Welcome to issue 20 of Smoking Cessation Research Review.

A recent paper in the New England Journal of Medicine reports that reduced-nicotine cigarettes decreased nicotine exposure and dependence, as well as the number of cigarettes smoked per day, when compared with standard-nicotine cigarettes. The 6-week study included people aged ≥18 years who smoked ≥5 cigarettes per day and had no current interest in quitting smoking. Based on their findings, the study authors suggest that reduced-nicotine cigarettes may reduce the harm that smokers experience by decreasing the number of cigarettes that they smoke per day or potentially playing a role in quitting smoking altogether. An accompanying editorial suggests that the study results could inform a new FDA regulatory paradigm, for mandating severe reductions in nicotine in all cigarettes as a way of potentially reducing the toll of cigarette smoking. However, as the study authors acknowledge, this study was of short duration and it was not statistically powered to measure clinical outcomes. The FDA requires more evidence in support of the contention that reduced-nicotine cigarettes benefit public health, before making any such determination.

CHAMPIX® (varenicline tartrate) 0.5 mg and 1 mg tablets. Indications: Aid to smoking cessation.

MINIMUM DATA SHEET:

Medicines Classification: Prescription Medicine; CHAMPIX is fully funded under Special Authority. Before prescribing please review Data Sheet. A regularly updated leaflet is available from Level 1, Suite 1.4, Building B, 8 Nugent St, Grafton, Auckland 1025 or call 0800 736 363.

Patients should set a date to quit smoking and start dosing 1-2 weeks before this date. Alternatively, patients can start treatment and quit smoking between days 8 and 35 of treatment. Days 1-3: 0.5 mg once daily. Days 4-7: 0.5 mg twice daily. Day 8 - end of treatment: 1 mg twice daily. Patients should be treated for 12 weeks. An additional 12 weeks of treatment can be considered for those who need additional support. Refinement with varenicline is encouraged in patients who are motivated to quit and did not succeed with prior treatment or who relapsed. Dose tapering not required at end of treatment. Dose reduction is required for patients with severe renal impairment. Patients who cannot tolerate adverse effects may have the dose lowered temporarily or permanently. See Data Sheet for details. Medicines Classification: Prescription Medicine; CHAMPIX is fully funded under Special Authority. Before prescribing please review Data Sheet available from www.medsafe.govt.nz or Pfizer New Zealand Ltd (www.pfizer.co.nz) Level 1, Suite 1.4, Building B, 8 Nugent St, Grafton, Auckland 1025 or call 0800 736 363. Registered trademark, 910175, P:01335 March 2015.

For more information, please go to http://www.medsafe.govt.nz

Contact Pfizer on 0800 736363 to discuss Champix and the support resources available.

Reference: 1. Pharmacovigilance. Symptoms, history of or underlying psychiatric illness, including changes in behaviour or thinking, anxiety, psychosis, mood swings, agitation, hallucinations, aggression, depressed mood, suicidal ideation and suicidal behavior; patients and families to monitor: patients to stop taking CHAMPIX at first sign of symptoms and contact a health care professional immediately; ongoing follow-up until resolution. Seizures, hypersensitivity reactions, cardiovascular events, driving or operating machinery, alcohol consumption, pregnancy, lactation, severe renal impairment. See Data Sheet for details. Adverse Effects: Smoking cessation/nicotine withdrawal symptoms. Most common: nausea, headache, insomnia, nasopharyngitis, abnormal dreams, abdominal pain, constipation, fatigue, diarrhoea, flatulence, vomiting, dysphagia, dysgeusia, dry mouth, sleep disorder, back pain, change in appetite, somnolence, weight increased, arthralgia, arachnoid, abdominal distension, rash, myalgia, dyspepsia, toothache, chest pain, parotid and submandibular inflammation, pyrexia. Post-marketing reports of myoclonic jerks, stroke, See Data Sheet for details. Dosage and Administration: Patients should set a date to quit smoking and start dosing 1-2 weeks before this date. Alternatively, patients may start treatment and quit smoking between days 8 and 35 of treatment. Days 1-3: 0.5 mg once daily. Days 4-7: 0.5 mg twice daily. Day 8 - end of treatment: 1 mg twice daily. Patients should be treated for at least 12 weeks. An additional 12 weeks of treatment can be considered for those who need additional support. Refinement with varenicline is encouraged in patients who are motivated to quit and did not succeed with prior treatment or who relapsed. Dose tapering not required at end of treatment. Dose reduction is required for patients with severe renal impairment. Patients who cannot tolerate adverse effects may have the dose lowered temporarily or permanently. See Data Sheet for details. Medicines Classification: Prescription Medicine; CHAMPIX is fully funded under Special Authority. Before prescribing please review Data Sheet available from www.medsafe.govt.nz or Pfizer New Zealand Ltd (www.pfizer.co.nz) Level 1, Suite 1.4, Building B, 8 Nugent St, Grafton, Auckland 1025 or call 0800 736 363. Registered trademark, 910175, P:01335 March 2015.

