Vaporised nicotine products for smoking cessation amongst people receiving drug and alcohol treatment or those with comorbidities

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Aim of Abstract: Among people in drug and alcohol (AOD) treatment, with mental health issues and/or living with Hepatitis C (HCV) or HIV, smoking rates continue to be substantially higher than the general community. Many factors related to addiction, lack of cessation support and high levels of smoking in their social network contribute to high relapse rates back to smoking in these populations. New ways of thinking about how to address smoking amongst these populations are needed. The aim of this 75 minute symposium is to highlight a number of current trials in Australia and New Zealand of vaporised nicotine products (VNPs or e-cigarettes) for smoking cessation in the drug and alcohol treatment setting or for people with comorbidities. A discussion with attendees will be facilitated considering a number of issues related to the use of VNPs in the drug and alcohol setting, including perceived safety, effectiveness, challenges, opportunities and Indigenous populations.
Presentation 1: Cessation And Relapse Prevention (CARP) Trial: VNP for people on opiate substitution therapy (OST), or who are living with HCV or HIV.

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Introduction: Compared to the general population, smoking prevalence is higher among people on OST, or are living with HCV or HIV. This trial will compare the effectiveness, safety and cost-effectiveness of providing VNP as a nicotine replacement therapy to these populations. Two conditions will be compared: A) concurrent delivery of VNP with standard smoking cessation treatment versus B) sequential delivery of VNP 6 months after quit attempt with standard smoking cessation treatment for participants who do not achieve or maintain abstinence after baseline quit attempt.

Method: Open–label, pragmatic partial crossover trial. Eligibility: People diagnosed with HIV or HCV, or on OST, smoking >10 cigarettes per day, and aged ≥18 years. Recruitment: Private and public clinics and community organisations located in multiple states of Australia. Intervention: Vaporizer kits and 12 weeks supply of liquid nicotine at no cost, and optional purchase of refill until 24 months. Standard smoking cessation treatment: Condition A receive patches + Quitline; Condition B receive patches + gum or lozenge + Quitline. Outcomes: The primary outcome is self-reported biochemically-verified continuous abstinence for ≥3 months, measured at six months post quit-date. Numerous secondary outcomes will be collected. Sample size: 810 participants will be sought for 80% power at p=0.05 level to detect ≥6% difference between conditions.

Results: The trial is commencing participant recruitment in May 2018 and progress recruitment data will be presented.

Discussion: This trial will be one of the largest trials to date on e-cigarettes for smoking cessation amongst comorbid groups.

Presentation 2: VNP combined with nicotine patches: Impact on mental health

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**Introduction:** Many countries only allow nicotine-free e-cigarettes to be marketed. In such an environment if an e-cigarette user wants nicotine, they could use their device in combination with NRT (i.e. medically approved nicotine products). No trials have investigated the impact of combination therapy of this nature on smoking abstinence or mental health. A randomised trial was undertaken in New Zealand between 2016-2018 to assess the effectiveness and safety of combining nicotine patches with e-cigarettes (with and without nicotine) on smoking abstinence.

**Method:** **Eligibility:** Daily/non-daily smokers, ≥18 years, naive e-cigarette users, and motivated to quit smoking. **Recruitment:** Multi-media community advertising. **Intervention:** 14 weeks of: 1) 21mg nicotine patches (n=201); 2) 21mg nicotine patches plus a 18mg/mL nicotine e-cigarette (n=804); or 3) 21mg nicotine patches plus a nicotine-free e-cigarette (n=804). Behavioural support was also provided. **Outcomes:** The primary outcome is self-reported biochemically-verified continuous abstinence at six months post quit-date. Numerous secondary outcomes were collected at quit date, one, three, six and 12 months post quit-date, including changes in mental health and adverse events. **Sample size:** 1,809 participants were sought for 90% power.

**Results:** The dataset will be locked in July 2018. No interim analysis are planned. Key results of the trial related to mental health will be presented at the meeting.

**Discussion:** The trial is one of the largest trials to date on e-cigarettes for smoking cessation. As a pragmatic trial focusing on the effectiveness of the interventions, the findings can be generalized to the unique tobacco control environment of New Zealand.

**Presentation 3:** VNPs for smoking cessation following discharge from a residential withdrawal unit: the QuitNic pilot trial.

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**Introduction:** In Australia, up to 95% of people entering alcohol and other drug (AOD) treatment smoke tobacco, which is five time greater than for the general adult population. Smokers receiving AOD treatment are interested in quitting and make quit attempts, however heavy nicotine dependence among these smokers contributes to high relapse rates. The purpose of this pilot trial is to explore the feasibility, acceptability, adherence and potential effectiveness of two forms of smoking cessation support for AOD clients following discharge from care.

