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Pharmacotherapies for Nicotine Dependence: Social and Economic Considerations

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ABBREVIATIONS

ATO	Australian Tax Office
BEACH	Bettering the Evaluation and Care of Health
CATI	Computer Assisted Telephone Interview
CBRC	Centre for Behavioural Research in Cancer
CEA	Cost Effective Analysis
DALY	Disability Adjusted Life Years
ETS	Environmental Tobacco Smoke
GDP	Gross Domestic Product
GP	General Practitioner
GST	Goods and Services Tax
NHS	National Health Service
HIC	Health Insurance Commission
HMO	Managed Care Organisations
HTA	Health Technology Assessment
ICER	Incremental Cost Effective Ratio
IDRS	Illicit Drug Reporting System
IQR	Incremental Quit Rate
MBS	Medical Benefit Scheme
NDARC	National Drug and Alcohol Research Centre
NHMRC	National Health and Medical Research Council
NRT	Nicotine Replacement Therapy
NT	Northern Territory
NTC	Nicotine Tobacco Company
NZ	New Zealand
OTC	Over-the-counter
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
QALY	Quality Adjusted Life Years
RACGP	Royal Australian College of General Practitioners
RCT	Randomised Control Trial
RPBS	Repatriation Pharmaceutical Benefits Scheme
RRMA	Rural and Remote Metropolitan Area
SAND	Supplementary Analysis of Nominated Data
UK	United Kingdom
US	United States
ZAP	Zyban Action Plan

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EXECUTIVE SUMMARY

Tobacco smoking and alcohol consumption are the two main causes of premature and preventable death and disease in Australia. It has been estimated that in 1998, 185,557 hospital separations were attributable to tobacco and alcohol related illness; 21,084 Australians died as a consequence of tobacco and alcohol related causes; and a total of 205,726 years of life were lost as a result of this premature mortality (Ridolfo and Stevenson, 2001). Recent cost estimates suggest that the total social costs of tobacco and alcohol use are approximately $28,623 million of which around 47% are potentially avoidable (Collins and Lapsley, 2002). The Australian Government supports the use of pharmacotherapies to alleviate the burden of harm associated with tobacco smoking and alcohol misuse. This document is a report on the work examining the uptake of bupropion following its listing on the PBS.

A survey of consumers examined their use of NRTs and bupropion, and the perceptions of the effectiveness and prescribing patterns of NRTs and bupropion by practitioners were examined. While the work examining the uptake and prescribing patters of the pharmacotherapies was underway, it was realised that the public health impact on smoking cessation was minimal given the low uptake of the pharmacotherapies. Therefore it was decided to broaden the report to include a chapter on the impact of smoking in Australia, and a general chapter on the economic literature on interventions to decrease the burdens of smoking, finally an examination of the costs and outcomes of specific treatment for excessive use of alcohol in Australia. This report was prepared alongside a report on interventions to decrease the burden related to excessive alcohol use.

Each chapter of the report deals with a separate topic, and as such there are key findings for the various chapters. The final chapter of the report brings together the various findings and discusses them in a policy context. Below are the key finding and recommendations from each of the chapters.

Key findings and recommendations

Chapter 2: Overview of interventions to reduce the burden of harm associated with tobacco use: an economic perspective

Key findings

- Review of the economic literature demonstrated that treatment interventions are cost beneficial, however while other strategies have been demonstrated to be effective there is little economic evidence as to their comparative economic benefits.

Recommendations

- Cost and economic analysis of the full range of smoking cessation methods should be undertaken as a part of a broader effort to maximise the return on the investment in smoking cessation approaches.

Chapter 3: Prescribing patterns of bupropion hydrochloride in Australia

Key findings

- Initial uptake of bupropion after listing on the PBS was significant.
- Prescription rate of bupropion fell off very quickly after the initial year of listing on the PBS.

Recommendations

- If bupropion is to continue to be recognised as a suitable strategy for use in smoking cessation, a strategy for promotion of pharmacotherapies should be considered.

Chapter 4: Pharmacotherapies for smoking cessation: a consumer survey

Key findings

- Only 11% of the sample recall being advised by their prescribing doctor to pursue the use of a quit line, counselling or some supportive alongside the pharmacotherapy.
- Less than 50% completed the full course of treatment.
- Main reason given for not completing treatment was side effects of the pharmacotherapy.
- 30% of sample had quit smoking at follow-up.

Recommendations

- Improve information flow to patients re the importance of supportive counselling when using NRT or bupropion.
- Investigation of the role of side effects in the premature cessation of pharmacotherapies.

Chapter 5: Use of pharmacotherapies for the management of nicotine dependence in clinical practice

Key findings

- 86% of GPs perceive that adjunctive therapies are likely to improve the likelihood of quitting over and above the effects of medication or pharmacotherapy.
- 83% of GPs prefer counselling by GPs as an adjunct to pharmacotherapy.
- Only 4% of the sample familiar with counselling approaches to use in smoking cessation.

Recommendations

- Communicate to GPs the apparent differences between patient recall and doctor perceptions about advice on adjuncts to pharmacotherapy.
- Address apparent knowledge gap of GPs on the 5A's of smoking cessation.

Chapter 6: Smoking status of general practice patients and their attempts to quit

Key findings

- Many former smokers attribute their success in ceasing smoking to what has been termed as "cold turkey" quitting or unassisted quitting. This level of self quitting is likely related to each individual's high frequency of number of self quitting events.

Recommendations

- While assessing the needs of individual patients, it is important for general practitioners to recognise that self-quitting is a viable and effective smoking cessation strategy for some people.

Chapter 7: The cost effectiveness of pharmacotherapies for smoking cessation: necessary but not sufficient?

Key findings

- Given apparent cost effectiveness of bupropion over NRT, the ongoing use of NRT given its increased cost to the individual appears to be non-rational.
- Reasons for these results may include the use of non-Australian data in the analysis, the exclusion of opportunity cost of individual's time to obtain script and purchase pharmacotherapy, or the 'medicalising' of smoking cessation by requiring a doctors visit.

Recommendations

- Explore the economic and clinical impact of listing NRT on the PBS in terms of the potential loss of uptake of treatment if listed.

Chapter 8: Cost and effects of various strategies for smoking cessation.

Key findings:

- Modelling demonstrates that telephone counselling appears to be the most cost-effective smoking cessation intervention.
- The incremental costs of adding telephone counselling to pharmacotherapies was minimal.
- After telephone counselling, bupropion was more cost effective than NRT.

Recommendations

- The role of general practitioners in referring patients, not just onto self-quitting attempts but also to telephone quit lines should be markedly encouraged as a cost-effective activity.
- Smoking cessation interventions (whether are counselling or pharmacotherapies) are cost effective, all fall below the NHMRC recommend guideline for cost effectiveness.

Chapter 9: Discussion

Findings

- At the current rates of use bupropion will have a minimal role at the population level for reducing the population level of smoking.

Recommendations

- Pharmacotherapies should remain a significant part of smoking cessation strategy. Support for pharmacotherapies should continue in a broad sense along with the promotion and funding of dial in telephone counselling lines
- Better dissemination to the public of smoking cessation information is required to promote smoking cessation interventions.

1. INTRODUCTION

Marian Shanahan and Jennifer Stafford

Tobacco smoking and alcohol consumption are the two main causes of premature and preventable death and disease in Australia. It has been estimated that in 1998, 185,557 hospital separations were attributable to tobacco and alcohol related illness, 21,084 Australians died as a consequence of tobacco and alcohol related causes, and a total of 205,726 years of life were lost as a result of this premature mortality (Ridolfo and Stevenson, 2001). Recent cost estimates suggest that the total social costs of tobacco and alcohol use are approximately $28,623 million of which around 47% are potentially avoidable (Collins and Lapsley, 2002). To address the burden of harm associated with tobacco smoking and alcohol misuse, the Australian Government supports the use of pharmacotherapies and other interventions.

This document, alongside the report on treatments for excessive alcohol use, is the culmination of work conducted at the National Drug and Alcohol Research Centre (NDARC) over that past two and half years examining the perceptions, use, effectiveness and cost-effectiveness of pharmacotherapies for smoking cessation. This technical report provides the results of this research agenda. The focus of the report, which is presented in a series of chapters, is on smoking cessation pharmacotherapies, bupropion hydrochloride (Zyban ®) (hereafter referred to as bupropion) and nicotine replacement therapies (NRTs) such as patches, gum and lozenges. Several methods and sets of data are used to explore the perceptions of prescribers and consumers as to the effectiveness of these pharmacotherapies, as well as the literature on the effectiveness and cost-effectiveness of pharmacotherapies relative to other non-pharmacotherapy methods to assist with smoking cessation.

Rates of smoking and burden of harm associated with tobacco use

Nearly one-fifth (19.5%) of the population aged 14 years and over smoke daily which is a decrease since 1998, when 21.8% of the population aged 14 years and over were smoking daily (AIHW, 2002b). Smoking prevalence is now higher among girls than boys with the rates increasing for both boys and girls among the 15 to 17 year olds. The current data suggests that soon smoking will be more common among women than men (National

Tobacco Strategy, 2002). The continued increase in the prevalence of smoking among the youth and women has considerable negative implications for health in the future.

Currently, smoking remains one of the major causes of Australia's health problems. The use of tobacco has been linked with mortality and specific causes of death and diseases such as lung cancer and ischaemic heart disease. Tobacco related deaths resulted in an estimated 19,019 deaths in 1998, the majority occurring aged 65 years and over (resulting in an estimated 184,579 potential life years lost). Cancer was responsible for the majority (43%) of smoking related deaths among males, followed by ischaemic heart disease (22%) and chronic obstructive pulmonary disease (19%). For females it is a little different, cancer was responsible for 32% of smoking related deaths, followed by chronic obstructive pulmonary disease (22%) and ischaemic heart disease (20%) (Ridolfo and Stevenson, 2001). It is estimated that in 1998 over 142,525 hospital separations could be attributable to tobacco use, the majority (74,379) occurring aged 65 years and over (Ridolfo and Stevenson, 2001). The largest number of tobacco related separations among men was for ischaemic heart disease followed by cancer. For females, the largest number of tobacco related separations was for chronic obstructive pulmonary disease, followed by cancer. For both males and females the most dominant cancer was lung cancer (Ridolfo and Stevenson, 2001).

Economic burden of tobacco use in Australia

Smoking is responsible for a range of undesirable health and social consequences with additional adverse consequences such as fires, increases in health care expenditure and loss of productivity. The morbidity and premature mortality associated with tobacco use has implications for health care expenditures (i.e. the direct health costs) and for the country's economic output (i.e. with less obvious costs such as loss of productivity resulting from tobacco use).

Collins and Lapsley estimated the economic impact of tobacco use by using epidemiological data to estimate the tangible and intangible costs of tobacco use (Collins and Lapsley, 2002). Tangible costs are those that can be valued in the market including health care costs (medical, hospital, nursing home services, pharmaceuticals and ambulances) and fires. The total tangible costs of tobacco were estimated at $7.6 billion in 1998-1999 dollars. An attempt was also made to place a value on intangible aspects arising from tobacco use. Intangible costs were estimated at $13.5 billion. The total

estimated cost of tobacco use was estimated at $21 billion in 1998-1999 dollars. This cost represents over 61% of the total cost of drug use ($34.4 billion) in Australia (Collins and Lapsley, 2002). These expenditures account for approximately 1% of GDP. There is an opportunity cost to these expenditures as they could be allocated elsewhere. Economic theory offers a framework to assess such opportunity cost and in doing so provide guidance on how best to spend resources to alleviate the burden of harm, and the consequential cost, associated with tobacco use. Such a framework requires information on the resources/costs and outcomes of each intervention to impact on the smoking rates and uptake.

About this report

As a consequence of the harms caused by smoking and government priority to improve health of all Australians, a National Tobacco Strategy has been developed. This evidence-based strategy for tobacco control expands upon the activities already in place by the Commonwealth, State and Territory governments and non-government organisations. The overall goal of the national strategy is to improve the health of all Australian's by eliminating or reducing their exposure to tobacco in all its forms. The six key strategy areas mentioned below try to achieve this goal: (Commonwealth Department of Health and Aged Care, 1999;Ministerial Council on Drug Strategy, June 1999):

1. Strengthen community action for tobacco control
2. Promoting cessation of tobacco use
3. Reducing availability and supply of tobacco
4. Reducing tobacco promotion
5. Regulating tobacco
6. Reducing exposure to environmental tobacco smoke (ETS).

The focus of this report is on the second of these strategy areas, promoting cessation of tobacco use. According to Vic Health, 90% of smokers wish to quit but 75% to 95% of those who have a serious attempt at quitting will fail (VicHealth Centre for Tobacco Control, 2001) which as discussed above has significant health, social and economic consequences.

There are a number of strategies to encourage individuals to quit smoking. In 1997, the National Tobacco Campaign (NTC) was introduced and implemented in a three stage

phase. The three phases included mass media campaigns (television, radio etc) and an Australian wide `Quitline' for smokers. An evaluation of the NTC was found to be successful with a reduction in smoking prevalence by 1.8% since it's launch in 1997 (Australian Government Department of Health and Ageing (Population Health Division), 2003a).

Quitline is available Australia wide through a central number to help smokers quit. It is a free confidential telephone information and advice service available 24hrs a days, 7 days a week. Quitline can help smokers plan their attempt to quit by providing information on quit techniques and programs available including some written material (Quitpack). Further information and services are available through the majority of the States and Territories Health Departments and Cancer Council Foundations (Cancer Control Victoria;The Cancer Council South Australia, 2004; The Cancer Council NSW, 2002;T he Cancer Council ACT; NSW Health Department, 2004). Such services include, for example, quit smoking groups, one to one counselling, and motivational seminars.

In addition to the Quitline, the company that produces bupropion provides the *SMOKE FREE* Clean Start Program which is available to help those smokers using the product to quit (previously called the Zyban Action Plan). The *SMOKE FREE* Clean Start Program offers comprehensive counselling and support through phone calls, SMS messages and newsletters over the treatment course of bupropion. Patients can enrol directly or through their doctor. The `Zyban Quit Line', a telephone counselling service to assist people to quit smoking is also available (Jame McInnes, February 2004, Zyban Associate Product Manager, Personal email communication).

A number of other smoking cessation treatments are available to assist smokers. Such treatments include pharmacotherapies and psychosocial interventions (i.e. cognitive behavioural therapy, relapse prevention). In addition, patients can visit their general practitioners (GP) for advice and/or to receive a prescription for a pharmacotherapy to aid in quitting. There are two types of pharmacotherapies available: bupropion and NRTs. Since February 2001, bupropion has been listed on the Pharmaceutical Benefits Scheme (PBS) and the Repatriation Pharmaceutical Benefits Scheme (RPBS) where as only two brands of NRT patches (Nicorette® and Nicabate®) are listed on the RPBS and none on the PBS. The brands vary in cost, strength and method of use but both are

recommended for those who have entered a support and counselling program (Australian Government Department of Health and Ageing, 2004b). Recent changes to how bupropion is prescribed were introduced by the PBS in January 2004 and are further discussed in Chapter 8. The uptake of bupropion by age and sex, the prevalence of its use and how the uptake varied over the first two years of its availability are explored in Chapter 3, *Pharmacotherapies for smoking cessation: Health Insurances Commission data.*

Chapter 4, *Pharmacotherapies for smoking cessation: smokers' survey* reports on a survey undertaken at the NDARC. Data was collected from a total of 228 individuals using bupropion and 168 using NRT. Recruitment occurred at pharmacies with the assistance of the Pharmacy Guild of Australia. This field study explores the characteristics of this group of smokers, their history of smoking, their previous quit attempts as well as collecting information on concurrent use of other interventions to help them quit.

Data on consumer (Chapter 4) and practitioner (Chapter 5) perceptions on the effectiveness of pharmacotherapies and the reported use of adjuncts to pharmacotherapies provide some interesting comparisons with practitioners that prescribe pharmacotherapies reporting that they offer adjuncts 86% of the time while only 18% of consumers recall receiving information on adjuncts to pharmacotherapies. Chapter 5, which was undertaken in conjunction with the Department of General Practice, Adelaide University, also reports on differences across general practitioners, psychiatrists and internists on prescribing practices when their patients are seeking to quit smoking.

Chapter 6, takes a different perspective and using data from the "Bettering the Evaluation and Care of Health" (BEACH) program, a national study of general practice in Australia; in particular, a sub-set of BEACH data focusing on smoking rates of adult patients and their quit attempts. In this chapter, the method both current and previous smokers used in their most recent quit attempts is discussed. Cold turkey is the most common method used by both former and current smokers suggesting that for some people cold turkey may be effective although for those who it is not, other treatment options must be provided.

As a first attempt to look at the relative cost and outcomes of NRTs and bupropion in the Australian context resulted in the following publication *"The cost-effectiveness of pharmacotherapies for smoking cessation: necessary but not sufficient?"* (Shanahan et al., 2003) This work raised a number of interesting issues and is reprinted in its entirety in Chapter 7. Here, a key question is why consumers are continuing to purchase NRTs to assist with smoking cessation when they are required to pay full price whereas the price for bupropion is subsidised by the PBS, and given bupropion is reportedly more effective that NRTs.

Chapter 8 fully examines the costs and effects of various strategies for assisting with smoking cessation. Here evidence from the literature for outcomes and resource use were used and a value was placed on the resource use in Australian dollars. The purpose of this project was to identify which interventions provide the most efficient use of health care resources at the population levels.

The final chapter discusses the implications of the findings of the various chapters, summarises the findings, and includes policy recommendations. But before moving to a discussion of specific treatment interventions, the next chapter provides context in terms of other interventions which are used to decrease the burden of harm related to smoking.

2. OVERVIEW OF INTERVENTIONS TO REDUCE THE BURDEN OF HARM ASSOCIATED WITH TOBACCO USE: ECONOMIC PERSPECTIVE

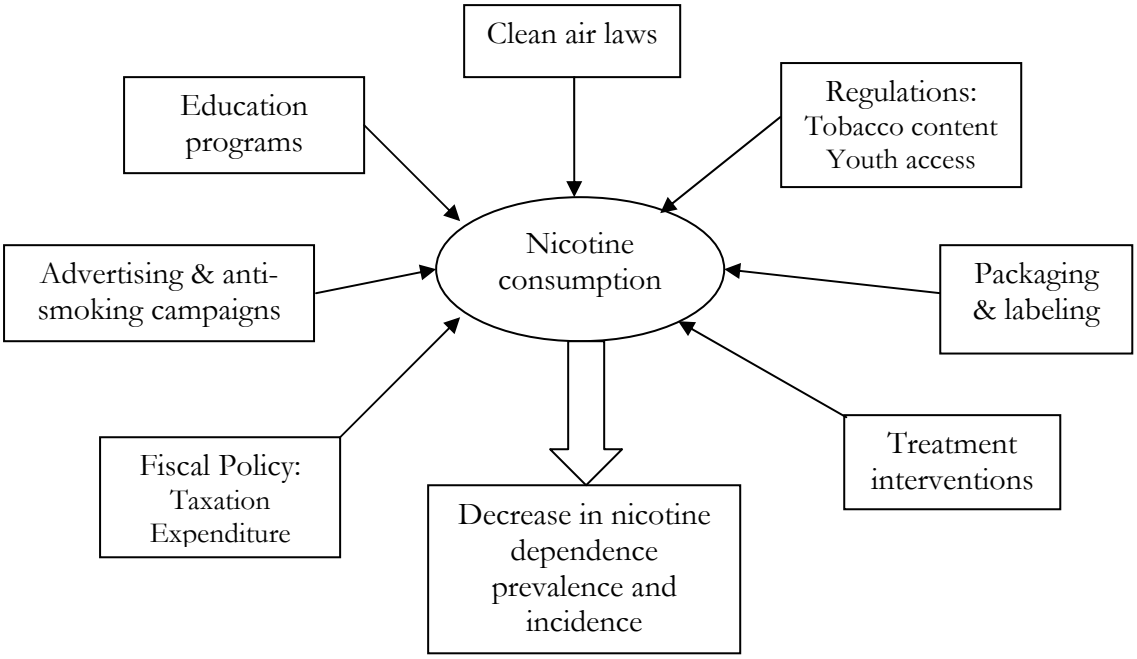
Jennifer Stafford, Marian Shanahan and James Shearer

2.1. What role can tobacco control interventions play in reducing social and economic harm?

A number of interventions have been shown to decrease the demand/uptake for tobacco products (Abelson et al., 2003;Jha and Chaloupka, 2000;Scollo et al., 2003;Chaloupka et al., 2002;Alchin, 1993;Centers for Disease Control and Prevention, 2000;Task Force on Community Preventive Services, 2001;Friend and Levy, 2002). Interventions can range from specialised clinical treatment to community-wide prevention such as increasing prices (fiscal policies), advertising bans, smoking restrictions and providing health information on tobacco harms. These interventions can be categorised into three broad, overlapping groups: primary, secondary, and tertiary interventions. The aim of primary interventions is to target populations and individuals to prevent tobacco use; such interventions include educational campaigns (mass media, secondary school education) as well as legislative approaches, such as the enforcement of clean indoor-air laws and underage licensing laws. Secondary interventions aim to identify and intervene with individuals early in the process of tobacco use for example advertising and packaging of cigarettes and price increases. Tertiary interventions are aimed at those already with problematic tobacco use such interventions include tobacco cessation pharmacotherapies (US Preventive Services Task Force, 1996).

This chapter discusses just some of the interventions undertaken in Australia and overseas to reduce the prevalence and incidence of tobacco smoking. Figure 2.1 provides an overview of the key primary (i.e. taxation), secondary (i.e. health information) and tertiary (i.e. treatments) interventions discussed in the chapter to reduce the burden of harm associated with tobacco use. Where evidence from economic evaluations is available it is presented, where it is not presented, a literature search failed to find any economic evaluations. Specific treatment interventions to assist with smoking cessation are discussed in more detail in Chapter 8.

Figure 2.1: Overview of key interventions to reduce the burden of harm associated with tobacco use



2.2. Fiscal Policy

2.2.1. Taxation

Fiscal policies, particularly sales and excise taxes can affect the price of tobacco products. Tobacco products in Australia have traditionally had three main government levied taxes: the Federal Government excise duties on domestically produced products, customs duties on imported tobacco products and state licence fees and taxes(Abelson et al., 2003). Prior to 1999, excise duties were based on the weight of the manufactured tobacco (not including packaging), however this changed in late 1999 to `per stick' excise duties with a resulting increase in cigarette prices. The price of cigarettes rose again when the Goods and Services Tax (GST) was introduced in mid-2000 (Australian Government Department of Health and Ageing (Population Health Division), 2003b). The excise rates on tobacco are subject to twice-yearly increases in line with the Consumer Price Index. In early 2003, the excise `per stick' for a cigarette containing 0.8 grams of tobacco was 21.53 cents and for tobacco products containing more than 0.8 grams the cost was $269.05 per kilogram (Australian Government Department of Health and Ageing (Population Health Division), 2003b).

While sales taxes (based on the price of the good purchased) and excise taxes (based on the quantity of tobacco) are revenue-generating instruments they have also been used to try to impact on smoking behaviours with the assumption that any increase in the excise tax would be passed on to the consumer. The economic theory behind this assumption is that an increase in taxes, leads to an increase in prices change, which then decreases the consumption of tobacco. The impact of a change in price on demand is measured by its price elasticity. Price elasticity is defined as the percentage change in demand for a good related to a 1% change in its price. If the price elasticity is found to be between 0 and -1, the demand for the good is referred to as inelastic, which means that a 1% price increase will have less than a 1% decrease in the demand for the good. If the price elasticity is equal to -1, then it is referred to as price elastic which implies that a 1% change in price will produce a 1% reduction in demand.

Table 2.1 provides a simple example of price elasticity, illustrating for a good which has an initial price of $10 with a price elasticity of either 0, -0.5, or –1. When the price elasticity is -1, and the price increases by $1 (10%) there is a drop in demand of 10%. When the price elasticity is 0, a change in price means there is no impact on demand, additionally, when the price elasticity is close to 0 an increase in price leads to increased revenue, for either for the seller (an increase in price) or government (a tax increase) with little or no improvement in health or social outcomes as the increase in price generates little or no decrease in consumption (decrease in smoking). Alternatively, if the price elasticity is near or below -1, an increase in price may lower consumption as well as having a significant impact on sellers/ tax revenue.

Table 2.1: Simple example of price elasticity

Price	Change in price	Price elasticity	Change in Quantity Demand	Quantity	Total revenue
$10.00	-	-	-	100	$1000
$11.00	10%	0	0	100	$1100
$11.00	10%	-0.5	-5	95	$1045
$11.00	10%	-1	-10	90	$990

One international study found that most estimates of the price elasticity of demand for cigarettes in high income countries have been found to be between -0.25 and -0.5 with many clustering around -0.4 suggesting that there is some reduction in use of tobacco

with an increase in prices(Chaloupka et al., 2000). Australian studies have found a price elasticity ranging from -0.1 to -0.59 (Table 2.2) (Industry Commission, 1994). One Australian study, Doran et al (1999) reported a price elasticity of -0.38 (-0.44 for males and -0.30 for females) for participation in smoking (Doran and Sanson-Fisher, 1999).

Table 2.2: Price elasticises of demand for tobacco products: Results from Australian studies

Author	Price elasticity
Koutsoyannis (1963)	-0.36
Clements, McLeod and Selvanathan (1985)	-0.2 to -0.3[a]
Johnson (1986)	-0.1 (1961-62); -0.22 (1982-83)
McLeod (1986)	-0.47 to -0.59[b]
Bewley (1991)	-0.34 (1984-85) to -0.43 (1988-89)[c]
Alchin (1992a)	-0.47
Bewley (1993)	-0.345

a Reasons for range not identified in source
b Range due to different forms of the estimating equation
c Range identified for social groups
Sources: Viscusi 1992, Alchin (Sub. 1), Philip Morris (Sub. 38)

Source: Industry Commission 1994(Industry Commission, 1994)

Research literature and reviews from around the world exploring the impact of increased prices, and the demand for tobacco products, have concluded that tax increases will discourage smokers (Jha and Chaloupka, 2000;Scollo et al., 2003;Chaloupka et al., 2002;Alchin, 1993). However, a number of other factors influence individual response to the price increase of tobacco products such as age, socio-economic factors, gender and level of dependence.

At the World Bank Conference 2001, Yurekli (2001) spoke on the effects of raising tobacco taxes and reported that a 10% increase in the price of retail cigarettes reduced cigarette consumption by 4% in developed countries and 8% in developing countries(Yurekli, 2001). One British study found that while the price elasticity for cigarettes was -0.5 for men, -0.6 for women, it was near -1 for the lowest socioeconomic group, and near zero for the highest socioeconomic group (Townsend et al., 1994). The Australian Industry Commission (1994) reported that low-income earners were more sensitive to price change with a price elasticity of -1.26 for unskilled workers and -0.15 for professional men (Industry Commission, 1994).

An Australian study collected data to investigate the impact of tax change on the type and price of tobacco products sold during a National Tobacco Campaign (NTC) (Scollo et al., 2003). They found a significant decrease in the number of cigarettes consumed daily by smokers over the period of the campaign, in particular among low income workers.

With respect to teenagers, Harris and Chan (1999) explored price changes on youth aged 15 to 29 and found that the 15-17 year olds were more price sensitive than either the 18-20 year olds or the 21-29 year old group(Harris and Chan, 1999). Emery et al (2001) confirms this finding but also adds that higher prices do not result in less experimentation with smoking by youth (Emery et al., 1999). In summary, teenagers and low income workers appear to be more likely to be effected by price changes, deciding not to start smoking or to change their level of use (Scollo et al., 2003;Jha and Chaloupka, 2000;Pinilla, 2001;Harris and Chan, 1999).

Increasing the price of tobacco products was strongly recommended by the `Task Force on Community Prevention Services' which was formed in the US to evaluate the effectiveness of a number of community interventions and preventative services. The key finding that increasing the price was effective in reducing the prevalence of new adolescent smokers led to a strong recommendation that prices be increased (Centers for Disease Control and Prevention, 2000;Task Force on Community Preventive Services, 2001).

However, there is anecdotal evidence that increased taxes may lead to cross border smuggling (Joossens et al., 2000), or the use of chop-chop (illegal tobacco) (Collins and Lapsley, 2002) as a response to increased prices and as one way of avoiding the tax increases. The Australian Taxation Office (ATO) was unable to fully quantify the revenue loss due to chop-chop however, attempts made were based on the increasing importation of cigarette tube and paper (Collins and Lapsley, 2002). Table 2.3 presents estimated revenue leakage associated with chop-chop from Collins and Lapsley (2002).

Table 2.3: Estimates of revenue leakage associated with chop chop

	Smoking prevalence rate	Amount of chop chop smoked as a proportion of licit tobacco	Annual excise evaded as a result of chop chop smoked
AIHW Household Survey 2001	21.1%	4.94%	$220m.
Health Tracking Survey 2001	19.8%	2.22%	$99m.
Industry estimates 2001	n.a.	n.a.	Approximately $450m.

Sources: Australian National Audit Office (2002) and PriceWaterhouseCoopers (2001)

Source: Collins and Lapsley 2002 (Collins and Lapsley, 2002)

2.2.2. Government expenditure

The tax revenue received from tobacco products in Australia from smokers is estimated at $4.6 billion ($240 per capita). Australia's expenditure on tobacco control has gradually increased over the years, yet it is still under funded and remains below international benchmarks. The Centre for Behavioural Research in Cancer (CBRC) compiled expenditure data on anti-smoking public health programs from 1984 to 2001. Data collected included educational and counselling activities aimed at adult smokers; quit programs, activities for special groups and prevention education activities. In 1984, total anti-smoking government expenditure was $3.2 million ($0.21 per capita), increasing to $13.2 million ($0.77 per capita) in 1990, expenditure fell to a low of $6.5 ($0.37 per capita) in 1993 and gradually increased to $19 million ($1 per capita) in 2000.

In real terms, using constant 1989/90 dollars, the per capita expenditure increased slighted from $0.32 in 1984 to $0.79 in 2000 (VicHealth Centre for Tobacco Control, 2001). Funding for tobacco control per capita in all US States exceeds Australian's expenditure as do United Kingdom, Ireland, Canada and New Zealand (VicHealth Centre for Tobacco Control, 2001).

In the UK in 1998, the government committed to: ban tobacco advertising, prevent tobacco smuggling and major education campaign (259 million pounds over 3yrs which is approximately 1.5 pounds per capita per annum (VicHealth Centre for Tobacco Control, 2001). Canada invests half of the tax revenue raised from tobacco sales into anti-smoking interventions, as well as investing around CAN$480 million to the Tobacco Control Strategy over a five year period, which is approximately CAN$3 per

capita per annum (VicHealth Centre for Tobacco Control, 2001). In New Zealand (NZ), expenditure on anti-smoking campaigns is over NZ$28 million (approximately NZ$7 per capita), a large investment for a smaller population per annum. In Ireland, expenditure on anti-smoking interventions (non-pharmacological) is more than 20 million Irish pounds (approximately 5 Irish pounds per capita) per annum (VicHealth Centre for Tobacco Control, 2001).

2.3. Tobacco advertising and anti-smoking campaigns

In Australia, the advertising of tobacco products has been banned from both radio and television since 1976. In 1992, the Tobacco Advertising Prohibition Act 1992 further restricted all forms of tobacco advertising including, broadcasting, print media and sponsorship with one exemption which permits the Minister for Health and Aged Care to grant an exception for international sporting and cultural events. However, the Act was amended in 2000 to eliminate this exemption by 2006 (Australian Government Department of Health and Ageing (Population Health Division), 2003a).

Data collected from tobacco industry sales and government excise receipts have shown a reduction in tobacco consumption with the introduction of the National Tobacco Campaign (NTC) in Australia. The NTC launched in 1997, targeted 18-40yrs olds and included three phases to the campaign. *Phase 1* included three televised health effect advertisements; *phase 2* included television and radio, the introduction of another health effect and an advertisement modelled on `Quitline' and *phase 3* continued the strategies that were successful in the first two phases (Hill and Carrol, 2003). Before the NTC, smoking prevalence was 23.5% and the after the NCT 21.8% (Hill et al., 2000). In the first six months of the NTC an economic evaluation found that a potential 920 premature deaths were prevented and an additional 3,338 person years of life prior to the age of 75yrs. The cost saved was around $24 million in health expenditure, which is more than twice the $9 million the Federal and State Governments spent on the first phase of the NTC. The NTC proved to be an important health and economical benefit in the first phase of the campaign (Carter and Scollo, 2000). There has been a reduction in smoking prevalence by 1.8% since the campaign launch in 1997(Australian Government Department of Health and Ageing (Population Health Division), 2003a).