HELP KIWIS BECOME SMOKEFREE NOW AND NZ CAN BE SMOKEFREE BY 2025.

At 12 weeks, smokers are around 4 x more likely to quit with Champix than if they had taken placebo2

OR 3.85, CI 2.69-5.50, p <0.0001 for CO confirmed 4 week continuous quit rate for week 9-12

And NZ can be smokefree by 2025.

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Disclosure Statement: Natalie Walker has provided consultancy to the manufacturers of smoking cessation medications, received honorariums for speaking at a research meeting and received benefits in kind and travel support from a manufacturer of smoking cessation medications. Natalie has also undertaken two trials of very low-nicotine content cigarettes, which were purchased from two different tobacco companies. The companies concerned had no role in development of the study design, data collection, data analysis, data interpretation, or writing of the trial publications.

Independent commentary by Dr Brent Caldwell.

Brent Caldwell is a Senior Research Fellow at Wellington Asthma Research Group, he is currently working on the Inhale Study. His main research interest is in identifying and testing improved smoking cessation methods, with a particular focus on clinical trials of new smoking cessation pharmacotherapies.

Independent commentary by Honorary Associate Professor Natalie Walker.

Dr Natalie Walker is an epidemiologist and leader of the Addiction Research programme at the National Institute for Health Innovation, University of Auckland. FOR FULL BIO CLICK HERE.

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- Second-hand smoke and the risk of tuberculosis
- Helping homeless clients to quit smoking
- Reduced-nicotine cigarettes: are they safer?
- Teen e-cigarette users more likely to later use tobacco
- How primary care can boost smoking cessation rates
- Health and cost impacts of tobacco tax
- Mental health status of varenicline and bupropion users
- Switching to e-cigarettes reduces toxicant exposure

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[Logo]
Attitudes and perceptions about smoking cessation in the context of lung cancer screening
Authors: Zeidart SB et al.
Summary: Between 29 May and 22 September 2014, these researchers conducted 45 in-depth semi-structured qualitative telephone interviews about health beliefs related to smoking and lung cancer screening with 37 current smokers (mean age 62 years) in the Veterans Affairs Health Administration who were about to undergo computed tomography (CT) lung cancer screening offered by their primary care physician. Eight participants were interviewed both before and after CT screening, 22 were interviewed after they had received their screening results, and 7 were interviewed after screening but before receiving results. Eighteen participants received some type of abnormal result. Lung cancer screening prompted most current smokers to reflect for the first time on what smoking means for their current and future health. However, 17 participants described mechanisms whereby screening lowered their motivation for cessation, including the perception that undergoing an imaging test yields the same health benefits as smoking cessation. Other misperceptions included a belief that everyone who participates in screening will benefit; the belief that screening and being able to return for additional screening offers protection from developing lung cancer; that detection of intermediate nodules could be monitored by follow-up; and a reinforced belief in some individuals that negative CT scans indicates that they are among the lucky ones who will avoid the harms of smoking.

