An Exploratory Study on Pharmacy-Based Vaping Related Health Services and Training in Australia

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A thesis submitted in fulfilment of the requirements for the degree of Master of Philosophy

Sydney Pharmacy School

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Statement of Originality

This is to certify that the content of this thesis, entitled "An Exploratory Study on Pharmacy-Based Vaping Related Health Services and Training in Australia," has been submitted in fulfilment of the requirements for the Master of Philosophy degree. The work and research presented in this thesis were conducted under the supervision of Professor Bandana Saini, Professor Smita Shah and Dr Maya Saba.

I certify that the intellectual content of this thesis is the product of my own work, and all assistance received in preparing this thesis and all sources have been acknowledged.

David Le

Date: 10th February 2026

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Author Attribution Statement

I, David Le, Master of Philosophy (MPhil) candidate, have made significant contributions to the research manuscripts presented throughout this thesis. I am the primary author of the manuscripts listed below. The Contribution Roles Taxonomy (CRediT) have been used to describe the authorship attribution statements. No content generated by generative AI tools has been used in the preparation of this thesis.

Chapter 3, of this thesis is published as "Le D, Saba M, Bhurawala H, Rahman MA, Shah S, Saini B. Pharmacists' Perspectives on Nicotine Vaping Products (NVPs) for Smoking Cessation in Australia: A Qualitative Analysis. *Pharmacy*, 13(1), 11.

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The CRediT roles I carried out in this study were Conceptualisation, Methodology, Software, Validation, Formal Analysis, Investigation, Resources, Data Curation, Writing - Original Draft Preparation, Writing – Review and Editing, Visualisation and Project Administration

Chapter 4 of this thesis is a revised manuscript as "Le D, Saba M, Dan E, Bussing J, Bittoun B, Shah S, Saini B. No-To-Nicotine: Developing and Evaluating a Smoking and Vaping Cessation Module for Pharmacy Students. *American Journal of Pharmaceutical Education*, (Under Review)"

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David Le

Supervisor Attestation

As the primary supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Bandana HK Saini

Date: 10th February 2026

Abstract

The rise in the use of electronic cigarettes (e-cigarettes) has exploded exponentially over the recent decades, leading to millions taking up vaping worldwide. The act of vaping involves inhaling vapour that contains a variety of chemicals and flavourings and that has been aerosolised from the device into the user's airways with immediate effects on the human body. However, there is limited evidence on the long-term harms and risks of vaping on the health of the individual and the wider population. Nicotine is a substance commonly found in e-cigarettes, where its concentration in combination with the device type leads to varying levels of exposure. Adolescents and young adults comprise a population subgroup that has seen increasing rates of vaping, which warrants concerns of nicotine addiction and dependence in this population. A myriad of factors have culminated in high uptake of vaping, particularly among adolescents and young adults, such as social media, marketing strategies, peer pressure and curiosity. The impact of using such devices, especially those containing nicotine, has led to an entire generation dependent on nicotine without even smoking a combustible tobacco cigarette. This highlights the importance of reducing vaping rates and managing vaping health-related issues in individuals, especially those who are particularly more at risk of taking up the habit.

Pharmacists and other primary care health professionals are well-versed in smoking cessation and providing behavioural support to manage an individual's quitting journey. However, there seems to be a lack of information and guidelines about vaping and vaping cessation, as well as the role of nicotine vaping products (NVPs) in smoking cessation. The rapidly evolving phenomenon is of a significant public health concern, with researchers and clinicians racing to keep up with the health effects and impacts of vaping. Governments around the world have introduced restrictions to curb the high rates of vaping, where in Australia, there have been a plethora of regulatory changes that have shifted the provision of nicotine vaping products to the pharmacy environment.

Pharmacists are at the forefront of primary care in Australia and are often the first point of call for patients experiencing a health ailment. Professional practice services, such as smoking cessation, are offered in pharmacies, where tailored advice and appropriate pharmacotherapy are provided in consultation with a pharmacist. The recent regulatory shift from a prescription model to a pharmacist-only medication (nicotine concentrations 20mg/mL or less) has prompted pharmacists to be well-equipped with the required knowledge and skills to address vaping-related health concerns within the community. Vaping clearly has health ramifications for individuals, the community, and societal health, amid new evidence surfacing and shifting regulatory frameworks. Hence, there is a need to understand the impact of the risks and harms of vaping as well as its role in smoking cessation and subsequent cessation. This could have the potential to improve vaping health-related management, optimise clinical practice for healthcare professionals and tailor health needs to benefit both individuals and communities.

Aims

The research work carried out in this thesis had two main aims:

1. To explore Australian pharmacists' perspectives on vaping and the support avenues needed to implement vaping-related health services. This included examining personal and professional opinions, including any current provisions of nicotine vaping products and various factors that would need to be addressed to implement vaping-related professional services in the pharmacy.

2. To examine Australian pharmacy students' attitudes, knowledge and skills in terms of nicotine-related cessation and develop a targeted training program based on current evidence, principles of adult learning as well as identified gaps.

Chapter 1

This chapter presents a thorough background on e-cigarettes, laying the foundational work that was carried out in this thesis. Key aspects of e-cigarette device types and their components, epidemiology, vaping topography, health effects, regulations, and social impact were covered. The roles of pharmacists in vaping-related health services were also presented, informed by a scoping literature review that highlighted vaping perspectives among pharmacists and pharmacy students, as well as any pharmacist-led interventions.

Chapter 2

This chapter presents the rationale for the methodology used in the studies presented in this thesis, along with a description of the design, delivery, and data analysis process. Two research studies were carried out: one cross-sectional qualitative study and one pre-post educational intervention study.

Chapter 3

This chapter presents the findings of an exploratory study that aimed to understand how pharmacists perceive vaping and its impact on the pharmacy profession in managing vaping-related health requests. Semi-structured interviews were conducted with 25 pharmacists from community and hospital settings in Australia. Three themes were derived from the data collected: 1. Risk Perception, 2. Professional Vaping Health-Related Services and 3. Professional Practice and Other Support Needs. Pharmacists in this study had limited exposure to the provision of nicotine vaping products in practice; the findings highlighted uncertainty and apprehension about the risks and harms of vaping amidst evolving regulatory measures. There was a need for greater training and education surrounding vaping and its role in smoking cessation, on which participants reiterated evidence-based practice to provide vaping-related health services.

Chapter 4

This chapter presents the intervention work with pharmacy students carried out in this thesis, which was informed by the exploratory work from both personal and professional perspectives surrounding vaping by pharmacists. No-to-Nicotine (N2N) was a pedagogically aligned education module about smoking and vaping that was designed and taught to second-year pharmacy students at the School of Pharmacy, The University of Sydney, Australia. A pre-/post-interventional design was utilised with a voluntary questionnaire, which assessed the knowledge and attitudes towards smoking and vaping. A total of 147 pharmacy students completed both questionnaires. There was a significant improvement in knowledge from a baseline of 18.9 ± 5.6 to 25.4 ± 5.0 ($p<0.001$) and a noticeable improvement in attitudes, increasing from 3.9 ± 0.5 to 4.0 ± 0.6 ($p=0.053$). Student engagement and satisfaction from N2N were positive, reflecting the knowledge and attitudes gained.

Chapter 5

This chapter presents a discussion of the thesis work conducted, extending upon the discussions included in Chapters 3 and 4. The study findings were contextualised within the Australian vaping reforms and the potential behavioural change adaptations for pharmacists to be equipped with the proficiency for nicotine vaping product (NVP) provision. This was followed by strengths and limitations of the two studies with future directions of practice in this area, derived from the findings across this MPhil research. A conclusion is presented with recommendations for pharmacy-based vaping related health services.

The introduction of regulatory measures around vaping procurement and supply has expanded the pharmacist's scope of practice to include NVP provision. The work conducted among pharmacists and pharmacy students highlighted various perspectives on vaping and gaps in clinical knowledge. Pharmacists expressed concerns about the

scarcity of evidence-based guidelines in the management of smoking and vaping cessation, along with barriers and support needs to be able to deliver a professional pharmacy-based vaping service. Educational interventions such as the pedagogically aligned N2N are able to demonstrate the ability of education and training to address gaps in clinical knowledge surrounding smoking and vaping cessation. These findings from this MPhil research provide the foundational framework for future research on vaping and its implications on the pharmacy landscape.

Abbreviations and Keywords

Authorised Prescriber (AP)

Electronic cigarette (E-cigarette)

Education

Educational Intervention

Nicotine

Nicotine Addiction

Nicotine Replacement Therapy (NRT)

Nicotine Vaping Product (NVP)

No to Nicotine (N2N)

Pedagogy

Pharmacists

Pharmacy

Pharmacy Practice

Pharmacy Students

Pharmaceutical Society of Australia (PSA)

Qualitative Research

Royal Australian College of General Practitioners (RACGP)

Special Access Scheme (SAS)

Smoking

Therapeutic Goods Administration (TGA)

Thematic Analysis

Vaping

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List of Tables

Please note that additional figures have been presented within the text of the published and revised submitted manuscripts.

Chapter 1

An Overview of Vaping and Exploratory Pharmacy Related Services

1.0 Chapter Overview

This chapter provides a comprehensive overview of vaping and its impact on human health, with a particular focus on pharmacy practice and the potential of vaping-related health services. It establishes the foundation for the research presented in this thesis.

Section A explores the development of e-cigarettes, including a classification of various devices and an overview of the common components found in e-liquids. This chapter provides an in-depth context and understanding of e-cigarettes, laying the foundational background before moving on to its public health impact.

Section B of this chapter presents the varying impacts of e-cigarettes on health, societal effects, and regulatory measures, including their prevalence both in Australia and globally. This chapter highlights the rapid phenomenon of vaping and its influence on population health, especially among adolescents and young adults.

Section C of this chapter presents a scoping review of the literature, exploring pharmacy based vaping related services and understanding the implications for pharmacists and pharmacy studies alike. The aims of the thesis were provided, based on findings from the literature, where further exploratory studies were conducted, a qualitative study and an educational intervention.

Section A – Context and Background

1.1 Introduction

Electronic cigarettes (e-cigarettes) have gained widespread popularity worldwide in recent years, particularly among adolescents and young adults. Vaping, which may be defined as the act of using an e-cigarette, involves inhaling aerosols produced by heating a liquid solution containing nicotine, flavourings, sweeteners and other substances such as propylene glycol (1). While e-cigarettes are often marked as a safe alternative to traditional cigarettes, concerns about the long-term impact of e-cigarettes on human health, especially on respiratory health, continue to grow. This is reflected in a statement by the World Health Organisation (WHO) that e-cigarettes are harmful to health and are not safe. However, it is too early to provide a clear answer on the long-term impact (2). While there may not be much known about the long-term potential health consequences of vaping, the increasing use of e-cigarettes and their impact on the global population comprise a significant public health concern.