Saffer (2000) conducted a review of the literature on advertising and the key findings were:

(a) Advertising increased in four Asian countries when US companies entered the market and tobacco consumption increased by 10%.

(b) Of the 13 international time series econometric analyses examining effect of advertising, nine studies found no effect of advertising and four a small positive effect.

(c) Three cross-sectional studies all found a positive effect of advertising.

(d) Three studies examined whether banning advertising had any effect. There were mixed results with two studies that banning advertising had no effect, and one study showed that advertising bans and warning labels did have a negative effect on consumption.

Saffer and Chaloupka (2000) examined advertising bans and their effect on consumption in 22 high-income countries between 1970 and 1992. They concluded that a comprehensive set of advertising bans can reduce tobacco consumption but that limitations on content and placement of advertising in only one or two media does not work (Saffer and Chalouka, 2000). In Australia, evidence is that the impact of advertising bans has resulted in only small reductions in the use of tobacco products (Clements et al., 1985) found in (Abelson et al., 2003).

Mass media messages are used to inform the pubic of the health risks and consequence of tobacco use. In the US, from 1967 to 1970, broadcasters were required to run counter-advertising, with result that for every three minutes of advertising there was one minute of counter-advertising. Studies suggested that there was a negative impact on the counter-advertising, as was also the finding in other similar international studies (Saffer, 2000).

Other reviews also found that mass media education that is well-funded and implemented in conjunction with other interventions such as price increases are associated with reduced smoking rates among adults and the young (Centers for Disease Control and Prevention, 2000;Task Force on Community Preventive Services, 2001;Friend and Levy, 2002).

2.4. Education programs

2.4.1. Health Information

Health information is targeted at groups such as potential smokers, adolescents and current smokers on the effects of smoking. Evidence from the US and UK have indicated that health information/programs are effective in the short to medium term and may discourage individuals from starting smoking (Abelson et al., 2003;Alchin, 1993).

2.4.2. School based education programs

School based education programs can have a significant impact on young people when used in conjunction with community based intervention (US Department of Health and Human Services, 2000). A meta-analysis of 94 studies which focused on smoking and school health education programs found that interventions did have a significant impact on knowledge outcomes and should be considered in school based programs with interventions adopting social reinforcement, social norms or developmental orientation (Bruvold, 1993). An Australian study investigated a school based health education program and found similar results; teacher-led programs did discourage the uptake of smoking among students (Armstrong et al., 1990).

2.5. Clean air (smoke free) laws

Introducing clean air (smoke free) laws transfers the property rights of the ambient air from the smokers to the non-smokers. Yet while trying to protect non-smokers from tobacco smoke, considerable costs to smokers and businesses may arise (Woollery et al., 2000). Currently, these clean air laws are enforced in health care facilities, elevators, schools, restaurants, bars, shopping centers and in many other workplaces.

Smoking bans are intended to protect non-smokers from environmental tobacco smoke (ETS); however these bans have also decreased the number of smokers and the average number of daily cigarettes consumed among remaining smokers (Woollery et al., 2000). A study investigating workplace-smoking bans, found a decline in the number of smokers after the bans were in place. This reduction was the same as the average reduction in previous years so it is uncertain what impact the ban had, however the number of cigarettes smoked did decline (Borland et al., 1990). Hocking et al (1991) conducted a similar study and looked at the impact of a workplace smoking ban and the

number smoking before and 18 months after the ban and found a reduction in the number of cigarettes smoked per day (Hocking et al., 1991) found in (Abelson et al., 2003).

Restrictions on smoking such as clean indoor-air laws were introduced to reduce per capita consumption. Yurekli and Zhang (2000) examined the impact of clean indoor laws in 50 US states during 1970-1995, concluding that clean indoor-air laws reduced per capita cigarette consumption. Those areas with more comprehensive restrictions had greater reductions (Yurekli and Zhang, 2000;Woollery et al., 2000).

From an economic perspective the argument is made that the costs of clean-air laws falls on smokers (fewer opportunities to smoke and having to go elsewhere), the hospitality industry (potential loss of customers in bars and restaurants) and businesses (workers taking time away from workplace, lost tourism business) (Woollery et al., 2000). However, to counter these costs are the potential cost savings of not working in smoke filled environment, reduced expenditures on cigarettes and potential health gains to the smoker. The literature on the economic benefits and costs to firms is not yet definitive (Woollery et al., 2000).

A number of studies have looked at the effect clean-air (smoke free) laws have had on the hospitality industry. An Australian review (Scollo and Lal, 2004) of these studies found that the introduction of smoke free laws had no negative impact on restaurants and bars. Research in California found that bars and restaurants suffered a 15% loss in business due to the anti-smoking laws enforced in 1998, however other studies have found that there were no economic effects when the laws were introduced (Woollery et al., 2000). Another aspect is workplace bans, in the US it was estimated that between $2000 and $5000 per employee annually would be saved on healthcare and fire insurance premiums, absenteeism, lost productivity and property damage. Smokers also tend to take more breaks than non-smokers (Woollery et al., 2000) which can lead to morale issues in the workplace.

Overall, smoking bans and restrictions are recommended by the `Task Force on Community Preventative Services'. The key findings from the literature found that smoking bans and restrictions were effective in reducing workplace exposure to smoke

and reduced daily tobacco consumption among smokers(Centers for Disease Control and Prevention, 2000;Task Force on Community Preventive Services, 2001).

2.6. Packaging and labelling

In Australia, warnings on the adverse health effects of smoking on cigarette packets were regulated between 1973 and 1994 through State and Territory legislation. The health warning required was `WARNING – SMOKING IS A HEALTH HAZARD'. In 1985, four health warnings were introduced and legislated separately through each State and Territory. In 1995, the Commonwealth introduced new labelling requirements under the Trade Practise Act, Trade Practices Regulations 1994 (Commonwealth Department of Health and Aged Care, 2001). The labelling required a health warning message (six rotating messages) in black writing with a white background covering 25% of the front of the pack to discourage people from smoking. A health message is also required in black writing with a white background covering the top 1/3rd of the packet. Information about tar, nicotine and carbon monoxide content in the cigarette is to be displayed in black writing with a white background on one side of the packet (Abelson et al., 2003;Australian Government Department of Health and Ageing (Population Health Division), 2004;Commonwealth Department of Health and Aged Care, 2001).

Borland and Hill (1997) investigated the awareness of the health messages pre and post the 1995 introduction. The research found that the new health warnings improved community knowledge (Borland and Hill, 1997).

In the review of the health warnings, 7 out of 10 smokers thought the health warnings were 'very' or 'quite' important but there has been a decrease in the awareness of the information on the side and back of the packets. Some evidence has suggested that new warnings are required to renew interest (Commonwealth Department of Health and Aged Care, 2001).

2.7. Regulations

Limits on tobacco content - tar, nicotine and carbon monoxide

Since January 1995, under the Trades Practice Act 1994, there are no limits on the average amounts of tar, nicotine and carbon monoxide cigarettes can contain. All tar,

nicotine, carbon monoxide levels and descriptions are to be clearly labelled on all tobacco/cigarette packs (Abelson et al., 2003).

2.7.1. Youth access restrictions - the legal smoking age

It is illegal in all Australian states to supply tobacco products to children aged less than 18 years. Laws include an age limit, banning self-service displays and limiting vendor machine to adult only locations such as pubs and banning the distribution of free tobacco samples to the young (Woollery et al., 2000). However, research has found that those aged less than 18 years are smoking. In 1996, surveys found that more than 336,000 Australian school children smoked more than 360 million cigarettes (VicHealth Centre for Tobacco Control, 2001).

Studies have explored the effectiveness of youth access restrictions on the sale or distribution of cigarettes to minors and have found that while these restrictions may reduce the chances of a young person smoking (depending on how well these laws are enforced by retailers etc), it did not reduce the number of cigarettes smoked per day among those that did smoke (Woollery et al., 2000). This is one method that may be feasible to impact on adolescent behaviours; however it is unlikely to work if the laws are not enforced. This enforcement comes at a cost; however no economic analyses were found as to the cost effectiveness of such enforcement. As it estimated that the Australian Federal government received more than $177 million in excise in 1998/99 and 2000/02 from cigarettes supplied to those less than 18 years of age, which is 20 times more than the amount invested ($8.3 million) in anti-smoking interventions over the same time frame, this might be a useful targeted expenditure (VicHealth Centre for Tobacco Control, 2001). Doran et al (1998) found similar results with a growing inequity in the expenditure on anti-smoking activities and the revenue gained from sales to minors. Expenditure on anti-smoking activities compared to revenue from sales to minors was 7.7% in 1990 and reduced to 5.1% in 1993 (Doran et al., 1998).

2.8. Treatment interventions to assist with smoking cessation

Treatment programs to assist with smoking cessation range from brief advice provided by general practitioners, through to pharmacotherapies such as bupropion or nicotine replacement with counselling. A body of evidence exists which demonstrates that smoking cessation is the 'gold standard' of healthcare cost effectiveness, that of all health

care interventions, those designed to assist with smoking cessation are the most cost beneficial from a societal perspective (Eddy, 1992). There, however remains some debate as to the most cost effective method to assist with smoking cessation.

Levy and Friend modelled the impact of healthcare coverage for various smoking cessation interventions in a decision theoretic model of quit behaviour. Their model predicted the greatest increase (37%) in quit rates from a policy that covered all treatments including behavioural, NRT and bupropion while policies restricted to behavioural intervention engendered the smallest increase (7%). Physician brief advice and counselling by pharmacist have been found to be cost effective (Cummings et al., 1989;Crealey et al., 1998). Although behavioural and brief interventions have been found to have the best (lowest) cost-effectiveness ratios they generate fewer additional quitters when compared to bupropion and NRTs (Levy and Friend, 2002).

The economic benefits of switching smoking cessation pharmacotherapies to over-the-counter (OTC) status were examined by Keeler et al. (2002) who concluded that OTC availability substantially increased the benefits to US society in the order of US$1.8-2 billion(Keeler et al., 2002). However, a population-based survey of Californian smokers between 1992 and 1999 found that, although NRT product use increased among quitters, long term cessation was only observed before the introduction of OTC NRT products in 1996(Pierce and Gilpins, 2002). Lack of efficacy outside controlled trials may be attributable to inappropriate use (i.e. NRT for specific periods of work or travel rather than as a quitting strategy), differences in motivation and support between clinical trial volunteers and patients in the community and differential efficacy between light and moderate/heavy smokers (Solberg et al., 2001).

Mongthuong et al (2002) in a non-randomised small study of 48 subjects who self-selected into unassisted quitting, NRT patch or gum and bupropion, found that a pharmacist-directed program was more effective and cost-effective than self-directed quit attempts with or without pharmacologic therapy (Mongthuong et al., 2002). McGahen et al (1996) conducted a cost-benefit analysis of self-care, behavioural programs, nicotine patches and pharmacist advice from the perspective of employers. They concluded that the greatest net benefit was achieved with nicotine patches, with pharmacist advice and participation in comprehensive behavioural programs (McGahen and Dix Smith, 1996).

NRT patches with GP counselling were found to be cost effective when compared to GP counselling alone (Wasley et al., 1997;Stapleton et al., 1999). Fiscella and Franks (1996) found that the NRT patch over and above GP counselling produced incremental costs per Quality Adjusted Life Years (QALY) that were less than the cost per QALY for screening for asymptomatic hypertension at all age groups (Fiscella and Franks, 1996). Oster et al (1986) found the incremental cost per life-year saved by nicotine gum ranged from US$4,113 to US$9,473 (1985) (Oster et al., 1986). Alterman et al. (2001) found no difference between low, high and moderate intensities of behavioural intervention in conjunction with NRT. They suggested that more expensive high intensity behavioural interventions may be more suitable for specific problematic populations (Alterman et al., 2001).

Two cost benefit studies demonstrated that funding bupropion therapy was of economic advantage from the perspective of US managed care organisations (HMOs) and employer health insurance plans. Halpern et al. (2000) estimated that the inclusion of bupropion SR in eight US HMOs contributed to healthcare savings over a 20-year period of between US $8.8 million and 14 million (Halpern et al., 2000). Nielsen and Fiore found that bupropion produced the highest net benefit per employee (US$338) in the first post quit year compared to NRT (US$26), combined NRT/BUP (US$178) or placebo (US$258). The positive results for placebo were attributable to the high quit rate achieved in the placebo group relative to the NRT group.

Johnson and colleagues conducted a limited cost effectiveness analysis of NRT patches versus bupropion based on a retrospective case-note review of 287 patients that compared medication costs only (Johnson et al., 2001). They found that while bupropion and NRT patches were equally efficacious, bupropion was more cost effective. Estimates of relative cost effectiveness of bupropion were conducted using decision-analysis models (Song et al., 2002) and Markov models (Cornuz et al., 2003). Song et al. (2002) (Song et al., 2002) estimated the incremental cost per life-year saved associated with brief advice plus NRT at between US$2,107 and 16,726 (2001 dollars), brief advice plus bupropion SR at US$1182 to US$14,535 and advice plus NRT and bupropion SR at US$1268 to 26,245. Concluding that the cost-effectiveness of adding NRT and bupropion to Brief Advice/Counselling is better than other medical

interventions, but the incremental cost-effectiveness of combined NRT and bupropion was less certain. Cornuz et al. (2003) using a Markov model found that bupropion and the nicotine patch were more cost-effective than nicotine spray, inhaler or gum (Cornuz et al., 2003) with incremental cost per life-year saved estimated between euros 2799 and 4567 for the nicotine patch and euros 960 and 2593 for bupropion (2002 euros).

Javitz and colleagues (2004) recently published a cost effectiveness study based on the results of an open-label study (Swan et al., 2003) which compared different combinations of bupropion dose (150mg/day versus 300 mg/day) and behavioural intervention (moderate intensity proactive telephone counselling versus low intensity tailored mail outs). They found that the lower dose bupropion 150mg/day was more cost effective than 300mg/day irrespective of the intensity of behavioural counselling. The authors found that the medication cost (presently under patent protection) was a substantial component of total treatment cost and they questioned the rationale for the manufacturer's dose recommendation. They further suggested that cost effectiveness could be improved by dividing scripts into an initial 3-week supply followed by an additional 5 weeks only for those patients who achieved abstinence – a proposal similar to the subsidy policy adopted by the PBS in 2004.

The issue as to which type of smoking cessation intervention is most cost effective remains under debate. A review by Warner found that more intensive smoking cessation interventions were more effective than less intensive ones but the associated costs increased faster than effectiveness (Warner, 1997). Thus, the least intensive interventions including self-help manuals and brief advice were more cost-effective than more intensive interventions including NRT patches and gum. In contrast, Cromwell et al (1997) (Cromwell et al., 1997) based their cost-effectiveness analysis on clinical guidelines developed by the US Agency for Health Care Policy Resources (Fiore, 2000). Costs ranged from US$1496 to $6135 with more intensive interventions and the nicotine patch being more cost-effective than less intensive approaches. These findings are supported by two specific cost-effectiveness analyses of NRT and brief physician advice that found NRT to be more cost-effective (Stapleton et al., 1999;Wasley et al., 1997).

2.9. Attempts to compare the cost effectiveness of tobacco control policies

Ranson et al. (2002) undertook a study to provide estimates of the effectiveness and cost-effectiveness of tobacco control polices (Ranson et al., 2002;Ranson et al., 2000). The study examines price increases, NRT and non-price interventions other than NRT such as advertising and promotional bans, public smoking bans, warning labels and mass communication. The effectiveness of the interventions was determined as a reduction in the number of smokers and attributed deaths. Costs were estimated for each intervention to determine the cost effectiveness.

The study used a 1995 baseline cohort of current smokers and smoking prevalence data for 139 countries to estimates age, region and gender of smoking prevalence. A number of steps were involved to estimate the global impact and cost effectiveness of price and non-price interventions. The steps involved determining the number of smoking-attributable deaths; conservative assumptions were made based on the number of smokers alive in 1995 and information from a number of countries. Next the potential impact of price increase was estimated using price elasticity for low, medium and high-income earners, price elasticity by age category and the impact of a price increase on the number of smoking-attributable deaths. Finally, using an estimate of the global effectiveness of NRTs of 0.5-2.5%, the cost effectiveness of non-price interventions were estimated. Cost effectiveness was calculated by weighing the appropriate public sector costs against the years of healthy life saved, measured in disability-adjusted life years (DALYs).

As a baseline comparator, it was estimated that one third (377 million) of the smokers in 1995 would die of a smoking related illness. Low and middle-income countries accounted for the majority (82%) of these deaths. Around 5 to 16 million smoking attributable deaths would be avoided and 40 million people would quit smoking with a price increase of 10%. The greatest impact of smoking attributable deaths avoided would be among the 15-19 year age group. With an effectiveness of 0.5% for NRTs, it was estimated that around six million people would give up smoking and around one million smoking attributable deaths would be avoided. An effectiveness of 2.5% would have five times the impact. The impact of non-price interventions estimated a 2% decrease in the prevalence of smoking, cause about 23 million to quit smoking and avoid around 5

million smoking attributable deaths. The majority (80%) of the avoided smoking attributable deaths would be male, in particular the young.

The cost effectiveness analysis of anti-smoking interventions found that price increases were the most cost-effective intervention, costing US$12-313 per DALY saved worldwide. Greater access to NRT's would cost between $358 and $1917 per DALY saved (depending on assumptions) and non-price intervention not including NRTs would cost between $145 and $2896 per DALY saved (depending on assumptions) (Ranson et al., 2000;Ranson et al., 2002). The study concluded that price increases of 10% would be the most effective and cost-effective of the interventions examined (Ranson et al., 2000;Ranson et al., 2002).

In an Australian study, Buck et al. (2000) evaluated the cost effectiveness of an Australian smoking cessation program which trained family physicians to assess and provide advice to smoking patients compared to other smoking cessation interventions (Buck et al., 2000). The study also examined costs from multiple perspectives (physician, smoker, societal) and included smokers who did not volunteer for treatment. They found that including costs of training increased the costs of treatment by 75% from the perspective of all parties. The intervention was less cost-effective than mass media approaches but more cost-effective than worksite smoking cessation programs and group programs.

Another study which examined the impact of training costs, compared self-help manuals to group therapy in Holland (Mudde et al., 1996). They found that self-help manuals were between three and four times more cost-effective than group therapy depending on the payer's perspective. They warned, however, that smoker characteristics were equally important to cost-effectiveness considerations in allocating treatment resources.

2.10. Summary

In Australia, smoking is responsible for a range of undesirable health and social consequences. In 1998-99, the burden of harm was estimated to be in excess of $21 billion, with over 19, 000 deaths and 142, 500 hospital separation attributable to tobacco use. Australia's expenditure on tobacco control has gradually increased, although not in real terms, yet is still funded below international benchmarks. Certain tobacco control interventions are known to affect the demand for tobacco products but there are little or

no economic evaluations of these interventions. Fiscal policies, particularly sales and excise taxes have some affect on the demand for tobacco products (price elasticity ranging from -0.1 to -0.59) in Australia. Other tobacco control interventions which reduce the demand for tobacco products or use include the National Tobacco Campaign, advertising bans, mass media and health information, school health education programs, clean indoor-air laws, packaging health warnings and youth access restrictions. Treatment interventions for smoking cessation are available with the literature suggesting that brief interventions and counselling have been found to be cost effective however, not as effective when compared to bupropion or NRTs. Chapter 8 explores the costs and outcomes of smoking cessation treatments in greater detail.

3. PRESCRIBING PATTERNS OF BUPROPION HYDROCHLORIDE IN AUSTRALIA

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This paper in part is in Doran, CM et al. **Current prescribing patterns of bupropion in Australia.** MJA 2002; 177: 162. ©Copyright 2002. *The Medical Journal of Australia* and was reproduced with permission (Doran et al., 2002).

Bupropion was listed on the PBS on the 1st February 2001 for use as a short-term adjunctive therapy for high nicotine dependence, with the goal of maintaining abstinence[1]. The listing of bupropion represented an exciting opportunity for smokers to use an effective smoking cessation medication at an affordable price. When originally listed, bupropion was dispensed in a packet of 120 tablets, taken at an initial dose of 150mg daily for 3 days, increasing to 150mg twice daily for a period of at least 7 weeks. The PBS listing of bupropion recommends its use for motivated quitters to be used in combination with a comprehensive treatment plan.

Since the February 2001 listing, bupropion has cost the PBS an estimated $116 million ($83.14 million in 2001, $21.7 million in 2002, $12 million in 2003)(Commonwealth Department of Health and Aged Care, 2002). The cost of $83.14 million in 2001 was equivalent to approximately 2% of total PBS-related drug expenditure in Australia (AIHW, 2001). Although reviews point to the effectiveness of bupropion as an aid to smoking cessation, little has been reported on the uptake of bupropion by age and gender or the field effectiveness of the medication. The purpose of this article is twofold. First to examine the proportion of smokers who fill a script for bupropion in the first year of listing and secondly, using HIC data, examine the proportion of smokers by age and gender who fill a script for bupropion in the calendar years 2001 and 2002.

[1] Changes were made to the PBS listing of bupropion as of February 2004, this is further discussed in Chapter 8.

3.1. Proportion of smokers, by state, filling a script for bupropion in 2001

One indicator of the extent of market penetration is the proportion of regular smokers who have filled a bupropion script (Table 3.1). The Health Insurance Commission (HIC) is responsible for managing the PBS. A part of HIC's responsibility is to collect data on the volume and value of bupropion scripts processed by month, age, gender and state, amongst other variables. Data pertaining to script data by state was obtained from the HIC website and then combined with information on the prevalence of smoking to ascertain an estimate of market penetration.

Estimates suggest that 22.8% of the population 20 years and over are current regular smokers (AIHW, 1999). Seventy-three percent (14,099,273) of the Australian population were aged 20 years or over in June 2001(ABS, 2001). Combining population and age-specific smoking prevalence estimates results in an estimated 3,198,738 current regular smokers (aged 20 years or over). Given that the PBS guidelines allow for only one script of bupropion per smoker per year, an estimated 11% (351,772 scripts / 3,198,738 smokers) of current regular smokers filled a script for bupropion in the calendar year 2001. Excluding smokers less than 20 years of age will have minimal effect on this estimate, since the incidence of high nicotine dependence in this group is likely to be low. Applying this method to each State and Territory reveals marked variation between them in the apparent proportions of smokers filling a script for bupropion. For example, an estimated 16.5% of all smokers in Tasmania had such a script filled compared with 8% in Victoria.

3.2. Proportion of smokers, by gender and age, filling a script for bupropion

In order to examine market penetration by gender and age a request was submitted to the HIC. Data were sought on bupropion scripts data by month, age and gender for the supply period February 2001 to December 2003 inclusive. Although HIC website provides aggregate level data, disaggregated data are more appropriate to these analyses. Further, it is important to note website information pertains to scripts filled, claimed and processed. Disaggregate data is supply based which equate to scripts filled and claimed and hence not

yet processed. As a consequence slight divergence exists between disaggregate and aggregate script data(Robertson et al., 2002).

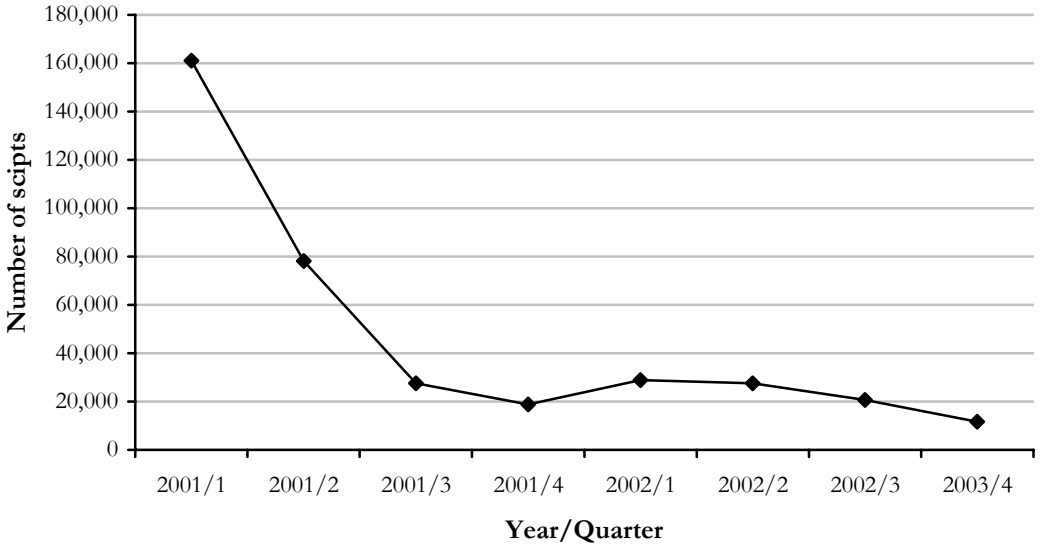
Table 3.1: Characteristics of bupropion hydrochloride (bupropion) use in Australian States and Territories February-December 2001 (inclusive)

Variables	Population (≥20 years)	Current regular smokers (≥20 years)	Bupropion scripts processed	Total cost bupropion scripts processed	Proportion of current regular smokers who used bupropion
ACT	225,797	53,448	4,470	$1,043,863	8.4%
WA	1,372,378	316,608	46,186	$10,854,828	14.6%
VIC	3,550,348	804,455	64,482	$15,253,431	8.0%
TAS	338,108	74,507	12,279	$2,920,481	16.5%
SA	1,110,897	245,553	32,455	$7,713,913	13.2%
QLD	2,602,539	593,268	81,619	$19,237,576	13.8%
NT	131,542	33,254	3,803	$881,709	11.4%
NSW	4,767,664	1,077,132	106,478	$25,238,851	9.9%
TOTAL	14,099,273	3,198,225	351,772	$83,144,652	11.0%

3.2.1. Total scripts processed in supply period 2001-2002

Figure 3.1 shows the total number of bupropion scripts by quarter for the calendar years 2001 and 2002. In the first two months of listing, demand for bupropion was at its peak at 161,039 scripts and steadily decreased thereafter. By the third quarter of 2001 scripts appear to have levelled off at around 28,000 scripts per month but then appear to have be declined again towards the end of 2003. Overall, demand for bupropion has declined considerably since it was first listed in 2001.

Figure 3.1: Bupropion scripts claimed in 2001 and 2002



Calculating the proportion of smoker using Bupropion by age and gender

A similar methodology to that described above was used to estimate of the proportion of current smokers using bupropion by age and gender for calendar years 2001 and 2002. Multiplying estimates of the resident population with the prevalence of smoking can derive an estimate of the number of smokers by age and gender. Using this method, Figures 3.2 and 3.3 provide an estimate of the proportion of current smokers using bupropion for the calendar years 2001 and 2002 respectively.

Using disaggregated HIC data it is estimated that in 2001, 8.9% of current smokers filled a script for bupropion with the proportion of use generally increasing with age; the 60+-age cohort had the highest relative use with 15.5% of males and 15.4% of females using bupropion. A higher proportion of female smokers (9.9%) than males (8.1%) filled a script for bupropion in 2001 with the largest difference between genders seen in the 50-59 year age cohort, 14.6% of female smokers compared with 11.6% of male smokers. In 2002, the proportion of current smokers filling a script for bupropion had decreased to 2.7%. Consistent with 2001 data, the proportion of use increased with age and was (marginally) more common among women smokers.

Figure 3.2: Proportion of smokers who filled a script in 2001

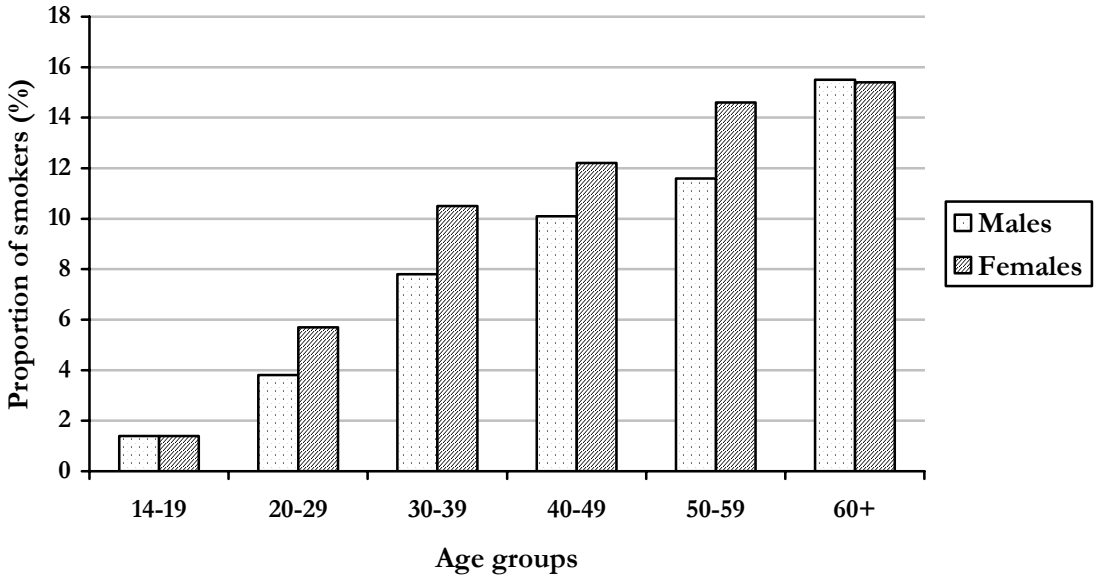
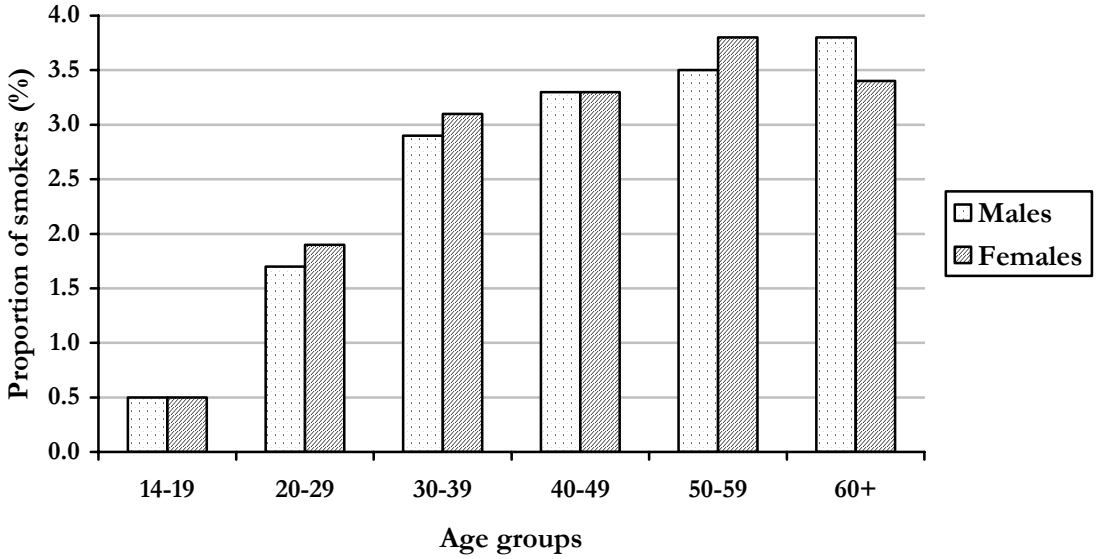


Figure 3.3: Proportion of smokers who filled a script in 2002



3.3. Summary

The results of this research highlight important differences in market penetration since bupropion was listed on the PBS in February 2001. A similar method was applied across two datasets, both from the HIC, to estimate the extent to which smokers filled a script for

bupropion in the first year of listing. As discussed above, divergence between datasets occurred for a number of reasons but the consistency of estimates does lend confidence to the reliability of the method adopted. Results from the first analysis estimated 11% of current regular smokers had filled a script for bupropion in the calendar year 2001. Uptake varied considerably by State with an estimated 16.5% of all smokers in Tasmania had such a script filled compared with 8% in Victoria. Results from analyses 2, revised downward the estimate of uptake to 8.9% in 2001. By 2002 it was estimated that only 2.7% of current smokers filled had filled a script for bupropion. Consistent across both years is the fact that a higher proportion of older smokers had filled a script for bupropion. The extent to which bupropion facilitated a reduction in smoking behaviour among these people filling a script is partially addressed in Chapter 4.