Comment (NW): The sudden flurry of news from the USA about lung cancer screening is because some high-risk Medicare beneficiaries now have coverage for an annual lung cancer screening test (using low-dose CT scanning). This comes despite a lack of consensus around the benefits of such screening. This study highlights the importance of ensuring people who undergo such tests truly understand what screening is (and isn’t), rather than assuming they know. Clearly, some serious misunderstandings and misinterpretation can occur, and I suspect it’s not restricted to just lung cancer screening.

Reference: JAMA Intern Med. 2015;175(9):1530-7
Abstract

Exposure to second-hand smoke and the risk of tuberculosis in children and adults: a systematic review and meta-analysis of 18 observational studies
Authors: Patra J et al.
Summary: This systematic review and meta-analysis examined the association of second-hand smoke (SHS) exposure with the risk of latent tuberculosis infection (LTBI) and active TB disease in children (aged <15 years) and adult (>15 years) non-smokers. Articles deemed eligible for inclusion were published up to 31 August 2014 and were original studies only, in which LTBI and active TB disease were diagnosed microbiologically, clinically, histologically, or radiologically. Eighteen studies met inclusion criteria and were included in the meta-analysis, with 30,757 children and 44,432 adult non-smokers. Twelve studies assessed children and 8 studies assessed adult non-smokers; 2 studies assessed both populations. The summary relative risk (RR) of LTBI associated with SHS exposure in children was similar to the overall effect size (pooled RR 1.64; 95% CI, 1.00 to 2.83), but there was substantial heterogeneity. Children had a more than 3-fold increased risk of SHS-associated active TB (pooled RR 3.41; 95% CI, 1.81 to 6.45), which was higher than the risk in adults (RR 1.32; 95% CI, 1.04 to 1.68). Each age group was at increased risk to SHS. SHS exposure in children living under the most crowded household conditions (>5 people per room) showed the highest relative risk (RR 5.88; 95% CI, 1.92 to 9.20) or both parents (7.40; 2.77 to 19.79) smoking.

Comment (NW): Whilst TB is relatively uncommon in New Zealand (2012 incidence: 6.7/100,000), it is twice as common in Pacific and socially disadvantaged populations. The co-existence of TB and smoking in New Zealand is currently unknown, although I am aware of researchers at the University of Auckland who are looking at the syndemic of TB, smoking and non-communicable diseases . . . so look out for this information in the not-too-distant future.

Abstract

Homeless clients benefit from smoking cessation treatment delivered by a homeless persons’ program
Authors: Segan CJ et al.
Summary: For this study, 14 nurses from Melbourne’s Royal District Nursing Service Homeless Persons’ Program offered weekly smoking cessation appointments with intermittent carbon monoxide measurements, doctor-prescribed free nicotine patch, bupropion or varenicline, and Quitline phone support to 49 clients enrolled in a 12-week program. Some of the homeless smokers were given a free second-hand mobile phone so that they could take calls. Surveys were completed at program enrolment, end of program (EoP) at 12 weeks) and 6 months post-enrolment. Clients attended on average 6.7 nurse-delivered appointments. The majority used pharmacotherapy (69%, n=34) and Quitline (61%, n=30, average 8.4 calls among users), EoP interviews revealed that 29% of clients had made a quit attempt; 24-hour point prevalence abstinence rates were 6% at EoP and 4% at 6 months (no participants achieved sustained cessation). Almost one-third (29%) reported 50% consumption reduction at 6 months, which was positively associated with increased Quitline use. By EoP, tobacco consumption and money spent on tobacco was halved from baseline; similar levels were maintained at 6 months. Discarded butt smoking reduced. Moreover, all participants reported either stable or fewer symptoms of anxiety and 92% reported stable or fewer depressive symptoms.

Comment (NW): I have no idea if any support services for the homeless in NZ offer smoking cessation treatment or conversely whether smoking cessation services approach this population. If you know of any, do let me know. Although this study was small, it shows some promising results, and it’s a good idea to do more with.

