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Program for the distribution of free nicotine patches: A smoking cessation program

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PRIORITISING SUMMARY

REGISTER ID: **000211**

NAME OF TECHNOLOGY: **PROGRAM FOR THE DISTRIBUTION OF FREE NICOTINE PATCHES**

PURPOSE AND TARGET GROUP: **SMOKING CESSATION PROGRAM**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- ☒ Yet to emerge
- ☐ Experimental
- ☐ Investigational
- ☐ Nearly established
- ☐ Established
- ☐ Established *but* changed indication or modification of technique
- ☐ Should be taken out of use

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- ☐ Yes — ARTG number
- ☐ No
- ☒ Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States	✓		

IMPACT SUMMARY:

TGA approval is not required for smoking cessation programs, however a number of brands of nicotine patches have TGA approval for use in Australia as aids to smoking cessation. Allied Master Chemists of Australia Ltd, Alphapharm Pty Ltd and Guardian Pharmacies Australia Pty Ltd all manufacture three strengths of nicotine patches: 17.5mg, 35mg and 52.5mg transdermal drug delivery sachets.

BACKGROUND

The deleterious effects of tobacco smoking have long been established. Current evidence has established a causal relationship between active smoking and 32 medical conditions, such as cancer (of the lung, mouth, pharynx, larynx, pancreas and kidney), chronic heart disease, stroke and chronic obstructive pulmonary disease. Sudden infant death syndrome, low birth weight of infants born to smoking mothers and asthma in exposed children, are well-documented effects of passive smoking (Ministry of Health 2004, Ministerial Council on Drug Strategy 1999)
Tobacco dependence is a chronic condition that may require repeated attempts to overcome. Approximately 70-80% of smokers make made numerous attempts to quit and fail. Three to five per cent of smokers do succeed in quitting each year and the number of ex-smokers now

outweighs the number of smokers in the Australian population (Miller & Wood 2002; AIHW 2002b).

The highest prevalence of smokers, particularly, heavy smokers, is in lower socioeconomic groups (higher unemployment, lower household income, lower educational attainment), it follows that the most effective intervention (nicotine replacement therapy, NRT) would be more accessible if it were more affordable (The Cancer Council of South Australia 2002). Tauras and Chaloupka (2003) estimated that a 10% price reduction of NRT products would increase their demand by up to 25%.

A systematic review of approximately 100 smoking cessation studies showed that in smokers who are motivated to quit, the cessation rate is 1.5 to 2 times higher in those using NRT compared to any other smoking cessation strategy (Silagy et al 2002). Most of the data were based on studies investigating the effectiveness of NRT gum or patches. Other NRT methods, including nasal sprays, inhalers, and lozenges, or non-nicotine therapies, such as bupropion (Zyban), show similar increased rates of smoking cessation in controlled trials. All of these methods have been shown to be equally effective (Silagy et al 2002). Moreover, the NRT is particularly effective in the more dependent heavy smokers who have a higher risk of developing smoking-related illness, find it more difficult to quit smoking and, therefore, are less able to quit smoking without assistance. In a placebo-controlled trial smoking cessation was two times more successful in heavy smokers who used nicotine patches compared to those who were given placebo patches, or who received counselling alone (Stapleton et al 1995).**CLINICAL NEED AND BURDEN OF DISEASE**

The proportion of regular smokers in Australia has fallen from 24.3% in 1991 to 17.4% in 2004, with 52.9% of the population having never smoked and 26.4% considered to be ex-smokers (AIHW 2005).

Smoking is the single, largest preventable cause of premature death and disease in Australia. The number of deaths attributable to tobacco in 1998, Australia wide was 19,019. The majority of these deaths (78%) occur in the 65+ age bracket but 21% of deaths occur in the 35-64 age bracket. This equates to an estimate of 184,579 of person years lost. Hospital separations associated with the effects of tobacco have increased from 126,414 in 1995-96 to 142,525 in 1998, representing an increased burden on the health system. Cancer, ischaemic heart disease and chronic obstructive pulmonary disease as a result of smoking are responsible for 40, 21 and 20% of mortality, and 19, 26 and 20% of hospital separations, respectively (Miller & Draper 2001).

The 2002-03 health survey in New Zealand reported that the proportion of all adults who smoked daily was 22.9% (range 21.8-24.0%). Large differences existed between ethnic groups with Maori being more likely to currently smoke. Female Maori had higher rates of smoking (approximately 51%) compared to Maori males (42.5%). Current smoking prevalence was significantly higher in the “most deprived” quintile (approximately 33% and 37% for males and females, respectively). In addition, the New Zealand Health Survey estimated 6.7% (range 6.1-7.4) of adult non-smokers were exposed to passive smoke inside their homes. No data were available on the prevalence of passive smoking in children (Ministry of Health 2004).