These data provide consistent and clear results; the uptake of bupropion by current regular smokers has been low over the first two years of listing. Although market penetration of around 9% for 2001 is consistent with earlier estimates, the major reduction in penetration for 2002 is perhaps a cause for concern. It represents a cause for concern for a number of reasons: as script demand falls, the opportunity for smokers to utilise an effective smoking cessation strategy diminishes. The sharp reduction in demand during 2001 may support anecdotal reports that although bupropion was sold, compliance with the medication may have been low and hence issues of wastage may have been prevalent. Another reason may be postulated for the decline in bupropion scripts since 2001 is that of the media prominence given to adverse effects of bupropion including deaths that were speculatively attributed to Zyban. For example, for the period November 2000 – August 2001, the Adverse Drug Reactions Advisory Committee (ADRAC) has received 1237 Australian reports of suspected adverse reactions in connection with the use of Zyban SR. In 1215 of these, Zyban SR was implicated as the sole suspected drug. The more commonly reported problems involved skin reactions (499 reports), psychiatric disturbances (427), the nervous system (406), and the gastrointestinal tract (258) (Australian Government Department of Health and Ageing., 2001;Australian Government Department of Health and Ageing, 2001)

Although important to understand, data on script demand can provide only a limited picture of the usefulness of the product. Key unanswered questions relate to the extent to which: smokers complete a full course of bupropion; the field effectiveness of bupropion

in aiding smoking cessation is comparable with abstinence rates achieved in clinical trials; bupropion is used in conjunction with a comprehensive treatment program. Research discussed in these chapters attempt to address such questions.

4. PHARMACOTHERAPIES FOR SMOKING CESSATION: CONSUMER SURVEY

Jennifer Stafford, Christopher Doran, Marian Shanahan and Richard P Mattick

This paper in part is published in Doran, C et al. **Bupropion and nicotine replacement therapies.** Pharmacy Review, September 2003; 27; 24-27. ©Copyright 2003, *Pharmacy Review* and reproduced with permission (Doran et al., 2003).

4.1. Introduction

There are a number of methods to assist with smoking cessation including counselling and pharmacotherapies. Two pharmacotherapies for nicotine dependence are currently available in Australia; NRTs and bupropion. Based on data from a consumer survey this chapter focuses on bupropion, patch, gum and lozenge.

Bupropion, an anti-depressant, is used as a short-term therapy for nicotine dependence with the goal of maintaining abstinence in smokers are ready to cease smoking and who have entered a comprehensive support and counselling program (Australian Government Department of Health and Ageing, 2004a). Bupropion assists people to stop smoking by reducing withdrawal symptoms and the urge to smoke. Based partially on results from randomised clinical trials, bupropion is recommended for use over a 7 week period (Jorenby et al., 1999;Hurt et al., 1997;Hays et al., 2001). These trials were conducted with smokers who were motivated to quit smoking in conjunction with an ongoing counselling and support.

A Cochrane review by Hughes et al. (2003) conducted a meta-analysis to assess the effectiveness of antidepressants for smoking cessation. The analysis selected randomised trials comparing antidepressant drugs to placebo or another therapeutic control. Sixteen trials of bupropion were analysed and the results concluded that bupropion assisted smoking cessation. However, there is lack of evidence to recommend bupropion over NRT or visa versa (Hughes et al., 2003b). Additional information about this Cochrane review may be found in Chapter 8.

NRTs are an alternative to bupropion which are available for the treatment of nicotine dependence as short-term support to smoking cessation, and are again to be used in

conjunction with an effective behavioural therapy program. The aim of NRTs is to replace nicotine from cigarettes, reduce withdrawal symptoms and help avoid the desire to smoke (Silagy et al., 2003). A variety of NRT's are available such as gum, patches lozenges, nasal sprays and inhalers.

Silagy et al. (2003) reviewed a total of 110 trials, 96 with a non-NRT control group with aim to examine the effectiveness of different forms of NRT to help smokers stop or reduce the amount smoked (Silagy et al., 2003). The review found that the use of any form of NRT is more effective than placebo or no NRT to help them to stop smoking. Some evidence also found that using NRT in combinations was more effective than one product alone. For further information about this Cochrane Review please refer to Chapter 8.

In September 2001, the listing of bupropion on the PBS raised issues of its relative effectiveness and patient compliance. Concerns were raised after anecdotal reports that people who were prescribed bupropion were stopping therapy after several days, raising questions as to the field effectiveness of bupropion. Some of these concerns subsequently led to changes in the PBS listing of bupropion. In response to these concerns, a study to investigate the use of bupropion compliance and field effectiveness compared to NRT's with a convenient consumer sample was undertaken. The NRTs included in the survey were the nicotine patch, gum and lozenges.

4.2. Method

4.2.1. Recruitment

Participants were recruited through community pharmacies nationally and a computer assisted telephone interview (CATI) was used to survey the respondents. Eligible participants were: aged 18 years or over; presenting to the pharmacy for bupropion or NRT; and English speaking.

The recruitment of smokers into the study involved four steps. The *first step* involved a facsimile sent to all pharmacies (with a facsimile machine) in Australia by the Pharmacy Guild of Australia to introduce the study and extend an invitation to participate (Appendix 3). The *second step* involved those pharmacies interested in the project sending their contact details by facsimile. Interested pharmacies were then posted an information

pack providing an overview of the project, describing the recruitment strategy (Appendix 4), an information form for participants and a participant's details form that requested written consent. One in ten pharmacies were randomly selected to recruit bupropion participants only (see later for rationale). The remainder recruited either bupropion or NRT participants presenting to their pharmacy. In s*tep three* participating pharmacies asked smokers who collected bupropion or NRT whether they were interested in participating in a smoking cessation survey. Those interested provided their name, medication collected and contact phone number (Appendix 5, 6 & 7). At the end of each month (over a four month time period) pharmacies faxed or posted NDARC a list of interested participants. Pharmacies were reimbursed $20 for every participant who completed the baseline survey. In the *final step* (with all those willing to participate) NDARC staff explained the study, obtained informed consent verbally, completed the baseline CATI survey, conducted the interview and asked permission to call them in three months for a follow up survey. Follow-up surveys were conducted with those participants who answered the baseline survey and agreed to be followed-up.

4.2.2. Surveys

The baseline and follow-up survey were designed and developed at the National Drug and Alcohol Research Centre (NDARC) with input from a number of interested parties, including the Pharmacy Guild of Australia and the Australian Government Department of Health and Ageing. The baseline survey was adapted after reviewing the Illicit Drug Reporting System (IDRS) survey, SF-36 Health Survey, Urbis Keys Young `Barriers to Access' and the Australian Population Census (National Drug and Alcohol Research Centre, 2002;Medical Outcomes Trust, 1994;Rintoul et al., 2002;ABS, 2002). The baseline surveys were completed over the four-month period November 2002 to February 2003 and the follow-up survey three-months after the baseline survey.

The baseline survey asked 61 questions on: (a) age first smoked and current smoking behaviours; (b) their current use of bupropion or NRT; (c) previous smoking cessation attempts and, (d) demographic information (Appendix 9).

The follow-up survey asked 23 questions on: (a) current smoking behaviours (b) experience with pharmacotherapy and, (c) smoker's perceptions of current health status (Appendix 10).

Both surveys were administered to current smokers using the CATI that generated questions dependent on the answers to previous questions.

4.2.3. Ethics approval

The UNSW Human Research Ethics Committee granted ethics approval.

4.2.4. Data analysis

The statistical program used in this study was SPSS version 10.0 (SPSS, 2000). All statistical tests used a 0.05 level of significance, 95% confidence intervals and all p tests were two-tailed. Continuous data were analysed using *t*-test and categorical data using *Pearson's chi square* test.

4.3. Results

4.3.1. Recruitment

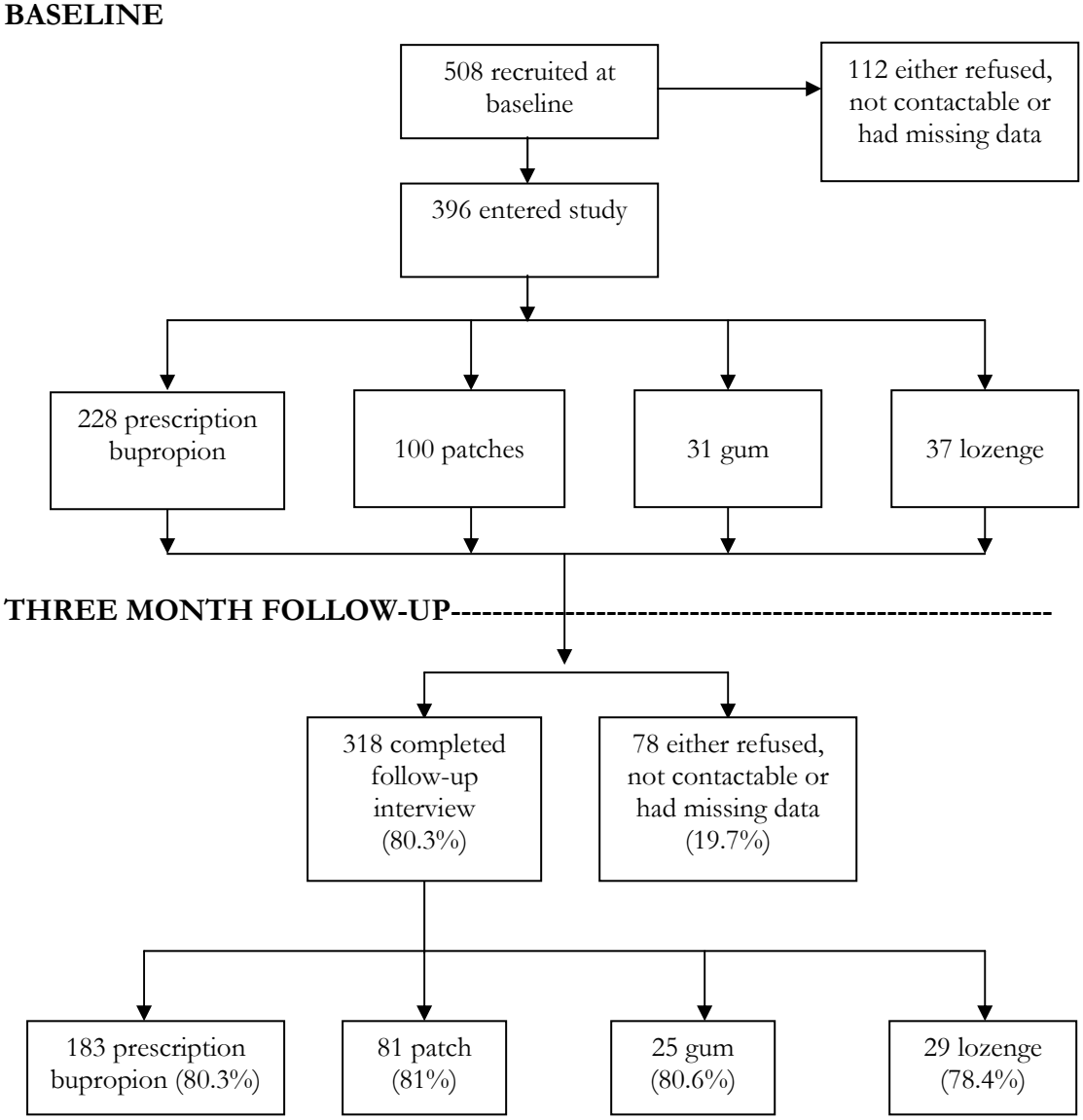
In September 2002, the Pharmacy Guild of Australia (on behalf of NDARC) contacted by fax 3,602 pharmacies out of total of 4,925. Four hundred and thirty nine pharmacies expressed an interest in the study and faxed NDARC their contact details. An information pack was posted to all of the interested pharmacies. A total of 99 pharmacies agreed to participate in the study. Table 4.1 provides a breakdown, by state of: the total number of pharmacies that were contacted by fax, the number and percentage responding to this fax and the number and percentage of pharmacies that recruited participants. With the exception of the NT and Tasmania, the population of pharmacies participating compared to those invited was similar.

Table 4.1: Recruitment of pharmacies

Areas	Number of pharmacies invited to participate	Number of pharmacies interested in participating (%)	Number of pharmacies participating (%)
NSW	1,206	145 (12)	30 (2.5)
VIC	825	79 (10)	13 (1.6)
QLD	699	109 (16)	24 (3.4)
WA	399	43 (11)	11 (2.8)
SA	284	40 (14)	9 (3.2)
TAS	129	19 (15)	10 (7.8)
ACT	48	2 (4)	1 (2.1)
NT	12	2 (17)	1 (8.3)
TOTAL	3,602	439 (12)	99 (2.7)

A flow chart of recruitment and participation is presented below (Figure 4.1). A total of 508 participants were recruited at baseline, of this number 396 completed the interview and 112 either refused, had missing data or were not contactable i.e. phone disconnected. Of the 396 participants, 228 were prescription bupropion and 168 NRTs (100 patches, 31 gum, and 37 lozenge). At follow-up, 318 completed (80%) the interview and 78 refused, had missing data or were not contactable. Of this number 22 were still using the medication at the time of the interview and were therefore excluded from a part of the analysis. Of the remainder, 174 were prescription bupropion, 75 patch, 22 gum and 25 lozenge.

Figure 4.1: Medication recruitment type at baseline and follow-up



4.3.2. Participant demographic and health characteristics

Table 4.2 presents demographic information for each medication type and where available comparable information on the whole Australian population from the Census 2001 (Australian Bureau of Statistics., 2001;ABS, 2002). Overall, little difference on demographic characteristics was found between the bupropion and the NRT groups. The gum group were on average slightly older than the other groups, less likely to be born in Australia and were more likely to be in full time work and married.

Fifty-five percent of the sample was female compared to 51% in the Census. The sample was on average older than the general adult population, 42yrs compared to 35yrs

(NOTE: The Population Census includes those under the age 18 years, except for marital status which is 15 years and above. Our sample only included those aged 18 years and over). Seventy-nine percent were born in Australia, 45% were in full-time work and 44% were married compared to the Census, 72%, 40% and 41% respectively. Over half (53%) of the sample had an annual income before tax of <$32,000 compared to 55% in the Census.

Nearly a third (30%) of the sample had completed either a technical trade or university compared to the census (27%). Over three quarters (77%) of the sample believed their current health status to either be excellent, very good or good. This is similar to the National Health Survey 2001 (82%). Visiting a GP in the last 4 weeks at least once was common among a quarter (24%) of the sample.

Table 4.2: Participant demographic and health characteristics

Demographic and health characteristics	Bupropion (n=228)	Patch (n=100)	Gum (n=31)	Lozenge (n=37)	Total (n=396)	Census 2001[c]
Mean age in years (SD)	43 (12.6)	41(13.1)	46(10.9)	40 (11)	42 (12.5)	35yrs
Women, N (%)	121 (53%)	61(61%)	15(48%)	20 (54%)	217 (55%)	51%
Aboriginal or TSI, N (%)	6 (3%)	1 (1%)	1 (3%)	0	8 (2%)	2%
Country of birth, N (%)						
Australia	178 (78%)	82(82%)	22(71%)	29 (78%)	311 (79%)	72%
Other	50 (22%)	18(18%)	9 (29%)	7 (22%)	82 (21%)	28%
Education Level, N (%)						
No Formal	1 (<1%)	1 (1%)	-	-	2 (<1%)	
Primary School	1 (<1%)	1 (1%)	-	-	2 (<1%)	
Some Secondary	103 (46%)	37(37%)	13(42%)	13 (36%)	166 (43%)	
Completed Secondary	53 (24%)	33(33%)	6 (19%)	9 (25%)	101 (26%)	
Trade/Technical/ University	66 (29%)	27(27%)	12(39%)	14 (38%)	119 (30%)	27%
Work Status, N (%)[a]						
Full-time	95 (42%)	44(44%)	18(58%)	23 (64%)	180 (45%)	36%
Home duties	27 (12%)	12(12%)	2 (7%)	1 (3%)	42 (11%)	
Part-time/casual	48 (21%)	17(17%)	7 (23%)	6 (17%)	78 (20%)	18%
Retired	20 (9%)	10(10%)	1 (3%)	2 (6%)	33 (8%)	
Student	5 (2%)	8 (8%)	-	2 (5%)	15 (4%)	
Unemployed	15 (7%)	6 (6%)	1 (3%)	1 (3%)	23 (6%)	7%
Volunteer work	1 (<1%)	-	-	-	1 (<1%)	
Other	13 (6%)	2 (2%)	2 (6%)	1 (3%)	18 (5%)	

Demographic and health characteristics	Bupropion (n=228)	Patch (n=100)	Gum (n=31)	Lozenge (n=37)	Total (n=396)	Census 2001[c]
Marital Status, N (%)[a]						
Divorced	25 (11%)	15(15%)	3 (10%)	1 (3%)	44 (11%)	7%
Married	99 (43%)	38(38%)	18(58%)	18 (49%)	173 (44%)	51%
Separated	10 (4%)	2 (2%)	2 (6%)	1 (3%)	15 (4%)	3%
Widowed	9 (4%)	5 (5%)	1 (3%)	1 (3%)	16 (4%)	6%
Never married[b]	80 (35%)	39(39%)	7 (23%)	15 (41%)	141 (37%)	32%
Annual income before tax, N (%) [a]						
<$21, 000	81 (36%)	34(34%)	5 (16%)	9 (24%)	129 (33%)	40%
$21,000 - $31,000	46 (20%)	22(22%)	6 (19%)	4 (11%)	78 (20%)	15%
$32,000 - $42,000	34 (15%)	16(16%)	8 (26%)	8 (22%)	66 (17%)	11%
$43,000 - $52,000	25 (11%)	3 (3%)	5 (16%)	4 (11%)	37 (9%)	7%
$53,000 - $78,000	15 (7%)	8 (8%)	4 (13%)	5 (14%)	32 (8%)	7%
>$78,000	9 (4%)	5 (5%)	-	2 (5%)	16 (4%)	4%
Perception of health, N (%)						
Excellent, very good or good	175 (77%)	75(75%)	23(74%)	30 (81%)	303 (77%)	82%[d]
Fair	31 (14%)	15(15%)	8 (23%)	5 (14%)	59 (15%)	
Poor	17 (7%)	7 (7%)	-	1 (3%)	25 (6%)	
Number of GP visits in the past 4 weeks. N (%) (not including this visit)						
None	122 (54%)	68(68%)	23(74%)	23 (62%)	236 (60%)	
Once	63 (28%)	21(21%)	5 (16%)	7 (19%)	96 (24%)	
Twice	17 (7%)	1 (1%)	1 (3%)	2 (5%)	21 (5%)	
3-4 times	12 (5%)	3 (3%)	2 (6%)	3 (8%)	20 (5%)	
5 or more times	10 (4%)	4 (4%)	-	-	14 (4%)	

a Percentages for the Census based on the population aged over 15years· b Defacto and single combined in the sample c Source: Population Census 2001 (ABS, 2002). d National Health Survey 2001(AIHW, 2002b)

4.3.3. Smoking characteristics

There were no major differences for smoking characteristics between the bupropion and NRT groups. The mean age of first starting to smoke was 16 years and 98% of the sample was daily smokers (Table 4.3).

Participants waited for approximately 24 minutes before having their first cigarette when waking (23 to 28 minutes). They smoked on average 169 cigarettes (range 146 to 201) per week or 24 cigarettes per day (Table 4.3).

Table 4.3: Participants smoking characteristics

Smoking characteristics	Bupropion (n = 228)	Patch (n = 100)	Gum (n = 31)	Lozenge (n = 37)	Total (n=396)
Mean age first started smoking in years (SD)	16 (4.2)	16 (3.4)	16 (3.3)	16 (3.5)	16 (3.9)
How often do you smoke? N (%)					
Daily	224(98%)	97 (97%)	30(97%)	36 (97%)	387(98%)
2-3 times per week	3 (1%)	3 (3%)	0	1 (3%)	7 (2%)
Once a week	0	0	0	0	0
Other	1 (<1%)	0	1 (3%)	0	2 (<1%)
Mean number of cigarettes per week (SD)	169 (72)	166 (72)	201(94)	146 (65)	169 (74)
Average minutes after waking up before first cigarette (SD)	23 (38)	24 (31)	26 (39)	28 (29)	24 (36)

4.3.4. Previous quit attempts

A high percentage of all participants had previously attempted to quit smoking, with a mean of three quit attempts in the last two years (Table 4.4). The average period of not smoking on a previous quit attempt was 14 months for the lozenge group, 9 months for the bupropion group, 8 months for the patch group and zero months for the gum group. Most people (64%) gave health as the most common reason for wanting to quit with expense (14%) as the next most common response.

In this sample nearly two thirds (59%) had previously used patches to help them quit smoking and nearly half (49%) had tried cold turkey. Surprisingly, given the short time bupropion has been available it had been previously used by 28% of participants in a sub sample of 257 participants who answered the question. Despite bupropion being part of an overall treatment plan, only 4 (1%) of the participants prescribed bupropion previously had used the Zyban Action Plan (ZAP). When asked which program or products was the most useful, the response overall was patch (43%), bupropion (24%), cold turkey (13%) and gum (10%). Each group most often stated that their own medication was the most useful.

Table 4.4: Previous quit attempts

Previous quit attempts	Bupropion (n=228)	Patch (n=100)	Gum (n=31)	Lozenge (n=37)	Total (n=396)
Number with at least one previous quit attempt	196 (86%)	81 (81%)	23(74%)	35 (95%)	335(85%)
Participants with previous quit attempts	**n=196**	**n=81**	**n=23**	**n=35**	**n=335**
Mean number of smoking quit attempts in the last two years, N (SD)	3 (3)	3 (3.8)	2 (2.8)	3 (3.7)	3 (3.3)
Previous success at quitting even for a short time, N (%)	104 (53%)	45 (56%)	12(52%)	23 (66%)	184(55%)
Longest period of time not smoked, mean months, (SD)	9 (8.4)	8 (8.5)	0	14 (0)	10 (7.2)
Main reason for previously quitting smoking, N (%)					
Health	123 (63%)	54 (67%)	15(65%)	21 (60%)	213(64%)
Expense	26 (13%)	13 (16%)	2 (9%)	6 (17%)	47 (14%)
Family	14 (7%)	2 (2%)	0	2 (6%)	18 (5%)
Other [a]	15 (8%)	5 (6%)	3 (13%)	5 (14%)	27(8%)
No reason given	18 (9%)	7 (9%)	3 (13%)	1 (3%)	30 (9%)

a Other reasons given included pregnancy and tired of smoking.

4.3.5. Bupropion and NRT experience

Overall, 94% of the sample had started the medication. The remainder either stopped smoking without the use of the medication or continued to smoke and planned to quit at a later date. Of those who had started their medication, 41% were currently using their selected medication at the time of the first interview. The main reason given for discontinuing their medication was adverse side effects (26%) with a range of 36% for bupropion group, to 14% for patches (Table 4.5).

Eighteen percent of the sample was advised to use either another product or a program with their selected medication. Quitline (5%) was the most popular recommendation followed by counselling (4%) (Table 4.5). Despite PBS and RPBS guidelines for bupropion and NRTs to be used within a comprehensive treatment program for nicotine dependence, only 11% were advised to use either counselling, Quitline or the ZAP by their doctor or pharmacist.

Table 4.5: Participants current experience with pharmacotherapies (survey one)

Experience with pharmacotherapies	Bupropion (n = 228)	Patch (n = 100)	Gum (n = 31)	Lozenge (n = 37)	Total (n=396)
Ever started using pharmacotherapy (yes), N (%)	210 (92%)	97 (97%)	29(94%)	37 (100%)	373(94%)
Currently using pharmacotherapy (yes), N (%)	94 (41%)	32 (32%)	17(55%)	18 (49%)	161(41%)
Did doctor or pharmacist advise other products with pharmacotherapy (yes)? N, (%)	43 (19%)	19 (19%)	5 (16%)	3 (8%)	70(18%)[a]
Quitline	8 (4%)	9 (9%)	3 (10%)	1 (3%)	21 (5%)
Counselling	8 (4%)	6 (6%)	0	1 (3%)	15 (4%)
Patch	11 (5%)	n/a	0	1 (3%)	12 (3%)
Gum	3 (<1%)	6 (6%)	n/a	0	9 (2%)
Zyban Action Plan	8 (4%)	n/a	n/a	n/a	8 (2%)
Lozenge	1 (<1%)	3 (3%)	0	0	4 (1%)
Zyban	n/a	1 (1%)	0	0	1 (<1%)
Other	17 (7%)	7 (7%)	2 (6%)	0	26 (7%)
Participants who quit medication	**n=116**	**n=65**	**n=12**	**n= 19**	**n=212**
Reason for stopping medication, N, (%)					
Adverse side effects	42 (36%)	9 (14%)	2(17%)	3 (16%)	56 (26%)
Couldn't stop smoke	22 (19%)	18 (28%)	6(50%)	5 (26%)	51 (24%)
Other[b]	52 (45%)	38 (58%)	4(33%)	11(58%)	105(50%)

a Participants were allowed to give more than one answer, b Other reasons include stressed, stopped smoking.

4.3.6. Follow-up interview

Demographic characteristics for the sample in the follow-up survey were similar to that of the baseline survey, indicating those who were unable to be followed up were similar to those followed-up. A total of 318 (80% of baseline) participants were followed-up. Of these, 22 (7%) participants were still using their selected medication at the time of the interview. Over two thirds (69%) were still smoking. The bupropion group had the largest percentage still smoking (73%), compared to the gum and patch (64%) and lozenge (55%) groups (Table 4.6).

Of those still smoking, 92% of the sample were smoking daily. The mean number of cigarettes smoked per week for all participants reduced from 169 at baseline (Table 4.4) to 116 at follow-up. The reduction was significant ($p<0.01$). The gum group smoked the most on average at follow-up (127 cigarettes). The length of time before smoking the first cigarette after waking significantly increased ($p=0.01$), with the average time

increasing from 24 minutes at baseline (Table 4.4) to 46 minutes at follow-up for the first cigarette after waking. Unable to stop smoking (46%) was the main reason for still smoking (Table 4.6).

Table 4.6: Follow-up smoking status at three months

Smoking status	Bupropion (n=183)	Patches (n=81)	Gum (n=25)	Lozenge (n=29)	Total (n=318)
Still smoking (yes), N (%)	136(74%)	52(64%)	16(64%)	16(55%)	220(69%)
How often are you smoking?	**n=136**	**n=52**	**n=16**	**n=16**	**n=220**
Daily	129(95%)	45(87%)	15(94%)	14(88%)	203(92%)
2-3 times/week	4 (3%)	3 (6%)	1 (6%)	0	8 (4%)
Once a week	2 (<2%)	2 (<4%)	0	1 (6%)	5 (2%)
Other	1 (<1%)	2 (<4%)	0	1 (6%)	4 (2%)
Mean number of cigarettes per week (SD)	122(70)	105 (60)	127(85)	93 (57)	116(69)
How long after waking up would you have your first cigarette (mean minutes)(SD)	44 (59)	54(82)	32(47)	60 (54)	46(64)
What is the main reason you are still smoking? N (%)					
Couldn't stop	68 (50%)	22(42%)	4 (25%)	7 (44%)	101(46%)
Stress	15 (11%)	7(<14%)	4 (25%)	2(<13%)	28 (13%)
Social	8 (6%)	5 (10%)	1 (6%)	3 (19%)	17(8%)
Side effects	7 (5%)	0	0	0	7 (3%)
Work	1 (<1%)	1 (2%)	2(<13%)	1 (6%)	5 (2%)
Family	3 (2%)	1 (2%)	0	0	4 (<2%)
Other	26 (19%)	9 (17%)	3 (19%)	1 (6%)	39 (18%)
No reason given	8 (6%)	7(<14%)	2(<13%)	2(<13%)	19 (9%)

4.3.7. Experience with the medication (follow-up survey)

Of the 318 participants followed up, 298 (94%) participants had started their selected medication at the time of the follow-up interview. Over two thirds (39%) of the participants completed the full course of the medication. The overall main reason for not completing the full course of medication was adverse side effects (25%) (Table 4.7a). Just under half (45%) of the sample that started their medication reported side effects. The lozenge group had the highest percentage of participants who experienced side effects (55%), followed by bupropion (45%), patch (44%) and gum (35%) group (Table 4.7b). Abnormal dreams/sleep disturbance as a group was the main side effect experienced by the sample (20%), followed by heartburn/hiccup/nausea as a group (18%). Abnormal dreams/sleep disturbance was the most common side effect for the bupropion group (23%) and patch group (26%). For both the gum group and lozenge group the most common side effect was heartburn/hiccups/nausea (30% and 45% respectively).

Over, two thirds (74%) of the sample that started the medication stated that their selected medication helped them to quit smoking at least for a short time and the result was significant between groups (p=0.03) (Table 4.7b). Only 10 (3%) participants used another product or program (gum, lozenge, and patch) with their selected medication and found it useful.

Table 4.7a: Medication experience at three months follow-up

Medication experience	**Bupropion (n=183)**	**Patch (n=81)**	**Gum (n=25)**	**Lozenge (n=29)**	**Total (n=318)**
Start the medication (yes), N (%)	168(92%)	78(96%)	23(92%)	29(100%)	298(94%)
Currently using the medication	9 (5%)	6 (7%)	3 (12%)	4 (14%)	22 (7%)
Started the medication minus those currently using the medication	**n=159**	**n=72**	**n=20**	**n=25**	**n=276**
Completed the full course of medication (yes)? N (%)[a]	59 (37%)	26(36%)	10(50%)	13 (52%)	108(39%)
Participants who quit medication	**n=90 (49%)**	**n=53 (65%)**	**n=10 (40%)**	**n=14 (48%)**	**n=167 (53%)[b]**
Reason for not completing the full course of the medication? N (%)					
Adverse side effects	31 (34%)	6 (11%)	3 30%)	2 (14%)	42 (25%)
Couldn't stop smoking	11 (12%)	11 (21%)	3 (30%)	1 (7%)	26 (16%)
Already stopped smoking	5 (6%)	7 (13%)	1 (10%)	2 (14%)	15 (9%)
Other	18 (20%)	10 (19%)	1 (10%)	1 (7%)	30 (18%)
No reason given	25 (28%)	19 (36%)	2 (20%)	8 (57%)	54 (32%)

a The 22 participants still using the medication were excluded from the analysis. b One person missing from analysis.

Table 4.7b: Medication experience at three months follow-up[a]

Medication experience at follow-up	Bupropion (n=168)	Patch (n=78)	Gum (n=23)	Lozenge (n=29)	Total (n=298)
Did the medication help you to quit smoking (yes)? N (%)*	114(68%)	65(83%)	16(70%)	25(86%)	220(74%)
Experienced side effects with pharmacotherapy, N (%)[b]	76 (45%)	34(44%)	8 (35%)	16(55%)	134(45%)
Did you use any other products with the medication? N (%)[b]	7 (4%)	3 (4%)	0	0	10(3%)
Have you used any other medication to help you quit smoking since your last interview (yes)? N (%)	18 (11%)	7 (9%)	6 (%)	6 (21%)	37 (12%)
Out of every strategy to help you quit smoking what has been the most useful? N (%)					
Bupropion (Zyban)	107(64%)	1 (1%)	2 (9%)	0	110(37%)
Patch	11 (7%)	56(72%)	3 (13%)	3 (10%)	73 (24%)
None	13 (8%)	7 (9%)	1 (4%)	0	21 (7%)
Lozenge	1 (<1%)	0	0	22(76%)	23 (8%)
Cold Turkey	14 (8%)	3 (4%)	1(4%)	0	18 (6%)
Gum	2 (1%)	1 (1%)	13(57%)	0	16 (5%)
Patch & Gum	0	1 (1%)	1 (4%)	0	2 (1%)
Other	20 (12%)	9 (12%)	2 (9%)	4 (14%)	35 (12%)

a Excluded from the analysis were those participants who had not started the medication.. * $p<0.05$

b Participants were allowed to have more than one answer.

4.3.8. Follow-up Health Status

The reported health status at baseline and follow-up did not change. Very little change was found between the baseline and follow-up surveys for the number of GP visits in the four weeks previous to the survey.

4.4. Discussion

This is the one of the first studies to investigate the use of bupropion and NRTs (patches, gum or lozenge) and to assess field effectiveness. With the help of the Pharmacy Guild of Australia, NDARC were able to involve a number of pharmacies from around Australia to help recruit participants for the smoking cessation survey. While this was a convenient sample it was also opportunistic because pharmacies are in an ideal position to seek interested participants to explore the field effectiveness and to gather valuable information about the use of bupropion and NRTs in Australia.

The results presented in this report provide baseline and follow-up data on the characteristics of smokers who use pharmacotherapies for smoking cessation. Little

difference was found on demographic characteristics among the bupropion and NRT groups.

Nearly the entire sample surveyed smoked daily, smoking on average 169 cigarettes per week at baseline and significantly reducing to 116 cigarettes per week at follow up. The length of time before smoking the first cigarette after waking changed significantly from 24 minutes at baseline to 46 minutes at follow up.

The majority of the sample had previously attempted, on average, to quit smoking three times in the last two years. When exploring the differences between each pharmacotherapy, lozenges were the most frequently used pharmacotherapy for the first time by participants. This is likely to be because they were new to the market at the time of the survey. At the baseline survey, less than half of the sample was currently using bupropion or NRT at the time of the surveys either because they had not yet started, they had quit because of side effects or because they had already stopped smoking.