Reference: Nicotine Tob Res. 2015;17(8):996-1001
Abstract

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### Randomized trial of reduced-nicotine standards for cigarettes

**Authors:** Donny EC et al.

**Summary:** This US investigation enrolled 840 subjects aged ≥18 years who smoked ≥5 cigarettes per day and had no current interest in quitting smoking. Participants were randomly assigned to smoke for 6 weeks either their usual brand of cigarettes or 1 of 6 types of investigational cigarettes, with nicotine content ranging from 15.8 mg per gram of tobacco (typical of commercial brands) to 0.4 mg per gram. 780 subjects completed the 6-week study. During week 6, the average number of cigarettes smoked per day was lower for participants smoking cigarettes containing 2.4, 1.3, or 0.4 mg of nicotine per gram of tobacco (who smoked 16.5, 16.3, and 14.9 cigarettes per day, respectively) than for participants assigned to their usual brand or to cigarettes containing 15.8 mg per gram (who smoked 22.2 and 21.3 cigarettes per day, respectively; p<0.001; control groups). Participants assigned to cigarettes with 5.2 mg per gram smoked an average of 20.8 cigarettes per day, which did not differ significantly from the average number among those who smoked control cigarettes. Cigarettes with lower nicotine content, as compared with control cigarettes, reduced exposure to and dependence on nicotine, as well as craving during abstinence from smoking, without significantly increasing the expired carbon monoxide level or total puff volume, suggesting minimal compensation. Interestingly, the majority of people in the nicotine groups were not significantly more likely to report quit attempts as compared to the control groups, but those assigned to the 0.4-mg product were more likely to report attempts to quit compared with controls (34.7% vs 17%; p=0.005). Adverse events were generally mild and similar among groups.

**Comment (NW):** Nicotine has been able to be removed from cigarettes since the 1930s. What would happen in NZ if the government said to the tobacco industry “You can’t sell tobacco here unless it has a very low nicotine content and yield”? Trial evidence indicates that in smokers motivated to quit, the use of very-low-nicotine content (VLNC) cigarettes, used alone or in combination with NRT, helps some smokers quit (more than using NRT alone). This USA trial (and NZ research) shows the same thing happens in people who aren’t motivated to quit – some will stop smoking. The problem is these products are still cigarettes and still harmful, just less addictive – so you really want their use to be short-term (6 weeks or so) – a steered approach to quitting. A less harmful alternative would of course be an e-cigarette. However, some countries have banned e-cigarettes, so could a time-limited reduced nicotine strategy work for them? Whatever the option, the greatest success will only occur if usual tobacco is removed completely from the market, otherwise, dual use of products does occur.

Don’t forget to check out the cool video with this paper. As an aside: the author of this trial will be on sabbatical in New Zealand next year (based at the University of Auckland), and will be doing a few lectures around the country – so keep a look out for the announcements.


### Association of electronic cigarette use with initiation of combustible tobacco product smoking in early adolescence

**Authors:** Leventhal AM et al.

**Summary:** This investigation recruited 2530 students (mean age 14.1 years) from 10 public high schools in Los Angeles, California, who had never used combustible tobacco control products at baseline; 222 (9%) had used e-cigarettes. The study participants completed follow-up assessments at 6 and 12 months. At each follow-up, students were asked about use of any of the following tobacco products within the prior 6 months: (1) any combustible tobacco product (i.e., cigarettes, cigars, or hookah) (yes or no); (2) combustible cigarettes (yes or no); (3) cigars (yes or no); (4) hookah (yes or no); and (5) number of combustible tobacco products (range: 0–3). At both assessments, e-cigarette users at baseline were more likely than never users to have used any combustible tobacco product during the previous 6 months (30.7% vs 8.1%, respectively, at 6 months; 25.2% vs 9.3%, respectively, at 12 months). Students who reported baseline e-cigarette use were more likely to use any combustible tobacco product averaged across the 2 follow-up periods in the unadjusted analyses (odds ratio [OR], 4.27; 95% CI, 3.19 to 5.71); this relationship persisted after adjusting for sociodemographic, environmental, and intrapersonal risk factors for smoking (2.73; 2.00 to 3.73). Baseline e-cigarette use was positively associated with combustible cigarette (OR, 2.65; 95% CI, 1.73 to 4.05), cigar (4.85; 3.36 to 6.96), and hookah (3.25; 2.29 to 4.62) use and with the number of different combustible products used (4.26; 3.16 to 5.74) averaged across both follow-up periods.

