupropion therapy consistency with restrictions

Table 11 shows that the compliance with the restriction requirement of a maximum 9 weeks supply of PBS subsidised bupropion was 90.8% in financial 2018/2019.

Table 11. Percentage of people receiving their first ever PBS subsidised therapy with bupropion by year of initiation and duration of therapy (people have been excluded if patient category was repatriation or closing the gap)

Weeks of coverage	2014/2015	2015/2016	2016/2017	2017/2018	2018/2019
2	52.7	46.8	44.2	43.4	44.9
4	2.1	3.7	4.7	3.5	4
6	3.5	10.7	17.1	19.3	22
8	34.4	29.7	24	21	19.9
10	1.2	2.5	2.2	2.1	1.7
12	0.5	1.7	2.6	3.8	3
14	0.7	2.4	2.8	2.4	2.1
16	0.3	0.8	0.8	1	0.5
18	0.1	0.4	0.4	1	0.6
20	0.1	0.4	0.4	0.8	0.5
Percentage of people compliant with restrictions	92.7	90.8	90	87.2	90.8

Note: Bupropion starter pack is with coverage of slightly more than 2 weeks, no repeats allowed.

Bupropion completion pack is with coverage of slightly more than 6 weeks, no repeats allowed.

2.5 Discussion

The National Drug Strategy Household survey 2019 reported a continuing decline in the rate of current smokers aged 18 years and over in Australia – from 23.8% in 2001 to 14.7% in 2019 [17]. In line with this, analysis of PBS data also have showed a gradual decline in the utilisation of R/PBS subsidised smoking cessation therapies – from 21 people per 1,000 population (2.1%) on smoking cessation treatment in 2010/2011 down to 12 people per 1,000 population (1.2%) in 2019/2020. The rates declined for both men and women across the years. In 2019, 10% of all current smokers aged 18 years and over in Australia accessed smoking cessation therapies under the PBS.

Varenicline was the most utilised smoking cessation therapy, followed by NRT and bupropion. The analysis found a high level of compliance with the PBS restriction requirements for the maximum supply per year of PBS subsidised therapies – 88% for NRT, 91% for bupropion and 98% for varenicline in financial 2018/2019. The 12% who were not compliant with the 12 week PBS restriction for NRT may indicate use for smoking reduction as opposed to cessation, reattempting quitting throughout the year, or may indicate that some consumers require longer than the 12 week period permitted under the PBS to quit.

Prior to 2019, all PBS subsidised therapies for smoking cessation were extended release formulations and the co-use of over-the-counter immediate release products was recommended to reduce cravings – we found that in 2018, the NRT market under the PBS was 7.4% from the overall NRT market indicating substantial use of immediate release NRT products sold over-the-counter.

A survey from 2012 found that many smokers make multiple quit attempts, with an average of 2 attempts reported by smokers [24]. Our results show that 60% of people who initiated smoking cessation therapy between 1 Jul 2010 and 30 Jun 2015 made only one attempt to quit smoking in the 5 years of follow-up. This may indicate successful quitting of smoking, a reluctance to use smoking cessation medicines due to a perceived lack of efficacy, or discontinuation due to concerns around safety. The remaining 40% made on average 1.7 attempts with breaks of 15 months between attempts.

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