1.1.1 *History*

Although e-cigarettes appear to be a relatively new phenomenon, these devices were conceptualised a century ago, though past failures did not result in commercialisation. The trajectory of e-cigarette development is depicted in Figure 1.1.

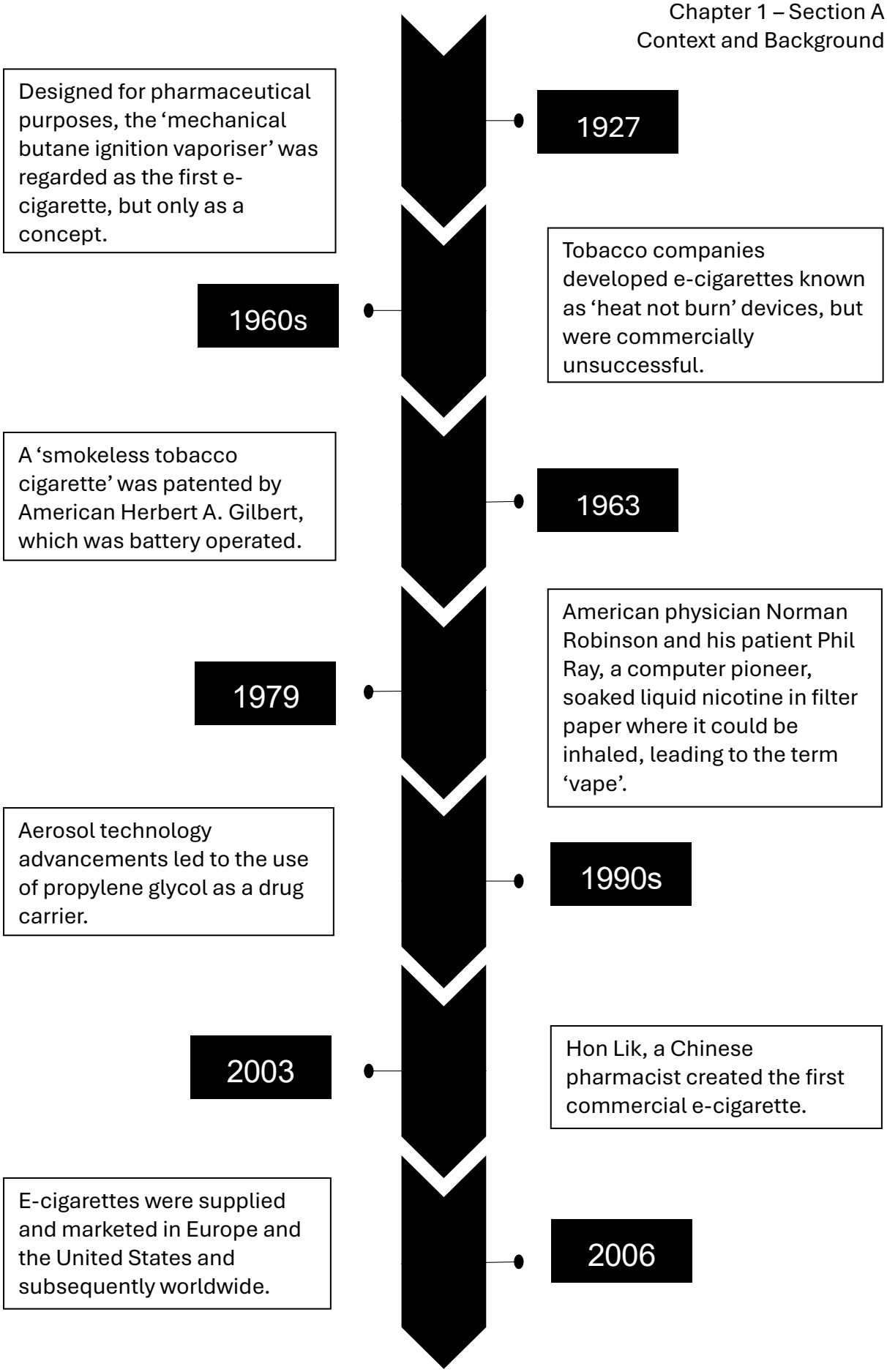

Figure 1.1: *Timeline of E-cigarette History* (3-5)

There are many terms that e-cigarettes are known by, including e-cigs, electronic nicotine delivery systems (ENDS), electronic non-nicotine delivery systems (ENNDS), alternative delivery systems (ANDS), nicotine vaping products (NVPs), e-hookahs, vape pens and vapes (6).

1.2 Anatomy of an E-Cigarette

E-cigarettes are available in four types of devices tabulated below (Table 1.1) and in a multitude of styles; while there are differences, some characteristics can be used to classify these devices more broadly (7, 8).

- **Open system devices**: The e-liquid needs to be poured in manually for use.
- **Closed system devices:** The e-liquid is sealed within the device
- **Disposable**: The device is to be discarded after the e-liquid is finished.
- **Rechargeable:** A battery is enclosed in the device, allowing multiple uses

In addition to refilling the e-liquid for open-system devices, the coil used to heat the device must also be replaced. E-liquid refills are available in ready-made solutions or as an option to formulate for personal use. This presents a high risk of the user being exposed to nicotine via dermal or oral ingestion, which may lead to nicotine poisoning. While closed-system devices are safer, as there is limited exposure to nicotine, they are only available in certain concentrations, making the titration of nicotine more difficult.

There are a variety of e-cigarettes; the common characteristics and their purpose can be seen in Table 1.1 and Figure 1.2.

Components of E-cigarettes	Purpose
Mouthpiece (Drip Tip)	The user inhales the vapour aerosolised from the e-liquid into their airways.
Cartridge	It encloses the e-liquid and can be prefilled/refillable.
E-liquid	A liquid mixture of chemicals that may or may not contain nicotine.
Atomiser (Coil)	The heating device that converts the e-liquid into vapour, usually made of metals consisting of iron, nickel or chromium,
Sensors (Power Button)	Turns the device on through activation of inhalation or pressing a button.
Battery	A rechargeable lithium ion supplies the power.

Table 1.1: *Components of E-cigarettes and their purpose* (9)

Essentially, the vaper presses the power button, which activates the battery, and the heating component begins to convert the e-liquid (containing nicotine) in the cartridge into vapour, inhaled into the person's lungs. When there is no power button, the e-cigarette usually has a sensor that is activated when the vaper breathes in, which is often present in newer devices. A change in air pressure is detected by the sensor, which causes the heating component to aerosolise the e-liquid, initiating the action of vaping (17). Regardless of subsequent generations of e-cigarettes coming into the market, the basic working structure of e-cigarettes has been relatively the same, with differing design customisations. E-cigarettes have become rechargeable, with the cartridges containing the e-liquid being prefilled or refillable, allowing greater options from the first disposable 'cig-a-like' e-cigarette. Additionally, the power output has been a feature that provides vapers with temperature adjustments, ultimately controlling the amount of vapour produced and the intensity of the sensation received when the chemical mixture is inhaled (18). E-cigarettes have been available in an array of characteristics, resulting in greater choice. However, the basic concept of 'vaping' has remained relatively the same.

Figure 1.2: *Diagrammatic Portrayal of an E-cigarette and its Components* (10)
Adapted from Biorender (10)

1.2.1 *E-Cigarette Categorisation*

As depicted in Figure 1.1, a Chinese pharmacist, Hon Lik developed the first commercialised e-cigarette in 2003, and since then a variety of e-cigarettes with differing characteristics have emerged in an evolving global market (Table 1.2).

Type of Device	Name	Usage and Product Specs	Advantages	Disadvantages
First Generation	Cig-a-like	▪ Mimics the feel and look of cigarettes ▪ Low voltage device that needs to be discarded when out of charge ▪ Nicotine liquid is in basic form and lower strength	▪ Less risk of nicotine exposure compared to newer generation devices	▪ Not rechargeable ▪ Not refillable ▪ Risk of harmful chemicals leaching from the coil to be vaporised with the e-liquid
Second Generation	Vape Pens	▪ Product resembles a pen ▪ Nicotine liquid is filled in a (usually clear) cartridge that contains a heating coil ▪ Due to clear cartridge, also known as tank systems ▪ Cartridge can be refilled ▪ Volume of liquid in cartridge higher than in cig-a-likes ▪ Batteries used are rechargeable and more powerful compared to cig-a-likes.	▪ Rechargeable ▪ Prefilled/Refillable cartridges ▪ Multiple Usage ▪ More powerful battery.	▪ More risk of nicotine exposure, due to use of refillable cartridges with higher volume and concentration

Third Generation	Box Mods/Mods	▪ Devices are larger than pens or cig-a-likes ▪ Liquid can be refilled ▪ Devices included replaceable heating coils, wicking materials, e-liquids, and batteries ▪ The heating coil may be set to sub-ohm resistance, resulting in more power output	▪ Larger ▪ Customisable functions such as adjusting temperature and power (hence called mods, e.g. modifiable) ▪ High power increases aerosol mass and increases the nicotine delivery level	▪ Stronger hit of nicotine delivered to the airways and lungs due to higher powered devices producing more aerosolised nicotine with each puff
Fourth Generation	Pods/ Pod Mods	▪ Require user to slide a 'pod' (*nicotine cartridge*) into the device prior to use ▪ Device size can be small e.g., resemble a USB stick ▪ Nicotine in the pod is protonated	▪ Sleek design ▪ Smaller ▪ Easy to use ▪ Refillable	▪ Higher concentrations of nicotine are delivered through nicotine salts ▪ Not customisable ▪ Less powerful than Mods

Table 1.2: *Categories of E-cigarettes* (7, 11-16)

The different generations of e-cigarettes in the global market have provided current and potential vapers with an array of choices with customisable features suited to personal preferences.

1.3 Anatomy of an E-Liquid

1.3.1 *Solvents and Humectants*

E-liquids contained in any of these devices usually contain a mixture of solvents, flavourings and nicotine; this solution is converted into an aerosol form and inhaled into the vaper's lungs. Solvents such as propylene glycol, glycerol and vegetable glycerin constitute the majority of e-liquids in which flavouring and nicotine are dissolved (19). These solvents are often used in pharmaceuticals and considered generally safe for ingestion, but not for inhalation (16). However, studies have found other substances present in e-liquids, including formaldehyde, acetaldehyde, acetone and acrolein, which are known to be toxic and harmful to human health (20). Thermal degradation of propylene glycol and glycerol occurs when in contact with the atomiser, undergoing oxidation, which forms traces of these harmful substances (16).