It has been estimated that in 2002, 195 per 100,000 deaths in New Zealand were avoidable (potentially preventable through population or individual-based interventions). Approximately 80% of these avoidable deaths occur in the 45-74 year old age group and are dominated by chronic diseases such as ischaemic heart disease, diabetes and smoking related cancers (Ministry of Health 2005).

It is difficult to estimate the number of individuals who would wish to participate in a smoking cessation program, however during the 2004-2005 year, 11,586 individuals in South Australia called the Quitline for help. The Health Omnibus estimates that in South Australia 78% of smokers have made an attempt to stop smoking at least once, 36% have attempted to stop smoking in the past 12 months and that 45% of smokers are seriously considering quitting in the next six months (Quit SA 2005). Based on a population of 1.5 million[1], approximately 0.7% of the population of South Australia attempted to stop smoking via the Quit line during 2004-2005. If this figure was extrapolated to the Australian population, then approximately 144,000[2] smokers may be motivated to cease smoking in one year.

DIFFUSION

Nicotine replacement therapy (either as transdermal patches, gum or pharmaceutical options) is currently available as a user pays system through dispensing chemists. Quitline which provides information, support and advice for smoking cessation is freely available.

COMPARATORS

A wide variety of strategies and interventions to encourage smoking cessation have been developed including: individual or group counselling sessions (including Quitline, a telephone help line); specialist therapies such as acupuncture and hypnosis; pharmacotherapies, such as nicotine replacement therapy and bupropion (Zyban) (The Cancer Council of South Australia 2002). Bupropion has been associated with a number of adverse events including neuropsychiatric symptoms (tremors, agitation or confusion), insomnia, dry mouth and rash (Kolber et al 2003). In a recent study by Paluck et al (2006), 205 adult smokers were enrolled in a smoking cessation study utilising bupropion. Although 21% of subjects abstained from smoking for 12 months, 70.4% experienced at least one adverse event and 29.6% reported stopping the drug due to adverse effects.

EFFECTIVENESS AND SAFETY ISSUES

A number of studies, mostly conducted in New York State, USA have examined the impact of providing free NRT on quit rates. Miller et al (2005) examined the impact of providing a free 6-week course of NRT patches and two follow-up counselling calls (level III-2 intervention evidence). Eligible[3] smokers (n=34,090) who contacted a toll-free Quitline were sent a two-week supply each of generic 21mg, 14mg and 7mg nicotine patches, together with the usual literature to assist smokers to quit. Counselling calls which included advice on patch usage, management of adverse reactions and encouragement to start or continue quitting were attempted to all NRT recipients at 3 and 14 weeks after the initial contact. At least one counselling call was received by 15,212 (45%) of NRT recipients and 5,125 (15%) received two calls. Promotional efforts and neighbourhood-specific media were used to target populations with the highest prevalence of heavy smokers.

At 6 months the smoking status of a randomly selected group of NRT recipients was assessed (n=1305) and compared to a group of eligible smokers (n=506) who did not receive NRT due to mailing errors. Adults ≥65 years of age and foreign-born smokers were under-represented in the

[1] Based on the current population level of 1,544,700 in South Australia. Australian Bureau of Statistics http://www.abs.gov.au

[2] Based on the current population level of Australia 20,647,116. Australian Bureau of Statistics http://www.abs.gov.au

[3] Eligible smokers defined as: ≥18 years of age; a resident of New York City; no medical contra-indications to NRT patches; not using other NRT or buproprion; agreement to quit within one week of the screening call; smoked ≥10 cigarettes per day for >1 year; and agreed to be contacted for follow-up

NRT recipients, whereas women were more likely to participate. No information was provided in the published report regarding safety issues.

NRT recipients who provided data on quit attempts were more likely to attempt to quit smoking (87%, 1135/1305, 95% CI [86%, 89%] $p<0.0001$) versus the comparison group respondents (53%, 84/159) odds ratio 6.0, 95% CI (4.2, 8.6). Successful quitters were more likely to report using all the patches (51%, $p<0.0001$) than those still smoking at 6 months (24%). Successful quitting was reported in 33% (435/1305) of NRT recipients and 6% (10/159) of the comparison group respondents ($p<0.0001$). Successful quits were associated with NRT receipt after adjustment for demographics and smoking status (adjusted odds ratio versus the comparison group respondents 8.8, 95% CI [4.4, 17.8]). If all follow-up survey non-respondents are assumed to continue to smoke then 20% of NRT recipients and 2% of comparison group participants quit smoking (attributable quit rate of 18%).