**Comment (BC):** This is an observational study, which did not control for important covariates (e.g., advertising exposure, sensation-seeking), from which causal conclusions cannot be drawn. It is likely that adolescents who are likely to smoke are also likely to vape and vice versa. Vaping among non-smoking adolescents should alert clinicians to intervene to reduce smoking initiation. Adolescents who use e-cigs could be advised to quit by using nicotine replacement therapy, or could be advised to switch to other brands of e-cigs in preference to switching to tobacco.

Reference: JAMA. 2015;314(7):700-7

### Primary care provider-delivered smoking cessation interventions and smoking cessation among participants in the National Lung Screening Trial

**Authors:** Park ER et al.

**Summary:** These researchers obtained data on 3336 smokers participating in the National Lung Screening Trial (NLST), to examine the prevalence of post-screening intervention methods used by primary care clinicians and the association of these methods with changes in smoking behaviour. These clinician-delivered smoking cessation interventions are grouped into the 5As (ask, advise, assess, assist [talk about quitting or recommend stop-smoking medications or recommend counselling], and arrange a follow-up). The rates of the 5A deliveries at 1 year after screening were as follows: ask, 77.2%; advise, 75.6%; assess, 63.4%; assist, 56.4%; and arrange a follow-up, 10.4%. In multivariate models that adjusted for sociodemographic characteristics, medical history, screening results, nicotine dependence, and motivation to quit, the data showed that the ask, advise, and assess methods were not significantly associated with quitting rates after lung screening. In contrast, the assist method increased an individual’s chances of quitting by 46% (OR, 1.40; 95% CI, 1.21 to 1.63), while an arranged follow-up increased the chances by 46% (1.46; 1.19 to 1.79).

**Comment (BC):** It’s almost a no-brainer that only asking, assessing, and advising smokers would not lead them to quit smoking, but assisting them with nicotine replacement therapy plus behavioural therapy and arranging follow-up would help them to quit. I fear that our approach to ABC often focusses on the Ask and Brief Advice (with some PHOs employing telephonists to boost the numbers of patients who are given A and B), without emphasising the Cessation component. Perhaps this is because not all patients are ready for cessation, but they should at least be encouraged to reduce their smoking with the aid of nicotine replacement therapy as a prelude to cessation.

Reference: JAMA Intern Med. 2015;175(9):1509-16

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**Note:** The references are provided for further reading and should be consulted for the complete studies.
Health, health inequality, and cost impacts of annual increases in tobacco tax: multistate life table modeling in New Zealand

Authors: Blakely T et al.

Summary: These researchers estimated the impacts of ongoing tobacco tax increases (10% annually from 2011 to 2031) compared with no tax increases from 2011 in New Zealand, where there are large ethnic inequalities in smoking-related and noncommunicable disease (NCD) burden. Sixteen tobacco-related diseases were modeled in parallel using national data by sex, age, and ethnicity, to estimate undiscounted quality-adjusted life-years (QALYs) gained and net health system costs over the remaining life of the 2011 population (n=4.4 million). Compared to the 2011 cohort exposed to no tax increases, 260,000 QALYs were gained among those exposed to annual tobacco tax increases from 2011 to 2031. Cost savings associated with this intervention amounted to US$2,550 million over the remainder of the 2011 population’s life. QALY gains and cost savings took 50 years to peak. The QALY gains per capita associated with annual tobacco tax increases were 3.7-fold higher for Māori compared with non-Māori because of higher rates of smoking and price sensitivity among Māori. Health inequalities measured by differences in mortality rates among Māori and non-Māori aged 45+ years were projected to be 2.31% lower in 2041 with ongoing tax rises, compared with no tax rises. Percentage reductions in inequalities in 2041 were maximal for 45–64-year-old women (3.01%).