Over two thirds of the sample was followed up three months after their baseline interview. At the time of the follow up survey, 31% had quit smoking and the remainder were still smoking, the majority daily. Stress and unable to stop smoking were the main reasons for why part of the sample were still smoking.

While the entire sample filled their prescription at their pharmacist who recruited them for the study, less than half completed the full course of the medication. The main reasons for not completing the full course were adverse side effects, stress and couldn't stop smoking. Abnormal dreams and sleep disturbance were the most common side effects. Others included heartburn, hiccups and nausea. Surprisingly, a larger percentage of the lozenge group experienced side effects with the medication however this did not stop them from taking the medication or completing the full course in comparison with the other groups. This is likely due to the severity and type of side effects experienced.

Despite the PBS and RPBS guidelines for bupropion and NRTs respectively, less than one fifth of the sample was recommended by their doctor or pharmacist to use another product or program with their selected medication. Only 11% were advised to use either counselling, Quitline or the ZAP. These results are extremely small considering PBS and

RPBS guidelines for these medications prescribed require an authority and the person is to have entered a comprehensive supportive and counselling program. The low uptake may be due to doctors and pharmacists been too busy or forgetting to inform the person but given the recommendations evidence which suggests these products are more effective as part of a comprehensive program this is very concerning.

The survey provides an opportunistic examination of smokers experience using pharmacotherapies for smoking cessation. The results shed light on patient utilisation of the medication in terms of uptake and completion, possible side effects experienced, and use of adjuncts in conjunction. A better understanding of the use and experience of bupropion and NRTs by smokers enables policy makers to refine and improve the use of such pharmacotherapies. Coupled with a better understanding of prescribing practices, scope exists to improve the field effectiveness of pharmacotherapies as an aid to smoking cessation. The next chapter reviews research that has been conducted to examine prescribing practices.

5. USE OF PHARMACOTHERAPIES FOR THE MANAGEMENT OF NICOTINE DEPENDENCE IN CLINICAL PRACTICE

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This paper has been submitted to *Addiction (2004)* and as such has been reproduced here in its entirety.

5.1. Introduction

Tobacco smoking is the risk factor that is responsible for the greatest burden on the health of Australians(Ridolfo and Stevenson, 2001) as is discussed in Chapter 1. As a consequence of the time lag between exposure to cigarette smoke and the onset of many diseases, many of the tobacco-related illnesses and deaths we are seeing today are a consequence of smoking practices in the past(Ridolfo and Stevenson, 2001). In 1945, the year in which reliable prevalence estimates were first made, rates of smoking in the population were as high as 72% for males and 26% for females. By the early 1960s, although rates of smoking had started to decline, over 50% of all adult males continued to smoke(Winstanley et al., 1995). Today, tobacco is smoked by approximately one quarter of all Australians(AIHW, 2002a). As the demographic profile of the population ages, the onset of smoking related morbidity and mortality has increased significantly with data suggesting that smokers aged 45-64 are three times more likely to die prematurely than lifelong non-smokers of the same age(Murray and Lopez, 1997).

As a consequence of the significant burden of harm caused by smoking, a key strategy goal of the Commonwealth Government is to improve the health of all Australian's by eliminating or reducing their exposure to tobacco in all its forms(QCF, 2001;Commonwealth Department of Health and Aged Care, 1999). To facilitate this objective, a multitude of strategies have been designed, implemented and evaluated. These strategies include: strengthening community action for tobacco control, promoting cessation of tobacco use, reducing the availability and supply of tobacco, regulating tobacco and reducing exposure to environmental tobacco smoke(QCF, 2001;Commonwealth Department of Health and Aged Care, 1999).

Of the range of smoking cessation strategies available, nicotine replacement therapies and bupropion are considered to be the most effective in assisting smokers achieve abstinence(Johnson et al., 2001;Jorenby et al., 1999;Jorenby, 2001). These strategies either replace the nicotine delivered by cigarettes (NRT) or act on central nervous system to reduce the withdrawal symptoms (bupropion) during smoking cessation. Bupropion was listed on the Australian PBS for use within a comprehensive treatment program for nicotine dependence. The supply of bupropion is two authority prescriptions per year with no increased maximum quantity or repeats (Australian Government Department of Health and Ageing, 2004b). Currently, NRTs are not included on the PBS however two brands are listed on the RPBS and are for assisting smokers who have entered a support and counselling program (Australian Government Department of Health and Ageing, 2004b).

As the key providers of primary medical care in Australia, general practitioners are in a strong position to offer treatment advice for tobacco consumption. Such a position is supported by guidelines for preventive activities in general practice. The guidelines suggest that smoking status should be assessed for every patient over the age of 10 years. Patients who smoke, regardless of the amount that they smoke, should be offered, at a minimum, brief advice to stop smoking (National Preventive and Community Medicine Committee of The Royal Australian College of General Practitioners, 2002). Despite empirical evidence on clinical efficacy of smoking cessation strategies, guidelines to suggest GPs should detect and advise smoking patients to abstain, it is important that population health and health improvements resulting from such strategies are monitored. The aim of this research article is to report the results of prescribing of pharmacotherapies for nicotine dependence in Australian general practice.

5.2. Methods

5.2.1. Design and participants

Data were derived from a 10-page, 46-item self-administered questionnaire sent to 2680 Australian doctors. The survey examined characteristics of doctors and their therapeutic preferences in managing patients with either nicotine or alcohol dependence, particularly with respect to the use of pharmacotherapies in these conditions. Data collected from the survey participants comprised demographic and professional information including age and gender, completion of professional training programs and further qualifications,

years worked in clinical practice and type of practice. Questions examining management of patients with nicotine or alcohol dependence related to training in providing an intervention, preferred treatment strategies, prescription of pharmacotherapies, relative effectiveness of pharmacotherapies and advocating adjuncts with prescription of pharmacotherapies. A similar discussion on findings as they pertain to assessment and treatment for alcohol dependence can be found in `Pharmacotherapies for alcohol dependence: social and economic considerations' (Shanahan et al., 2005).

Doctors comprised three specific doctor specialities including general practitioners, psychiatrists and gastroenterologists. These three groups of doctors were identified as being consistent with the opportunity to routinely manage large numbers of patients with nicotine or alcohol dependence. The three specialties were defined by the Health Insurance Commission's (HIC) Derived Major Specialty classification codes and formed a national sample, stratified by both state (and territory) as well as Rural and Remote Metropolitan Area classification (HIC designation of rurality). The seven RRMA groupings were aggregated into the three categories: capital city (RRMA 1), other metropolitan centre (RRMA2) and non-metropolitan (RRMA 3-7).

5.2.2. Selection

In all, there were 16,798 general practitioners, 670 psychiatrists and 82 gastroenterologists regarded as eligible according to criteria described. Of these, all psychiatrists and gastroenterologists were surveyed while only a 10% random sample of doctors categorised as general practitioners, were surveyed. In this latter group, a minimum of 50 doctors in each state and RRMA were surveyed. In total, 2680 surveys were sent to 670 psychiatrists, 82 gastroenterologists and 1,928 general practitioners.

5.2.3. Survey mail out

The survey was developed by the National Drug and Research Centre (NDARC) and piloted with staff associated with both NDARC and the Department of General Practice at the University of Adelaide (Appendix 11). All survey documentation was distributed by the HIC using their stationary and contained a cover letter from the HIC clarifying the process of selection. The project team were provided with de-identified data only. The initial survey was first distributed in March 2003 and sent a subsequent two times to non-responding doctors.

5.2.4. Statistical analysis

The data were initially analysed with the statistical software, Stata release 8.2 2001 (SAS Proprietary Software Release 8.2, 2001). Descriptive and summary statistics, where appropriate, were generated for all questions, by the three specialties. Logistic regression was then undertaken to examine associations (odds ratio) between the two categories of pharmacotherapy (bupropion for nicotine dependence and pharmacotherapies used in the treatment of alcohol dependence), and other variables. Where the overall p-value for univariate models was <0.2 these variables were included in the multivariate model.

5.3. Results

5.3.1. Sample

In all, 2680 surveys were distributed, of which 1291 surveys were returned and considered valid for inclusion in the analysis. A further 113 surveys were excluded where doctors were on leave, had retired from clinical practice or were unable to be contacted. Taking into consideration those 1257 surveys for which no response was received and the 19 doctors declining to participate, the response rate was 48.9% (1310/2680). The specialty-specific response rates were 48%, 48.7% and 43.9% for GPs, psychiatrists and gastroenterologists, respectively.

5.3.2. Comparison between responders and non-responders

A comparison between responding and non-responding doctors using demographic, state and RRMA data provided by the HIC, revealed no differences apart from gender between the two groups. Significantly more female doctors returned a survey when compared with males ($p<0.0001$).

5.3.3. Characteristics of sample

Table 5.1 details the characteristics of the three categories of respondents. The sample, comprised of 71.7% GPs, 25.5% psychiatrists and 2.9% gastroenterologists, was predominately male (68.2%). Gastroenterologists had the largest proportion of males (100%) compared with 79% of psychiatrists and 63% of general practitioners. Mean age of the overall sample was 49 years ± 10.7 SD, being similar across the three specialties. Almost 60% of respondents had been born in Australia with general practitioners having the fewest Australian born respondents (57%), compared with 70% of gastroenterologists and 61% of psychiatrists. Three-quarters of the sample indicated that

they had completed their undergraduate medical training in Australia and this proportion was similar across all specialties except gastroenterology, where the proportion was higher (84%). A higher proportion of gastroenterologists (68%) reported that they were less than 25 years of age upon completion of their undergraduate degree compared with 58% of GPs and 55% of psychiatrists. Two-thirds of GPs practised in a capital city geographic location compared with 83% of psychiatrists and 70% of gastroenterologists. More than 53% of the sample indicated that they had been in clinical practice for more than 20 years, although for the psychiatric specialty this proportion increased to 64%. A third of the sample indicated that their primary practice size included between 3-5 doctors, while 20% of doctors recorded that their practice was solo in nature. The mean number clinical sessions practised per week was 8+/- 3 sessions, comparable across the three specialties.

5.3.4. Prescription of pharmacotherapies for nicotine dependence

Table 5.2 examines the use of pharmacotherapies in treating patients with nicotine dependence. Almost 85% of the overall sample, and of both general practitioners and psychiatrists, indicated that they solicited information about a patient's smoking habit while almost 75% of the sample gave advice on the benefits of smoking cessation. However, little more than 27% of GPs, 19% of gastroenterologists and 8% of psychiatrists had undertaken any form of training associated with the provision of a brief smoking intervention. Even a simple intervention such as the Five A's was recognised by only 4% of GPs and 2% of psychiatrists.

In managing patients with nicotine dependence, general practitioners most frequently advocated counselling by themselves (87%), followed by recommendation of nicotine replacement therapy or NRT (79%). A similar order of preference was advocated by gastroenterologists. Psychiatrists preferentially advocated management with NRT (61 %), followed by counselling with another health professional (54%). Close to 80% of psychiatrists, gastroenterologists and 97% of GPs, had made recommendations of NRT for dealing with nicotine dependence. Of the 96 doctors (7%) who did not support the use of NRT only 1% cited the effectiveness of the pharmacotherapy as reason for not recommending this form of treatment.

Table 5.1: General characteristics of survey sample

Characteristic	GP	Psychiatrist	Gastroenterologist	Total
N (%)	925 (71.7)	329 (25.5)	37 (2.9)	1291 (100)
Male n(%)	583 (63)	261 (79.3)	37 (100)	881 (68.2)
Mean age (SD)	48.21 (10.8)	50.78 (10.3)	50.03 (9.4)	48.92 (10.7)
Country of birth				
Australia	527 (57.0)	201 (61.1)	26 (70.3)	754 (58.4)
Other	389 (42.1)	127 (38.6)	10 (27.0)	526 (40.7)
Country where undergraduate medical training completed n(%)				
Australia	680 (73.5)	252 (76.6)	31 (83.8)	963 (74.5)
Other	237 (25.6)	77 (23.4)	5 (13.5)	319 (24.7)
Age at (undergraduate) graduation n(%)				
≤ 24 years	532 (57.5)	180 (54.7)	25 (67.6)	737 (57.1)
25-34 years	343 (38.1)	140 (42.6)	10 (27.0)	493 (38.2)
≥ 35 years	19 (2.1)	3 (0.9)	0 (0.0)	22 (1.7)
Doctors working in capital city (n/%)	611 (66.1)	272 (82.7)	26 (70.3)	909 (70.4)
Years in clinical practice n(%)				
< 1 year	1 (0.1)	0 (0)	0 (0)	1 (0.1)
1-2 years	2 (0.2)	0 (0)	0 (0)	2 (0.2)
3-5 years	20 (2.2)	9 (2.7)	1 (2.7)	30 (2.3)
6-10 years	102 (11.0)	22 (6.7)	1 (2.7)	125 (9.7)
11-20 years	288 (31.1)	88 (26.7)	15 (40.5)	391 (30.3)
>20 years	499 (53.9)	209 (63.5)	20 (54.1)	728 (56.4)
Mean clinical sessions per week (SD)	8.29 +/- 2.71	8.91 +/- 2.44	8.84 +/- 2.43	8.47 +/- 2.65
Average practice size n(%)				
Solo	142 (15.4)	108 (32.8)	14 (37.8)	264 (20.4)
2 doctors	159 (17.2)	48 (14.6)	8 (21.6)	215 (16.6)
3-5 doctors	362 (39.1)	73 (22.2)	5 (13.5)	44 (3.4)
6-8 doctors	162 (17.5)	46 (14.0)	1 (2.7)	209 (16.2)
> 8 doctors	88 (9.5)	48 (14.6)	8 (21.6)	144 (11.2)

Almost 97% of general practitioners had prescribed bupropion compared with 61% of psychiatrists and 49% of gastroenterologists. Of the 167 doctors who indicated they had not prescribed this pharmacotherapy and providing a reason for not doing so, only 14 (1.3%) indicated that they perceived the treatment was ineffective as a strategy to manage patients with nicotine dependence. Patient request was overwhelmingly the principal reason (89%) cited by both the overall sample, and also by each specialty for prescribing bupropion.

Table 5.2: Pharmacotherapies for nicotine dependence

Characteristic	GP	Psychiatrist	Gastroenterologist	Total
n (%)	925(71.7)	329 (25.5)	37 (2.9)	1291 (100)
Doctors identifying patients smoking habit (n/%)	761(82.3)	273 (82.9)	36 (97.3)	1070 (84.9)
Doctors providing advice on benefits of smoking cessation (n/%)	726(78.5)	195 (59.3)	28 (75.7)	949 (75.3)
Doctors with training in providing a brief smoking intervention (n/%)	251(27.1)	24 (8.2)	7 (18.9)	282 (22.4)
Doctors familiar with 5 As' (n/%)	41 (4.4)	7 (2.1)	0 (0)	48 (3.8)
Doctors preferred Rx in smoking cessation management (n/%)*				
Counselling by GP	802(86.7)	161 (48.9)	25 (67.6)	988 (78.4)
NRT	733(79.2)	201 (61.1)	17 (46)	951 (75.4)
Bupropion	615(66.5)	130 (39.5)	12 (32.4)	757 (60.0)
Quitline	450(48.6)	129 (39.2)	12 (32.4)	591 (46.9)
Counselling by health professional	208(22.5)	178 (54.1)	17 (46)	403 (32.0)
Doctors recommending NRT (n/%)	901(97.4)	251 (76.3)	29 (78.4)	1181 (92.5)
Doctors perceiving NRT not effective (n/%)	7 (0.7)	5 (1.5)	0 (0)	12 (1.0)
Doctors prescribing bupropion (n/%)	895(96.7)	202 (61.4)	18 (48.7)	1115 (93.7)
Doctors perceiving bupropion ineffective (n/%)	3 (0.3)	9 (4.5)	2 (11.1)	14 (1.3)
Patient request cited by doctors as predominant reason for prescribing bupropion (n/%)	813(90.1)	168 (83.2)	14 (77.8)	995 (89.2)
% Main adjuncts advised by doctors with bupropion Rx (n/%)*				
Counselling by GP	748(83.5)	68 (33.7)	8 (44.4)	824 (73.9)
Quitline	520(58.1)	89 (44.1)	9 (50)	618 (55.4)
Literature	428(47.8)	59 (29.2)	6 (33.3)	493 (44.2)
Zyban action plan (ZAP)	350(39.1)	28 (13.9)	3 (16.7)	381 (34.2)
Counselling by other health professional	178(19.9)	133 (65.8)	12 (66.7)	323 (29.0)
NRT	112(12.5)	36 (17.8)	2 (11.1)	150 (13.5)
Doctors perceiving adjuncts improve likelihood of quitting (n/%)	769(85.9)	163 (80.7)	16 (88.9)	948 (85.0)
Doctors perception of most effective adjunct with bupropion (n/%)*				
Counselling by GP	359 (40.1)	25 (12.4)	5 (27.8)	389 (34.9)
Other	182(20.3)	42 (20.8)	2 (11.1)	226 (20.3)
ZAP	83 (9.3)	10 (4.9)	1 (5.6)	94 (8.4)
Quitline	62 (6.9)	14 (6.9)	1 (5.6)	77 (6.9)
Counselling by other health professional	15 (1.7) 20 (2.2)	45 (22.3.)	4 (22.2)	64 (5.7)
NRT	2 (0.2)	15 (7.4)	1 (5.6)	36 (3.2)
Literature		0 (0)	0 (0)	2 (0.2)

* Note that some respondents may have responded to multiple response categories.

As an adjunct to bupropion pharmacotherapy, GPs most frequently advocated counselling by themselves (84 %), followed by referral to Quitline (58%). Both psychiatrists and gastroenterologists more frequently advocated counselling by other health professionals (66% and 67%, respectively), followed by referral to Quitline (44% and 50%, respectively). At least 85% of the three specialties advising the use of adjuncts together with bupropion pharmacotherapy indicated that the implementation of adjuncts increased the probability of a patient relinquishing cigarettes. Both GPs and gastroenterologists recorded that GP counselling was the most effective adjunct to bupropion pharmacotherapy, cited by 40% and 27% of these specialties, respectively. Psychiatrists more preferentially advocated (22%) counselling by another health professional (including themselves), followed by 'other' strategies (20%).

5.3.5. Multivariate analysis

Multivariate analysis was used to examine characteristics of the practitioners on their prescribing patterns for pharmacotherapies for nicotine dependent patients. Multivariate analysis revealed that doctors prescribing bupropion were significantly more likely to be associated with a practice comprising), from South Australia (adjusted OR, 2.62; 95% CI 1.17 to 5.89; p=0.02), have an additional mental health qualification (adjusted OR, 5.52; 95% CI 2.68 to 11.38; p<0.001), be trained in the provision of a brief smoking intervention (adjusted OR, 6.29; 95% CI 1.12 to 35.21; p=0.04), and recommend nicotine replacement therapy (adjusted OR, 10.11; 95% CI 4.26 to 23.99; p<0.001) (Table 5.3). Practices with more than 8 doctors were less likely to prescribe bupropion (adjusted OR, 0.28; 95% CI 0.08 to 0.97; p=0.05) than solo practices.

Table 5.3: Multivariate associations between pharmacotherapy prescription for nicotine dependence and selected variables

Variable		Odds ratio (95% CI)	SE	P-value
Gender	Male	1.00 (reference)	-	-
	Female	0.92 (0.40 to 2.12)	0.39	0.85
Age		0.97 (0.94 to 1.00)	0.015	0.08
Clinical sessions worked in average week		0.98 (0.95 to 1.01)	0.02	0.19
Practice size (doctors)	Solo	1.00	-	-
	2 doctors	0.75 (0.22 to 2.54)	0.47	0.64
	3-5 doctors	0.85 (0.28 to 2.60)	0.48	0.77
	6-8 doctors	0.50 (0.16 to 1.58)	0.29	0.24
	> 8 doctors	0.28 (0.08 to 0.97)	0.18	0.05
Doctor state origin	NSW	1.00	-	-
	NT	1.02 (0.22 to 4.76)	0.80	0.98
	Vic	0.84 (0.33 to 2.15)	0.40	0.72
	QLD	0.88 (0.29 to 2.68)	0.498	0.82
	SA	2.62 (1.17 to 5.89)	1.08	0.02
	WA	1.51 (0.23 to 9.92)	1.45	0.67
	ACT	0.39 (0.38 to 4.05)	0.47	0.43
Additional mental health qualification				
	No	1.00	-	-
	Yes	5.52 (2.68 to 11.38)	2.04	<0.001
Establishing patient smoking status	No	1.00	-	-
	Yes	1.88 (0.63 to 5.62)	1.05	0.26
Provision of advice on benefits of smoking cessation	No	1.00	-	-
	Yes	0.81 (0.38 to 1.74)	0.32	0.59
Training in provision of brief smoking intervention to patients	No	1.00	-	-
	Yes	6.29 (1.12 to 35.21)	5.52	0.04
Smoking cessation as a preventive priority	No	1.00	-	-
	Yes	0.87 (0.71 to 1.07)	0.09	0.18
Recommendation of nicotine replacement therapy in treatment of nicotine dependence	No	1.00	-	-
	Yes	10.11 (4.26 to 23.99)	4.45	<0.001
Effectiveness of bupropion in smoking cessation	Effective	1.00	-	-
	Not effective	0.54 (0.33 to 0.88)	0.14	0.01

5.4. Discussion

This is the one of the first studies to investigate practitioners' behaviours associated with the use of pharmacotherapies for nicotine dependence. With assistance from the HIC a total of 1,291 prescribers completed the survey representing an overall response rate of 49%. However before the main findings of this study are discussed, several limitations need to be raised. First, results were procured from a self-administered questionnaire distributed by the HIC. Self-administered surveys are prone to poor completion rates and biases in reporting of activities. Although this survey obtained a response rate of 50%, the influence that running the survey through the HIC had on reporting behaviour is difficult to judge. As the HIC reimburses prescribers of pharmacotherapies it is feasible to speculate that the behaviours of prescribing may have been portrayed in a favourable light. Second, as only a 10% random sample of doctors categorised as general practitioners were surveyed and hence may not reflect overall prescribing behaviour in the population of general practitioners. Also as this is a survey of practitioners the characteristics of their patients are unknown; for example some practitioners may have a larger number of their clients who are nicotine dependent and this may affect their prescribing behaviours.

Recent guidelines for preventive activities in general practice suggest that practitioners should establish smoking status for every patient over the age of 10 years. Findings from our research suggest that 85% of respondents asked patients' about their smoking status however, we don't know if they ask all patients.

The finding from this research that almost 75% of the sample gave advice on the benefits of smoking cessation is generally consistent with the guidelines for preventive activities in general practice that suggest, for patients who smoke, regardless of the amount that they smoke, should be offered, at a minimum, brief advice to stop smoking (National Preventive and Community Medicine Committee of The Royal Australian College of General Practitioners, 2002). For a smoker, the process of quitting is often a long and arduous one. Prochasta and DiClemente have defined the stages of change as: pre-contemplation, during which time the smoker is not thinking about quitting; contemplation, during which period the smoker seriously considers quitting smoking; action, commencing with actual cessation; maintenance, the process of sustaining abstinence; and, termination of smoking behaviour

or relapse into smoking behaviour (Prochaska and DiClemente, 1983). A quitting smoker may cycle through each stage a number of times before successfully quitting. It is therefore important that as well as detecting a patients smoking status the practitioner is able to provide advice consistent with the preparedness of the smoker to quit. However, the results of this research suggest that practitioners may not have the adequate training to provide the necessary and relevant advice with only 22% of the sample indicating that they had undertaken formal training in providing a brief smoking intervention. Further, only 4% of the overall sample was familiar with the 5 As', the corner stone of a successful smoking cessation strategy.

The prescription of pharmacotherapies for nicotine dependence is, in accordance with the products listing, for motivated quitters although GPs may use the discussion of the pharmacotherapies to motivate smokers to quit. Results from the multivariate analysis suggests that those practitioners that had undergone additional training in the provision of a brief smoking intervention were more likely to recommend a pharmacotherapy, and in particular, nicotine replacement therapy. It is reasonable to speculate that those practitioners better equipped to provide advice with nicotine dependence may be in a better position to ascertain the preparedness of smokers to quit and hence the likelihood that the use of a pharmacotherapy is appropriate.

The requirements for prescribing bupropion stipulate that the patient must have entered a comprehensive support and counselling program (Australian Government Department of Health and Ageing, 2004a). Although no clear parameters of a formal support program are outlined, the main adjuncts used with bupropion in this sample were counselling by GP (74%), Quitline (55%), literature (44%) and the Zyban action plan (34%). Further at least 86% of the three specialties advising the use of adjuncts together with bupropion pharmacotherapy, indicated that the implementation of adjuncts increased the probability of a patient relinquishing cigarettes with GP counselling perceived to be the most effective adjunct to bupropion pharmacotherapy. An interesting policy question arising from this finding is whether GP counselling does in fact meet the criteria of a comprehensive treatment program. Perhaps if the majority of practitioners were better equipped to deal with nicotine dependence the effectiveness of this type of adjunct would improve.

The results from this research provide useful information into the prescribing of pharmacotherapies for nicotine dependence in Australian general practice. Given that practitioners are in a strong position to offer treatment advice for tobacco consumption, a position that is supported by guidelines for preventive activities in general practice, the prescribing practices and underlying behaviours are important. By addressing particular issues raised from this research, scope exists to improve the appropriateness and effectiveness of pharmacotherapies for nicotine dependence.

6. SMOKING STATUS OF GENERAL PRACTICE PATIENTS AND THEIR ATTEMPTS TO QUIT

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6.1. Introduction

As discussed in Chapter 1, smoking is responsible for considerable health, social and economic burdens. As a consequence of these harms caused by smoking, a key strategy goal of government agencies is to improve the health of all Australian's by eliminating or reducing their exposure to tobacco in all its forms (Commonwealth Department of Health and Aged Care, 1999). To facilitate this objective, a number of strategies have been designed, implemented and evaluated including: strengthening community action for tobacco control, promoting cessation of tobacco use, reducing the availability and supply of tobacco, regulating tobacco and reducing exposure to environmental tobacco smoke (Commonwealth Department of Health and Aged Care, 1999).

Evidence from the Cochrane Tobacco Addition Review group has demonstrated that, in order of effectiveness, antidepressants, in particular bupropion (OR=2.73), (Hughes et al., 2003b) nicotine replacement therapies (OR=1.73), (Silagy et al., 2003) individual behavioural counselling provided by a physician (OR=1.69), (Silagy and Stead, 2003;Stead and Lancaster, 2003b) individual behavioural counselling provided by a specialist counsellor (OR=1.55) (Lancaster and Stead, 2003) and self-help materials such as written materials (OR=1.23) are significantly more effective than placebo in achieving continued abstinence. The review by Hughes et al. also found that combined bupropion and nicotine patch appeared to be more efficacious than nicotine patch alone (OR=2.65) but no more efficacious than bupropion alone (Hughes et al., 2003b).

Despite evidence on the effectiveness of various tobacco control strategies, research has demonstrated that smokers differ in their readiness and ability to quit smoking (US Department of Health and Human Services, 1989). For a smoker, the process of quitting is often long and arduous. Prochaska and DiClemente have developed a stage of change

model describing the stages a smoker passes through to achieve smoking cessation. These stages are pre-contemplation, contemplation, action, maintenance and termination of smoking behaviour or relapse (Prochaska and DiClemente, 1983). A quitting smoker may cycle through each stage a number of times before successfully quitting. While most smokers would like to quit, (COMMIT Research Group, 1995) only a minority of motivated smokers (10%) achieve permanent abstinence in an initial quit attempt, with the majority continuing to smoke for many years and typically cycle through multiple periods of relapse and remission (The Tobacco Use and Dependence Clinical Practice Guidelines Panel Staff and Consortium Representatives, 2000). Evidence suggests that the cycle of repeated quit attempts and relapse is an important skill building process for successful long-term abstinence (Gritz et al., 1998).

The vast majority of former smokers attribute their success to quitting on their own (i.e. cold turkey) (Fiore et al., 1990). In a study by Fiore et al (1990) up to 88% of successful quitters had used cold turkey during their last quit attempt while only 8% used some form of assisted strategy (i.e., some type of program, hypnosis, acupuncture or gum) (Fiore et al., 1990). However, as indicated above, successful quitters make numerous prior quit attempts and may have already tried a variety of methods to help them stop smoking (Prochazka, 2000). Further, evidence suggests that it is motivated smokers that are generally successful in quitting unaided (Fiore et al., 2002). In general, when motivated smokers try to quit on their own, the self quitting rate ranges from approximately 7-14% (Fiore et al., 2002;Baillie et al., 1995a;Cohen et al., 1989). When smokers engage in other strategies such as counselling, nicotine replacement therapies or other pharmacological aids, success rates can be as high as 33% (Lancaster et al., 2000b).

Despite empirical evidence on clinical efficacy of smoking cessation strategies, it is important that population health and health improvements resulting from such strategies are monitored. Given that 85% of the population visit a GP in any given year (Britt et al., 2003), general practice provides a suitable basis to monitor many aspects of population health. The aim of this paper is to describe smoking rates, quit attempts made by smokers, methods used and success-rates among adult patients attending Australian general practice. The findings are considered in the context of the smoking cessation literature.

6.2. Method

This study was based on data from the "Bettering the Evaluation and Care of Health" (BEACH) program, a national study of general practice in Australia; in particular, a sub-set of BEACH data called SAND (Supplementary Analysis of Nominated Data) focusing on smoking rates of adult patients and their quit attempts collected during February and March 2002 and March 2003. The method is described fully elsewhere (Britt et al., 2003). Briefly, BEACH is an ongoing cross-sectional survey of general practice activity in Australia, enrolling about 1,000 randomly selected GPs each year. These GPs each provide details on 100 general practice encounters including patient characteristics, problems managed and treatments recommended. SAND collects additional data on other aspects of patient health or health care delivery not covered in the consultation-based information.

6.2.1. Smoking cessation SAND

Adult patients attending general practice were asked to indicate which of five statements describes their smoking status (Appendix 12). A list of 12 quit methods was provided (Appendix 12), including cold turkey, nicotine patches and bupropion. These analyses define current smokers as all patients who were current daily or current occasional smokers, and former smokers as all patients who were former daily or former occasional smokers. Former smokers were asked how long since they last smoked, and which of the twelve-method/s they had used to successfully quit. Current smokers were asked to indicate if they had attempted to quit during the last 5 years, and if so how long ago and the quit method/s used at their last attempt. Both current and former smokers were asked to indicate all methods used at their last/final-quit attempt.

6.2.2. Statistical methods

Proportion of sample and 95% CIs (adjusted for the design effect of the cluster (GP) sample) is reported. SAS v8.2 software was used for analysis (SAS Proprietary Software Release 8.2, 2001). A success-rate was calculated for each quit method by dividing number of successful patients (former smokers) by total number of patients attempting to quit (former plus current) using that method. A current smoker who tried to quit during the past five years was not successful as they were still current smokers, but a former smoker was successful at their final quit attempt.

6.2.3. Ethics

Ethics committees of the University of Sydney and Australian Institute of Health and Welfare approved the study.

6.3. Results

Characteristics of the sample are provided in Table 6.1. The patient age and sex distributions of this SAND sample were not significantly different to the age sex distribution for all BEACH encounters with patients aged 18 or more for the time period under study (Table 6.1).

Table 6.1: Patient characteristics

	Sample under analysis			Sample drawn from		
	SAND			BEACH:		
Patient age-group	Feb-Mar02 and Mar03			Jan-Mar02 and Jan-Mar03		
	N=8,333	**%**	**95%CI**	**N=43,380**	**%**	**95%CI**
18-24 years	712	8.6%	(7.6-9.6)	3,753	8.7%	(8.0-9.3)
25-44 years	2,532	30.5%	(28.9-32.2)	12,921	29.8%	(28.6-30.9)
45-64 years	2,559	30.5%	(29.6-32.1)	13,487	31.1%	(30.4-31.8)
65-74 years	1,185	14.3%	(13.2-15.4)	6,207	14.3%	(13.7-15.0)
75+ years	1,304	15.7%	(14.2-17.3)	7,012	16.2%	(15.0-17.3)
Missing	41			-	-	
Patient sex						
Male	3,008	36.4%	(34.6-38.1)	15,879	36.9%	(35.5-38.2)
Female	5,267	63.6%	(61.9-65.4)	27,186	63.1%	(61.8-64.8)
Missing	58			315	-	

The smoking status/cessation questions were asked at 8,435 general practice encounters with adult (18+) patients. Smoking status was given at 8,333 (98.8%) encounters with 328 GPs. Approximately one in five (21.5%; 95%CI: 20.1-22.9) adult general practice patients were current smokers, and over a quarter (27.3%; 95%CI: 26.0-28.7) were former smokers. The majority of patients (51.1%) however had never smoked (Table 6.2). As indicated in Table 6.2, the overall profile of smoking status in this study is comparable to that of adult Australians reported by the 2001 National Drug Strategy Household survey (AIHW, 2002b). Further, these estimates are consistent with the total BEACH 2002-03 sub-sample (n = 32,651) where the results were: current smoker 21.3%, former 27.2% and never smoked 51.4% (Britt et al., 2003).