1.3.2 *Flavourings*

In addition, the flavourings in e-liquids have been identified to contain compounds that could present a hazard to human lungs. Flavours such as berry, caramel and menthol make e-cigarettes attractive, especially among adolescents and young adults. Butter is a cream-based flavouring derived from a chemical compound called diacetyl, 2,3-butanedione $(CH_3CO)_2$. This chemical has been shown to cause a form of severe and irreversible obstructive lung disease when inhaled, while otherwise it is safe when ingested (21). Hence, chemicals used in food flavourings may not be safe when inhaled and should be examined carefully.

1.3.3 *Metals and Metalloids*

Heavy metals, such as arsenic, lead, and nickel, have been detected in e-liquids (22). The device's design, such as the atomiser, soldered parts, wick and storage material of the e-liquid, may lead to heavy metal contamination, highlighting the potential risk posed by e-cigarettes, discussed in health effects (17).

1.3.4 Nicotine Forms

Nicotine is the main active ingredient in e-liquids. There are two types of nicotine used in e-cigarettes: free base nicotine and nicotine salts. Nicotine is a weak base alkaloid, whose free base form allows for rapid absorption, which often causes a harsh sensation on the throat upon vaping (18). Nicotine salts are formed by the protonation of one of the nitrogens on nicotine, following the addition of an acid (19). This protonation allows the pH of the e-liquid to be reduced, resulting in less irritation on the throat and leading to greater absorption, which enhances nicotine bioavailability, allowing for higher concentrations of nicotine to be used (20). A comparison of free-base and salt nicotine formulations highlighted an enhanced appeal for the usage of nicotine salts in e-liquids, resulting in a greater sensory experience when vaping (21). The reformulation of nicotine from free base to salt paved the way for a new generation of e-cigarettes to be manufactured, such as JUUL, which became one of the most popular brands for American vapers.

1.4 Nicotine

1.4.1 *Pharmacology*

Nicotine is a stimulant, naturally occurring substance that is commonly found in combustible tobacco cigarettes and, more recently, e-cigarettes. When inhaled, nicotine is rapidly absorbed into the body's bloodstream, where it enters the brain within 10-20 seconds and binds to nicotinic cholinergic receptors (nAChRs) (24). Upon binding, rewarding neurotransmitters, such as dopamine, are released, and this plays a major role in the cycle of nicotine addiction and dependence (20).

With the vast majority of e-cigarette users being adolescents and young adults, the effects of nicotine are concerning. According to the U.S. Surgeon General report, the effects of nicotine can damage the developing adolescent brain, which reaches maturity at around 25 years of age (25). The brain has areas that regulate learning, memory and behaviour and are impacted by the effects of nicotine, namely the hippocampus and prefrontal cortex. People with a developing brain are more

susceptible to these damaging changes that cause lasting effects on attention, mood, and potentially fuelling addiction to drugs of abuse (22).

The amount of nicotine in an e-liquid is variable. Differing nicotine levels among a variety of similar brands and e-cigarette devices indicate the complexity of determining the amount of nicotine inhaled into the vaper's body, with values ranging from 0-87.2 mg/mL (23). The inaccurate labelling of nicotine amounts further highlights the lack of standard concentrations of nicotine within e-cigarettes compared to actual measured levels (24). This labelling inaccuracy is of particular concern as this infers that the exact amount of nicotine inhaled from the e-cigarette device is unknown, which correlates to the inaccuracies of 'nicotine-free' e-cigarettes that have been found to contain amounts of nicotine. The amount of nicotine also varies across different generations of devices, with older generations containing lower nicotine levels in the e-liquid compared to newer e-cigarettes. Specifically, nicotine levels were 1.4 times higher in the third generation compared to the second generation (25). Thus, it is much more difficult to determine the amount of nicotine absorbed into the human body.

1.4.2 *Puff Topography*

It is well known from research on conventional smoking that nicotine delivery to the lungs during cigarette smoking depends on a range of variables known as 'topography variables' (26). These include puff volume, inhalation depth, the rate of puffing, the intensity of puffing, as well as the extent of dilution of the cigarette smoke within the environment or room air (26).

Puff topography may also be different when vapers have been previous smokers or are naïve to conventional cigarettes when they take up vaping. In a study comparing differences in puff topography between cigarette and e-cigarette users, researchers measured puffing characteristics in an experimental protocol with e-cigarette naïve participants smoking a conventional tobacco cigarette, and about 24 hours later, asked to use a first-generation e-cigarette (27). More puffs were observed when smoking a conventional cigarette, but per-puff volume, flow rate and peak flow rate were

significantly higher with e-cigarettes compared to the initial cigarette smoking activity, though puff duration was not different (27).In another study, researchers measured the puffing topography of a small sample of experienced e-cigarette users (second-generation type) during a 10-puff session (28). These users took larger volumes per puff and longer puffs, but the flow rate with e-cigarettes was lower compared to previous studies of conventional cigarette smoking (28). Given that these comparisons are not within the subject, the findings should be treated cautiously. In another study where conventional smokers switched to e-cigarettes, researchers observed that the duration of each puff increased with e-cigarette use, though the duration between puffs decreased (29). Based on the above studies, it would appear that puff duration and volume may be higher with e-cigarette use compared with conventional cigarette use. Of course, more research on this topic is certainly warranted, given that the experimental studies were of small sample size and had other limitations.

Reviews of experimental studies highlighted that there may be differences between experienced users of e-cigarettes versus naïve users. Farsalinos et al. (2013) demonstrated that more regular vapers (who vaped more consistently) usually took larger and deeper breaths (higher puff duration and volume) compared to those who did not vape regularly, where the nicotine content inhaled would vary based on puff rate and duration (30).

Of course, the puffing topography may be dependent on the e-cigarette device; higher-power devices use more energy to increase the nicotine levels aerosolised in the e-liquid, exposing the user to higher concentrations of nicotine compared to lower-power ones (31). Due to the high variability of these factors, in combination with the inconsistency of nicotine concentrations, determining the approximate nicotine absorption by users is challenging.

Section B – Public Health Impact of Vaping

1.5 Epidemiology

Since the introduction of the e-cigarette, there has been an increasing global prevalence of people using electronic nicotine delivery systems (ENDS) (32). The WHO released an updated report in 2023 on the Global Tobacco Epidemic, which states that 'ENDS are addictive and harmful, particularly for young people' (33). This is of particular concern as vaping is becoming common among adolescents and young adults in Western countries such as Canada, England, and America, where there has been an increased prevalence of vaping in over 19% of American teenagers from 2011 to 2018 (34). In the Global Youth Tobacco Survey, e-cigarette use was demonstrably higher among a large proportion of American school students, highlighting that many young people have experimented with vaping (35). While there is evidence that vaping is becoming increasingly prevalent among the global youth population, much of this data comes from high- and middle-income countries. According to the WHO, there have been a few low-income countries that have monitored e-cigarette use among adolescents and young adults. However, there has been a strong trend in the proportion of people around the world, particularly among younger age population groups, using e-cigarettes.

1.5.1 *Vaping – The Australian Scenario*

Like the rest of the world, Australia is experiencing an increased number of people using e-cigarettes (Figure 1.3).

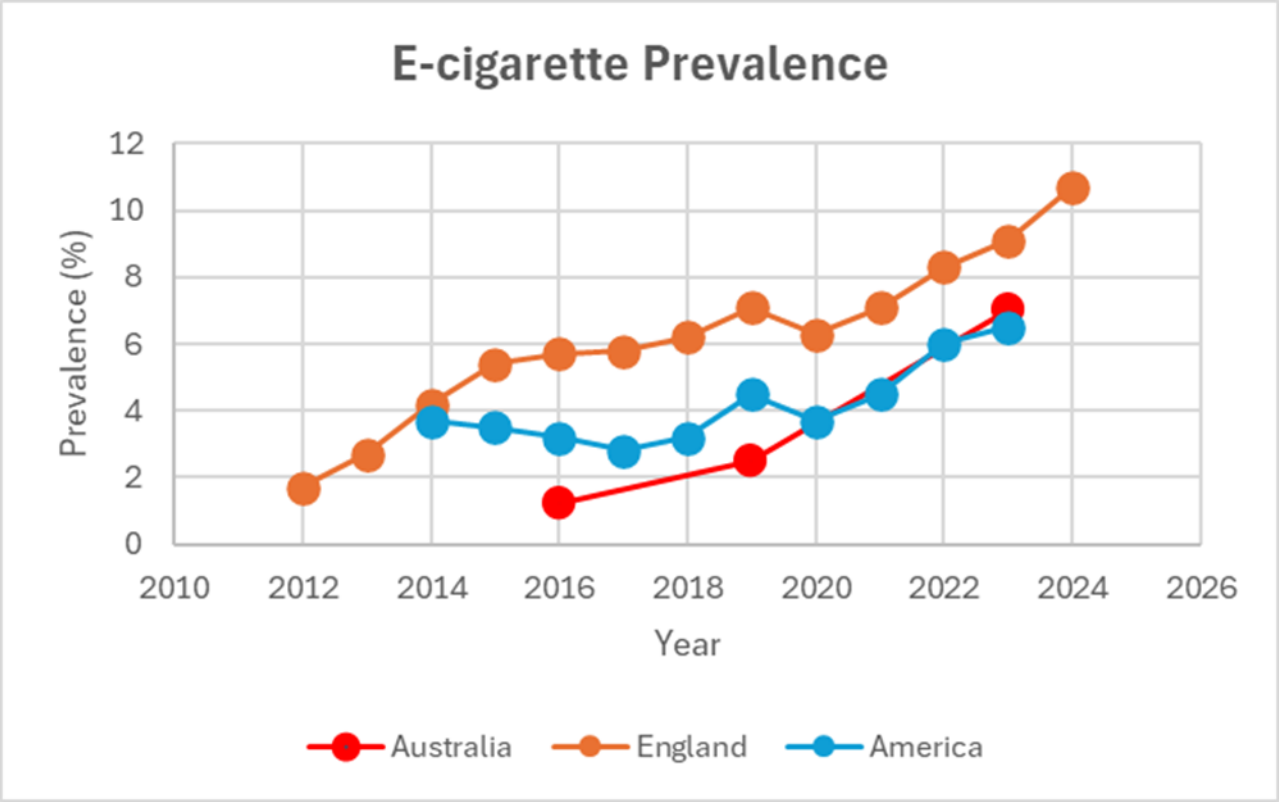

Figure 1.3: *E-cigarette Prevalence* (36-39)

There has been an upward trend of vaping among the Australian population aged 14 years and over, with a large increase from 2.5% in 2019 to 7.0% in 2023. The highest prevalence age population group were those aged 18-24, highlighting the high usage of e-cigarettes among adolescents and young adults (40). This is reflected in the 2023 National Drug Strategy Household Survey, where it was reported that 19.8% of the Australian population aged 14 years and over had tried an e-cigarette. When comparing data from 2019, there has been a significant increase in the lifetime use of e-cigarettes from 11.3%, corresponding to the increasing trend in vaping globally (39). The highest number of vapers were adolescents and young adults aged 18-24 at 49%, indicating this particular population has continued using e-cigarettes at rates greater than other age groups, doubling from 26.1% in 2019 (41). Adolescents and young adults are most likely to have vaped or are currently vaping, which is also seen worldwide.