NRT recipients who received counselling calls were more likely to stop (38%) than those who did not (29%) adjusted odds ratio 1.5, 95% CI (1.1, 1.9). Counselling calls were only effective in those who smoked <20 cigarettes per day. The quit rate in those who smoked <1 pack per day at enrolment who received a counselling call was 50 per cent versus 27 per cent for those that received no call ($p<0.001$).

The additional cost of the programme including purchase of NRT, Quitline and counselling staff and shipping was estimated to be US$2.8 million. Therefore the cost per successful quit was estimated to be US$266 using the 33% quit rate reported by NRT recipient respondents (alternatively, US$464 per successful quit using the 18% attributable quit rate). Given that these data were not derived from an RCT they may overestimate effectiveness.

A study by Bauer et al (2006) compared the quit rates in smokers who redeemed a voucher for a free 2-week supply of nicotine gum or patches obtained by calling the Quitline (level III-3 intervention evidence). A follow-up survey was conducted 4-6 months after this initial contact. A historical comparison group of 515 smokers who had called the Quitline prior to the free NRT voucher also completed a follow-up survey (Bauer et al 2006). Of the enrolled smokers, 75% redeemed their vouchers for patches and 25% for gum. Quit rates for smokers who used patches and gum were 30 and 26 per cent, respectively. The quit rate in the historical comparison group was 12 per cent. The adjusted relative risk for quitting was 1.77 (95% CI 1.17, 2.68) for those who received a free NRT voucher compared with those that did not controlling for smokers age, gender, race, type of health insurance, and use of other quit methods. Of the smokers who completed the follow-up survey and used the patch or gum at least once, 7% (35/513) stated they had discontinued therapy due to side effects.

Hawk et al (2006) compared the quit rates in smokers who entered a “quit and win contest” (level III-3 intervention evidence). The contest offered daily smokers the chance to win prizes (n=849), including a grand prize of US$1,000, if they stopped smoking for a month, versus smokers screened via the Quitline who received a voucher for a free 2-week supply of nicotine gum or patch (n=690). A smaller group of smokers participated in both programmes (n=230). After a median length of 5.5 months (range 4-7 months), participants in the quit and win (38%), NRT voucher (44%) and combination group (97%), respectively were followed up. Abstinence rates of 29%, 26% and 27% respectively were reported for each programme and a longer follow-up period was associated with reduced abstinence. Assuming that non-respondents in the survey continued to smoke, the reported quit rates were between 15-17%. Smokers who entered the quit & win competition tended to be younger than those who signed up for free NRT.

A summary of four NRT giveaway intervention programmes (level III-3 intervention evidence) in New York State utilising the Smokers' Quitline reported 21-33% of survey respondents were not smoking at the time of the follow-up survey compared with 12% of Quitline callers who received counselling support and a free cessation guide but no free NRT (Cummings et al 2006). Table 1 below, summarises the relative risks of quitting for each NRT giveaway programme versus the quit rate without free NRT adjusted for demographics, type of health insurance, cigarettes smoked per day at enrolment and use of other quit smoking methods. All participants received a stop smoking guide and an information sheet on local stop smoking programmes and all participants that could be contacted received a telephone counselling them about quitting smoking. Quit rates were reported at the 4-month follow-up telephone interview.

Table 1 Quit rates of each free NRT programme compared with a similar group of smokers who called Quitline and did not receive free NRT (Cummings et al 2006)

Intervention	Number enrolled in programme	Number of respondents	% of respondents that quit	RR	95% CI	Estimated cost of intervention US$
No NRT	515	422	12%	1.0	-	-
Free voucher for a 2-week supply of NRT	1,099	464	27%	2.9	1.9, 4.4	46,365
1-week supply of nicotine patches mailed	1,334	469	21%	2.0	1.3, 3.1	38,441
2-week supply of nicotine patches mailed	2,323	472	24%	2.4	1.6, 3.7	96,826
6-week supply of nicotine patches mailed	35,334	578	33%	3.9	2.6, 5.7	2.7 million

Approximately 30% of participants reported ≥2 side effects whilst using NRT. 27-46% reported side effects in the 1-week or 2-week programme whilst 52% reported side effects in the 6-week programme. 3-9% of participants discontinued medication because of side effects. 32-44% of patients that reported side effects experienced sleep disturbance, 7-17% skin rash and 4-15% heart palpitations.