Table 6.2: Smoking profile of adult general practice patients compared to 2001 National Drug Strategy Household survey

Status	BEACH (SAND): 2002-03			2001 National Drug Strategy Household Survey
	N=8,333	Per cent	95% CI	
Current smoker	1,794	21.5%	(20.1-22.9)	23.1%
Former smoker	2,278	27.3%	(26.0-28.7)	26.2%
Never smoked	4,261	51.1%	(49.4-52.9)	50.6%

The average time since last smoking for all former smokers (N=2,247) was 180 months. For younger smokers (patients aged 18-24 years) mean quitting time was 16 months ago compared with 290 months for the older smokers (aged 75+). One in two current smokers (53.9%; 95%CI: 50.7-57.0) had attempted to quit during the past 5 years with the mean time since last quit attempt at 13 months. The mean time since last quit attempt by current smoker varied by age group; the shortest time since quitting in the 18-24 year age group (9 months) and the longest in the 65 or older age-group (16 months).

Table 6.3 provides detail on the main smoking cessation method/s used at the last quit attempt. Of the 2, 207 former smokers indicating the last quit method/s used, 92% used only one method, and a further 6% used two methods. A lower proportion of current smokers (80%) had tried only one quit method at their last quit attempt with 11% using two methods. Cold turkey was the most common method used by both former (88%) and current (62%) smokers at their last quit attempt, followed by nicotine patches used by 7% of former and 28% of current smokers.

In order of effectiveness, for all former smokers, most success in smoking cessation attempts occurred with cold turkey (77%), other medications (70%) and "other (unspecified) methods" (70%). Bupropion was the least successful strategy with 23% of patients using this method to successfully quitting.

However, since the time to quitting for all former smokers was 180 months (15 years), these results are not very informative for the current situation. For example, Bupropion has only been available by private prescription since November 2000 and available by government subsidy since February 2001; NRT was not widely available 10 to 15 years ago; and further, the historical recall of quit smoking manuals, Quit lines and GP advice as smoking cessation aids may be unreliable. The data was re-examined to account for these

issues. Re-examination involved limiting quit attempts from February 2001 onwards, i.e., data from smokers who had attempted to quit post-bupropion listing, using any strategy, were included in the re-analysis.

The data from one year are in Table 6.3. The results are noticeably different although the numbers are small for six of the quit methods and their rates should be considered unreliable (those shaded in Table 6.3). For a sample of 358 former smokers, and 672 current smokers the success rates are in order of effectiveness: other methods (41%), cold turkey (40%) and GP support (39%). The success rate for bupropion and NRTs were 21% and 20%, respectively.

Table 6.3: Smoking cessation method used at last attempt and success rate

Quit method	All Data						February 2001 onwards[4]					
	Former Smokers N=2,207		Current Smokers[1] N=928		Success Rate		Former Smokers N=358		Current Smokers[1] N=672		Success Rate	
	n	%[2]	n	%[2]	%	95% CI	N	%[2]	n	%[2]	%	95% CI
Cold turkey	1,942	88.0	575	62.0	77.2	75.0-79.3	269	75.1	400	59.5	40.2	36.3-44.1
Nicotine patches	145	6.6	259	27.9	35.9	30.9-40.9	52	14.5	190	28.3	21.5	16.2-26.8
Nicotine gum	52	2.4	93	10.0	35.9	27.2-44.6	8	2.2	62	9.2	11.4	3.0-19.9
Nicotine inhaler	12	0.5	22	2.4	35.3	16.6-54.0	4	1.1	14	2.1	22.2	1.0-43.5
Hypnotherapy	31	1.4	27	2.9	53.5	38.7-68.2	5	1.4	23	3.4	17.9	2.3-33.5
Herbal preparations	12	0.5	7	0.8	63.2	44.2-82.2	2	0.6	6	0.9	25.0	0.0-67.1
SmokeStop/Quitline	19	0.9	24	2.6	44.2	29.0-59.4	5	1.4	21	3.1	19.2	3.6-34.9
Bupropion	36	1.6	122	13.2	22.8	16.5-29.1	30	8.4	114	17.0	20.8	14.4-27.3
Other medications	7	0.3	3	0.3	70.0	33.1-100.0	1	0.3	3	0.5	25.0	0-100
Quit smoking manual	48	2.2	34	3.7	58.5	45.4-71.7	13	3.6	26	3.9	33.3	18.0-48.7
GP support	71	3.2	47	5.1	60.2	50.4-69.9	23	6.4	36	5.4	39.0	25.4-52.6
Other methods	81	3.7	35	3.8	69.8	60.1-79.5	21	5.9	30	4.5	41.2	24.9-57.5
Nicotine Replacement Therapy[3]	190	8.6	322	34.7	37.1	32.6-41.6	58	16.2	228	33.9	20.3	15.5-25.1

Shading means that RSE>33 therefore unreliable estimate (due to small sample size)

1 = Includes only current smokers that have attempted to quit during the previous 5 years

2 = Percentages do not add to 100 as multiple responses allowed

3 = Nicotine Replacement Therapy (NRT) includes nicotine patch, gum or inhaler. Some patients used more than one nicotine product, so individual N's do not add to total for NRT

4 = Post bupropion listing

6.4. Conclusion

Before consideration is given to the primary findings and policy recommendations a number of caveats require attention. First, although the BEACH sample may be representative of patients encountered in general practice, it may not be representative of the population as a whole or for that matter the population of smokers attending general practice. Second, the specific nature of the SAND smoking analysis imposes constraints on the number and type of questions asked. For example, the SAND smoking questions, while providing a useful indication of smoking status among general practice patients' do not adequately capture the process of smoking cessation or the numerous quit attempts usually made by smokers. Further, the particular focus on methods used in the most recent quit attempt may not be an adequate representation of all possible smoking cessation methods used by that smoker. Third, the reliability of the success rate used in this analysis is contentious. The magnitude of former smokers in the denominator may bias the results towards self-help methods such as cold turkey. Such a bias may also be reinforced by a smoker's recollection of the last quit method used given that, for former smokers, the average time since last quit attempt was 180 months and over 7% of former smokers and 20.3% current smokers who indicated using cold turkey as a quit method also indicated using another method/s. To a certain extent, this bias is minimized when success rates are limited to quit attempts from February 2001 onwards but the degree of variability in all but one of these methods (bupropion) as a consequence of the re-analysis is evidence that the success rate measure may not be stable.

In spite of potential limitations, these data provide a useful indication of smoking rates, quit attempt methods and success rates among adult Australian patients seen in general practice. Rates of smoking (21.5% current smokers) were consistent with the prevalence of smoking in the general population (23.1% current smokers). In their last quit attempt, 92% of former smokers and 80% of current smokers used only one method to aid cessation with cold turkey the most common method used by both former (88%) and current (62%) smokers. Success rates of strategies varied from 77% for cold turkey to 23% for bupropion. To improve the reliability and comparability of success rates these data were re-analysed to take into account the bupropion listing in February 2001. As a consequence of this re-analysis the success rates for cold turkey was reduced to 40% while bupropion remained reasonably constant at 21%.

While not capturing the true extent of the natural history of smoking cessation and the fact that smokers generally engage in multiple strategies to assist cessation over numerous attempt, the finding that the majority of smokers used cold turkey in their last quit attempt is consistent with previous research (Fiore et al., 1990;Baillie et al., 1995b). However, the finding of a 40% success rate (post February 2001) with cold turkey is inconsistent with the literature. It is also implausible; if 40% of smokers who attempt to stop each year were successful we would not have any smokers left. Research from the Cochrane library has demonstrated that bupropion is the most effective cessation therapy available in Australia (OR=2.73) (Hughes et al., 2003b) and significantly more effective than placebo in achieving continued abstinence. According to the survey data presented here, the effectiveness of bupropion in aiding smoking cessation (23%) is reasonably consistent with clinical efficacy.

In spite of the potential shortcomings of this research, these findings have important implications for GPs who are currently encouraged to assess nicotine dependence in their patients. While it may be reasonable for the GP to promote cold turkey as a viable smoking cessation strategy for motivated quitters, for those who cannot quit unassisted or for those that fail at cold turkey, medications such as bupropion and NRT should still be regarded as first line treatment options. GP can play an important role in helping their patients to stop smoking and by better tailoring the smoking cessation strategy to a smokers' preparedness to quit, significant reduction in the prevalence of smoking are possible.

7. THE COST EFFECTIVENESS OF PHARMACOTHERAPIES FOR SMOKING CESSATION: NECESSARY BUT NOT SUFFICIENT?

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7.1. Introduction

More than one-fifth of the Australian population aged 14 years and over smoke daily (AIHW, 2002a) resulting in significant health, social and economic consequences: 142,525 hospital episodes; 19,019 deaths; and 184,579 potential years of life lost in 1998 (Ridolfo and Stevenson, 2001). Collins and Lapsley (2002) estimated the total economic costs of tobacco smoking in 1998-99 to be $21.01 billion with 45% of these costs being potentially avoidable (Collins and Lapsley, 2002).

Due to an increased awareness of these negative health effects, additional strategies have been introduced to reduce the prevalence and uptake of tobacco smoking in Australia. These strategies include legislative changes, increases in tobacco taxes and anti-smoking campaigns (Applied Economics, 2003)which combined, have led to more smokers quitting (Higgins et al., 2000;Applied Economics, 2003). In recent years, there has also been an increase in the use of pharmacotherapies to assist with smoking cessation. These appear to result in higher quit rates than counselling alone (Jorenby et al., 1999;Silagy et al., 2001;Silagy et al., 2003;Hays et al., 2001)or unassisted attempts to quit (Baillie et al., 1995b). However, the available evidence suggests that individuals wishing to quit smoking may not be making economically rational choices regarding purchasing smoking cessation pharmacotherapies. Evidence for this apparent lack of rationality is presented here, and a number of potential explanations for this observation will be discussed.

Until recently, NRTs, such as patches, gums, or inhalers were the only form of pharmacotherapies available in Australia. In February 2001, the anti-depressant

medication, bupropion, was listed on the Australian PBS and the Australian RPBS, which means that its purchase is subsidised. Bupropion is a sustained-release therapy to assist with smoking cessation. The only NRTs that are currently listed for subsidies are NRT patches, with this subsidy limited to war veterans through the RPBS (not available on the PBS). The decision to list bupropion was based on its relative cost effectiveness compared to alternatives (PBAC, 2000). While the cost effectiveness data on which this decision was based remain commercial-in-confidence, it is possible to estimate the costs and effectiveness of providing pharmacotherapies using published literature.

7.2. Costs and effects: government perspective

As illustrated in Table 7.1, the cost of providing the recommended 9-weeks of bupropion treatment for one person is approximately $263. This includes the cost of the medication (Commonwealth Department of Health and Ageing, 2003) and the one required visit to the general practitioner (GP) (Commnwealth Department of Health and Ageing, 2002). It is useful to make comparison between patches and bupropion (which is generally available on the PBS). The cost to the government of providing Nicabate® patches (one of two types of NRT patches included on the RPBS) for 12 -16 weeks (the recommended treatment period) for one person is approximately $444 (12 weeks) to $569 (16 weeks). Detailed costs for 12 weeks are provided in the second row of Table 7.1, and include the cost of the medication and three visits to the general practitioner (Health Insurance Commission, 2003;Commonwealth Department of Health and Ageing, 2003). If patches are obtained through the RPBS, multiple prescriptions are required from the GP. However, if they are obtained over-the-counter (OTC), the patient pays the full cost and no prescription is required.

Table 7.1: Costs and effects

Pharmacotherapy	Abstinence at 12 mos	Cost to government			Cost to individual		
		Med	GP visit	Total cost	Med	GP visit	Total cost
Bupropion*	21 to 35%	$238.89	$24.45	$263.34	$23.10	$5.66	$28.76
Nicabate® (RPBS)**	14% to 21 %	$371.38	$73.35	$444.43	$18.50	$16.98	$35.48
Nicabate® (OTC***)		-	-	-	$396.00	-	$396.00

* 9 weeks of treatment, **12 weeks, 3, GP visits, 5 prescriptions filled, ***OTC – over-the-counter, 12 weeks at $33/ week

Reported abstinence rates for bupropion range from 21% to 35% at twelve months (Jorenby et al., 1999;Hurt et al., 1997;Hays et al., 2001;Ahluwalia et al., 2002)in comparison to 14% - 21% for patches (Silagy et al., 2003). These costs and outcomes suggest that bupropion is the most cost effective option, being both more effective and less expensive.

7.3. Costs: smokers' perspective

Although patches are not available on the PBS for the general population, they are available OTC at $30 - $35 for a seven-day supply. The cost to the individual for the full-recommended period of 12 - 16 weeks would be $396 to $560. (Costs for 12 weeks at the OTC cost of $33 per seven days are found in the last row of Table 6.1). For bupropion, the PBS subsidised cost for an individual seven week course of treatment would be $23.10, plus a fee of $5.66 (on average) over and above the Medicare Benefit Schedule payment for a GP visit (Health Insurance Commission, 2002). So, for the individual, over-the-counter NRT patches are 13-19 times *more* expensive than bupropion via the PBS, with the latter being more effective, as discussed in the section above.

7.4. Implications

Given that bupropion appears more cost effective than NRTs, both for government and for the individual, a decline in demand for NRTs after the PBS listing of bupropion could have been anticipated. However, for the year from February 2001, OTC sales of NRTs actually increased by 4.15% (Reed Business Information, 2002)despite a government expenditure on bupropion of A$83 million (Health Insurance Commission, 2003). This may be due to an overall growth in the demand for smoking cessation products.

A closer examination of the monthly expenditure on bupropion from February to December 2001 (Health Insurance Commission, 2003), however, indicates a gradual decline since its listing. While it may not be surprising to see a reduction in demand for a new medication after its listing, the sustained decline in demand is of concern, given bupropion's apparent greater cost-effectiveness. This suggests that some individuals using NRTs to quit smoking are making economically irrational choices in that they are

choosing to pay 13 - 19 times more for a less effective medication. This raises a range of issues for clinicians, health economists and policy makers.

There are a number of possible explanations that may exist for this apparent lack of rationality. One may be that the cursory analysis of costs and outcomes presented here do not reflect the results from the actual, commercial-in-confidence CEA (cost-effectiveness analysis). For example, if the individuals' opportunity cost of time were included, the results might have been quite different. Time required for bupropion included time to make an appointment (5 minutes) and visit to the GP (1 hour including travel) compared to time to purchase an OTC medication (5 minutes plus travel). The difference in time may be quite important for some individuals.

A second explanation may be that the outcome measures are not from Australian-based field effectiveness studies, but derived from randomised controlled trials conducted in the United States. As such, the extent to which the results are generalisable to the Australian context is uncertain. This may be important, given anecdotal comments by clinicians and patients in Australia that their perception of the frequency and severity of the side effects may deter them from prescribing or taking this medication. Alternatively, use of an outcome measure such as abstinence may not reflect the choices being made. People wanting to quit smoking may use bupropion, whereas NRTs may be used as a substitute for smoking, given, for example, increased restrictions on smoking in public spaces in Australia.

A third explanation is that a CEA may not adequately capture all important factors. For example, an individual's revealed preferences may be influenced by the need to obtain a prescription for bupropion. This may 'medicalise' the decision to quit smoking to such a degree that individuals actually prefer to pay the higher cost for NRTs. Another factor not captured by CEA is the different awareness of the public and general practitioners relative to intensely advertised NRTs.

While it is beyond the scope of this paper to address these specific issues, their importance is reflected in the apparent trend away from bupropion. Current information suggests that policy-makers, those wanting improved smoking cessation rates, and smokers themselves may be making economically irrational choices. Although such

choices are not limited to smoking cessation products, the ongoing harm from smoking, plus the millions of dollars spent each year to assist with smoking cessation, suggests a need for methodologically rigorous data. One place to start might be to conduct economic evaluations in Australia examining the cost effectiveness of NRTs and bupropion using field effectiveness data. The results of the cost effectiveness analysis ought to be complemented by analyses of consumers' and medical practitioners' preferences, to ensure that relevant determinants of choice for smoking cessation products are identified and quantified.

8. COST AND EFFECTS OF VARIOUS STRATEGIES FOR SMOKING CESSATION

James Shearer and Marian Shanahan

8.1. Introduction

Twenty-three percent of Australians aged 14 years and older smoke, with 19.5% reporting smoking on a daily basis in 2001 (AIHW, 2002a). Thirty-one percent of Australian smokers reported an unsuccessful quit attempt in the previous year. Nineteen percent reported switching to lower tar or nicotine content cigarettes (male 17.3%, female 21.6%) although a recent major study has shown that the risk of lung cancer did not vary between very low, low and medium tar filter cigarettes (Harris et al., 2004). In the 1998 UK General Household Survey, 27% of adults smoked and 70% reported wanting to quit. In the US, 46.4% of smokers reported a serious attempt to quit in the year prior to the US 1994 National Health Interview Supplement but only 5.7% of smokers successfully abstained from smoking for a period of 1 month or more and only 2.5% achieved an abstinence of 1 year (Song et al., 2002).

In light of the burden of harm due to tobacco (Chapter 1), determining effective and cost effective methods for assisting with smoking cessation is important. There are two questions often asked and answered with respect to smoking cessation: are the economic benefits greater than the economic costs of providing a given treatment, and is the treatment cost offset by savings to the health care system? The answers to these questions are clear. There exists a body of literature which demonstrates that smoking cessation strategies are the most cost beneficial interventions in health care (Eddy, 1992). Other studies support this conclusion. For example, Parrott et al. (1998) reviewing the British guidelines on the cost effectiveness of smoking cessation interventions, confirmed that even the most costly interventions for smoking cessation were considerably more cost-effective per life-year gained than the average of 300 other medical interventions. They recommended the implementation of smoking cessation interventions as a core health service (Parrott et al., 1998). Cromwell et al. (1997) also contrasted the cost effectiveness of smoking cessation interventions favourably with other preventative strategies, including cervical cancer screening in older women, pneumonia vaccination for the elderly, hypertension screening in men aged over 40 years and annual mammography in women aged 40-49 years (Cromwell et al., 1997). Croghan

et al. (1997) examined cost and outcome data for a cohort of 5,544 patients who attended a non-physician counsellor-led nicotine dependence treatment plan which included individually tailored follow up, NRT, group therapy and programs directed to hospital inpatients (Croghan et al., 1997). They estimated the cost per net year of life saved at US$6,828 (1993 dollars), which compared favourably with other medical services.

While it is clear that smoking cessation assistance is cost beneficial there is, however, debate about which interventions are the most cost effective and whether there is any difference across provider type and setting (i.e. group counselling, general practitioner, etc.). The reader is referred to Chapter 2 for a review of the economic literature on treatment. A review by Warner found that while more intensive smoking cessation interventions were more effective than less intensive ones, the associated costs increased faster than effectiveness (Warner, 1997). Thus, the least intensive interventions, including self-help manuals and brief advice, were more cost-effective than more intensive interventions including NRT patches and gum. In contrast, Cromwell et al. (1997) found the nicotine patch more cost-effective than less intensive approaches. One might argue if all interventions for assisting with smoking cessation fall within the 'gold standard' of health care cost effectiveness, then all smoking cessation interventions that increase the probability of smokers quitting should be provided. Given limited societal resources, we are interested in whether one program is more cost-effective than another. Here, the interest is in the opportunity cost of a given intervention, i.e. what is forgone by the provision of one type of intervention over another? A particular question of interest is when pharmacotherapies (bupropion or NRT) are provided with counselling (as is often analysed in the literature), are they more or less cost effective than without counselling? This is an important question to answer given the anecdotal reports, and evidence from observational and opportunistic studies (Chapter 4) that currently in Australia there is a very small proportion of users of NRT or bupropion who are actually receiving any counselling (Zwar et al., 2002;Paul et al., 2003).

The purpose of this chapter is to:

- identify effective evidence-based interventions to assist smoking cessation;
- synthesize the most recent effectiveness evidence on interventions to assist smoking cessation;

- estimate the relative cost effectiveness of various interventions for assisting with smoking cessation in the Australian context; and
- provide some credible estimate of the costs faced by government in supporting smoking cessation interventions.

8.2. Methods

8.2.1. Modelling

Currently available information comparing the costs and cost effectiveness of various interventions to assist with smoking cessation are limited, and to our knowledge, there is little or no data available in the Australian context. Therefore, one way forward is to use a modelling exercise to pool together what is known (from the Australian and the international literature) in terms of effectiveness, with the NHMRC guidelines for smoking cessation in Australia and estimates of costs of those interventions. Prior to discussing the data used in the model it is worth describing modelling, the methods, and the benefits of using this method of economic analysis.

What is decision-modelling and why use it?

Modelling, whether descriptive or predictive in aim, essentially provides a method for integrating information about the policy or clinical choices to be made, known or estimated epidemiological data about disease processes, and the costs and effectiveness of alternative interventions. Models are often used in economic evaluations when valid and reliable empirical data (e.g. from randomised controlled trials) on costs, the epidemiology of disease, or screening/treatment effectiveness are not available for each alternative intervention, or when the relationship between costs and effects needs to be estimated under different assumptions (O'Malley, 1997;Claxton et al., 2002). Moreover, even where good quality trial data exist, modelling is usually required to extrapolate the empirically demonstrated short-term effects, or to predict any longer-term outcomes of interest such as reductions in morbidity or mortality.

What did we do?

In this chapter the data from international studies was reviewed to determine which smoking cessation interventions should be included. Effectiveness estimates were then derived from the literature review. Resource use for each intervention was derived from a review of the literature and Australian guidelines and practice. Australian cost data

were applied to the resource estimates and finally cost and effects were assessed using incremental cost effectiveness and sensitivity analysis.

8.2.2. Effectiveness of smoking cessation interventions

Search strategy

The literature search strategy began with identifying relevant systematic reviews of clinical and cost effectiveness of interventions for smoking cessation. The literature review benefited from updated reviews undertaken by the Cochrane Tobacco Addiction Review Group, a recent Health Technology Assessment (HTA) of the clinical and cost effectiveness bupropion and nicotine replacement therapy (Woolacott et al., 2002), a recent Australian review of the evidence for smoking cessation interventions (Miller and Wood, 2001) and US guidelines (Fiore, 2000). The Cochrane Database of Systematic Reviews, the Health Technology Assessment database and the NHS Economic Evaluation Database were searched in November 2003 using the terms 'smoking cessation' and 'nicotine'. This was updated database searches of Medline, EconLit, Embase and PsychInfo based on the terms 'smoking cessation', 'nicotine', 'bupropion', smok*, tobacco, and 'nicotine replacement therapy' and then each term plus 'cost*'. The search of the Cochrane Library revealed 50 completed reviews and 9 protocols for reviews currently underway. This was reduced to 15 reviews and 3 protocols after prevention, health promotion and special populations and settings (such as pregnancy, hospital patients, adolescents, workplaces) were excluded. While it is recognised that these are important, it was beyond this chapter to explore these specifically.

Choice of interventions

The following interventions were excluded due to lack of evidence of effectiveness based on the relevant Cochrane Reviews: acupuncture (White et al., 2003); antidepressants other than bupropion and nortriptyline (Hughes et al., 2003b); anxiolytics other than clonidine (Hughes et al., 2002); aversive smoking strategies (Hajek and Stead, 2004); exercise (Ussher et al., 2004); hypnotherapy (Abbott et al., 2002) and self-help interventions (Lancaster and Stead, 2001). The antidepressant nortriptyline was excluded as it is not currently marketed as a smoking cessation aid while clonidine which has prominent side effects was also excluded(Gourlay et al., 2004). Cochrane Reviews found six smoking cessation approaches were supported by sufficient clinical evidence to warrant further consideration: physician-delivered brief advice (Silagy and Stead, 2003),

group behaviour therapy (Stead and Lancaster, 2003a), individual behavioural counselling (Lancaster and Stead, 2003), telephone counselling (Stead and Lancaster, 2003b), nicotine replacement therapy (Silagy et al., 2003) and the antidepressant bupropion (Hughes et al., 2003b)

Choice of outcome measure

The most conservative estimate of treatment success is based on a continuous 12-month quit rate validated by a biological measure such as exhaled carbon monoxide levels (Hughes et al., 2003a). While continuous abstinence deems any missed visit or minor lapse (even a puff) as treatment failure, point prevalence estimates abstinence at the time of follow up - often the preceding 7 days. However, most meta-analyses have accepted a six-month point or continuous quit rate whether self-reported or biologically validated (Fiore et al., 2000;Silagy et al., 2003;Hughes et al., 2003b;Hughes et al., 2003a). Following the accepted practice in these reviews, and as this study is comparing the relative cost effectiveness of various interventions to assist with smoking cessation, it was determined that the either self-reported point or continuous quit rate at 6 months would be sufficient.

Issues related to selecting interventions to improve smoking cessation rates

The aim was to identify effective smoking cessation interventions and their associated incremental quit rates and odds ratios. Smoking cessation interventions are generally categorised into behavioural (varying in intensity and format), pharmacological (nicotine replacement therapies and antidepressants) and other (hypnotherapy, acupuncture and alternative or natural remedies). Smokers are also able to quit unaided and so the effectiveness of interventions needs to be adjusted for the estimated natural or spontaneous quit rate. Behavioural interventions have been variously categorised as minimal/brief advice or high versus low intensity. Questions also arise as to whether one form of counselling (group therapy, individual therapy, telephone counselling) is more effective than another; or whether there is any difference between the five different forms of nicotine replacement. Combined therapies (eg. NRTs with counselling, or NRTs plus bupropion) further complicate the task of disentangling treatment effects that can be attributed to each treatment component. This is an issue for example in the early bupropion studies where subjects received substantial amounts of behavioural counselling (Harrison et al., 2001).

8.2.3. Resources used in providing smoking cessation interventions

Estimating resource use in each of the interventions can be done by a number of methods. One method is to use the data from previous economic evaluations, however, very few of these were from Australia so arguably the resources and prices would be different. Another important issue was that many economic evaluations were done on studies that provided a substantial amount of intensive treatment and follow-up, which is unlikely in the Australian context, yet may well have been responsible for achieving the reported results.

Therefore a two-pronged approach was used:
1) documenting resource use as reported in selected studies and Australian guidelines (where available) and then
2) describing resource use in Australian practice and costing this resource use.

Resource use was examined in the largest effectiveness studies contributing to the Cochrane Reviews plus recent studies not yet incorporated into the Cochrane analyses. Common features were identified such as type of counselling used, frequency and duration of sessions, materials, training of counsellors and support calls. This provided a resource list to which local prices were applied. The literature review was used to determine the mean and range of resources used for sensitivity analysis.

8.2.4. Analysis of costs and outcomes

Resource use was estimated based on recommended guidelines and assumed 100% compliance to treatment protocols. Once costs and outcomes were determined, an average cost per quitter was estimated for each intervention with an adjustment for the natural quit rate. An incremental cost effectiveness analysis (which is the difference in costs between two treatments divided by the difference in outcomes of those treatments) was calculated with brief advice as the base comparator. Two sets of ICERs were estimated, one where NRTs were compared to brief advice, counselling, proactive counselling, and NRTs plus bupropion; the second being similar comparisons using bupropion. Actual resource use for pharmacotherapies (NRT and bupropion) was also estimated. This was necessary as PBS and post-marketing studies indicated that the actual uptake of medication and adjunctive counselling was significantly less than recommended in treatment guidelines. Sensitivity analyses are used by economists to explore whether variations in effects significantly change cost effectiveness outcomes

(Drummond et al., 2000). Assumptions about the uptake of treatments, resource use, and prices were tested in sensitivity analyses.

8.3. Results

8.3.1. Evidence on the effectiveness of smoking cessation strategies

No intervention

It is clear that many smokers will quit without assistance and it is necessary to adjust outcomes by this rate. The natural quit rate can also be used in the economic analysis as a baseline comparator; the 'do-nothing' strategy. A recent comprehensive review (Hughes et al., 2004) of relapse among smokers, who tried to quit without treatment, estimated 6-12 month abstinence rates of 3-5%. Often control conditions are described as minimal interventions or usual care which can range from no treatment, very brief advice to the simple provision of self help materials. A Cochrane meta-analysis of brief physician advice (Silagy and Stead, 2003) found that 4% of 5,870 subjects in 16 studies who received usual care had quit for 6 months or longer compared to 6% who received brief advice from their physician. Based on Hughes et al. (2004), and Silagy et al. (2003), the estimated six-month natural or spontaneous quit rate for the purposes of this cost effectiveness analysis is 4%. A summary of effectiveness appears in Table 8.1.

Brief advice

Brief advice and other minimal interventions such as identification of smoking status (Milch et al., 2004) modestly increase smoking cessation rates and are important in motivating smokers to quit (Fiore et al., 2000). A Cochrane Review of physician-based brief advice for smoking cessation compared to no advice or usual care (Silagy and Stead, 2003) is relevant to our analysis due to the physician time required to assess and prescribe pharmacotherapies such as bupropion. Brief advice was defined as a single consultation lasting less than 20 minutes, plus up to one follow up visit where a physician delivered a specific, verbal "stop smoking" message. The meta-analysis included 16 studies with 13,575 subjects (7,705 treated; 5,870 control) and found a small but significant increase in the odds of quitting (Odds Ratio 1.69 (95% Confidence Interval 1.45-1.98) which yielded a quit rate of 6% (95% Confidence Interval 5-7%) compared to 4% for usual care which provided an incremental quit rate estimate of 2%. An earlier meta-analysis conducted by Fiore and colleagues (Fiore et al., 2000) identified only seven studies which compared no

advice to physician advice to quit. This analysis found a similarly small incremental quit rate of 2% (Odds Ratio 1.3 (95% CI, 1.1-1.6). Based on Fiore et al. (2000), and Silagy et al. (2003), our estimated incremental quit rate associated with brief physician delivered advice compared to no treatment is 2%.

Counselling

More intensive behavioural interventions to support smokers to quit are recognised as more effective than minimal interventions such as brief advice or no intervention (Miller and Wood, 2001). Counselling approaches vary according to type, delivery, availability, setting and frequency although the content is generally comparable - consisting of skills, education, support and relapse prevention. Individual counselling can be delivered by trained health professionals, smoking cessation specialists or trained telephone-based counsellors. Group counselling, where individuals learn behavioural techniques for smoking cessation, also provide additional mutual support. Relapse sensitive timing and availability of interventions at peak periods of risk of relapse, for example, in the early stages of quitting, may also be important elements for success (Hughes et al., 2004;MacLeod et al., 2003). Both Cochrane Reviews and US Clinical Practice Guidelines concluded that individual, group and telephone counselling approaches were superior to minimal intervention (no intervention, brief advice, self-help materials or a combination) but found no evidence to support one counselling format over another. Given the consensus among meta-analytical studies that the effectiveness of counselling approaches was broadly comparable (Fiore et al., 2000;Miller and Wood, 2001;Stead and Lancaster, 2003a), it was decided that only one counselling approach would evaluated in this analysis. Telephone counselling was selected as it has been used with some success in recent studies of smoking pharmacotherapies including bupropion (Swan et al., 2003)and NRT patches (MacLeod et al., 2003). Telephone counselling is also explicitly recommended in Australian treatment guidelines. Based on Fiore et al., and Stead et al, our estimated incremental quit rate associated with telephone counselling compared to brief advice is 2%.

Nicotine Replacement Therapy (NRT) with counselling

Ninety-six controlled studies of five forms of NRT, mostly nicotine gum (n=51) or patch (n=34), formed the basis of the Cochrane Review (Silagy et al., 2003) which found all commercially available forms of NRT with counselling were effective in motivated smokers with high levels of nicotine dependence. The pooled odds ratio of abstinence

for all forms of NRT with counselling was estimated at 1.74 (95%CI: 1.64-1.86) compared to a placebo or other non-NRT approaches. The estimated continuous quit rate for six months or greater was 17% or an incremental quit rate of 7% compared to counselling alone or placebo. To simplify the analysis only one type of NRT (patches) was used, as nicotine patches and gum appear to be largely comparable both in terms of effectiveness and local cost.

Bupropion with counselling

The Cochrane meta-analysis of 16 placebo controlled trials concluded that there was sufficient clinical evidence to support the use of bupropion with counselling as an aid in smoking cessation compared to placebo (Hughes et al., 2003b). The pooled odds ratio for abstinence was 1.97 (95% CI: 1.67-2.34) with an estimated quit rate of 19% (95% CI: 16-23%) and incremental quit rate of 9% compared to placebo.