1.6 Health Effects

1.6.1 *Immediate Health Effects*

Vaping can certainly impact the health of users much like conventional cigarettes. (Figure 1.4). Inhaling a vapour of aerosolised chemicals into the airways has immediate adverse effects on the body. The major components of e-liquids are solvents, such as propylene glycol and vegetable glycerin, which contribute to some of the side effects experienced by e-cigarette users, including mouth and throat irritation and dry mouth (42). These symptoms depend on the topography of use, including the characteristics of the e-cigarette, as well as variables such as puff length and the composition of the e-liquid. While these solvents are classified as safe as food additives when inhaled, particularly propylene glycol, has been found to cause airway irritation during short-term occupational exposure (43). Hence, this poses the question of whether e-cigarette users can inhale these solvents at levels without impacting their respiratory health. In addition, there have been reports of nausea, vomiting, dizziness, confusion and palpitations from e-cigarettes containing nicotine (44). These short-term adverse effects have been related to the nicotine content present in the e-liquid, where higher concentrations were reported to be associated with severe outcomes akin to nicotine poisoning (45). This is of particular concern when a large proportion of vapers are adolescents and young adults, whose bodies are not fully developed, and are exposed to nicotine. Due to the inconsistency of amounts of nicotine and inaccurate labelling, there is potential for vapers to be exposed to dangerous levels of substances within the e-liquid, endangering lung health. While there are immediate adverse effects of using an e-cigarette, more studies are needed to determine the overall effect of vaping on our health.

Seizures are another concerning consequence of using e-cigarettes. A majority of seizures in e-cigarette users occur in adolescent and young adult populations, which highlights potential links from reported cases that provide limited information on the nature of this adverse event (46). There have been case reports of adolescents presenting with a first-time generalised seizure after vaping and having taken a full inhalation of an e-cigarette containing 5% nicotine (47). A high concentration of nicotine

being vaped at once, in combination with nicotine's rapid absorption into the body and brain, poses a risk of seizures within a short span of vaping. A study about seizures and e-cigarettes has suggested that nicotine toxicity from the high levels inhaled was the reason for this reported event, where 62% of cases have resulted from minutes of using e-cigarettes (48). The association between cigarettes and seizures is emerging as more studies come to light. Seizures are a serious adverse effect of concern for e-cigarette users, and studies have shown that there were consequences that require medical treatment and hospitalisation.

1.6.2 *Safety Risks*

There have also been reports of accidents posing safety risks associated with e-cigarettes, causing burn injuries. E-cigarettes contain lithium batteries that are either disposable or rechargeable. As new types of e-cigarettes were released on the market, there have been modifications to make the lithium batteries more compact and powerful. A stronger lithium battery enables a greater charge to be delivered, allowing an increase in the amount of vapour that is inhaled. The use of lithium-powered e-cigarettes has been associated with injuries caused by explosions resulting in burns and fires, which have been caused while the battery was in charge when using the device and during storage (49). A retrospective review of burns related to e-cigarettes reported that a majority of burns were localised to one area of the body, namely the thigh and the hand (50). Hence, the explosion of e-cigarettes was more likely to occur in the user's pocket or while holding them. This was supported by a 2018 systematic review of 31 studies of burn injuries caused by e-cigarettes, which reinforced the location of these burns following the explosion. Most of the burns sustained from e-cigarettes were second-degree, some with a combination of second and third, where some patients required skin grafting and hospitalisation (51).

1.6.3 *Long Term Health Effects*

Electronic or vaping product use-associated lung injury (EVALI) has been reported, with cases rising with the ongoing popularity of e-cigarettes. There have been 2602 cases of EVALI in America reported since January 2020, with 57 resulting in death, where all cases have been vaping (52). Patients with EVALI present with symptoms such as shortness of breath, nausea, vomiting and fever. Diagnosis of EVALI is dependent upon a combination of factors such as history of vaping, lung opacities shown on the chest x-ray and eliminating sources of infection causing respiratory illness (53). Lung opacity refers to areas on the chest x-ray that appear cloudy when they should be of a darker colour (54). Studies have highlighted that around 80-92% of patients with EVALI have vaped an e-cigarette containing tetrahydrocannabinol (THC), which also contained nicotine; however, the cause is not known, and there are ongoing investigations to determine this (55). A 2019 survey by the Illinois Department of Public Health in America found that EVALI was reported in patients exclusively using THC-containing products, which indicated that THC contributes to a higher risk of EVALI (56). While THC appears to be present in EVALI patients, more evidence is needed to understand how this chemical is associated with EVALI clinical presentations. In addition, an analysis of lung fluid from patients with EVALI was found to contain Vitamin E acetate (57). Vitamin E acetate has been acknowledged as a harmful chemical that has contributed to vaping-related illnesses, while THC has been linked with symptoms of pulmonary disease, some of which have required hospitalisation and treatment.

The acute adverse respiratory health outcomes of vaping have largely included mouth and throat irritation and cough, with EVALI the major consequence, primarily due to people using e-cigarettes containing THC. However, there is not much known about the long-term effects of vaping on respiratory health, including those with asthma, bronchitis and COPD. A study assessing the acute impact of vaping in smokers and non-smokers indicated the worsening of respiratory symptoms with increased flow resistance in lung function (58). While studies on mice, which have been exposed to long-term e-cigarette vapour, revealed that they began to develop respiratory symptoms that have been closely aligned with COPD in humans (59).

This indicates the possible long-term effects where the airways become inflamed and hyper-reactive, with damage to the lung tissue. Chemicals in the e-liquids, such as benzene and acrolein, have also been identified as oxidative and pro-inflammatory, and this could have an impact on respiratory health, particularly with long-term use of e-cigarettes (60). There have been mixed results from evidence in terms of respiratory effects, such as lung function, and there were only studies about vaping-related health outcomes, with case reports about EVALI (61). Thus, long-term, reliable studies are needed to assess the full impact of chronic use of e-cigarettes on respiratory health outcomes; evidence is slowly emerging and may suggest a lasting effect on lung health.

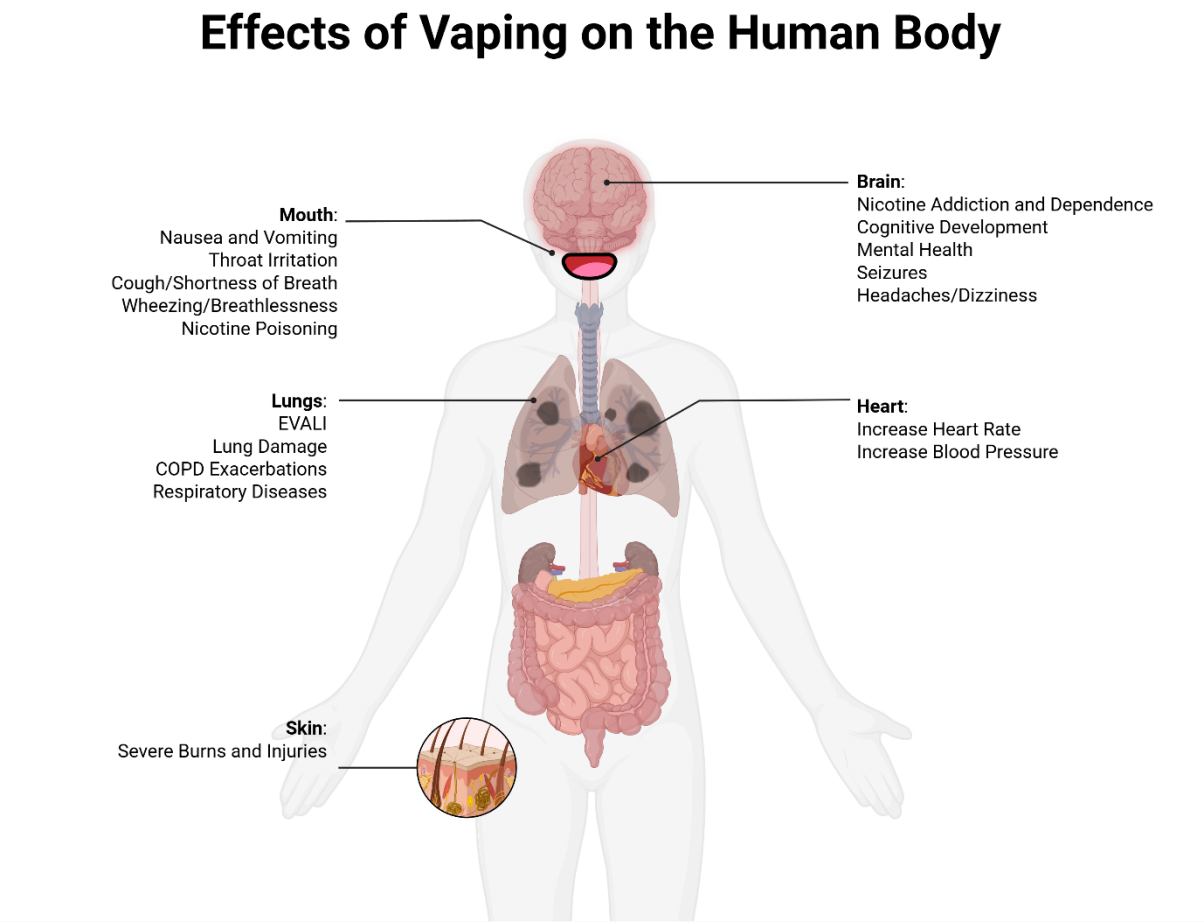

Figure 1.4: *Risks of Vaping on the Human Body*

Adapted from Biorender (10, 62)

1.7 Social Phenomena of Vaping

The popularity of e-cigarettes, particularly among adolescents and young adults, has led to increasing rates of vaping worldwide. This novel phenomenon has introduced a wave of curiosity, where the vast array of flavours and sleek designs of e-cigarettes have enticed users to experiment and potentially cause nicotine addiction to a generation of people who have never smoked a combustible cigarette.

1.7.1 *Socio-Demography*

The consequences of e-cigarettes in a nicotine-naïve population are only beginning to come to light, with adolescents and young adults being most at risk of harm. A cross-sectional study of American students in Connecticut reported that many adolescents (34.1%) were not aware of the nicotine concentration in the e-liquid, indicating the dangers of inhaling unknown amounts of such an addictive substance into the airways (63). Several characteristics such as age, gender, ethnicity and sexual orientation are contributing factors to the increased uptake of vaping among adolescents and young adults. A 2022 systematic review on the influences of e-cigarettes found that males were more likely to vape than females (64). Males were more sensitive to the nicotine reward effects, as females metabolised nicotine quickly due to the presence of oestrogen, leading to higher usage (65). Due to the appeal of e-cigarettes and the social influences of their peers, adolescents and young adults were vaping more than older age groups(66). E-cigarettes are used as a coping mechanism for those of ethnicity and sexual orientation due to a higher risk of stigma and discrimination due to social and cultural determinants (67). The increasing uptake among adolescents and young adults warrants public health concern and potential healthcare professional involvement within this evolving space.