Comment (BC): While it is great news that tax rises would improve inequality in tobacco-related health outcomes for Māori, it is less clear from this study what impact tax increases would have on financial inequality and non-tobacco-related health inequality that may result from financial inequality (such as having less money to buy healthier food, and financial stress). No account was taken of smokers’ nicotine dependence – an Australian study found low socioeconomic smokers with higher nicotine dependence were less likely to respond to price hikes. As taxes rise, it is essential for clinicians to encourage lower socioeconomic smokers to use as much nicotine replacement therapy as possible to reduce/quit smoking.


Abstract

Mental health status of varenicline and bupropion users during a quit attempt compared to current smokers, other quitters, and non-smokers

Authors: Shewale AR et al.

Summary: This study compared the mental health status of individuals using varenicline or bupropion with nonusers (current smokers, smokers who quit without medication, and non-smokers). Data were taken from the 2006–2011 Medical Expenditure Panel Survey for 453 bupropion use episodes and 125 varenicline use episodes. Mental health status was assessed using the mental component summary (MCS) from the 12-item Patient Health Questionnaire (PHQ-2), and Kessler 6 Scale (K6). Differences in MCS score were compared using linear regression. In analyses controlling for psychiatric disorders, prior mental health and medications used, varenicline was not associated with worse mental health compared with current smokers or those who quit without medication, but varenicline users had worse mental health than non-smokers. In contrast, the analyses revealed that bupropion was associated with worse mental health than smokers, former smokers who quit without medication, and non-smokers.

Comment (BC): This is an example of a study whose results should be treated with great suspicion. It has many flaws: a cross-sectional cohort study design cannot assess causality, there is selection bias because clinicians are less likely to have prescribed varenicline or bupropion to people with severe pre-existing psychiatric conditions, 11% of subjects were excluded due to missing data, and all outcomes were self-reported. Furthermore, the sample size of 125 varenicline users is extremely small and no power calculation is reported. Failure to reject the null hypothesis does not necessarily imply that the null hypothesis is true. Readers of the medical literature must always be on guard: peer-review is of variable quality, commercial interests are powerful, and there is huge pressure on academics to publish.


Abstract

Effects of switching to electronic cigarettes with and without concurrent smoking on exposure to nicotine, carbon monoxide, and acrolein

Authors: McRobbie H et al.

Summary: These researchers examined exposure to acrolein (as measured by its primary metabolite, S-(3-hydroxypropyl)mercuric acid [3-HMPA] in urine), nicotine (as measured by cotinine in urine) and carbon monoxide (CO), among 40 smokers before and after 4 weeks of e-cigarette use. Thirty-three participants were using the e-cigarette at 4 weeks after quitting, 16 (46%) were abstinent (CO-validated) from smoking during the previous week (e-cigarette-only users), and 17 (52%) were “dual users”. Significant decreases from baseline in CO were observed in e-cigarette-only users (~12 ppm; 80% decrease) and dual users (~12 ppm; 52% decrease). Cotinine levels also declined, but to a lesser extent (e-cigarette-only users: −184 ng/mg creatinine; 17% decrease; and dual users: −976 ng/mg creatinine; 44% decrease). At 4 weeks, mean 3-HMPA levels were decreased from baseline by 1,280 ng/mg creatinine (79% decrease) in e-cigarette-only users and by 1,474 ng/mg creatinine (60% decrease) in dual users. In dual users, e-cigarette use significantly reduced exposure to CO and acrolein because of a reduction in smoke intake.

Comment (BC): Yet more evidence that e-cigs expose people to much lower levels of harmful chemicals than tobacco smoke. Importantly, this study shows that this remains true even if people still smoke while using e-cigs. Although this study used a first-generation e-cig, other research on second- and third-generation e-cigs also demonstrates that toxicants in e-cigs are many orders of magnitude lower than in cigarette smoke, despite the higher battery power and heating temperature of these more modern e-cigs. Is it time to legalise e-cigs in New Zealand?


Abstract

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