Bupropion versus NRT

Few studies have examined NRT versus bupropion versus combined NRT/bupropion and these have provided conflicting evidence. Jorenby and colleagues (Jorenby et al., 1999) found bupropion superior to NRT patch (OR 2.07 95% CI: 1.22-1.53). Johnson and colleagues (Johnson et al., 2001) found a non-significant difference in six month quit rates between bupropion (31%) and NRT patches (28%) in a retrospective case note study of 287 Veterans Affairs patients.

Bupropion plus NRT

In direct comparisons between bupropion and NRTs, Jorenby and colleagues (Jorenby et al., 1999) found bupropion combined with an NRT patch was superior to NRT patch alone (OR 2.65 95% CI: 1.58-4.45). However, an unpublished report by Simon and colleagues cited in the Cochrane Review (Simon et al., 2002) found no difference in 239 smokers between bupropion plus NRT patch compared to NRT patch alone (OR 0.75 95% CI: 0.41-1.39). Gold and colleagues (Gold et al., 2002) found higher six month abstinence rates in patients who self-selected combined bupropion and NRT patch (34%) compared to bupropion alone (28%) and NRT patch alone (15%) although the differences were non-significant due to small sample sizes.

NRT with varying intensities of counselling

The Cochrane Review of telephone counselling (Stead and Lancaster, 2003a) analysed four studies of telephone counselling as an adjunct to NRT compared to NRT alone and found no significant difference in abstinence odds ratios (OR 1.08 95% CI: 0.82-1.43). A recent, large (n=854) Australian study (MacLeod et al., 2003) found NRT patches plus proactive telephone counselling with a relapse-sensitive call schedule (i.e. more calls were made in the early high relapse risk period) was superior to NRT patches alone (OR 1.6 95% CI: 1.16-2.21). Ninety day continuous abstinence rates at 6 months were 27% in the NRT/telephone counselling group and 19% in the NRT alone group yielding an incremental quit rate of 8%. The authors differentiated their study from the less successful studies in the Cochrane Review by the use of the rapid relapse-sensitive call schedule and the use of highly trained and experienced counsellors. Both features have resource implications.

Bupropion with varying intensities of counselling

Most of the larger bupropion studies provided subjects with brief counselling at each weekly clinic visit (between 7 and 9 sessions) plus brief supportive calls usually scheduled after a planned quit day and during post-treatment follow up. Patients would also have benefited from the motivation and support inherent in participation in a clinical trial including regular clinical contact and monitoring. Two studies have specifically examined more intensive or structured psycho-social support as an adjunct to bupropion therapy for smoking cessation. Hall and colleagues (Hall et al., 2002) compared brief physician advice plus bupropion (n=37) to five sessions of group therapy plus bupropion (n=36) and found no difference in point abstinence 12 months (25% versus 24%). Swan and colleagues (Swan et al., 2003) crossed two bupropion doses with two intensities of counselling (a proactive telephone counselling program versus a lower intensity tailored mail out approach) in a large study involving 1,524 smokers. Collapsing on dose, the odds ratio for abstinence (point prevalence) at 12 months was 1.21 (95% CI: 1.08-1.35) with associated quit rates of 32.3% and 24.6% respectively and an incremental quit rate of 7.7% associated with proactive telephone counselling.

Summary of effectiveness data

Effectiveness data has been summarised in Table 8.1. Quit rate estimates are sourced from the referenced meta-analyses. Meta-analysis is not available in the case of bupropion plus counselling and bupropion plus NRT and quit rate estimates for these

are based on the relevant studies. The incremental quit rate (IQR) is based on the intervention quit rate minus the comparison quit rate as estimated in the relevant meta-analysis - it is not the difference between the estimated quit rate of an intervention and that of the intervention preceding it in the table.

Table 8.1: Summary of effectiveness data for smoking cessation interventions (abstinence at 5-6 months or longer)

Intervention (Source)	Quit rate	Comparator	Incremental quit rate (range)	Odds ratio (95% Confidence Interval)
No intervention[1]	4%	-	4% (3-5%)	nc
Brief advice[2]	6%	No intervention	2% (1-3%)	1.69 (1.45-1.98)
Telephone counselling[3]	9%	Brief advice	2% (1-3%)	1.56 (1.38-1.77)
NRT plus counselling[4]	17%	Counselling	7% (6-8%)	1.74 (1.64-1.86)
NRT plus proactive telephone counselling[5]	27%	NRT plus counselling	8% (6-11%)	1.6 (1.16-2.21)
Bupropion plus counselling[6]	19%	Placebo plus counselling	9% (6-13%)	1.97 (1.67-2.34)
Bupropion plus proactive telephone counselling[7]	32%	Bupropion plus counselling	8% (7-9%)	1.21 (1.08-1.35)
Bupropion plus NRT[8]	36%	NRT alone	20% (12-34%)	2.65 (1.58-4.45)

[1] (Hughes et al., 2004{Silagy, 2003 #270;Silagy and Stead, 2003); [2] (Silagy and Stead, 2003;Fiore et al., 2000); [3] (Stead and Lancaster, 2003b); [4] (Silagy et al., 2003); [5] (MacLeod et al., 2003); [6] (Hughes et al., 2003b); [7] (Swan et al., 2003);[8] (Jorenby et al., 1999)

8.3.2. Estimating resources in Australia for smoking cessation strategies

Recommended Treatment Guidelines

Brief advice

Guidelines for preventive interventions in primary health care have been published by the Royal Australian College of General Practitioners (RACGP, 2002;RACGP, 1998) (RACGP) and the National Health and Medical Research Council(NHMRC, 1996). These guidelines recommend the five **A**'s: **A**sk and record patients' smoking status; **A**dvise to quit in a non-judgement but personalised manner; **A**ssess willingness to quit;

Assist in quitting provide information, referral to the national telephone Quitline, pharmacological treatment; and **A**rrange follow-up monitoring.

Telephone counselling

Referrals to government and company sponsored telephone counselling services, such as the national Quitline network and the Zyban Quit Line, have been incorporated into treatment guidelines for pharmacological interventions, although there are no specific guidelines for operating telephone counselling programs

Bupropion

Bupropion was originally listed for public subsidy on the Australian PBS in February 2001 as single prescription of 120 tablets for use over nine weeks. In September 2002 the Pharmaceutical Benefits Advisory Committee (PBAC) recommended changes to the PBS listing due to evidence that most patients receiving bupropion did not complete the entire course of twice-daily 150 mg tablets (PBAC, September 2002). As of February 2004, the nine week course of treatment requires two prescriptions consisting of an initial prescription of 30 tablets (150 mg sustained release) and a repeat prescription of 90 tablets. This course of treatment is subsidised by PBS only once per annum. A condition of the authority to prescribe is that patients have entered a comprehensive support and counselling program and this must be specified in the authority application. Support services include general practitioners, Quitline, and a company sponsored SMOKE FREE Clean Start Program (formerly Zyban Action Plan).

NRT patches

The only form of NRT that is currently listed for subsidy in Australia is the nicotine patch which is subsidised for war veterans through the RPBS. A condition of the authority to prescribe is that patients have entered a comprehensive support and counselling program.

Supplementing Information in the Guidelines

For the most part the guidelines (RACGP, NHMRC and PBS) were not sufficiently detailed to permit costing therefore the descriptions of resource use from the literature were used to supplement the guidelines.

Brief Advice

For example, brief, repeated non-judgemental advice has been estimated to take less than one minute in the Australian primary care context (Litt, 2002). A review of resource use in eight effectiveness studies of brief advice found estimates of physician time ranging from 20 second "stop smoking" messages up to 10 minutes (Hollis et al., 1993; Pieterse et al., 2001; Glasgow et al., 2000;Ockene et al., 1992; Slama et al., 1990; Lang et al., 2000; British Thoracic Society, 1990;Butler et al., 1999). Other resources included self-help materials, referral to other programs and physician training; only the first is included in this analysis. Resource use described in Australian guidelines and study protocols is assumed to reflect the actual use of clinical resources (Table 8.2).

Table 8.2: Resource use estimates for brief advice (recommended)

Resource	Quantity	Range	Duration	Range
Self-help booklets	1			
GP Visit	2	1-2	5 minutes	(20 secs –10 mins)

Telephone counselling

Telephone counselling studies provided a mean of between 2 and 7 telephone calls mostly lasting ten to fifteen minutes with the initial call lasting between 20 and 30 minutes (Borland et al., 2001;Lando et al., 1997;Solomon et al., 2000;Reid et al., 1999 {Zhu, 2002 #337;Zhu et al., 2002). Borland et al., (Borland et al., 2001)found that up to 2 calls post cessation attempt improved the odds for abstinence but that the benefit declined with extra calls and disappeared altogether after six or more calls. Most studies employed telephone counsellors who received specific training in smoking cessation techniques (between 4 and 60 hours). Other resources included supervision of telephone counsellors by a clinical psychologist, promotion costs and toll free telephone access. Resource use is summarised in Table 8.3 below.

Table 8.3: Resource use estimates for telephone counselling (recommended)

Resource	Quantity	Range	Duration	Range
Telephone calls	3.9	2-7	10 minutes	5-15 minutes
Counsellor time	-	-	39 minutes	20 minutes – 70 minutes
Self help materials	1	-	-	-

Proactive telephone counselling

Proactive telephone counselling has been delivered with some reported success in conjunction with NRT patches (MacLeod et al., 2003)and bupropion (Swan et al., 2003). Proactive telephone counselling, as its name suggests, involves telephone counsellors actively calling clients using individually tailored call back schedules that match clients' personal circumstances and identified peak relapse risk periods. The average number of calls made per subject by Macleod et al was 4.7, which was above our estimate for telephone counselling of 3.9 drawn from Borland et al. This slightly higher estimate is similar to data from a proactive 12-week telephone call-back service conducted by Quit SA which averaged 4.4 calls per client lasting an average of 9 minutes for each call (L.Abram, Quitline co-ordinator, Quit SA, personal communication, May 2004). The use of more highly trained and experienced counsellors and supervisors may also have resource implications. To account for these additional resources required for proactive telephone counselling, the number of calls and hence counsellor contact time is estimated at 47 minutes described by Macleod et al with an additional 25% loading on hourly rates to reflect higher training and supervision costs.

Bupropion

One area where resource use may vary between study protocols and the guidelines, and what actually occurs, is the uptake of counselling or intensive support with pharmacotherapies. In nine bupropion effectiveness studies examined, subjects received extensive counselling with seven studies reporting weekly brief (15 minutes or less) face-to-face counselling from research assistants, trial nurses and counsellor/psychologists (Hurt et al., 1997; Jorenby et al., 1999; Gonzales et al., 2001; Hall et al., 2002; Ahluwalia et al., 2002; Tonnesen, 1999; Tashkin et al., 2001; Swan et al., 2003; Patterson et al., 2003). On average subjects were scheduled to receive 8 contacts of around 15 minutes duration. For costing purposes, the counselling resources in this study have been based on those identified in the telephone counselling as described above. Sensitivity analysis will be used to test the impact of this assumption on costs. Resource use is summarised in Table 8.4 below.

Table 8.4: Resource use estimates for pharmacotherapies with counselling

Resource	Quantity	Source
	Bupropion	
Booklet	1	Study protocols
GP visit	2	PBS
First Script	30 tablets	PBS
Second Script	90 tablets	PBS
Counsellor contact	39 minutes	Telephone counselling
	NRTs	
Booklet	1	Study protocols
GP visit	3	RPBS
First Script	21 mg patches (pack of 7)/6 packets	RPBS
Second Script	14 mg patches/2 packets	RPBS
Third Script	7 mg patches/2 packets of 7	RPBS
Counselling	39 minutes	Telephone Counselling

Bupropion plus NRT patches

When bupropion and NRT are used in combination, the resources are as in Table 8.4, with the exception that the duplicated GP and counsellor visits are not required.

8.3.3. Australian prices

Each of the resources outlined above were costed using local prices. The hourly cost of telephone counselling has been based on initial consultation fee for social workers paid by the Australian Federal Government (http://www.health.gov.au/pbs/pubs/manual/index.htm accessed 18th June 2004). This estimate which is recommended for submissions to the Pharmaceutical Benefits Advisory Committee (PBAC) includes on-costs and infrastructure costs, thus increasing the comparability to government paid medical consultation fees. Other prices were obtained, as listed below, from the PBS (http://www.health.gov.au/pbs/scripts/dispgp.cfm) and MBS (http://www.health.gov.au/pubs/mbs/MBSNov2003_DHTML). Costs included are only government costs and have been standardised into 2003 Australian dollars using the CPI. Individual co-payments were not included. The prices in Table 8.5 were applied to the estimates of resource use to produce the total costs associated with treatment as recommended (i.e. complete compliance and completion).

Table 8.5: Price List – Smoking Cessation Interventions

Resource	Prices in 2003 dollars*	Source
Telephone counsellor	$42.75	PBAC/DVA 2002
Self help materials -booklets	$2.50	Drug Health Services (2003)
Medical Practitioners Standard Consultation (5-25 minutes)	$21.00	MBS (2003) Code 53
Bupropion SR		
Initial Script (30 tablets)	$89.01	PBS 2004 Items
Second Script (90 tablets)	$197.78	8465M, 8710K
NRT patches (prescribed)		
Initial Script 21 mg (pack of 7)	$215.25	RPBS 2004
Second Script 14 mg	$65.25	Items 4571N,
Third Script 7 mg	$59.67	4572P, 4573Q

*Analysis based on government costs only

8.3.4. Costs and outcomes

The costs for each intervention, based on recommended treatment, and appropriate outcomes as they would apply to a sample of 100 smokers are summarised in Table 8.6.

Table 8.6: Costs and outcomes for 100 smokers attempting to quit relative to the spontaneous quit rate (2003 AUS$)

Intervention	Quit rate estimate	Quit rate less 4% spontaneous quit rate	Total costs of recommended treatment	Average cost per additional quitter
Spontaneous	4%			
Brief physician advice	6%	2%	$3,820	$1,910
Telephone counselling	9%	5%	$3,029	$606
Bupropion with counselling	19%	15%	$35,278	$2,352
NRT with counselling	17%	13%	$40,453	$3,112
NRT with proactive counselling**	27%	23%	$41,959	$1,824
Bupropion plus proactive TC**	32%	28%	$36,783	$1,314
NRT+BUP**	36%	32%	$69,133	$2,160

*** effectiveness based on a single study*

Relative to the spontaneous quit rate, which has an estimated rate of 4% and zero cost of treatment to government, the lowest average cost per quitter is $606 for telephone counselling. Bupropion with proactive counselling is next at $1,314 per average quitter and NRT with proactive counselling and brief physician advice having similar average costs per quitter at $1,824 and $1,910 respectively. Note that the effectiveness of combinations of NRT, bupropion and proactive telephone counselling are based on single studies and thus may be over estimates of actual outcomes while the other interventions have been based on meta-analyses involving multiple studies of tens of thousands of patients and estimated treatment effects are generally more conservative. Also note that only one study has compared NRT directly with bupropion and there may be no difference between the approaches.

8.3.5. Incremental cost effectiveness ratios

While an average cost per quitter is useful in understanding the mean costs, a more meaningful estimate is the incremental gain at the margin. The incremental cost effectiveness ratio (ICER) is used to help answer this question. This is estimated by:

> ICER = [Cost of Intervention – Cost of Comparator] / [Outcome Intervention – Outcome Comparator]

The interventions are ordered by outcomes in Table 8.7 where each outcome has been adjusted by the spontaneous quit rate of 4%. The comparator for each intervention is therefore the preceding less effective intervention which appears above it in the table. Two sets of ICERs are calculated – one for NRTs and the other for bupropion.

Table 8.7: Stepwise Incremental Cost Effectiveness Analyses

Intervention	Quit rate less 4% spontaneous quit rate	Incremental quit rate (IQR)	Recommended treatment cost (n=100)	Incremental costs (IQC)	ICER (IQC/IQR*100)
NRT					
Brief physician advice	2%		$3,820	-	-
Telephone counselling	5%	3%	$3,029	-$791	Dominates
NRT with counselling	13%	8%	$41,163	$38,134	$4,767
NRT with proactive counselling	23%	10%	$42,668	$1,505	$151
NRT+BUP with counselling	32%	9%	$69,842	$27,174	$3,019
Bupropion					
Brief physician advice	2%		$3,820	-	-
Telephone counselling	5%	3%	$3,029	-$791	Dominates
Bupropion with counselling	15%	10%	$35,278	$32,249	$3,225
Bupropion plus proactive TC	28%	13%	$36,783	$1,505	$116
NRT+BUP with counselling	32%	4%	$69,842	$33,059	$8,265

The NRT comparisons illustrate that telephone counselling is dominant over brief physician advice, that is, telephone counselling is both less expensive and more effective. When NRTs are added, there is an additional cost of $4,767 per quitter. The addition of proactive telephone counselling to NRTs has an incremental cost of only $151, whereas NRT plus bupropion with telephone counselling has an incremental cost of just over $3,000. A similar pattern is seen with bupropion with the exception of combined NRT and bupropion with counselling which is the highest additional cost per quitter of $8,200 compared to bupropion plus proactive telephone counselling. These analyses would suggest that the most cost effective treatment is telephone counselling, and the move to either bupropion or NRT, while achieving increased quitters comes at some cost.

8.3.6. Actual uptake of medication and counselling

Compliance with pharmacotherapies and counselling appears to be a major issue with respect to pharmacotherapies for smoking cessation. For example, Zwar and colleagues (Zwar et al., 2002) examined compliance in 151 patients prescribed bupropion in eight general medical practices in Sydney. They found the most common length of treatment was 4 weeks although those who completed 7 weeks were significantly more likely to report achieving both continuous and point-prevalence smoking abstinence at ten weeks. Uptake of ancillary counselling programs is also problematic. Zwar and colleagues found 46% of their sample accessed one or more support services. Among those who accessed support services, most used their GP (75%), 30% accessed the ZAP service and 28% accessed Quitline. However, patients who used one or more support services were no more likely to report point-prevalence abstinence than those who did not. In 1999, the actual uptake of counselling among Californian smokers who used bupropion to quit was 20.8% and median duration of use was 14 days (Pierce and Gilpins, 2002).

Data, which became available following changes to how bupropion was prescribed which were introduced by the Australian Pharmaceutical Benefits Scheme in January 2004, were used to estimate current actual uptake. These changes required an initial prescription for 2 weeks followed by a repeat 7-week prescription (rather than the full 9 week prescription at once). Prescribing data from HIC website for the dates between January 2004 and June 2004 (http://www.hic.gov.au/statistics/dyn_pbs/forms/pbs_tab1.shtml accessed 20th August 2004) was examined. During this period the PBS subsidised 38,807 initial scripts for bupropion and 12,363 repeat scripts representing an uptake of the second script of 32%. Zwar et al. 2002 estimated compliance with medication at an average of 4 weeks when the full prescription was available at once. Zwar also estimated 46% of patients using bupropion took up counselling with most using the GP (75%) i.e. effectively 34.5% of all patients. Thirty percent of 46% took up telephone counselling i.e. effectively 14% of all patients.

Paul et al. examined patterns of NRT use as part of a wider community survey of cancer-related perceptions and behaviours in New South Wales (Paul et al., 2003). They found that 75% of NRT patch use was for less than six weeks which reflects early failure and possibly an inadequate duration of treatment to cover the entire period of withdrawal symptoms. They also found that 59% of all NRT users reported recommendations or

advice from either a doctor or pharmacist. They did not examine use of counselling and support services. In 1999 the actual uptake of counselling among Californian smokers who used NRT to quit was 16.8% and median duration of use was 14 days (Pierce and Gilpins, 2002). A study of proactive telephone counselling as an adjunct to NRT patches conducted in Sydney (MacLeod et al., 2003)found that less than 10% participants in the control group (usual counselling) had used other forms of assistance or counselling (Zane Macleod, February 2004, personal communication). RPBS data for the year July 2003 to June 2004 showed 2111 scripts for the initial script for NRT patches with 723 second scripts (34%) and 348 for third scripts (16%) (http://www.hic.gov.au/statistics/dyn_pbs/forms/pbs_tab1.shtml accessed 20th August 2004).

Actual cost of pharmacological interventions

Actual resource use in the real world varies from recommended treatment guidelines, particularly in terms of compliance with medication. Table 8.9 presents the total costs for 100 persons based on recommended treatment and our best estimate of actual resource use for the two pharmacotherapies. Based on these assumptions the costs per 100 persons are less than half of the recommended costs however the quit rate is unknown given this uptake. Thus it is inappropriate to estimate an actual cost per quitter. One caveat is that the uptake of 32% for the second bupropion script has been based on 6 months of data (since the new PBS guidelines introduced for bupropion) and may be an underestimate the actual uptake of the second prescription. Nonetheless, it would appear that the current cost implication for government is significantly less than for recommended guidelines, and one might argue that this is because the provision of a 'comprehensive' treatment program is low.

Table 8.8: Estimated costs for 100 persons based on recommended and actual resource use of pharmacotherapies.

Intervention	Cost of recommended treatment	Cost of actual treatment
Bupropion with counselling	$35,278	$18,011
NRT with counselling	$40,453	$13,831

An actual cost per quitter has not been calculated in Table 8.8 since the assumption that outcomes will not change is not likely to hold where there is poor medication

compliance. For example our estimated quit rate for bupropion is 19%, is unlikely to be achieved when estimated medication compliance at 2 weeks is only 32%.

8.3.7. Sensitivity Analysis

Sensitivity analysis was used to examine the impact of uncertainty on resource use, prices and outcomes on the costs of treatments (see Table 8.9). While resource use was varied, it was assumed that effectiveness remained constant and vice-versa. Sensitivity analysis was not conducted on combinations of NRT, bupropion and proactive counselling.

Table 8.9: Sensitivity analysis (resources and prices) by intervention

Category	Description of variation	Average cost per additional quitter
Brief Advice	Recommended treatment	$1910
GP visit	Reduce to one visit (from 2)	$1,018
GP visit	Reduce consultation to less than 5 minutes - $9.35 (from $17.85)	$1,060
Lower efficacy estimate	1% quit rate	$3,820
Upper efficacy estimate	3% quit rate	$1,273
Telephone counselling	Recommended treatment	$606
Telephone calls	Reduce calls to 2 (from 3.9)	$335
	Increase calls to 7 (from 3.9)	$1,047
Counsellor costs	Increase by 25% for infrastructure costs	$761
Lower efficacy estimate	4% quit rate	$757
Upper efficacy estimate	6% quit rate	$505
NRT + counselling	Recommended treatment	$3,112
Counselling	Compliance as per actual estimates (17% from 100%)	$2,934
Lower efficacy estimate	12% quit rate	$3,371
Upper efficacy estimate	14% quit rate	$2,890
Bupropion + counselling	Recommended treatment	$2,353
Counselling	Compliance as per actual estimates (17% from 100%)	$2,193
Lower efficacy estimate	13% quit rate	$2,714
Upper efficacy estimate	21% quit rate	$1,680

The sensitivity analysis examined variations in resources and prices and outcomes (see Table 8.6 with incremental quit rate ranges estimated using the 95% confidence intervals around the relevant odd ratios in Table 8.1). Reducing the number of GP consultations from two to one reduced the cost per quitter of brief physician advice by 47% but still leaves the cost per quitter more than for telephone counselling. Using the lower estimate for telephone calls to counsellors (2 calls) also reduced the cost per quitter of telephone counselling by 45% while using the upper limit (7 calls) increased the cost per quitter by

73%. Estimated actual counselling uptake made very minor changes in cost for both NRT (6%) and bupropion (7%).

Several uncertainties about prices were tested. The estimated cost associated with telephone counselling may have underestimated the cost of training, loadings for overtime, infrastructure costs such as telephone centre and toll free access for smokers, promotion and advertising costs. The potential underestimation was adjusted by adding a loading of 25% onto the hourly fee for telephone counsellors which increased the cost per quitter by 26%. The estimated cost associated with physician brief advice may overestimate the cost of a consultation if the entire 5 to 25 minute consultation was not devoted to smoking cessation. The cost of a medical consultation of $9.35 for a consultation of not more than 5 minutes reduced the cost per quitter by 45%.

Varying outcomes had low impact on the relative cost per quitter except at the lower estimate for brief advice. Telephone counselling remained the most cost effective strategy across the entire range of outcome estimates. Bupropion also remained more cost effective than NRTs across the entire range of outcome estimates. Newer pharmacotherapies, particularly bupropion and combinations of bupropion, NRT and more intensive counselling, are relatively under-studied when compared to behavioural interventions and thus estimated outcomes should be treated with caution. Only two randomised studies have directly compared NRT and bupropion, one finding strongly in favour of bupropion, the other in favour of NRT. Assuming Bupropion is equally as effective as NRT, a quit rate of 13% was applied to both medications. If the efficacy of the two pharmacotherapies were equivalent, then the cost per quitter for bupropion increases by 15% to $2,714 which is less than that of NRT at $3,112.

Population benefits of the adoption of interventions

The AIHW estimated that there were 3.6 million smokers in Australia in 2001. Thirty-one percent (1.1 million smokers) reported an unsuccessful quit attempt in the past 12 months (AIHW, 2002a). The total costs of treating 1.1 million quit attempts ranged from $33 million (telephone counselling) to $768 million (combined NRT and bupropion). If an weighted average of 1.5 life years saved per long term quitter(Woolacott et al., 2002)is adjusted for post 12-month relapse rate of 40% (Song et al., 2002) the total life years saved is 0.9. Using this approximation, the total cost of life years saved could range from $667 (telephone counselling) to $2,423 (combined NRT

and bupropion). All these cost per life year saved projections fall well below the NHMRC recommended threshold of $30,000 per life-year gained considered as good value (NHMRC, 2001).

Another way of looking at these data is to hypothesize what might be achieved with an additional budget of say $20,000,000. If it were allocated all to telephone counselling approximately an estimated 33,000 additional quitters might be gained, whereas if it was all used for bupropion with counselling only 8,000 quitters might result, when proactive counselling is added the quits increase to 15,000. However, as a single method of smoking cessation does not work for everyone, it is useful to explore what happens if half of the additional budget goes to telephone counselling, and the remainder is split between bupropion with proactive counselling and NRTs with proactive counselling. This hypothetically achieves 23,000 additional quitters.

8.4. Discussion

Smoking, like most drugs of dependence, is highly-treatment refractory. Smoking cessation has been described as the 'gold standard' of healthcare cost effectiveness (Eddy, 1992), but the probability of smokers quitting tobacco, whether through self quitting, counselling, psychotherapy or pharmacotherapy, remain low. Clearly much work remains to identify an optimal mix of smoking cessation strategies. Smoking cessation interventions are generally categorised into behavioural (varying in intensity and format), pharmacological (nicotine replacement therapies and antidepressants) and other (hypnotherapy, acupuncture and alternative or natural remedies). Smokers are also able to quit unaided and so the effectiveness of interventions needs to be adjusted for the estimated natural or spontaneous quit rate. While the new pharmacotherapies have improved the proportion of smokers quitting, this comes at a significant cost per successful quitter. Further, the very optimistic outcomes associated with early pharmacotherapy trials become more subdued as larger studies with longer follow up are included in meta-analyses. In the case of bupropion, the original efficacy studies included substantive psycho-social support due to the need for side effect monitoring. However, post-marketing studies are now showing that very few bupropion patients actually receive counselling. The impact this may have on the efficacy of bupropion remains unknown.

This study used data from international studies to determine which smoking cessation interventions were most effective, derived effectiveness estimates from a literature review, and resource use was derived both from the literature review and Australian guidelines and practice. Costs and effects of smoking cessation interventions were estimated for the Australian context. Once costs and outcomes were determined, an average cost per quitter was estimated for each intervention with an adjustment for the natural quit rate. An incremental cost effectiveness analysis (which is the difference in costs between two treatments divided by the difference in outcomes of those treatments) was calculated with brief advice as the base comparator. Two sets of ICERs were estimated, one where NRTs were compared to brief advice, counselling, proactive counselling, and NRTs plus bupropion; the second being similar comparisons using bupropion.

Overall telephone counselling appears to be the most cost-effective smoking cessation intervention as a first line approach, although it may not be effective for all smokers wanting to quit. Further, our analysis did not directly estimate the advertising and promotion activity associated with telephone quit lines. Telephone counselling was both more effective and less costly than physician based brief advice, and even if the costs were the same, telephone counselling was more cost-effective than physician brief advice. Assumptions about resource use and costs were tested in a sensitivity analysis, reducing the time and cost of medical consultations and increasing telephone counsellor contact time and adding a 25% infrastructure charge to telephone counsellor costs. Even under these conditions telephone counselling achieved lower costs per quitter. The dominance of telephone counselling also persisted across the range of efficacy estimates. GPs are likely to have extensive contact with smokers, including those who do not wish to quit or who are at an earlier stage of readiness to change, and so GPs are an important first contact and motivator for smoking cessation and provide an important referral point to quit lines.

The incremental cost effectiveness ratio of NRT compared to telephone counselling was $4,767 per additional quitter. Relaxing the underlying assumption of 100% compliance to the actual uptake of pharmacotherapies halved total costs but had reduced the marginal cost by 5.7% when our estimate of actual counselling compliance was tested in the sensitivity analysis. Adding proactive counselling based on Macleod et al., (2003) the

incremental cost effectiveness ratio was $151 per additional quitter, which suggest the increased effectiveness comes at a small cost. The incremental cost effectiveness ratio for bupropion when compared to telephone counselling was $3,225. As with NRT, applying actual compliance to medication reduced the cost by half while applying actual counselling compliance had a marginal reduction of 7%. Adding proactive telephone counselling as per Swan et al., (2003) provided additional quitters at a low cost of $116. Combined NRT and bupropion were no more effective or cost-effective than other the interventions.

Bupropion with proactive telephone counselling was the most effective intervention based on the result of one study only. Bupropion was more cost-effective than NRT, being both less costly and more effective, across a range of outcome estimates. However, as the aim of the study was to examine cost effectiveness from the government perspective, the treatment protocols for NRT were based on RPBS guidelines. Most NRT in Australia are purchased over-the-counter at a lower price than paid by government subsidy. Further the RPBS schedule required three medical consultations compared to two for bupropion. This may have inflated the costs attributable to NRT compared to bupropion. There may be an argument for RPBS NRT treatment guidelines to be amended to match those for bupropion.

There are several limitations to these analyses. It has been assumed that smokers are a homogenous treatment population. However, smokers respond differently to different forms of smoking cessation delivered in different contexts. More severely dependent smokers may not respond to self-help or psycho-socially based interventions. Several attempts and combinations of interventions may be needed. Our model assumes only one intervention per quit attempt. Our cost per life years saved is not age adjusted. While outcomes varied between studies in terms of follow up time and abstinence measures (continuous versus point) most meta-analyses have accepted a six-month point or continuous quit rate whether self-reported or biologically validated (Fiore et al., 2000;Silagy et al., 2003;Hughes et al., 2003b;Hughes et al., 2003a)and we follow this accepted, if somewhat flawed practice and compared interventions and their costs at six months.

Policy implications

The assumption of 100% medication compliance is unrealistic given that most smokers receiving pharmacotherapy fail to quit smoking and discontinue medication. This would have also occurred to some extent during efficacy trials. However, the risk is that in actual practice, medication compliance is less than that achieved during clinical trials. The preliminary PBS data show 32% compliance for bupropion at 2 weeks, which if sustained, is not likely to support the 19% quit rates estimated from meta-analyses of the clinical trials. This becomes a serious issue when successful quit rates are quite low in the first place. Some studies have suggested that without psychosocial support NRTs may not be used appropriately to the extent that they are do not increase the number of successful quitters (Pierce and Gilpins, 2002). These efficacy issues become cost effectiveness issues, as it is only by increasing the number of successful quitters that the economic benefits of supporting smoking cessation treatments are realised. On a more positive note, two recent studies (MacLeod et al., 2003;Swan et al., 2003) of proactive telephone counselling as an adjunct respectively to NRT and bupropion, demonstrated significantly improved quit rates. The cost effectiveness analysis undertaken in the current study suggests that the cost per additional quitter achieved by targeted and flexible counselling schedules such as those employed by Macleod and Swan (2003), was potentially very modest. Estimates based on only two studies must be interpreted with caution, but further research is warranted. It is perhaps surprising that NRT and bupropion have to date rarely been directly compared, with only two studies with conflicting outcomes (Jorenby et al., 1999;Simon et al., 2002). Even assuming the most optimistic outcomes identified by Jorenby, the cost per additional quitter from combined NRT/bupropion derived in our model are just over $3200 per quitter compared to telephone counselling at approximately $600 per quitter. As such it would the telephone counselling option is the more cost effective option. This is not to suggest that pharmacotherapies should not be offered or covered by the PBS, but rather they should not be the first line approach for those who are attempting to quit smoking.