1.7.2 *Social Perceptions*

There was an overwhelming preconception that e-cigarettes were notably less harmful than smoking a combustible cigarette, which was a primary appeal of vaping. Fifty

vapers, consisting of smokers, former smokers and non-smokers from 16 to 26 years, were interviewed. They recognised the risks of cigarette smoking and perceived them to be more harmful, while acknowledging vaping had its potential dangers (68). A key driver of vaping initiation was curiosity, where the participants viewed the risk perception of vaping as much lower than smoking (68). While curiosity is an innate part of human nature, social media has played an influential role in adolescents and young adults taking up vaping. The constant exposure of social media, where marketing and promotion of e-cigarettes have portrayed vaping in a positive light, has normalised social behaviours and interactions. Thematic analysis of transcripts from focus groups in 2018 conducted with American young adults who were vaping portrayed the ease and visual appeal of e-cigarettes from social media, contributing to their marketability and how vaping can be 'cool and trendy', which influences users' attitudes and behaviours (69). Media coverage of e-cigarettes in England and Scotland from 2007 to 2012 underwent thematic analysis, revealing marketing messages of a healthier and effective choice compared to cigarettes, with celebrity endorsements (70). The normalisation of vaping has been instrumental to peer pressure, where adolescents and young adults viewed their friends and celebrities using e-cigarettes on various social media platforms, prompting them to satisfy their curiosity while lowering their perceived risk of the handheld movement. In combination with their flavouring and design, factors such as their portability, low cost, and ability to use the device discreetly compared to combustible tobacco cigarettes have significantly shifted the focus and attention of adolescents and young adults to vaping (71).

1.8 Regulation

As the demand for e-cigarettes reached exponential levels worldwide, governments have begun to introduce regulations about the sale and supply, in accordance with emerging evidence about the impact of vaping on human health. In 2013, the WHO commissioned a report on ENDS as part of the free tobacco initiative to provide a regulatory framework for countries around the world concerning e-cigarettes. Some policy suggestions included in the report were banning the sale and use of e-cigarettes

and restrictions on marketing; these are, of course, quite similar to what has been done with combustible tobacco cigarettes (72). This suggests that lessons can be learnt from what governmental agencies and health organisations can apply with e-cigarettes. The latest WHO report on the global tobacco epidemic in 2023 documented that 121 countries regulate e-cigarettes in some manner, and highlights the need to protect adolescents and young people (33). A literature review of international regulations on e-cigarettes has indicated progress, with policies being introduced, such as restrictions on nicotine concentration, the placement of health warnings on packaging, and the prohibition of e-cigarette advertising (73). One example is North America, where the Food and Drug Administration has authority over all e-cigarettes under the Federal Food, Drug and Cosmetic Act, and these devices are subject to regulatory requirements (74). Countries with their respective governmental agencies and independent organisations have been adopting regulatory restrictions on e-cigarettes, particularly due to the risk posed to populations worldwide, especially adolescents and young people.

Australia, a world leader in tobacco control, was the first country to legislate that combustible tobacco cigarettes be sold in plain packaging. Australia has also led policies around e-cigarettes by introducing regulatory restrictions on availability and supply. From 1 October 2021, the purchase of a nicotine vaping product required a prescription regardless of whether the product was outsourced from overseas or within Australia (75). This made nicotine-containing e-cigarettes much more difficult to purchase, as previously they were widely available in many places, such as tobacco shops and petrol stations, where adolescents and young people had easy access. The aim of restricting supply via a prescription format was to reduce the number of people using e-cigarettes and being exposed to their health effects. Further restrictions surrounding nicotine vaping products were announced on the 2nd of May 2023, with the Australian government taking a hardline approach in the fight against vaping through stronger legislation and enforcement of controls on e-cigarettes. Overall, Australian policies have been aligned with what has been seen in the international space with a ban on single-use disposable vapes, restrictions on flavours and nicotine concentrations and a requirement for all nicotine vaping products supplied to have

pharmaceutical-like packaging (76).

Since the announcement that e-cigarettes would be only available on prescription, this model has expanded to pharmacist-only medications of nicotine concentration of 20mg/mL or less (77). Pharmacist-only medications allow pharmacist consultation, ensuring safe and effective use and minimising harm and workload pressures for general practitioners. Since Australian states and territories have legal jurisdiction over the poisons standard, Tasmania and Western Australia have restricted the supply of e-cigarettes to prescription only, while in the rest of Australia, e-cigarettes can be obtained from a pharmacist (78, 79). Hence, these rapidly evolving regulatory measures surrounding e-cigarettes have seen the closures of local corner shops and tobacconists in an effort to curb the growing public health concern. With this spotlight on e-cigarette regulation, Australia endeavours to continue to be a tobacco control leader, minimising e-cigarette exposure, particularly to its younger populations.

1.9 Role of Vaping in Smoking Initiation and Cessation

With the higher rates of e-cigarette users in the adolescent and young adult populations compared to other age groups, there is concern that vaping could be a gateway to smoking. Due to Australia's stance against combustible/conventional tobacco cigarettes, numerous regulatory restrictions have been implemented, including the tobacco excise tax, age restrictions, and smoke-free laws, which have led to a decrease in smoking among the general Australian population (80). The proportion of current smokers in Australia has fallen from 14.7% to 10.0%, with young Australians less likely to be current smokers, which has also fallen from 16.0% to 7.4% in the past decade from 2013 (81, 82). Thus, smoking prevalence in Australia has been declining, possibly or at least in part due to the restrictions introduced by various Australian governments and increased awareness of the damaging health effects of smoking combustible tobacco cigarettes. An umbrella review of three systematic reviews and a secondary systematic review of 12 studies globally up to 2020 indicated that using e-cigarettes was associated with an increased smoking risk in never smokers, i.e. it served as a gateway to smoking (83). Studies have shown that people who use e-cigarettes are

three to five times more likely to smoke tobacco cigarettes (84, 85). If this were to occur, one could hypothesise that an increase in the proportion of smokers would eventuate in the well-documented damaging health effects of tobacco smoking, putting a strain on health systems and communities. This is of particular concern due to the vast majority of vapers being of a young age, and such a risk could be fuelling a new generation of tobacco smokers (or even, indeed, which would undo all of the gains achieved in the past decades in the fight against tobacco companies) (86). Whilst the evidence for a gateway effect between e-cigarette use and tobacco cigarette smoking is limited, the causal relationship between adolescent vapers becoming tobacco smokers was unclear, as reported in a 2019 systematic review and meta-analysis of longitudinal studies (87). Hence, the prevalence of smokers in Australia may begin to rise again, especially among the adolescent and young adult populations. A 2019-2020 tobacco study conducted with adolescents in California revealed a susceptibility to tobacco products through peer influences and poor mental health (88). This also suggests that vaping should not decrease the public health focus on the harms of conventional/combustible cigarette use.

Smoking cessation has been suggested as a possible outcome of using e-cigarettes. There have been widely documented techniques of quitting combustible tobacco cigarettes using varenicline, nicotine replacement therapy (NRT), bupropion and support services (89). The current evidence surrounding the use of e-cigarettes for smoking cessation is limited and mixed; more long-term, reliable studies are needed. A systematic review and meta-analysis of 6 randomised controlled trials compared smoking cessation for users of NRT with people who used e-cigarettes to shed light on the effectiveness of vaping as a smoking cessation tool. However, upon conclusion of the review, the study found no difference between smoking cessation and reduction, citing a need for long term reliable studies of the use of vaping in this space (90). This draws attention to the point where more studies need to be conducted to determine whether vaping can be used as a method for smoking cessation or reduction. A recent (2025) Cochrane review stated that e-cigarette users who were previous smokers quitting had higher rates of quitting conventional combustible tobacco cigarettes compared to NRT, particularly those devices that contain nicotine (91). While the

authors rated this finding as having moderate level of certainty, many included studies were assessed as having high risk of bias, some were sponsored by tobacco companies, the dosing, devices and clinical protocols used for NVP in these trials were variable, and the effect sizes were not remarkable (91). Clearly, larger, long-term studies are needed to further confirm this conclusion, especially with the growing body of research on the dangers of recreational vaping. The harms and safety of e-cigarettes in smoking cessation therefore require robust investigation, particularly on the long-term health effects. In addition, a meta-analysis from the Australian National University suggested that higher smoking cessation rates were achieved for nicotine vaping products compared to NRT but there was not enough quality evidence to determine this finding (92). Hence, there are a variety of reviews with mixed conclusions about the possibility of using e-cigarettes as an aid for smoking cessation. While there is limited evidence, more studies are required to ascertain the role of vaping in the space of smoking combustible tobacco cigarettes.

Section C – Literature Review and Pharmacy Professional Focus

1.10 Literature Review

A scoping literature review was performed to explore the notions of vaping within the pharmacy environment and to understand the implications for pharmacists and pharmacy students.

The aims of the literature review were as follows:

1. To identify pharmacist/pharmacy student perspectives about vaping.
2. To investigate if there has been any evidence of pharmacist-led interventions of vaping-related cessation or using vapes as a smoking cessation aid.

Literature searches were performed in the databases Scopus, CINAHL, Embase, and Medline using the terms vaping and pharmacy (Table 1.3). Results were checked for duplicates, and then a manual search of the main titles and abstracts was reviewed to assess suitability in accordance with the aims.