**Method:** A pragmatic pilot randomised trial is being conducted with 100 adult clients recruited from a smoke-free residential withdrawal unit in Melbourne. All participants receive a proactive referral to Quitline, and upon discharge a 12-week supply of either a) electronic nicotine device and liquid nicotine supply (18 or 12 mg/mL), or, b) combination nicotine replacement therapy (patch plus oral dose). **Outcomes:** The primary outcome is self-reported continuous abstinence at 6 and 12 weeks following discharge. 7-day point prevalence from smoking; point prevalence abstinence from all
nicotine (including NRT and ENDS); cravings and withdrawal; time to relapse; and treatment adherence (use of NRT, ENDS and Quitline) will also be assessed.

Results: The dataset will be unlocked in July 2018. No interim analysis are planned. Key results of the trial will be presented at the meeting.

Discussion: Time in smoke-free residential withdrawal presents an opportunity to encourage and support a quit attempt. VNP may be a solution to low quit rates amongst this population.

Presentation 4: Challenges in clinical research involving people with mental illness and addictions: Lessons learned from the STATUS trial for smoking cessation

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Introduction: Many people with mental health conditions and alcohol and drug dependence smoke tobacco and have tried but failed to quit with standard cessation treatment approaches. Varenicline and behavioural support are the best available treatments in smokers. We sought to test if, in people who hadn’t quit or reduce smoking consumption after two weeks of varenicline, adding a nicotine e-cigarette would improve quitting rates at 6 months, relative to remaining on varenicline and behavioural support alone.

Method: Eligibility: Smokers with mental health and/or drug & alcohol dependence, ≥18 years, motivated to quit smoking. Recruitment: We aimed to randomise 338 participants from community treatment services. After 6 months, a proactive approach was tried, providers referring clients to the researchers, who then contacted clients directly; some were identified from database searching. Intervention: 12 weeks of varenicline or varenicline plus 18mg/mL nicotine e-cigarette, with behavioural support for all. Outcomes: Primary outcome: self-reported, verified continuous abstinence at 6 months. Secondary outcomes were collected at quit date, one, three, six months post quit-date, including changes in mental health and adverse events.

Key findings: Recruitment fell well below target. Reasons included ethics restrictions, commonplace e-cigarette use, the adaptive period too drastic, catchment area too limited, clinician resistance, concerns about safety of varenicline or e-cigarettes.

Implications for Translational Research: We failed to recruit sufficient participants to answer the primary research question. Cessation trials are still urgently needed in this group. Qualitative research with clinicians and clients may help identify barriers and how to overcome them.
Discussion Section Dr George Laking (Discussant), from the Waitemata District Health Board, Auckland, New Zealand, will lead a discussion regarding the use of VNPs to help people receiving drug and alcohol treatment or with comorbidities such as mental health or HCV or HIV stop or reduce tobacco smoking. Dr Laking is an oncologist and economist and a highly engaging presenter and speaker. From a shared European and Indigenous heritage, he is active in the Royal Australian College of Physicians, where he chairs the Māori Health Committee and the NZ Policy and Advocacy Committee, and is a member of the College’s Reference Group on Electronic Cigarettes. The discussion will aim to explore challenges in the use of VNPs and will ask the symposium attendees whether they believe VNPs will be effective. A special consideration will be given to the use of VNPs for smoking cessation amongst Indigenous people.

Disclosure of Interest Statement (Presentation 1): This trial is funded by a National Health and Medical Research Council project grant. The vaporisers used in the trial are purchased from EasyVape Australia. The e-liquid used in the trial is manufactured specifically for this study by a TGA-licensed pharmaceutical manufacturer.

Disclosure of Interest Statement (Presentation 2): This trial is funded by the Health Research Council of New Zealand (15/202). The e-cigarettes used in the trial were purchased from NZVAPOR. NZVAPOR are not involved in the design, conduct or analysis of the trial, but did provide on-line and phone support to participants regarding use of their allocated e-cigarettes. The e-cigarettes used in the trial and NZVAPOR (including the Managing Director) have no links with the tobacco industry. The e-juice used in the trial was purchased directly from Nicopharm, Australia. The nicotine patches were supplied by the New Zealand Government via their contract with Novartis. Nicopharm and Novartis were not involved in the design, conduct or analysis of the trial and have no known links with the tobacco industry.

Disclosure of Interest Statement (Presentation 3): This trial is funded by a National Health and Medical Research Council project grant. The vaporisers used in the trial are purchased from EasyVape Australia. The e-liquid used in the trial is manufactured specifically for this study by a TGA-licensed pharmaceutical manufacturer.

Disclosure of Interest Statement (Presentation 4): This trial is funded by the Health Research Council of New Zealand (16/066). The e-cigarettes were purchased from NZVAPOR. NZVAPOR has no links to the tobacco industry and are not involved in the design, conduct or analysis of the trial, but did provide on-line and phone support to participants regarding use of their allocated e-cigarettes. The e-juice used in the trial was purchased directly from NZVAPOR. The vareniciline was supplied by the New Zealand Government via their contract with Novartis.