Australian government guidelines for subsidised prescription of bupropion and NRT require that they be prescribed as part of a 'comprehensive treatment program' which is not further defined. One would assume that this is meant to involve ongoing counselling of some nature, presumably following the RACGP guidelines. These involve brief physician advice, referral to a telephone quit line with a follow up consultation. In nine

bupropion effectiveness studies examined, subjects received extensive counselling with seven studies reporting weekly brief (15 minutes or less) face-to-face counselling from research assistants, trial nurses and counsellor/psychologists (Hurt et al., 1997); (Jorenby et al., 1999;Gonzales et al., 2001;Hall et al., 2002); (Ahluwalia et al., 2002;Tonnesen et al., 2003;Tashkin et al., 2001;Swan et al., 2003;Patterson et al., 2003). However, Australian studies have shown that smokers enrolled in smoking cessation pharmacotherapies are unlikely to actively participate in counselling (Zwar et al., 2002;Paul et al., 2003). Chapter 4 also reports a very low rate of consumers engaging in the use of telephone quit lines, ongoing counselling, or even remembering that their GP or pharmacist suggested they should initiate this activity. The weight of research suggests that counselling does increase successful quit rates among smokers. Therefore when the government subsidises smoking cessation pharmacotherapies money is wasted when smokers do not participate in counselling. More directive counselling adherence guidelines are unlikely to be acceptable to patients or clinicians. Proactive, relapse-specific counselling may be more acceptable and cost-effective particularly when delivered through telephone counselling. We are aware of two such programs in Australia, one was the program described by Macleod which is no longer in operation and the second is a program currently operated by the South Australian quit line. Further research is needed into the relative effectiveness and cost effectiveness of proactive telephone counselling and reactive telephone counselling. Such research should also contribute to more detailed guidelines for telephone counselling.

There is another question which is also pertinent: if an intervention is cost effective, should government automatically provide it, be it pharmaceutical, medical or counselling? Warner suggests that based on the first principles of true insurance, coverage should only apply to high cost events which occur rarely, and smoking cessation which is relatively inexpensive, in most instances less expensive than smoking itself if provided by government is in effect a subsidy (Warner, 1997). However, the argument is also made that many other items of low cost are covered. In order to create a level playing field for preventative interventions, smoking cessation interventions should also be covered. The low costs, combined with the evidence that smoking cessation pays for itself through later reductions in health care costs, make smoking cessation interventions a good investment. The cost per life year saved was low and well below the NHMRC recommendations. On this basis alone, all interventions are worthy of support.

However, an investment in telephone counselling, particularly proactive, relapse - sensitive programs, more formally linked to treatment guidelines for both bupropion and NRT would appear to be a cost-effective strategy.

9. DISCUSSION AND RECOMMENDATIONS

This monograph began with a consideration of the extent of harm and the economic burden associated with tobacco consumption in Australia. While there is much evidence about the burden of illness associated with use of the licit drugs alcohol and nicotine frequently nicotine does not get the attention of illicit drugs. Given the extent of the economic burden, this lack of attention needs to be redressed, and specific additional interventions put in place to reduce smoking prevalence in Australia.

Recognition that there is a role for a range of different interventions to reduce tobacco consumption leads to a consideration of the relative value of these methods of approaching smoking reduction. Different interventions should not be seen as alternatives, but rather as complementary strategies in the attempt to reduce tobacco consumption in Australia and to work in a synergistic fashion to that end. This monograph, while recognizing there are other interventions (taxation, education, clean air laws etc.) which impact on smoking has as its task to consider pharmacotherapies for nicotine dependence and the extent to which they are useful, their impact, and their cost effectiveness in the context of other treatments.

Likely impact of bupropion given rates of prescribing

The introduction of bupropion into Australia as a pharmacotherapy for the management of nicotine dependence in many ways heralded a new opportunity for the reduction of smoking prevalence. The listing of the medication on the Pharmaceutical Benefits Scheme (PBS) was an important step in enhancing availability of the medication. Whilst in the first year bupropion was prescribed to a substantial number of smokers, the prescription rate fell off very quickly after the initial year of listing on the PBS (Chapter 3). While this is not uncommon following the introduction of a new medication, it is important when considering the impact of bupropion as a smoking cessation strategy.

While approximately 11% of smokers in Australia took up bupropion in 2001 (the year it was placed on the PBS), this rate of use dropped dramatically in 2002 so that only a little over 2.7% (1 in 40) of current smokers had apparently filled a prescription for the

medication in that year. With this very low rate of uptake of medication the population health impact will be quite limited.

Specifically, we can model the rate of impact on the population of smokers by making some reasonable assumptions about the effectiveness of bupropion. Table 1, models the current situation of 2.7% of the adult smokers taking up bupropion, and for 10% of smokers. Presuming approximately 25% of smokers who fill a prescription for bupropion cease smoking for a significant period of time, we could expect that less than 1% of all smokers in Australia would benefit from the medication in the 2002 year). If this rate of use of the medication continues in the future, less than 1% of smokers would gain benefit. Then, allowing for some relapse to smoking (even amongst those who attain some substantial period of abstinence), the cumulative effect of bupropion prescribing on the smoking prevalence rate could be a reduction of as little as a half percent of smokers or less per annum remaining abstinent. Whilst it is true that over a number of years the number of abstinent smokers would increase, this would be at a very slow rate.

Table 9.1: Modelling population impact of bupropion**

	Current Uptake	Most likely best-case scenario
Annual uptake of bupropion	2.7%	10.0%
Persons who fill prescription	86,352	319,823
25% quit rate	21,588	79,956
Relapse rate of 20%	4,318	15,991
Quit at end of 1 year	17,270	63,965
% of smokers who quit (one year)	0.5%	2.0%
% adult population quit (one year)	0.1%	0.5%
Quit after 10 years	172,704	639,645
% smokers quit after 10 years	5.4%	20.0%
% adult population quit after 10 years	1.2%	4.5%

** The data in the table uses an adult population of 14,099,273, of which 3,198,225 are smokers.

On the above assumptions that 0.5% of current smokers become abstinent through the use of bupropion in a given year, and continue this abstinence for a substantial period, it

would take 10 years for an estimated 5% of current smokers to become abstinent in a lasting fashion. Five percent of current smokers is equivalent to a little over 1% of the adult population becoming non-smokers. Thus it could take 10 years to reduce population prevalence by 1%.

The implication of this brief modeling exercise might be to recommend the increased promotion of bupropion as a smoking cessation method. It may be possible through enhanced advertising of bupropion to increase the market penetration to approximately 5% to 10% of smokers per annum. If it were possible to maintain prescription levels at 10% of current smokers per annum (although given past patterns it seems unlikely), and presuming that 25% of those who were prescribed the medication became abstinent for an initial period, there would be initial effect of 2.5% of all smokers becoming abstinent per annum. Allowing for some relapse to smoking, assuming some of those who were initially abstinent return to smoking, this would translate to 2% of smokers per annum achieving lasting abstinence. This rate of abstinence would accumulate and result in a reduction in the population level of smoking of 0.45% of all adults becoming non-smokers per year.

However, as even in the first year when considerable media coverage accompanied the introduction of bupropion, the uptake was only at best 11%, it is appears unlikely that 10% of smokers will be prescribed bupropion per annum. Therefore a more realistic middle ground needs to be considered. Possibly, the number of smokers that can be prescribed this medication may be 5% per annum and this would allow for a 2% to 2.5% decrease in the population prevalence of smoking across a 10 year period.

Of course, the results of the analyses presented earlier in this report also show that nicotine replacement therapies brought about substantial levels of abstinence. Whilst NRTs are currently not underwritten through the Pharmaceutical Benefits Scheme, they do have a significant contribution to reducing population prevalence of tobacco smoking and should be viewed in this way. Nicotine replacement therapy as an alternative to bupropion pharmacotherapy needs to be supported, possibly on the PBS.

Adding to the effects of the pharmacotherapies

Of course, the results from pharmacotherapies could be increased in a cost effective fashion. In this regard, it is a major concern for the area of pharmacotherapy for nicotine dependence that there is a lack of any true additional counselling or intervention over and above the pharmacotherapy. It is known from other research that the addition of behavioural strategies with pharmacotherapies such as nicotine replacement therapy enhance the outcomes from the pharmacotherapy (MacLeod et al., 2003). The failure to provide such additional behavioural intervention in this context is of significant concern especially given the cost of the pharmacotherapies, compared to the relatively small additional cost of behavioural intervention. It is likely that there could be a significant increase in effectiveness, possibly a doubling of abstinence rates, with the addition of behavioural strategies. These behavioural strategies really do need to be made a true part of the pharmacotherapy approaches, especially those which are underwritten by the pharmaceutical benefits scheme. To do otherwise, is to miss an important opportunity to greatly enhance the reduction in smoking rates in the adult population.

In this context, it is notable that prescribers also think that counselling is an important adjunct to treatment and that they do provide it or recommend it when prescribing bupropion (Chapter 5), but this is not consistent with patients' views given the data in Chapter 4. Here in a survey of individuals who were prescribed either bupropion, or sought nicotine replacement therapy it was clear that very few individuals were aware of being told that they should pursue any other treatment apart from the pharmacotherapy. There were very low rates of advice to use other approaches in conjunction with pharmacotherapy. Only 18% or less than one in five patients were aware that they had been advised by their prescribing doctor to pursue some other form of intervention, and most of these were for other forms of pharmacotherapeutic intervention rather than the use of a Quitline, counselling or some supportive plan such as Zyban Action Plan (now called SMOKE FREE Clean Start Program).

Conversely, the results from Chapter 5 show that 86% of GPs, the doctors most involved in the prescription of these medications, perceive that adjunctive therapies are likely to improve the likelihood of quitting over and above the effects of medication or pharmacotherapy. Doctors believe that they frequently provide counselling directly or advise patients to pursue assistance through quit lines, literature, or through specialist

counselling or supportive plans. There is obviously a difference between patient recall and doctor perceptions about advice, although it is likely that doctors overestimate the extent to which they provide clear advice about additional interventions and the patients underestimate the extent to which they were given such information. No doubt the truth is somewhere between the two but given the clear advantage provided by alternative therapy or counselling over and above pharmacotherapies, there is certainly extensive room for improvement of the activities of doctors in providing support or referring patients directly to other forms of assistance in their smoking cessation attempts.

Part of the advice that should be delivered to consumers is demonstrated in Chapter 6. This analysis of data, from a representative sample of patients encountered in general practice, shows that many former smokers attribute their success in ceasing smoking to what has been termed as "cold turkey". This is a term which refers to simply stopping unassisted. The reason for very high rates of self reported cessation without assistance is because ceasing smoking does require multiple efforts. It is more likely that patients will attempt unassisted, and therefore recall that they did stop alone. However, this partly reflects the fact that they more frequently attempt to stop on their own rather than self-quitting being superior to other methods. Indeed the literature in this area is quite clear that nicotine replacement therapy, bupropion or structured counselling programs are more effective than self quitting in terms of smoking cessation. Where self-quitting wins out, of course, is that it is attempted again and again, increasing a likelihood that eventually a patient will stop because they are using a particular method. As was noted in Chapter 6, whilst it is important for general practitioners to promote self-quitting as a viable and effective smoking cessation strategy for smokers who are keen to cease smoking, it is not the only method. Indeed, for those who have difficulty ceasing smoking without some assistance pharmacotherapies should still be regarded as a first line treatment option. General practitioners do play an important role in helping patients to stop smoking, and they do this by tailoring their messages to the needs of the patient.

The final parts of this monograph assess the cost effectiveness of various interventions. Again, whilst pharmacotherapies are important they are not the most cost effective approaches to smoking cessation. Results of the analyses show that telephone counselling is probably the most cost effective smoking cessation intervention available in Australia. While telephone counselling may not be suitable or effective for all smokers

wanting to quit, it is relatively easily available. The role of general practitioners in referring patients, not just to self-quitting attempts but also to telephone quit lines should be markedly encouraged as a cost effective and accessible treatment option to reduce the prevalence of smoking in Australia.

As is shown in Chapter 8, the simple addition of some proactive counselling increases effectiveness at a small additional cost. It is important in Australia that these self-quitting and counselling approaches through telephone dial in lines are promoted as a way of smokers ceasing smoking.

However, the pharmacotherapies should remain a part of the spectrum of interventions. Bupropion with proactive telephone counselling was more cost effective than nicotine replacement therapy, being less costly and more effective in its impact on the smoking status.

Of course, in order to place these current results into context is important to recognize that ceasing smoking is achieved through a range of tobacco control methods, not just direct intervention with smokers in the counselling or pharmacotherapeutic approach. There is no doubt that the effectiveness of counselling, self-quitting, and pharmacotherapeutic approaches to smoking cessation in terms of achieving sustained abstinence are reasonably modest, with moderate incremental improvements on natural quit rates. Nonetheless, the cost effectiveness of smoking cessation interventions is, by standards of health care intervention, extremely good, because of the relatively low cost of the interventions concerned and the huge burden of disease that tobacco smoking causes. This cost effectiveness remains true, even when poor rates of compliance are factored into the analysis.

Bupropion and nicotine replacement therapies are cost effective health care interventions. So are telephone counselling approaches, either as interventions in their own right but also as adjuncts to nicotine replacement therapy or bupropion. It is unfortunate, in a context where pharmacotherapies are supported so strongly on the PBS that telephone counselling approaches have a level of cost effectiveness which has been under appreciated.

We recommend that there should be better dissemination to the public of effective tobacco control strategies, to provide a more balanced overview of what is effective and for whom. In particular, there should be better advertising that self quitting is effective and that repeated attempts will bring about positive results. The pharmacotherapies should be recognized as useful and as cost effective both by smokers and by the governments concerned relative to other health care interventions, but the outcomes are enhanced if there are additional therapies such as counselling or some structured plans to assist in smoking cessation approaches. Of course, such structured approaches are available through the telephone dial in lines for self referred quitters. Telephone counselling should be strongly promoted in the community and there should be a more efficient use of funds directed at self quitting through quit lines. Indeed if some of the money used to support pharmacotherapies in Australia had been used to fund self-quitting lines, the impact to public health level would have been more substantial than is achieved through the pharmacotherapies under the Pharmaceutical Benefits Scheme. Nonetheless, it is also a recommendation of this report that larger proportions of money be allocated to supporting and promoting pharmacotherapies in the future to enhance their uptake by smokers.

Of course, the question arises as to whether nicotine replacement therapy should be on the PBS. The analysis conducted in the foregoing chapters presumes that it is on the Pharmaceutical Benefits Scheme. Here it is certainly suggested it could be listed on the scheme. However, it is also apparent that members of the public are already accessing nicotine replacement therapy, possibly as a consequence of the reasonably heavy advertising and ease of availability. If nicotine replacement therapies were listed on the Pharmaceutical Benefits Scheme, then those products listed could not be advertised or marketed in any way directly to patients. In addition a prescription would be required for their use. This could lead to a reduction in the use of NRTs by smokers in Australia. Indeed the fact that bupropion is being prescribed in lower rates over time, may be because of public are not aware of the medication and therefore do not seek it from their doctor. All the weight of the evidence is not supportive of nicotine replacement therapies being equally cost effective to bupropion, however on balance it probably does have considerable public health effect and should be supported. As well as considering the cost effectiveness, determination of whether NRTS should or should not be placed on the Pharmaceutical Benefits Scheme would depend on whether it would be more

likely taken up by members of the public if were listed compared to the uptake when it is advertised widely through electronic media. A study examining the difference in uptake of NRTs between individual required to pay the full price (OTC) compared to a group requiring a visit to a general practitioner to obtain a script and then paying only the PBS dispensing fee might help address this issue.

In any case, the arguments for better dissemination to the public of smoking cessation methods seem convincing. It is also arguably convincing that we should be spending more to support the pharmacotherapies and other interventions. Notably cholesterol-lowering drugs cost the PBS budget a quarter of the total amount spent. Given that pharmacotherapies for smoking cessation are relatively inexpensive, it would seem that some balance could be struck by supporting those pharmacotherapies in a broader sense along with the promotion and funding of dial in telephone counselling lines.

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APPENDICES

Appendix 1: Pharmacy guild of Australia publication

Bupropion and Nicotine Replacement Therapies

By Chris Doran, Jennifer Gates, Julia Fawcett & Richard P Mattick from the National Drug and Alcohol Research Centre.

Introduction

Nicotine dependence is one of Australia's largest health problems with approximately one in five people aged 14 years and over who smoke daily (AIHW, 2002a). In 1998, tobacco smoking was responsible for 142,525 hospital episodes, 19,019 deaths and 184,579 potential years of life lost (Ridolfo and Stevenson, 2001). The total economic cost of tobacco smoking in 1998-99 was estimated at $21.01 billion (Collins and Lapsley, 2002).

Reducing the prevalence and uptake of smoking remains one of Australia's most important health care priorities (Commonwealth Department of Health and Aged Care, 1999). In 1974 rates of cigarette smoking in Australians aged 14 years and over was 41% of males and 29% of females (Gray, 1975) compared to 21% of males and 18% of females in 2001 (AIHW, 2002a). Much of the success in the reduction of smoking prevalence can be attributed to strategies that have been designed, implemented and evaluated.

Of the smoking cessation strategies available, pharmacotherapies are very effective. There are a number of Nicotine Replacement Therapies (NRTs) available in Australia, all freely available over the pharmacy counter. These include gums, patches, lozenges and inhalers. Patches are available on the Repatriation Pharmaceutical Benefits Scheme (RPBS). In a recent review of over 90 trials NRTs were found to help people to quit smoking (Lancaster et al., 2000a). The quit rates were higher when offered brief advice to intensive support with the NRT (Lancaster et al., 2000a). There is little evidence as to which nicotine product is most effective (Lancaster et al., 2000a).

In February 2001, Bupropion became the first pharmacotherapy to be listed on both the Pharmaceutical Benefits Scheme (PBS) and RPBS (Doran et al., 2002). The listing was for use as a short-term adjunctive therapy within a comprehensive treatment program over a 7-9 week period for high nicotine dependence with the goal of maintaining abstinence {Australian Medicines Handbook Pty Ltd, 2002 #296;MIMS Australia, 2002 #295}. The decision to list bupropion on these schemes was based on evidence that this medication was more effective and more cost-effective than patches (Croghan et al., 1997;Jorenby et al., 1999;Hays et al., 2001). Patients can receive only one PBS/RPBS application per year.

As a part of the NDARC research agenda we sought to undertake computer assisted telephone interviews (CATI) to investigate the use of Bupropion and NRTs.

Method

A survey was designed and developed by NDARC, with input from a number of interested parties, including the Pharmacy Guild of Australia and the Commonwealth Department of Health and Ageing. The survey had four sections. *Section A* focused on current smoking characteristics of the participants such as how often they smoked and how much. *Section B* asked a string of questions relating to the use of bupropion or NRT, such as side effects. *Section C* considered prior smoking cessation attempts and s*ection D* focused on participant demographic information.

The survey was administered via a computer assisted telephone interview (CATI). The CATI system allows the survey to take place on a computer, questions are generated depending on the participant's answers and all information is stored in a database for analysis.

Recruitment

Recruitment involved a number of steps. As we were interested in talking with smokers that had obtained bupropion or NRTs from a pharmacist, the *first step* was to contact pharmacies through the Pharmacy Guild of Australia asking for expressions of interest. The *second step* involved pharmacies interested in the project faxing back a form to NDARC with their contact details. An information pack was sent to all pharmacies interested in the project. *Step three* involved participating pharmacies asking smokers who collected bupropion or NRT whether they were interested in participating in a smoking

cessation survey. Those interested provided their name, medication collected and contact phone number. At the end of each month, over a four month time period, pharmacies faxed or posted NDARC a list of interested participants. Pharmacies were reimbursed $20 for every participant who completed the baseline survey. The *final stage* involved NDARC staff completing the CATI survey with interested participants. Follow-up surveys are currently being conducted.

The inclusion criteria included participants aged 18 years or over presenting to the pharmacy for bupropion or NRT and English speaking.

Results

Recruitment

In September 2002 the Pharmacy Guild of Australia on behalf of NDARC contacted 3,602 pharmacies. A total of 439 expressed an interest in the project with 99 pharmacies ultimately participating in the study. Of this number, 30 were from NSW, 24 QLD, 13 VIC, 11 WA, 10 TAS, 9 SA, 1 NT and 1 ACT. A total of 508 participants were recruited over a four-month period. A total of 396 (78 percent) participants completed the survey.

Participant Characteristics

A total of 228 bupropion and 168 NRT participants (100 patches, 31 Gum, 37 lozenge) were surveyed. Fifty five percent of the sample was female, the most common age group was 30-39yrs (27%) and the average age of participants was 42 years. Seventy nine percent were born in Australia, 56% had completed secondary school or higher, 45% were in full-time work and 52% were married. Little difference was found between bupropion and the NRT groups.

Smoking characteristics

Outlined in Table 1 are the smoking characteristics and previous quit attempts of the participants. Mean age to first start smoking was 16years. Ninety eight percent were daily smokers. Participants who used lozenges smoked an average of 22 cigarettes per day compared to the gum group who smoked an average of 27 cigarettes per day. Ninety five percent of those who used lozenges had previously attempted to quit smoking, compared to 85% of those who used bupropion, 81% of those who used patches and 74% of those who used the gum. The average number of previous quit attempts was three. The average period of non-smoking was 10 months and health was the main reason participants wanted to quit smoking.

Bupropion and NRT experience

Ninety-two percent of the participants stated that this was the first time they had used lozenges, compared to 68% of the bupropion group, 44% of the patch group and 55% of the gum group. Forty nine percent were currently using the lozenges, 55% gum, 41% bupropion and 32% patches at the time of the survey. Around two thirds (68%) of the lozenge group experienced side effects, compared to 49% of the bupropion group, 48% of the patch group and 42% of the gum group. Sleep disturbance (21%) was the main side effect experienced by the bupropion group followed by nausea (13%) and headaches (12%). Participants using patches experienced abnormal dreams (25%), rash (16%) and sleep disturbance (14%). The gum group experienced irritability (10%), nausea (1%) and dizziness (1%). Participants using lozenges experienced nausea (30%), hiccups (24%) and sore throat (16%). Overall the number who reported side efforts as the main reason for not continuing with bupropion or NRT was 26% (Table 2).

Discussion

For the first time NDARC developed and administrated a CATI survey to investigate the use of bupropion or NRTs (patches, gum or lozenge) in a non-threatening and confidential manner. With the help of the Pharmacy Guild of Australia, NDARC were able to involve a number of pharmacies from around Australia to help recruit participants for the smoking cessation survey. Pharmacies are in a good position to seek interested participants to gather valuable information about the use of bupropion and NRTs in Australia.

The results presented in this report provide baseline data on the characteristics of smokers who use pharmacotherapies for smoking cessation. The most common age was between 30-39yrs (27%), this result is similar to that of the 2001 National Drug Household Survey with around 26% of the population aged 30 – 39 years smoking daily(AIHW, 2002a). Nearly all of the participants surveyed were daily smokers and smoked around 25 cigarettes per day. The majority of participants had previously attempted to quit smoking with an average of three attempts. When exploring the differences between each pharmacotherapy, participants most frequently used the lozenges for the first time. This is likely to be because they are new to the market. Surprisingly, less than half of the participants were currently using bupropion or NRT at the time of the surveys. This may be due to the side effects or because they had already

stopped smoking. Sleep disturbance was the main side effect experienced by bupropion users, abnormal dreams for the patch, irritability for the gum and nausea for the lozenge.

This research is extremely valuable to help us understand the use and experience of bupropion and NRTs by smokers. While this article does not cover the statistical analysis between groups it provides an outline of the participants who use pharmacotherapies to assist with smoking cessation, their characteristics and experiences with pharmacotherapies. Further analysis will be performed by NDARC over the next few months. A follow-up survey is currently underway which will provide more detail and estimates of point prevalence and continuous abstinence.

Acknowledgments

NDARC would like to thank the Pharmacy Guild of Australia and in particular Khin Win May, the Pharmacies who help recruit participants and to the smokers that participated in the survey.

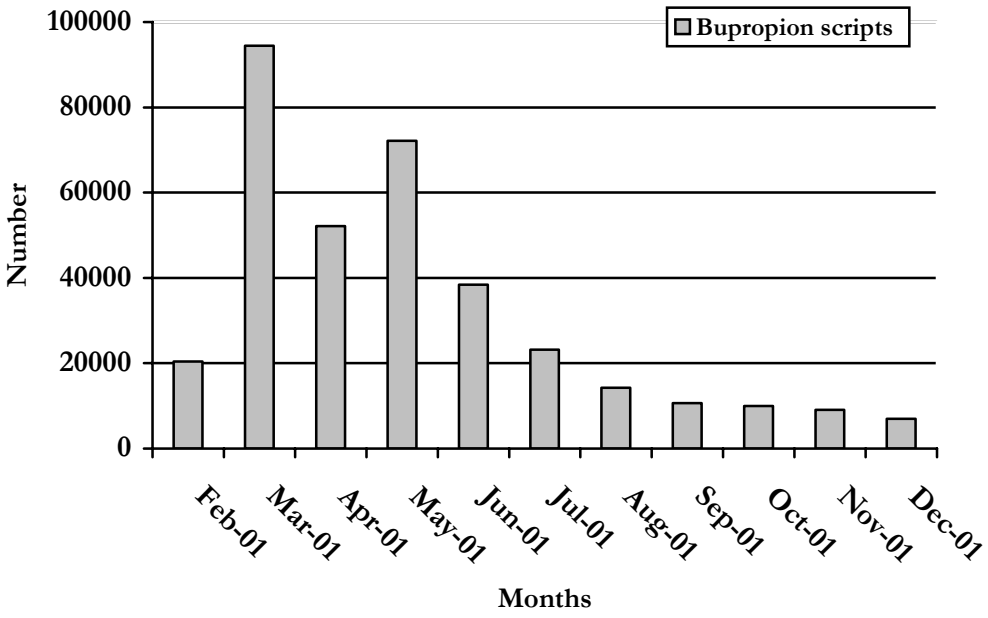
Table 1: Smoking characteristics and previous quit attempts.

Smoking characteristics	Bupropion (n = 228)	Patch (n = 100)	Gum (n = 31)	Lozenge (n = 37)	Total (n=396)
Mean age first started smoking in years (SD)	16 (4.2)	16 (3.4)	16 (3.3)	16 (3.5)	16 (3.9)
Daily smoker, N (%)	224 (99%)	97 (97%)	30 (97%)	36 (97%)	387 (98%)
Mean number of cigarettes per day (SD)	25 (11.4)	24 (10.7)	27 (14.7)	22 (10.3)	24 (11.4)
Average minutes after waking up before first cigarette (SD)	26 (59.8)	36 (94.1)	25 (35.5)	28 (27.7)	29 (66.8)
Previous quit attempts, N (%)	196 (86%)	81 (81%)	23 (74%)	35 (95%)	335 (85%)
Mean number of smoking quit attempts in the last two years, N (SD)	3 (3)	3 (3.8)	3 (2.9)	3 (3.7)	3 (3.3)
Previous success at quitting even for a short time, N (%)	104 (53%)	44 (54%)	12 (52%)	23 (68%)	183 (55%)
Longest period of time not smoked, mean months, (SD)	9 (8.4)	8 (8.5)	No data	14 (0)	10 (7.2)
Number quitting due to health, N, %	123 (69%)	54 (73%)	15 (75%)	21 (64%)	213 (70%)

Table 2: Prior and current experience with pharmacotherapies.

Experience with pharmacotherapies	Bupropion (n = 228)	Patch (n = 100)	Gum (n = 31)	Lozenge (n = 37)	Total (n=396)
First time ever used pharmacotherapy, N (%)	154(68%)	44 (44%)	17 (55%)	34 (92%)	249 (63%)
Currently using pharmacotherapy, N (%)	94 (41%)	32 (32%)	17 (55%)	18 (49%)	161 (41%)
Experienced side effects with pharmacotherapy, N (%)	113(49%)	48 (48%)	13 (42%)	25 (68%)	199 (50%)
Abnormal dreams	Notasked	25 (25%)	Not asked	Not asked	25 (6%)
Dizziness	22 (10%)	7 (7%)	1 (3%)	Not asked	30 (8%)
Headache	27 (12%)	Not asked	Not asked	3 (8%)	30 (8%)
Hiccup	Notasked	Not asked	Not asked	9 (24%)	9 (2%)
Irritability	16 (7%)	9 (9%)	3 (10%)	Not asked	28 (7%)
Nausea	30 (13%)	7 (7%)	1 (3%)	11 (30%)	49 (12%)
Rash	10 (4%)	16 (16%)	Not asked	Not asked	26 (7%)
Sleep disturbance	47 (21%)	14 (14%)	1 (3%)	Not asked	62 (16%)
Sore throat	Notasked	Not asked	Not asked	6 (16%)	6 (1.5%)
Side effects main reason for not continuing pharmacotherapy N. (%)	42 (36%)	9 (14%)	2 (17%)	3 (16%)	56 (26%)

Appendix 1: Bupropion Scripts processed (PBS/RPBS) between Feb and Dec 2001.



Source: Health Insurance Commission (2001) (Health Insurance Commission, 2001)

Appendix 2: Number of smokers who have used bupropion between Feb and Dec 2001

State	Current Regular smokers[1]	Scripts processed[2]	% of smokers who have used bupropion
NSW	1,077,132	106,478	9.9%
VIC	804,455	64,482	8.0%
QLD	593,268	81,619	13.8%
SA	245,553	32,455	13.2%
WA	316,608	46,186	14.6%
TAS	74,507	12,279	16.5%
NT	33,254	3,803	11.4%
ACT	53,448	4,470	8.4%
Total	**3,198,225**	**351,772**	**11.0%**

1. (Doran et al., 2002;Swan et al., 2003)
2. Health Insurance Commission (HIC), www.hic.gov.au(Health Insurance Commission, 2003)

Appendix 3: Letter facsimiled all pharmacies from the Pharmacy Guild of Australia.

The PHARMACY GUILD of AUSTRALIA

19 September 2002

Dear Colleague,

The Pharmacy Guild of Australia has agreed to assist the National Drug and Alcohol Research Centre (NDARC) at the University of New South Wales (UNSW), on research into the effectiveness of Zyban and nicotine replacement therapies (NRT) as an aid to smoking cessation. As part of these research activities, a survey has been designed to gather data on the behaviours, and adverse side effects associated with the use of pharmacotherapies by Australian smokers. It is anticipated that the results from this survey will assist in the understanding of compliance, safety and field effectiveness of Zyban and NRTs and facilitate the improvement of tobacco control messages and strategies.

The Guild is seeking your co-operation with recruitment of participants for this survey. The project will require pharmacists to ask people who present with a prescription for Zyban or request for NRT, whether they are willing to be contacted by NDARC staff by telephone. You would need to take the individual's first name and their best contact telephone number. You should also explain that the person could refuse to participate in the future. You would then provide these phone numbers to NDARC who would ring the person, explain the study, obtain informed consent, and enrol them in the study. It is anticipated that recruitment will take place over a three-month period.

For your efforts in enrolling patients into the study, NDARC has offered to provide $20 per person enrolled. The number of people enrolled per pharmacy will be monitored by NDARC and pharmacies will be reimbursed accordingly.

If you are interested in being part of this study please complete the details on the following page and **facsimile back to the NDARC on 02 9385 0222 by 3 October 2002**. Once expressions of interest have been received, NDARC will forward an information kit to those interested in the study outlining study objectives, methodology, timeframes and contact details of project officer. Please note that receipt of the information package does not commit you to the study.

On behalf of the Pharmacy Guild of Australia and NDARC, I hope that you will consider being part of this important project which will provide useful information to assist smokers wanting to quit and which will assist to keep smoking cessation products in pharmacy If you have any questions regarding this project please feel free to contact Ms Julia Fawcett at NDARC on 02 9385 0333 or Ms Khin Win May on 02 6270 1888 at the National Secretariat of the Guild.

Yours sincerely

John Bronger
National President

TO: **NATIONAL DRUG AND ALCOHOL RESEARCH CENTRE (NDARC)**

ATTENTION: MS JULIA FAWCETT

FASCIMILE: 02 9385 0222

FROM: PHARMACY STAMP & CONTACT NAME

DATE:

If you are interested in being part of this National survey please answer the following questions and facsimile this page back to NDARC on the above number.

On average, how many scripts for Zyban do you fill per month?

_____

On average, how many requests for Nicotine Replacement Therapy (NRT) products do you receive per month?