Database	Search	Reference Yield
Scopus	vaping OR "electronic cigarette*" OR "e-cigarette*" OR "electronic nicotine delivery system*" **AND** pharmacy OR pharmacist* OR pharmacies* OR pharmacy students*	24
CINAHL	vaping OR "electronic cigarette*" OR "e-cigarette*" OR "electronic nicotine delivery system*" **AND** pharmacy OR pharmacist* OR pharmacies* OR pharmacy students*	15
Embase	vaping OR "electronic cigarette*" OR "e-cigarette*" OR "electronic nicotine delivery system*" **AND** pharmacy OR pharmacist* OR pharmacies* OR pharmacy students*	195
Medline	vaping OR "electronic cigarette*" OR "e-cigarette*" OR "electronic nicotine delivery system*" **AND** pharmacy OR pharmacist* OR pharmacies* OR pharmacy students*	72
	Total Reference Yield	306
	Deleted Duplications	88
	Articles deleted following abstract and title check	181
	Final Reference Yield	**37**

Table 1.3: *Literature Review*

1.10.1 *Pharmacist Vaping Related Interventions*

The role of the pharmacist in delivering information about e-cigarettes in the community as an aid to smoking cessation has been notionally studied. A 2019 longitudinal mixed-methods evaluation involving six pharmacies in Northwest England was conducted. Pharmacists with previous training in smoking cessation offered e-cigarettes combined with behavioural support to examine the effectiveness of e-cigarettes in smoking cessation. Data was collected from patients and pharmacists' experiences through qualitative interviews about this intervention. There was evidence that there was a reduction or cessation in smoking cigarettes, with positive experiences from patients about pharmacist support (93). Another prospective six-week non-randomised cohort study examined the effectiveness of e-cigarettes with or without NRT as a smoking cessation strategy in community pharmacies in England. Pharmacists followed smoking cessation guidelines during consultations with the patients, during which e-cigarettes were offered as a choice to assist in their quitting journey. The success rate of quitting while using e-cigarettes was three times that of patients using NRT alone (94). These studies indicate the potential role of e-cigarettes as an aid to smoking cessation. Given the extended scope of professional practice, further studies are warranted to examine pharmacists' viewpoints.

Pharmacists with smoking cessation training can potentially employ their professional expertise for individuals wanting to quit vaping. A 2019 clinical case report of a male (a previous smoker now vaper) who participated in a pharmacist-led vaping cessation program over 12 weeks. Behavioural support was provided by the pharmacist, who also tapered the reduction of nicotine concentration in the e-cigarette, along with vaping sessions (95). The success of this program demonstrated the role that pharmacists can play in helping reduce the prevalence of vaping in the general population. While more evidence is needed to establish the roles of pharmacists, exploring pharmacist perspectives could aid in the development of clinical vaping cessation guidelines.

Patient education and promoting the general health and well-being of the community are a part of the primary responsibilities of pharmacists. A 2023 educational

intervention in Wisconsin, US, using an infographic, Parent E-cigarette and Vaping Educational Resource (Ph-EVER), was distributed in pharmacies. Qualitative interviews were conducted with participants exploring potential pharmacist roles on vaping (96). This infographic provided information about the contents of vaping, health impacts and resources for vaping cessation. The findings indicated that parents viewed pharmacists as trusted sources of knowledge, and the relationship between pharmacists and patients allowed open conversations about topics such as vaping. This allowed pharmacists the opportunity to dispel misconceptions and empower individuals with accurate information, enabling them to make informed choices (96). Pharmacists' knowledge and understanding of vaping are essential for communicating appropriate, clinically informed, patient-centred information. Their attitudes and perspectives were necessary to determine the current levels of education and health promotion surrounding e-cigarettes.

These studies have highlighted the potential expanding roles of pharmacists in vaping related interventions. Pharmacists need to practice within professional guidelines and regulatory measures to ensure every vaping-related health request is handled accordingly and is clinically appropriate (97). Professional pharmacy services to promote individual and community health, such as those encompassing vaping, pharmacist perspectives are required on its implementation and practicality.

1.10.2 *Vaping Cessation and the Role of the Pharmacist*

Information about vaping is rapidly evolving. Governments and organisations have implemented regulations restricting the use of e-cigarettes, and more data on the health effects have been released in an attempt to curb the high rates of usage, especially among adolescents and young adults. In Australia, with the shift of the regulatory framework from a prescription model to pharmacist-only medication of e-cigarettes with concentrations of nicotine up to 20mg/mL, there is a need for pharmacists to display appropriate clinical judgement with e-cigarette supply. As e-cigarettes are currently unapproved therapeutic products, pharmacists need to ensure they are adhering to the appropriate protocols when ordering or dispensing e-cigarettes.

For supply on prescription, pharmacists need to ensure the patient has a prescription with a valid Special Access Scheme (SAS) or Authorised Prescriber (AP) approval from the prescriber (98). Prescribers may apply to prescribe unapproved therapeutic goods (e-cigarettes) for individual patients through SAS or for multiple patients via AP. SAS is divided into three components: A-the patient is critically ill; B-application pathway where the prescriber awaits approval for prescribing; C-an unapproved therapeutic good that has an established history of use (99) . When pharmacists supply e-cigarettes as a pharmacist-only medication to a patient, pharmacists need to advise the Therapeutic Goods Administration (TGA) via the SAS C pathway within 28 days of supply. For supply either on a prescription or as a pharmacist-only, besides the TGA regulations, state and territory legislative requirements also apply (77).

Nowadays, there is a focus on vaping cessation and how to help individuals who vape to quit successfully. The Royal Australian College of General Practitioners (RACGP) has released clinical vaping cessation guidelines for health professionals, with the Pharmaceutical Society of Australia (PSA) following suit, about nicotine dependence support recommendations for pharmacists (100, 101). In addition, the Thoracic Society of Australia and New Zealand has recently published guidance on the safe and effective handling of vaping cessation in adolescents and adults (102). These guidelines and standards have highlighted the need for prescribers and pharmacists alike to be aware of their role in the management of e-cigarette usage and supply amidst the regulatory measures. A qualitative study in Canada, exploring youth vaping perceptions, revealed similarities between vaping and smoking cessation, such as barriers and reasons for quitting, as well as social benefits and dependence(103). The guidelines would be a resource for health professionals and pharmacists alike to address these barriers to aid people in their cessation journey. This points to the possibility that what has already been done in the smoking cessation space, such as the use of NRT, can be applied to vaping cessation (100). However, a 2023 scoping review of vaping cessation interventions concluded that there was hardly any evidence regarding established vaping cessation techniques (104). With limited information about proven vaping cessation methods, this represents an area where pharmacists can play a crucial role in

this rapidly evolving space.

Pharmacists are accessible health professionals at the forefront of primary healthcare. In addition to various roles and responsibilities such as counselling, dispensing medication and ensuring optimal medication use, they serve their wider community with a focus on overall health and wellbeing. Pharmacists are well-versed in smoking cessation and can provide sound advice on pharmacological therapies such as prescription medications and NRT in addition to referral to support services (105). However, with the increasing trends of e-cigarette use in the community, pharmacists are well-placed to provide guidance on vaping and possible interventions such as vaping cessation. A 2015 survey of community pharmacists in London, UK, revealed concerns about the use of e-cigarettes and their health effects, which reflected the unregulated nature of this subject (106). The role of the pharmacist was highlighted through the promotion of wellbeing and safety of individual and community health. There was also a 2020 randomised small sample study on vaping cessation methods (NRT, e-cigarettes and control group) in Michigan, US, where pharmacist behavioural support following a vape-tapering method allowed successful vape quitting attempts after six months (107). While there is limited data on vaping cessation, more research is warranted, especially in terms of vaping cessation. There is a need to explore what Australian pharmacists know about vaping and how this information can assist in providing clear vaping-related health services.

1.10.3 *Pharmacists' Perspectives on Vaping*

Some studies have been conducted to assess the views of pharmacists on vaping around the world. Globally, pharmacists have expressed concerns about the potential short- and long-term health impacts that e-cigarettes could have on human health (106). In addition, there were mixed perceptions, for example, among Californian pharmacists that e-cigarettes could be used as a smoking cessation aid; with some participants uncertain of their potential use, highlighting the seemingly addictive and harmful nature of e-cigarettes (108). In exploring views of Malaysian pharmacists and

doctors, there appeared to be an overwhelmingly negative view of e-cigarettes as a smoking cessation aid, where the risks and harms of addiction and side effects caused warranted caution and a need for more evidence (109). Meanwhile, in Australia, there have been limited studies involving pharmacists. At the point in time when regulatory changes to vaping were limited to e-cigarettes containing nicotine available only on prescription, healthcare professionals, including pharmacists, were asked about their perspectives. Similar to results overseas, there was also uncertainty surrounding e-cigarette usage for smoking cessation (110). While the regulatory changes to e-cigarettes as prescription and pharmacist-only medications have led to increased responsibility, these perspectives could have been potentially influenced by the culmination of the negative portrayal of e-cigarettes by Australian pharmacy news sources (111). Collated results from a range of studies globally conducted with pharmacists and other healthcare professionals have concluded that e-cigarettes were potentially or equally as harmful as cigarettes and have called for further studies about their usage as a smoking cessation aid. Perceptions surrounding e-cigarettes need to be informed, and evidence-based guidelines should be followed so that pharmacists can form an objective opinion when handling requests related to this issue.

1.10.4 *Pharmacy Student Perspectives on Vaping*

With the increased uptake of vaping around the world and its potential health implications, there is a need for future pharmacists to be trained and aware of the usage and implications of e-cigarettes. Several studies have been conducted examining pharmacy students' knowledge and attitudes surrounding this issue. A cross-sectional study of American pharmacy students indicated varying levels of e-cigarette knowledge, with no statistically significant difference in knowledge scores, suggesting that additional education could be beneficial to improve knowledge (112). Similar studies in Thailand and Saudi Arabia involving pharmacy and allied health students highlighted the confusion and uncertainty of information, as well as misconceptions about the contents of e-cigarettes. (113, 114). This lack of knowledge about e-cigarettes among pharmacy students and their allied healthcare colleagues from global studies demonstrates the need for educational interventions to address the knowledge gaps

and misinformation about vaping in the healthcare context. The inclusion of e-cigarettes within the curriculum would equip students with the knowledge and skills to prepare them as future health professionals for handling vaping-related health requests (115, 116). Currently, there are no studies to date exploring the perceptions of vaping among Australian pharmacy students; therefore, there is a clear need to establish initial attitudes and knowledge and examine how an educational intervention can better prepare future Australian pharmacists amidst this growing public health concern.

1.10.5 *Australian Pharmacy Vaping Implications*

The scoping of the literature presented above around vaping and pharmacists' roles has identified and highlighted exploratory data on pharmacist-led vaping interventions as well as initial perspectives. While there is a need for further research to establish the effectiveness of e-cigarettes as a smoking cessation aid in which the pharmacist's role can assist in supporting patients, misconceptions and knowledge gaps around vaping need to be clarified. Hence, the aims of the research were as follows:

1. Explore Australian pharmacists' perspectives on vaping and the support avenues needed to implement vaping-related health services
2. Examine Australian pharmacy students' attitudes, knowledge and skills with respect to nicotine-related cessation

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Chapter 2

Research Methods

2.0 Chapter Overview

This chapter describes the methods that were used to conduct the studies for the purposes of this Master of Philosophy degree. The background theory for the methods used and rationale for their use will be presented in detail, in alignment with the research study aims, which were to:

1. Explore Australian pharmacists' perspectives on vaping and support avenues needed to implement vaping-related health services**. (Study 1- qualitative)**

2. Examine Australian pharmacy students' attitudes, confidence, knowledge and skills in implementing for nicotine-related cessation. **(Study 2- quantitative)**

Each of the research studies presented in this thesis has an individual methods section within a published or revised (submitted for review) manuscript. This chapter presents a thorough approach to method selection, along with an explanation of the methods employed in the two studies reported: one qualitative (Chapter 3) and one quantitative (Chapter 4). Whilst some methods are detailed ahead, this Chapter allowed an additional space for describing methods used, unrestricted by the word counts, as is the case with a manuscript submitted to a journal. An attempt to discuss issues not highlighted in the manuscripts ahead is made by limiting this Chapter to issues not described ahead in Chapters 3 and 4.