Only one study provided long-term follow-up data (18 months), assessing the addition of free NRT to a group behavioural cessation programme (level III-3 intervention evidence) (Alberg et al 2004). The group behavioural cessation programme consisted of two sessions per week for four weeks covering topics such as tips for quitting, fears of quitting, recovery symptoms, positive self-talk and how to develop a quit plan (n=601). Programme participants who enrolled later (n=311) received a free 6-week supply of 14mg or 21mg 24-hour patches. Patches were distributed at weekly intervals for 3 weeks and then the remaining amount was supplied. Quit rates were significantly higher in patients that received free NRT at the end of the programme (66%) versus those that participated in the programme alone (38%) (38% vs 66%; risk difference 27%, 95% CI [21%, 34%]). Adjustment for potential confounding variables (gender, age, education, years smoked, cigarettes/ day, pack years, and sessions attended) reduced the risk difference to 17%, 95% CI [11%, 22%]. However, the quit rates were *not* sustained during the 18-month follow-up period. Quit rates were lower (6.7%) in the programme plus free NRT participants compared to 14.3 per cent in smokers who participated in the programme alone. No information was provided in the published report regarding safety issues.
In conclusion, the provision of free nicotine patches to smokers appears to be more effective for smoking cessation than counselling alone in the short-term. Long-term follow-up data were reported by only one study, which indicated that cessation rates were greater in smokers who received counselling alone compared to smokers who received free NRT.

COST IMPACT

Alphapharm Pty Ltd provides 3 doses (7mg, 14mg and 21mg) of nicotine patches (QuitX) in packs of seven (one weeks supply), ranging in price from $17.64 - $21.30 (cost price available to chemists) (personal communication May 1st Alphapharm Pty Ltd). A six week[4] cessation program would therefore cost approximately $106 - $128 per individual. Based on the figure that approximately 144,000 individuals in Australia may be motivated to commence a smoking cessation program in any one year, the base price for the supply of patches, not including overheads to run the program, might range from $15-18 million per calendar year.

In a randomised placebo-controlled trial, Stapleton et al (1999) estimated the cost-effectiveness for the National Health Service in Britain if general practitioners (GP) were able to prescribe nicotine patches for 12-weeks (Stapleton et al 1999). The health benefits in number of life years saved by stopping smoking at various stages of life were calculated, comparing brief counselling by the GP in conjunction with the prescription of nicotine patches, to brief counselling alone (results see Table 2). The incremental cost per life year saved ranged from £398 per person under 35 years, to £785 per person aged 55-65 years. The relatively low cost per life year saved was viewed by the authors as a small investment for a potential future that will require less expenditure in smoking-related illnesses.

Table 2 Cost-effectiveness of GP counselling plus nicotine patches, incremental to brief counselling by GP alone

Age when treated	Extra cost per patient treated (£)	Extra life years saved per patient treated	Incremental cost-effectiveness ratio (£)
Under 35 years	34.15	0.086	397.95
35-44 years	34.15	0.099	344.68
45-54 years	34.15	0.079	432.32
55-65 years	43.08	0.055	785.43

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

There is a clear association between low socio-economic status and a high prevalence of smoking. Individuals in lower socio-economic groups may be less likely to access nicotine replacement therapy due to the perceived initial expense.

OTHER ISSUES

No issues were identified/raised in the sources examined.

CONCLUSION:

The provision of free nicotine patches to smokers appears to be more effective for smoking cessation than counselling alone in the short-term. However, there is a lack of long-term follow-up of all participants in the majority of studies included in this assessment. There is also a lack of good quality, current economic data but the data available suggests a low cost per life year saved may result in long-term savings for the health system.

[4] The 1999 study by Stapleton et al found that, on average, 4.4 boxes of seven patches were used by each subject

HEALTHPACT ACTION:

Given the potential benefits of free nicotine patches in rural and remote communities where limited smoking cessation alternatives are available, an horizon scanning report is recommended.

SOURCES OF FURTHER INFORMATION:

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Tauras, J. A. & Chaloupka, F. J. (2003). 'The demand for nicotine replacement therapies', *Nicotine and Tobacco Research,* 5 (2), 237-243.

The Cancer Council of South Australia (2002). *Tobacco Control Research and Evaluation Report Vol 1, 1998-2001*, Adelaide.

LIST OF STUDIES INCLUDED

Total number of studies	
Level III-2 intervention evidence	1
Level III-3 intervention evidence	4

SEARCH CRITERIA TO BE USED:

Nicotine/ administration and dosage
Nicotinic Agonists/ administration and dosage
Smoking/ prevention and control
Smoking Cessation
Smoking/legislation and jurisprudence/prevention & control
Smoking Cessation
Health Promotion
Tobacco Use Disorder/therapy
Health Education/methods