_____

I am interested in this study but can you provide more information (please tick)
☐

PLEASE FASCIMILE THIS PAGE BACK ONLY IF YOU ARE INTERESTED IN PARTICPATING IN THIS SURVEY OR YOU WOULD LIKE MORE INFORMATION

THANKYOU FOR YOUR TIME AND CO-OPERATION

Appendix 4: Information letter to Pharmacists from NDARC

Date

Contact person
Pharmacy name
Address
Suburb
State, Postcode

Dear Contact person,

Recently you received a facsimile from the Pharmacy Guild of Australia on behalf of the National Drug and Alcohol Research Centre (NDARC) at the University of New South Wales. The facsimile outlined research into the effectiveness of Zyban and nicotine replacement therapies (NRT) as an aid to smoking cessation. We thank you for your response to this facsimile and would like to take this opportunity to provide more detail about this study and the logistics of working with you to recruit participants.

A survey has been designed by NDARC to gather data from Australian smokers on the behaviours, adverse side effects and field effectiveness associated with the use of Zyban and NRTs for nicotine dependence. The survey is approximately 10 minutes long and will be administered through a computer assisted telephone interview by NDARC staff. If you would like copy of this survey please call Ms Jennifer Gates (Project Officer) or Ms Julia Fawcett on 02 9385 0333 or facsimile 02 9385 0222. It is anticipated that the results from this survey will help us better understand the issues surrounding the use of Zyban and NRTs as an aid to smoking cessation and facilitate an improvement of tobacco control messages and strategies.

To successfully complete the survey we need your help in recruiting smokers. The study is planned to commence in November and continue for a three-month period (November – January inclusive) or until our target sample is acquired. We are aiming to enrol 300 Zyban users and 900 NRT users across Australia. For the NRT part of this study we are focusing our attention on patches, gum and lozenges. Based on the information we have received from the pharmacies around Australia, for every Zyban script filled there are, on average, 18 requests for a NRT. Therefore, our ability to recruit the required number of NRT users will be easier than recruitment of Zyban users. To this extent we have asked nine out of every ten pharmacies to recruit Zyban users only, with one in ten requested to recruit both Zyban and NRT users. The participants you have been asked to recruit are (Zyban or Zyban/NRT) users.

To help us recruit the required amount of people into the study we would like you to do a number of things that may be summarised in the following steps.

Step 1: Ask the person presenting for the medication whether they are willing to be involved in a study concerning their medication.
Step 2: Provide the person with the participant information statement (participant can keep first page for their records)
Step 3: Ask the person to record their contact details on the second page of the participant information statement and return to you

Step 4: Facsimile or mail the completed participant detail forms to NDARC at the end of each month.

Attached to this letter you will find copies of the participant information sheet and participant details sheet, and three return facsimile sheets (one for each month). If you prefer to mail the completed participant detail forms please use the reply paid envelope provided. If you require additional copies of written material or envelopes please contact Jennifer or Julia on 02 9385 0333 or facsimile 02 9385 0222 and we will forward additional copies to you.

Upon receipt of the participant detail forms, NDARC will contact the relevant people, discuss the study in more detail, obtain informed consent, and enrol them in the study proper. NDARC will monitor the number of patients that **enrol in the study** as a consequence of your efforts and will reimburse you $20 for each person enrolled. A cheque will be made out to *pharmacy name* and forwarded to you at the completion of the recruitment period.

If you would like to discuss the project in more detail or have any concerns please contact Jennifer who will be happy to answer your questions. If you are interested in participating in this study we would ask that you commence recruitment at the start of November. If you are unable to be involved in this study could you please facsimile Jennifer on 02 9385 0222 so that your details are removed from our database and you will not receive unnecessary correspondence.

We thank you for your interest in this study and look forward to working with you over the coming months. If you would like more information on the type of research conducted at NDARC please visit our website at http://ndarc.med.unsw.edu.au/ndarc.nsf.

Yours sincerely,

Dr Christopher Doran
Health Economist

National Drug and Alcohol Research Centre

Appendix 5: Participant information statement

THE UNIVERSITY OF NEW SOUTH WALES

PARTICIPANT INFORMATION STATEMENT

TITLE OF PROJECT: SURVEY OF NICOTINE CESSATION THERAPIES

You are invited to participate in a study examining the safety and effectiveness of Zyban and nicotine replacement therapies as aids to smoking cessation. We hope to learn from the study how these medications are being used, what side effects (if any) you may have experienced when using these medications, and whether these medications helped you give up smoking, and if so, for how long. You were selected as a possible participant in this study because you have presented to your pharmacy for a script of Zyban or have requested nicotine replacement therapy.

If you decide to participate in this study, we will contact you by telephone using the number that you have provided to your pharmacy. During this phone call we will explain the study, seek your consent to participate, and if you agree to participate, enrol you in the study. The study is in the form of telephone-administered survey that involves asking you a series of short questions in relation to your experience with Zyban and/or nicotine replacement therapies. The interview should take no more than 10 minutes of your time.

We cannot and do not guarantee or promise that you will receive any direct benefits from this study but we can assure you that your responses will be of considerable benefit to us by helping us understand the issues around the use of Zyban and nicotine replacement therapies.

As per our ethics requirements, any information that is obtained from you will remain entirely confidential. If you provide your consent to be part of this study, we plan to write a report for the Commonwealth Department of Health and Aging. In any report, information will be provided in such a way that you cannot be identified.

If you would like to be involved in this study could you please write down your name and contact details on the next page and hand it to your pharmacist. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time. If you have any questions, please feel free to contact either Ms Jennifer Gates or Ms Julia Fawcett on 9385 0333. Complaints may be directed to the Ethics Secretariat, University of New South Wales, Sydney 2052 (phone 9385 4234, facsimile 9385 6648).

Appendix 6: Recruitment form for Zyban and NRT group

NATIONAL DRUG AND
ALCOHOL RESEARCH CENTRE

THE UNIVERSITY OF NEW SOUTH WALES

PARTICIPANT DETAILS

TITLE OF PROJECT: SURVEY OF NICOTINE CESSATION THERAPIES

If you would like to be involved in this study could you please fill out this page and hand it to your pharmacist. Staff from the National Drug and Alcohol Research Centre will contact you shortly to explain the study in more detail, seek your consent to participate, and if you agree to participate, enroll you in the study. The study is in the form of telephone-administered survey that involves asking you a series of short questions in relation to your experience with nicotine replacement therapies. The interview should take no more than 10 minutes of your time.

Medication provided (please tick)

Zyban ☐

NRT – patches ☐

NRT – gum ☐

NRT – lozenge ☐

Date medication supplied: _____

Your first name: _____

Your surname: _____

Home contact number: _____

Work contact number: _____

Mobile contact number _____

Preferred contact number (please tick)

Home ☐

Work ☐

Mobile ☐

Appendix 7: Recruitment record form for Zyban only

THE UNIVERSITY OF NEW SOUTH WALES

PARTICIPANT DETAILS

TITLE OF PROJECT: SURVEY OF NICOTINE CESSATION THERAPIES

If you would like to be involved in this study could you please fill out this page and hand it to your pharmacist. Staff from the National Drug and Alcohol Research Centre will contact you shortly to explain the study in more detail, seek your consent to participate, and if you agree to participate, enroll you in the study. The study is in the form of telephone-administered survey that involves asking you a series of short questions in relation to your experience with nicotine replacement therapies. The interview should take no more than 10 minutes of your time.

Date Zyban supplied: _____

Your first name: _____

Your surname: _____

Home contact number: _____

Work contact number: _____

Mobile contact number _____

Preferred contact number (please tick)

Home ☐

Work ☐

Mobile ☐

Appendix 8: Thank you and invoice request letter for pharmacies

Date

Contact person
Pharmacy name
Address
Suburb
State, Postcode

Dear Contact person,

Over the past few months you have been helping the National Drug and Alcohol Research Centre (NDARC) recruit participants into a smoking cessation study. As a consequence of your efforts we have recruited over 400 participants into the study. Your assistance in recruiting patients and forwarding their contact details is greatly appreciated. Without your help this project would not have been possible.

As discussed in previous correspondence, NDARC agreed to reimburse you $20 for each person enrolled in the study. The definition of enrolment was the actual completion of an interview. Our records indicate that from your pharmacy a total of XX participants were recruited with YY of these being enrolled into the study. As a consequence we would like to reimburse you $20 multiplied by YY.

As per University policy we would ask you to send us an invoice for this amount plus GST. **The invoice needs to be sent to Jennifer Gates by mail (Jennifer Gates, NDARC UNSW Sydney 2052)**. Please state the purpose of the invoice as **Research Contract**. Payment will follow upon receipt of your invoice. The University is sometimes slow at processing invoices so it may take a few weeks for the cheque to arrive.

If you would like to discuss this procedure, or clarify number of patients enrolled, please call Jennifer Gates on 2 9385 0333.

Yours sincerely,

Dr Christopher Doran
Health Economist
National Drug and Alcohol Research Centre

Appendix 9: Patient smoking cessation baseline survey

Patient smoking cessation survey

Introduction

Hello may I speak to _____.
(*If not available ask when they might be home or available*

Good morning/afternoon/evening _____. My name is _____ and I am ringing from the National Drug and Alcohol Research Centre at the University of NSW.

Section A: Smoking status pre-medication use

Now I am going to ask you about your smoking status before using your current medication

1. At what age did you first start smoking?	Patient response
2. How often did you smoke?	Daily 2-3 times per week Once a week Other (please specify)
3. On average, how many cigarettes did you smoke a week?	Patient response
4. How long after waking up did you smoke your first cigarette (minutes)?	Patient response

Section B: Medication

Now I am going to ask you about your current medication use

5. What medication did you collect from your pharmacist to help you quit smoking?	Zyban Patch 21mgs 14mgs 7mgs 15mgs 10mgs 5mgs Gum 2mgs 4mgs Lozenge 2mgs 4mgs
6. Is this the first time you have ever used **(insert medication nominated in Q5)**?	Yes No
7. Are you currently using **(insert medication nominated in Q5)**?	Yes No ***Go to Q9***
8. How long ago did you start using **(insert medication nominated in Q5)**?	**Drop down calendar** (if possible) – need to calculate 12 weeks from this for purpose of follow-up – flag date at

	end of survey ***(go to section B1-4 relating to current medication use)***
9. Did you ever start using **(insert medication nominated in Q5)**?	Yes ***Go to Q10*** No ***Go to Q11***
10. Why did you stop using **(insert medication nominated in Q5)**?	Adverse side effects Please list Adverse media reports Couldn't stop smoking Other (please specify) ***(go to section B1-4 relating to current medication use)***
11. Why didn't you start using **(insert medication nominated in Q5)**?	Cost Negative publicity Not interested Prefer other method Other (please specify)

Section B1: Current Zyban use

(This section to be answered only by those patients who nominated Zyban in Q1)

12. How often do you take Zyban?	Once daily Twice daily Alternate days Other (please specify)
13. Have you experienced any side effects with Zyban?	Yes Anxiety Chest pain Confusion Dizziness Headache Increased BP Irritability Nausea Rash/skin reaction Sleep disturbances Seizures Tremor Other (please specify) No
14. Did your doctor advise you to use any other products or programs with Zyban?	Yes Counselling by GP Counselling by other Gum Lozenge Patch Quitline Zyban Action Plan Other (please specify) No **G*o to Q18***
15. Did the pharmacy staff advise you to use any other products or programs with	Yes Counselling by GP

Zyban?	Counselling by other Gum Lozenge Patch Quitline Zyban Action Plan Other (please specify) No **G*o to Q18***
16. Have you used any of these products or programs?	Yes Counselling by GP Counselling by other Gum Lozenge Patch Quitline Zyban Action Plan Other (please specify) No ***Go to Q18***
17. How useful do you think these programs or products have been? **NB: Only interested in rating those programs or products used as indicated in preceding questions Q1, 15 & 16**	Counselling by GP Not useful Slightly useful Useful Very useful Don't know Counselling by other Not useful Slightly useful Useful Very useful Don't know Gum Not useful Slightly useful Useful Very useful Don't know Lozenge Not useful Slightly useful Useful Very useful Don't know Patch Not useful Slightly useful Useful Very useful Don't know Quitline

	Not useful Slightly useful Useful Very useful Don't know Zyban Action Plan Not useful Slightly useful Useful Very useful Don't know Other Not useful Slightly useful Useful Very useful Don't know
18. Has Zyban helped you to quit smoking?	Yes ***Go to Section C*** No ***Go to Section C***

Section B2: Current patch use

(This section to be answered only by those patients who nominated patch in Q1)

19. How often do you use patches?	Once daily Alternate days Other (please specify)
20. Have you experienced any side effects with the patches?	Yes Abnormal dreams Diarrhoea Dizziness Dry mouth Irritability Nausea Rash/skin reaction Sleep disturbances Sweating Other (please specify) No
21. Did your doctor you to use any other programs or products with the patches?	Yes Counselling by GP Counselling by other Gum Lozenge Quitline Zyban Other (please specify) No **G*o to Q25*** ***Didn't go to doctor***
22. Did the pharmacy staff advise you to use any other products or programs with patches?	Yes Counselling by GP Counselling by other Gum

	Lozenge Quitline Zyban Other (please specify) No **G*o to Q25***
23. Have you used any of these programs or products?	Yes Counselling by GP Counselling by other Gum Lozenge Quitline Zyban Other (please specify) No ***Go to Q25***
24. How useful do you think these programs or products have been?	Counselling by GP Not useful Slightly useful Useful Very useful Don't know Counselling by other Not useful Slightly useful Useful Very useful Don't know Gum Not useful Slightly useful Useful Very useful Don't know Lozenge Not useful Slightly useful Useful Very useful Don't know Quitline Not useful Slightly useful Useful Very useful Don't know Zyban Not useful Slightly useful Useful Very useful Don't know

	Other Not useful Slightly useful Useful Very useful Don't know
25. Have the patches helped you to quit smoking?	Yes ***Go to Section C*** No ***Go to Section C***

Section B3: Current gum use

(This section to be answered only by those patients who nominated gum in Q1)

26. How often do you use the gum?	1 piece every 1-2 hours 1 piece every 3-4 hours 1 piece every 5-8 hours Other (please specify)
27. How many pieces of gum do you usually have each day?	Patient response
28. Did you experience any side effects with the gum?	Yes Dizziness Irritability Nausea Sleep disturbances Ulcers Other (please specify) No
29. Did your doctor advise you to use any other programs or products with the gum?	Yes Counselling by GP Counselling by other Lozenge Patch Quitline Zyban Other (please specify) No **G*o to Q33***
30. Did the pharmacy staff advise you to use any other products or programs with patches?	Yes Counselling by GP Counselling by other Lozenge Patch Quitline Zyban Other (please specify) No **G*o to Q33***
31. Have you used any of these programs or products?	Yes Counselling by GP Counselling by other Lozenge Patch Quitline

	Zyban Other (please specify) No ***Go to Q33***
32. How useful do you think these programs or products have been?	Counselling by GP Not useful Slightly useful Useful Very useful Don't know Counselling by other Not useful Slightly useful Useful Very useful Don't know Lozenge Not useful Slightly useful Useful Very useful Don't know Patch Not useful Slightly useful Useful Very useful Don't know Quitline Not useful Slightly useful Useful Very useful Don't know Zyban Not useful Slightly useful Useful Very useful Don't know Other Not useful Slightly useful Useful Very useful Don't know
33. Has the gum helped you to quit smoking?	Yes ***Go to Section C*** No ***Go to Section C***

Section B4: Current lozenge use

This section to be answered only by those patients who nominated lozenge in Q1

34. How often do you use the lozenges?	1 piece every 1-2 hours1 piece every 3-4 hours 1 piece every 5-8 hours Other (please specify)
35. How many lozenges do you usually have each day?	Patient response
36. Did you experience any side effects with the lozenges?	Yes Coughing Diarrhea Flatulence Headache Heartburn Hiccup Nausea Sore throat Other (please specify) No
37. Did your doctor you to use any other programs or products with the lozenges?	Yes Counselling by GP Counselling by other Quitline Gum Patch Zyban Other (please specify) No ***Go to Q41***
38. Did the pharmacy staff advise you to use any other programs or products with the lozenges?	Yes Counselling by GP Counselling by other Quitline Gum Patch Zyban Other (please specify) No ***Go to Q41***
39. Have you used any of these programs or products?	Yes Counselling by GP Counselling by other Gum Patch Quitline Zyban Other (please specify) No ***Go to Q41***
40. How useful do you think these programs or products have been?	Zyban Not useful Slightly useful Useful

	Very useful Don't know Patch Not useful Slightly useful Useful Very useful Don't know Gum Not useful Slightly useful Useful Very useful Don't know Counselling by GP Not useful Slightly useful Useful Very useful Don't know Counselling by other Not useful Slightly useful Useful Very useful Don't know Quitline Not useful Slightly useful Useful Very useful Don't know Other Not useful Slightly useful Useful Very useful Don't know
41. Have the lozenges helped you to quit smoking?	Yes ***Go to Section C*** No ***Go to Section C***

Section C: Smoking cessation attempts

Now I am going to ask you about your previous quit smoking attempts not including the current one

42. Have you ever attempted to quit smoking?	Yes No ***Go to Section D***
43. How many times have you attempted to quit smoking during the last two years for at least one week?	Patient response
44. Were you successful in your attempts to quit smoking, even for a short time?	Yes No
45. What is the longest period of time that you haven't smoked?	Patient response □
46. What was the main reason you decided to quit smoking?	Cost Family Health Social Work Other (please specify)
47. What type of products or programs have you ever used to help you quit smoking? **NB: If only <u>one</u> response then go to Q49, if multiple answers go to Q48**	None (cold turkey) Counselling by GP Counselling by other Herbal product Hypnosis/Acupuncture NRT Gum Lozenge Patches Quitline Written material Zyban Other (please specify)
48. Which of these products or programs did you find most useful to help you quit smoking, even for a short time?	None (cold turkey) Counselling by GP Counselling by other Herbal product Hypnosis/Acupuncture NRT Gum Lozenge Patches Quitline Written material Zyban Other (please specify)
49. If a new vaccine was developed that could help you quit smoking for a year, how much would you be prepared to pay for an annual dose?	Patient response

Section D: Demographics and Background Details

Now I am going to ask you some demographic and background questions

50. How old are you?	Patient response
51. What is the country of your birth?	Australia Asia Canada Europe Middle East New Zealand South Africa United Kingdom and Ireland United States Other (please specify)
52. What is your gender?	Male Female
53. Are you of Aboriginal or Torres Strait Islander origin?	Yes No
54. Is English your first language?	Yes No
55. What is your home postcode?	Patient response
56. What is the highest level of education that you have completed?	No formal Primary school Some secondary Completed secondary Trade/technical qualification University
57. What is your work status?	Full-time Home duties Part-time/casual Retired Student Unemployed Volunteer work Other (please specify)
58. What is your annual income before tax?	< $21,000 $21 to 31,000 $32 to $42,000 $43 to $52,000 $53 to $78,000 >$78,000
59. What is your marital status?	De facto Divorced Married Separated Single Widowed
60. In general how would you describe your health?	Excellent Very good

	Good Fair Poor
61. How many times in the past four weeks have you seen a doctor or other health professional because of your health?	None Once Twice 3 – 4 times 5 or more times

Conclusion

That is the end of this survey. Thank you very much for your participation. We would, however, like to ask you some more questions at a later date to see how you have gone with your medication. . Would you mind if we contacted you around ***(date to be automatically calculated from date when medication was started)***. Please not a more convenient date and time?) ***(Need to be able to enter this date and time so it can be flagged as a reminder).***

Thanks again for your help and good morning/afternoon/evening

Appendix 10: Patient Smoking Cessation Follow-up Survey

Patient Smoking Cessation Follow-up Survey

Introduction

Hello may I speak to _____.
(*If not available ask when they might be home or available)*

My name is _____ and I am ringing from the University of NSW.

A few months ago you completed a quit smoking survey. Have you got time now to answer a few follow-up questions from that survey?

(*If not able to complete now,* then ask when is a more convenient time to call back?)
(*If not interested*, thank you very much, good bye).

Section A: Smoking Status

Now I am going to ask you a few questions about your current smoking status.

1.	Are you still smoking?	Yes No
2.	Have you had a cigarette in the last 7 days?	Yes No ***(go to Q6)***
3.	How often are you smoking?	Daily 2-3 times per week Once a week Other (please specify)
4.	On average, how many cigarettes do you smoke a week?	Patient response
5.	How long after waking up do you smoke your first cigarette (minutes)?	Patient response ***(Go to Q8)***
6.	How long ago did you stop smoking?	Patient response
7.	What is the <u>main</u> reason you decided to quit smoking?	Cost Family Health Social Work Other (Please specify) **(Go to Section B)**
8.	What is the <u>main</u> reason you are still smoking?	Family Work Social Couldn't stop Not interested Side effects (medication) Withdrawals Other (Please specify)

Section B: Current medication use

Now I am going to ask you a few questions about the medication that you were interviewed about in the last survey.

9.	What medication did you collect from your pharmacist to help you quit smoking?	Zyban Patch 21mgs 14mgs 7mgs 15mgs 10mgs 5mgs Gum 2mgs 4mgs Lozenge 2mgs 4mgs
10.	Did you complete the full course of **(insert medication nominated in Q9)**?	Yes **(Go to Q15)** No
11.	Are you currently using **(insert medication nominated in Q9)**?	Yes **(Go to Q15)** No
12.	Did you ever start using **(insert medication nominated in Q9)**?	Yes No ***(Go to Q14)***
13.	Why didn't you complete the full course **(insert medication nominated in Q9)**?	Adverse side effects Please list Adverse media reports Couldn't stop smoking Other (please specify) ***(Go to Q15)***
14.	Why didn't you start using **(insert medication nominated in Q9)**?	Cost Negative publicity Not interested Prefer other method Still smoking Other (please specify) ***(Go to Q19)***
15.	Did **(insert medication nominated in Q9)** help you to quit smoking?	Yes No
16.	Did you experience any side effects with **(insert medication nominated in Q9)**?	Yes Abnormal dreams Anxiety Chest pain Confusion Coughing Diarrhoea Dizziness Dry mouth Flatulence Headache Heartburn Hiccups

	Increased BP Irritability Nausea Rash/skin reaction Sleep disturbances Seizures Sore throat Sweating Tremor Ulcers Other (please specify) No
17. Did you use any other products with **(insert medication nominated in Q9)**?	Yes Counselling by GP Counselling by other Gum Lozenge Patch Quitline Zyban Zyban Action Plan Other (please specify) No ***Go to Q19***
18. How useful were these products**? NB: Only interested in rating those products used as indicated in Q17.**	Counselling by GP Not useful Slightly useful Useful Very useful Don't know Counselling by other Not useful Slightly useful Useful Very useful Don't know Gum Not useful Slightly useful Useful Very useful Don't know Lozenge Not useful Slightly useful Useful Very useful Don't know Patch Not useful Slightly useful

	Useful Very useful Don't know Quitline Not useful Slightly useful Useful Very useful Don't know Zyban Not useful Slightly useful Useful Very useful Don't know Zyban Action Plan Not useful Slightly useful Useful Very useful Don't know Other Not useful Slightly useful Useful Very useful Don't know
19. Have you taken any other medication to help you to quit smoking since your last interview?	Yes **(if yes what medication? Insert list from Q9)** No
20. Out of every strategy you have ever used to help you quit smoking which one has been the most useful?	Patient response
21. **[For NRT users only]** What was your original intent for using NRTs?	To quit smoking To decrease amount smoked To use as a substitute (because inconvenient to smoke at work/school etc) Possibly a few more options

Section C: Current Health Status

Now, I am going to ask you about your current health status

22.	In general how would you describe your health?	Excellent Very good Good Fair Poor
23.	How many times in the past four weeks have you seen a doctor or other health professional because of your health?	None Once Twice 3 – 4 times 5 or more times

Conclusion

That is the end of this survey. Thank you for your time. We might be doing follow-up surveys to find out how people are going. Would you mind if we contacted you **towards the end of the year – YES / NO option.** Bye and GOOD LUCK.

Appendix 11: Practitioner survey

NICOTINE & ALCOHOL CESSATION THERAPIES

Medical Practitioner Survey

National Drug and Alcohol Research Centre
The University of New South Wales
with
The Department of General Practice
The University of Adelaide

Part A: Demographic and Background Details

Firstly, we would like to obtain some general information about yourself:

1. What is the year of your birth?	19 _ _
2. In which country were you born?	Australia New Zealand United Kingdom Other (please specify) .....
3. What is your gender?	Male Female
4. In what year did you graduate from medical school?	19 _ _
5. Where was your undergraduate medical training completed?	Australia New Zealand United Kingdom Other (please specify) .....
6. Have you completed FMP/RACGP (or overseas equivalent) training?	Yes No Current training
7. Are you vocationally registered as a GP?	Yes No
8. Do you have a specialist qualification either as a psychiatrist or gastroenterologist?	Yes No
8a. Please specify qualification:	
9. Do you have a postgraduate medical qualification?	Yes No **SKIP to Q11**

10. Is your postgraduate qualification in mental health?

Yes
No

10a. Please specify the postgraduate qualification:

.....
.....

11. How many years have you worked in general/specialist practice?

< 1 year
1 - 2 years
3 - 5 years
6 -10 years
11 - 20 years
> 20 years

12. How many sessions would you normally work per week? *(A session equals 3.5 hours or half day).*

…….……..

13. What is the postcode of your major practice address? _ _ _ _

14. How many doctors (FTE) work at the practice where you do most of your consulting?

Solo
2 doctors
3-5 doctors
6-8 doctors
More than 8 doctors

15. Please indicate the extent to which computers are used at the practice where you do most of your consulting. *(Please tick all boxes which apply).*

Not at all
Billing/accounting
Administration
Prescribing
Medical records
Pathology/report downloads
Other *(please specify)*
.....

Part B: Nicotine Cessation Therapies

We would like to obtain some information about management of patients with nicotine dependence:

(**Note**: buproprion hydrochloride=**Zyban** & nicotine replacement therapy =**NRT**)

16. Do you establish the smoking status of all of your patients?

Yes
No

17. Do you provide advice on the benefits of smoking cessation to all patients who smoke?

Yes
No

18. Have you undertaken training in providing a brief smoking intervention eg. smokescreen?

Yes
No

19. Do you regard smoking cessation as a preventative priority?

Yes
No

20. Are you familiar with the five "As" of smoking intervention?

Yes
No

What aspects of care do the five "A's" cover?

.....
.....
.....
.....
.....

21. What is your preferred treatment strategy(ies) for nicotine dependence? *(Please tick as many boxes which apply).*

NRT
Zyban
Counselling by GP
Counselling by other health professional
Quitline
Pamphlets
Herbal product
Hypnosis
Acupuncture
Other *(please specify)*
.....

22. Have you ever recommended NRT for nicotine dependence?

Yes
No

Please state your reason(s) for NOT prescribing NRT: *(Please tick all boxes which apply).*

22a. Treatment not effective
22b. Cost
22c. Patient not motivated
22d. Possible adverse effects of medication
22e. Other *(please specify)*
.....
.....
.....

23. How effective do you think Zyban is in helping patients to achieve long-term abstinence?

Not effective
Slightly effective
Effective
Very effective
Don't know

24. Have you ever prescribed Zyban for nicotine dependence?

Yes **SKIP to Q25**
No

Please state your reason(s) for NOT prescribing Zyban. *(Please tick all boxes which apply).*

24a. Treatment not effective
24b. Cost
24c. Patient not motivated
24d. Possible adverse effects of medication
24e. Other *(please specify)*
.....
.....
.....

If answered "NO" to Q24, please SKIP to Q32 in Section C.

25. How many scripts of Zyban do you estimate you have prescribed?
……..……..

26. What factors trigger a decision to prescribe Zyban rather than another form of treatment? *(Please tick all boxes which apply).*

Patient request
Request by family member
Health status of patient
Other *(please specify)*
.....
.....
.....

27. In prescribing Zyban do you advise patients to pursue other programs or products to assist smoking cessation?

Always
Frequently
Rarely
Never **SKIP to Q29**

28. Please indicate the programs or products which were advised by you for use in conjunction with Zyban. *(Please tick all boxes which apply).*

Zyban Action Plan (ZAP)
NRT
Counselling by GP
Counselling by other health professional
Quitline
Pamphlets
Other *(please specify)*
.....

29. Do you think that programs or products in association with Zyban improve the likelihood of smoking cessation?

Yes
No **SKIP to Q32**

30. Which program or product do you think is the most effective when used in conjunction with Zyban? *(Please tick only one box).*

Zyban Action Plan (ZAP)
NRT
Counselling by GP
Counselling by other health professional
Quitline
Pamphlets
Other *(please specify*
.....

31. What proportion of your patients prescribed Zyban, do you estimate returned for a follow-up consultation related to smoking cessation?

……..……..

Part C: Alcohol Cessation Therapies

We would like to obtain some information about management of patients with alcohol dependence:

32. Do you establish the drinking status of all your patients?

Yes
No **SKIP to Q34**

33. In general, do you use a screening instrument to detect drinking status?

Yes
No

33a.
Which screening instrument(s) do you use? *(Please tick all responses which apply).*

AUDIT (Alcohol use disorders identification test)
Drinking diary
Other *(please specify)*.....

34. Do you provide advice on the health risks of excessive alcohol use?

Yes
No

35. Have you undertaken training in providing advice to patients about excessive alcohol use?

Yes
No

36. Do you regard advice for excessive alcohol use as a preventative priority?

Yes
No

37. What is your preferred treatment strategy(ies) for excessive alcohol use? *(Please tick as many boxes which apply).*

Pharmacotherapy
Counselling by GP
Counselling by other health professional
Pamphlets
Herbal product
Other *(please specify)*
.....

38. Have you ever prescribed a pharmacotherapy for excessive alcohol use?

Yes
No

Please state your reason(s) for NOT prescribing pharmacotherapies for alcohol dependence. *(Please tick all boxes which apply).*

38a. Treatment not effective
38b. Cost
38c. Patient not motivated
38d. Possible adverse effects of medication
38e. Other *(please specify)*
.....
.....
.....

SKIP to Q46 if answered "NO" to Q38.

39. What factors trigger a decision to prescribe a pharmacotherapy rather than another form of treatment? *(Please tick all boxes which apply)*

Patient request
Request by family member
Health status of patient
Other *(please specify)*
.....

40. Which pharmacotherapy(ies) have you prescribed? *(Please tick all boxes which apply).*

Naltrexone (Revia)
Acamprosate (Campral)
Disulfiram (Antabuse)
Other *(please specify)*
.....

41. Please indicate how effective you think pharmacotherapies are in helping patients to reduce excessive alcohol use *(Please tick one box only):*

Not effective
Effective
Very effective
Don't know
Slightly effective

42. Please indicate the effectiveness of pharmacotherapies in helping patients to reduce excessive alcohol use *(Please tick one box only for each medication):*

Naltrexone	**Acamprosate**	**Disulfiram**
Not effective	Not effective	Not effective
Effective	Effective	Effective
Very effective	Very effective	Very effective
Don't know	Don't know	Don't know
Slightly effective	Slightly effective	Slightly effective

43. In prescribing pharmacotherapies for excessive alcohol use, were patients advised to pursue other programs or products in conjunction with the pharmacotherapy?

Always
Frequently
Rarely
Never **SKIP to Q46**

44. Please indicate the programs or products which were advised for use in conjunction with pharmacotherapies for excessive alcohol use. *(Please tick all responses which apply).*

Counselling by GP
Counselling by other health professional
Pamphlets
Other (please specify)
.....

45. Do you think that these programs or products improve the likelihood of reducing alcohol consumption?

Yes
No

46. Do you have any further comments?

_____
_____

Thank you for completing this survey.

Please return the survey in the reply-paid envelope provided.
Alternatively, post to:
Nicotine & Alcohol Cessation Therapies
Department of General Practice
The University of Adelaide
Reply Paid 65650
UNIVERSITY OF ADELAIDE SA 5005
For any queries, please phone Katherine on (08) 8303 3467.

Appendix 12: Quit smoking key list

CURRENT SMOKING STATUS

Please describe your smoking status

- ☐ Current smoker - daily.
- ☐ Current smoker - occasional.
- ☐ Former smoker - daily
- ☐ Former smoker - occasional.
- ☐ Never smoked

QUIT SMOKING KEY LIST

Listed below are methods available to assist smokers to stop smoking. In this study, 'smoking' includes all tobacco products.

1. **'Cold Turkey' i.e. immediate cessation with no method of assistance**
2. **Nicotine patches**
3. **Nicotine gum**
4. **Nicotine inhaler**
5. **Hypnotherapy**
6. **Herbal preparations**
7. **Support / counselling eg 'SmokeStop', 'Quitline'**
8. **Zyban (Bupropion)**
9. **Other medication**
10. **Self-help material e.g. quit smoking manual**
11. **GP assistance other than above eg counselling**
12. **Other methods not listed above**