Ethics approval for the conduct of the two research studies presented in Chapters 3 and 4 was obtained from The University of Sydney Human Research Ethics Committee (HREC).

2.1 Rationale for Qualitative Research Design for Study 1

As outlined in Chapter 1, the potential harms and risks of vaping to the human body have caused concern among health professionals and public health experts. The rapidly evolving information about vaping, as well as regulatory changes, has thrust the provision of nicotine vaping products(NVPs) into prominence in Australian pharmacy practice, given that they are only available on prescription or as pharmacist-only medications in pharmacies. In healthcare settings, both patient and practitioner experiences around a particular issue, such as vaping, may be shaped by emotions, perceptions and expectations, stemming from personal, professional and societal viewpoints (1). For example, a similar issue around which there has been professional debate in Australia was opioid substitution therapy and naloxone supply from pharmacies. To develop feasible and acceptable services around opioid substitution therapy provision in Australian pharmacies, both patients' and pharmacists' beliefs and opinions were investigated employing qualitative research methods, which have been crucial in ensuring the sustainability of such services (2, 3). Importantly, the results of such exploratory studies have indicated that for such harm reduction services to be embedded in pharmacies, there are many challenges related to system barriers, clarity of pharmacist roles and personal views (4). Hence, emotions, perceptions and expectations around the provision of NVPs by pharmacists were likely to be similar, if results for other such health services can be extrapolated (5, 6). Therefore, a qualitative research approach was deemed to be suitable to explore the perspectives of pharmacists about vaping and vaping-related health service provision.

2.1.1 *Qualitative Research Methods*

In qualitative research, data is gathered to generate a rich range of differing perspectives to investigate and understand the "phenomena" in question (7). The common methods for gathering qualitative data include, but are not limited to: (8)

- **Focus groups**
- **Interviews**
- **Observations**

Focus groups involve the interaction of a small number of participants, whose experiences are discussed, exchanged and explored, bringing about a variety of viewpoints (9). For observational data collection, researchers would be immersed in the chosen setting, taking note of what is happening around them, gaining a deeper insight into the intricacies of their investigation. An example of the application of this method in pharmacies could be to observe and analyse pharmacist-patient interactions. In another example, Flynn et al.(2003) report collecting data on prescription errors observed during the dispensing process in pharmacies, resulting in recommendations for practice (10). As per our aim for Study 1, the current exercise involved seeking to examine the individual thoughts and attitudes of pharmacists regarding the impact of vaping on professional pharmacy services; hence, the interview method was deemed appropriate, particularly when contemplating the advantages and disadvantages of common qualitative approaches to data collection (Table 2.1).

	Advantages	Disadvantages
Focus Groups	▪ Range of responses elicited ▪ Flexibility ▪ Group interactions enrich discussions ▪ Explore views not elicited in individual interviews	▪ Lack of anonymity ▪ Lack of personal narrative ▪ Can be costly and time-consuming to organise ▪ Moderator bias ▪ Dominant participants can hijack discussions
Interviews	▪ Individual experiences and perspectives can be explored ▪ Sensitive topics can be delved into ▪ Flexibility in questions and the sequence of discussion ▪ Personal rapport enriches the discussion and the data collected	▪ Accessibility ▪ Time-consuming process as multiple interviews have to be conducted ▪ Lack of anonymity ▪ Lack of breadth
Observation	▪ Flexible and exploratory ▪ In-depth account of the environment and activities ▪ Interactions of people in context ▪ Some implicit biases can be addressed in directly collecting data on site	▪ Time-consuming ▪ Ethical considerations ▪ Researcher influence ▪ Observation bias ▪ Accessibility

Table 2.1: *Characteristics of Qualitative Methods* (11, 12)

Considering the time constraints of this study in getting a group of participants to agree to suitable times and the potential loss of independent views in focus groups and observation, as seen in Table 2.1, interviews were selected as the appropriate form of qualitative data collection for Study 1. Our choice is supported within the literature where several studies conducted with various healthcare professionals involved the use of qualitative interview methods to explore professionals' perceptions, attitudes and experiences around vaping (13, 14). This research, therefore, sought to examine pharmacists' individual thoughts and attitudes regarding the impact of vaping on professional pharmacy services using the interview method.

2.1.2 *Interviews*

Interviews allow researchers to delve deeper into the participants' experiences and feelings, gaining an enriched insight into the research question posed (15). Qualitative interviews are often categorised as structured, semi-structured or unstructured and often involve interaction between the participant and the researcher (15). In structured interviews, predetermined questions provide a framework to direct the discussion; however, there is a lack of depth and scope for probing based on the responses provided, which limits the scope of participant responses. Unstructured interviews are strongly participant-led, where their responses guide the discussion based on the topic in question. Semi-structured interviews provide a good compromise on the interview type spectrum. Semi-structured interviews employ a series of open-ended seeding questions which are underpinned by prompts/probes to facilitate discussion and provide the participant with flexibility around an area of interest. In healthcare settings, these types of interviews offer an exploratory approach to gather rich and detailed information about beliefs, experiences and factors influencing professional practice behaviours (16). A rich body of literature demonstrates that previous studies have sought the perspectives of pharmacists about potential professional practice services using semi-structured interviews (17, 18). Therefore, for the purposes of our study aim (Study 1), we used a semi-structured framework to interview pharmacists about their opinions and explore factors influencing their practice around the provision of nicotine vaping products (e-cigarettes).

2.1.3 *Interview Guide*

To employ the semi-structured interview method, an interview guide was necessary to be developed. A review of the literature (as presented in Chapter 1) around pharmacists' views and opinions around vaping, as well as a general reading of recent research on Australian pharmacists' experiences or preferences for health services provision, informed the development of this guide. The guide was constructed to include seed questions as well as prompts. The style of the seeding questions posed was reviewed to ensure that questions were open-ended, neutral, clear and could be tailored to the

participants' demographic, employment and professional role (19). These questions were planned to be administered in a logical sequence, beginning with general topics, allowing the interviewer a chance to establish rapport and then to use probing questions as the interview proceeded towards more intricate points of discussion (19). Time and effort were expended on the development of this interview guide, knowing that it would enable interactive discussion, especially given the somewhat contentious issue of NVP supply within pharmacies.

2.1.4 *Sampling*

The sampling approach selected was for a purposive, convenience-based, and passively snowballed sample of participants to be recruited (20). Purposive sampling involves selecting participants who have an understanding or experience of the phenomenon in question (21). Convenience sampling aimed to select potential participants through proximity and willingness to participate, often using the researchers' networks and contacts (21). Snowball sampling allowed participants to recommend research participation to other potential participants to take part in the research study (22). A passive approach implied that participants merely forwarded information about the project to contacts rather than actively linking researchers to potential participants by contact sharing. These sampling methods were applied due to the nature of the participants (busy pharmacists with variously rostered hours of duty) and the time constraints of the study.

2.1.5 *Recruitment Process*

Potential participants were emailed about the research study if they were professional contacts of the research team or were also known to be interested in smoking cessation or respiratory research.

2.1.6 *Interview Conduct*

Zoom™ was selected as the platform of choice for conducting these semi-structured interviews. A quick review of the literature indicated that previous qualitative interviews carried out on Zoom were found to be convenient, accessible and acceptable from both a researcher and a participant viewpoint (23, 24). This allowed both parties to manage the scheduling of the interviews with flexible timing with no added cost burden of travel to a location, in addition to interviewing in a comfortable environment where meaningful connections and rapport can be developed. Additionally, the generation of interview transcripts via Zoom™ using the closed captioning feature facilitated ease of data collection, which was later verified against the audio recordings to ensure accuracy.

Due process to de-identify transcripts and store confidentially was followed and is reported in Chapter 3.

2.1.7 Qualitative Analysis

The decision to choose a method of analysis for the qualitative data collected was influenced by considering the three theoretical paradigms informing the research process as follows: (25)

1. Abduction: This method of analysis involves searching for the 'best explanation', which is informed by the existing theory and its anomalies using inference to generate plausible interpretations of the data.
2. Deduction: This method involves using an existing theory and applying it to the data gathered.
3. Induction: This method allows the data collected to guide the researchers' understanding and establish data driven conceptualisation and meanings about the phenomena under study.

Given that vaping is a relatively new phenomenon, and there is limited literature on existing theory, this rendered both the abduction and deduction paradigms unsuitable. An inductive paradigm was therefore deemed to be the most appropriate for addressing the aim of this research study (Study 1), which was to explore pharmacists' perspectives on vaping and related professional health services. This enabled the identification of meaningful data, and findings and themes were developed to explain the phenomenon in question.

2.1.8 *Thematic Analysis*

For conducting the inductive analysis, the process of thematic analysis was selected to identify, analyse and interpret qualitative data by generating codes and coalescing codes into broader themes (26). Using this method of data analysis allows a deeper understanding of the multiple viewpoints influencing participants' experiences, attitudes and perspectives within data gathering. Previous qualitative studies surrounding pharmacists' professional roles towards mental health and chronic pain garnered individual ideas and notions, on which thematic analysis was utilised to examine the responses with the emergence of meaningful ideas that could drive future health services (27, 28). Rich data from the experiences of pharmacists regarding vaping would be able to be thematically categorised to understand factors influencing perspectives on professional roles.

NVivo™ 14 software was used to thematically analyse the uploaded interview transcripts following *Braun and Clarke's six-step framework for qualitative analysis* (26). The results of the thematic analysis are presented in Chapter 3.

2.1.9 *Trustworthiness in Qualitative Research*

High-quality qualitative research should be representative and rigorous of the data collected, and the obtained findings should reflect transparency, coherency, reflexivity and transferability (29, 30). The consolidated criteria for reporting qualitative research (COREQ) ensure that any qualitative studies undertaken can be assessed for rigour and high-quality standards within three domains (31)

Domain	Features	Reasoning
Research Team and Reflexivity	▪ Personal Characteristics ▪ Relationship with Participants	▪ Potential biases can be highlighted for the interviewer, analysts and participants.
Study Design	▪ Theoretical Framework ▪ Participant Selection ▪ Setting ▪ Data Collection	▪ Examine how research aims were explored. ▪ Relevance of the findings from participants in the given context.
Analysis and Findings	▪ Data Analysis ▪ Reporting	▪ Assessing quality, validity and consistency of results.

Table 2.2: *COREQ Checklist*

A COREQ checklist was used to guide the reporting of the results of this study and is in the appendix, as indicated in Chapter 3.

The rationale for the methodological approach, which aligns with the research study aims of this thesis, provided the background for conducting the qualitative research study (Study 1). The results of this study are presented in a published manuscript, as outlined in Chapter 3.

2.2 Rationale for Scholarly Inquiry for Study 2

Given the second aim of this thesis (Study 2), a scholarly inquiry approach was needed to examine the attitudes, knowledge and skills of Australian pharmacy students regarding nicotine-related cessation. Pedagogical approaches support educational delivery, which is tailored towards engaging learners and evaluating the impact of these approaches based on several theoretical models (32).

- ***Behaviourism:*** This theoretical approach considers that learning is a response to a specific stimulus, and the teacher guides the student through the learning process (32).
- ***Constructivism****:* This approach suggests that learners are active participants as their experiences and interactions with others and with teachers occur in a stimulated learning environment to create learning constructs.
- ***Cognitive models of learning:*** This approach suggests that learning is determined by how students process and understand the knowledge and skills delivered by those delivering these.

In order to deliver a pedagogically aligned educational module about nicotine-related cessation (named No-to-Nicotine (or N2N) module), a constructivist design was proposed.

2.2.1 *Pedagogical Principles*

Pharmacy education has been continually evolving through specific attention to emerging research, adapting to accommodate different learning styles and using innovative techniques for engaging pharmacy student learners to build clinical skills and competence for future practice (33).

This evolution requires close attention to pedagogical principles, some of which are highlighted below and others discussed in more depth in Chapter 4.

Active learning

There has been an increasing use of active learning strategies in pharmacy education, with robust evidence demonstrating that students retain and effectively apply knowledge taught using these approaches (34). Myriad active learning strategies can be used; some important ones include:

- Flipped classroom learning approach
- Authentic case-based learning
- Reflection

All three of these approaches facilitate student engagement and participation and align with a constructivist approach. These educational strategies have led to significant improvement in knowledge and clinical skills, which enhances student learning experiences and academic performance in pharmacy education (35-37).

The N2N educational module followed the flipped classroom approach. Lectures on smoking and vaping were delivered, and learning material was made available on CANVAS (a university learning platform) prior to the N2N module. This encouraged students to facilitate their own learning, which was applied in self-assessing nicotine-related awareness in the pre-N2N questionnaire and then in a workshop. Active learning and engagement were promoted during this model, which was highlighted by past research as facilitating pharmacy students' satisfaction and improved knowledge (38). The use of authentic cases stimulates practical scenarios in which knowledge and skills are applied, in conjunction with case-based problem solving, which guides and fosters critical thinking, enabling the development of clinical competency for smoking and vaping cessation (39, 40). This approach was therefore incorporated into the N2N module educational methods.

Finally, it is known that student learning preferences through visual, aural or kinaesthetic modes assist in determining teaching and learning styles; this understanding has been applied to students of various health disciplines (41). The N2N

workshop activities used a variety of teaching methods, where hands-on learning using demo NRT products, refusal strategies (saying 'no' to an offered cigarette or vape), and poster making were all able to cater for these preferences, fostering creativity and reflection. Hands-on learning allows students to demonstrate their understanding of knowledge and skills effectively. For example, a simulation activity with asthma devices in pharmacy students demonstrated improved inhalation technique skills (42). In addition, as the use of creativity was more likely to increase engagement, confidence and motivation to apply knowledge and skills in an innovative manner, this was included in the N2N design (43). The tasks of poster making and refusal strategies outlined ahead in Chapter 4 enabled students to incorporate their learning by devising imaginative methods, fostering active engagement and reflection. Refusal strategies were based on two decades of evidence gathered by a research team member (Shah S et al.), highlighting that the active process of practising to say 'no' to cigarettes can empower adolescents. In the Triple A program, an evidence-based, peer-led asthma educational program for school students, Shah et al. have demonstrated that students have found the refusal activity to be useful and engaging (44). This opportunity for reflective thinking prompted students to process and apply their understanding about smoking and vaping cessation, enhancing their skills for future practice (37).

2.2.2 *Study Setting*

This educational module needed to be embedded within an existing unit of study for the undergraduate Bachelor of Pharmacy and/or Management (Honours) and Master of Pharmacy Practice program at The University of Sydney. The content of the N2N focused primarily on clinical pharmacy practice, involving risk assessment and communication, for which the Pharmaceutics and Professional Practice (PHAR 2911) unit of study learning outcomes aligned with our learning objectives. As such, the N2N module was embedded within PHAR2911, a second-year undergraduate unit that emphasises in-depth clinical knowledge and counselling skills related to non-prescription medications and professional pharmacy services such as smoking and vaping cessation. In addition, the age of the second-year cohort is of particular interest as these students and their

peers are most likely within the 18-24 year age group, where vaping has been most prevalent (45).

2.2.3 *Rationale for Pre-/Post- Research Design*

A research study design was necessary to demonstrate the impact of N2N on pharmacy student attitudes, knowledge and skills. Some possible study designs included randomised controlled trials, pre/post designs and stepped wedge randomised control designs – as all these could have been used to measure the impact of the educational module (46). A randomised clinical trial would involve assessing the effectiveness of the intervention with participants randomly assigned; this would not be feasible in such an educational study, where every student was required to be involved in the N2N intervention. Similarly, in a stepped wedge design, the proposed intervention would be delivered at different times to different students, making coordination of the research study laborious, given the tight scheduling of the PHAR2911 curriculum. A rigorous experimental study design, including randomisation, multiple groups and a control, would have been nearly impossible to obtain within the space and time logistics of delivering any unit of study in the pharmacy degree. Other reasons for the impracticability of an experimental study design included a high potential of students swapping classes due to illness or misadventure, and the ability of students to communicate with their peers and different group classes in co-requisite units of study. A pre-/post-intervention study design, though a weak study design, offered the most pragmatic method to test the impact of the N2N method. Educational modules about smoking and vaping have previously used a pre/post study design to measure the impact of the intervention, which participants have received well (47, 48). Thus, a pre-/post-interventional research study design was undertaken. Clinical knowledge and attitudes about smoking and vaping were measured prior to and after the delivery of an educational intervention to measure its impact.

2.2.4 *Questionnaire Format*

A questionnaire was formulated to examine attitudes, knowledge and skills and the overall impact of the intervention and was informed by the literature and discussion with a range of experts. Previous questionnaires on smoking cessation for pharmacy students have assessed changes pre- and pre-/post-intervention on knowledge and skills (49, 50). Key issues regarding vaping, with respect to its harms and risks and social acceptability among adolescents and young adults, were highlighted (51, 52). The format of the questions used comprised multiple-choice options, Likert scale responses and open-ended questions.

Multiple choice options offer structure and objectivity in providing a valid measurement to analyse gains in knowledge and skills (53). Likert scale responses, due to their ease and adaptability, allow different constructs to be measured like confidence, satisfaction and impact (54). Open-ended questions enable participants to elicit their individual experiences and perceptions, where students have previously evaluated teaching methods (55). Previous scholarly inquiries have used similar mixed-type questionnaire formats to assess the impact of educational interventions on the understanding and perceptions of pharmacy students (56, 57).

Finally, to measure the outcomes of the N2N on student awareness, there were no validated questionnaires available for smoking and vaping cessation. Previous questionnaires on smoking cessation for undergraduate health discipline students have been validated, translating to measurable outcomes on knowledge and attitudes (58, 59). Exploratory cross-sectional questionnaires on vaping attitudes and perspectives have been conducted among undergraduate students with limited measurable outcomes (60, 61). Thus, after constructing the N2N questionnaire, the next step was to consider its validity and reliability.

2.2.5 *Psychometric Validation*

Psychometric validation ensures that results obtained from participants reflect what is being measured accurately and consistently across participants (62). Different aspects of validity, such as face validity, content validity and construct validity, can be used to measure validity through feasibility and statistical analysis (63). Face validity allows the questionnaire delivery to be transparent and coherent to its intended audience (58). Content validity ensures the accurate reflection of the topic of interest, determining the feasibility of the questionnaire (58). Construct validity uses statistical analysis to assess the accuracy of the measurement of the concepts being examined (58). For the N2N questionnaire, face validation was achieved through a thorough review by educators, experts in the smoking and vaping fields and practising pharmacists in order to ensure it was relevant for second-year pharmacy students.

Given the nature of this educational intervention, it was proposed that assessment design indices would be appropriate to measure outcomes instead of a full psychometric validation of the questionnaire. Item response theory describes how parameters can be used to estimate students' performance on a questionnaire such as the N2N questionnaire (In the appendix as part of Chapter 4). This then allows the scores from the questionnaire to be analysed and student performance to be evaluated (64). These parameters include item difficulty, item discrimination, guessing effect and ceiling effect. For these indices to be calculated, students' responses are examined for accuracy, learning ability, random guessing and discerning between learning capabilities. ***Item difficulty*** and ***item discrimination*** were the assessment design indices chosen to measure the validity of the outcomes of the N2N questionnaires. This allowed the evaluation of the pre-/post- N2N questionnaire, where student responses could be analysed and standardised, leading to an educational tool that is both reliable and valid (65).

The rationale for the methodological approach, aligning with the research study aims of this thesis, provided the background to conduct the scholarly inquiry study (Study 2),

the results of which are which are presented within a published or revised (submitted for review) manuscript, ahead in Chapter 4.

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Chapter 3

Qualitative Study

3.0 Chapter Overview

This chapter presents the findings of an exploratory research study that aimed to examine the influences surrounding Australian pharmacists' perspectives about vaping-related health services and the potential resources needed. A published research manuscript entitled *Pharmacists' Perspectives on Nicotine Vaping Products (NVPs) for Smoking Cessation in Australia: A Qualitative Analysis* is presented. The formatting style and references in this manuscript adhere to the publication guidelines set out by the *MDPI Pharmacy* journal.

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3.2 Author Contributions

The Authorship Contribution Statement will be described using the *Contribution Roles Taxonomy (CRediT)*

David Le: Conceptualisation, Methodology, Software, Validation, Formal Analysis, Investigation, Resources, Data Curation, Writing - Original Draft Preparation, Visualisation, Project Administration

Maya Saba: Formal Analysis, Writing – Review and Editing

Habib Bhurawala: Conceptualisation, Validation, Writing – Review and Editing Muhammad

Aziz Rahman: Conceptualisation, Validation, Writing – Review and Editing Smita Shah:

Conceptualisation, Validation, Writing – Review and Editing, Supervision

Bandana Saini: Conceptualisation, Validation, Formal Analysis, Writing – Review and Editing, Visualisation, Supervision, Funding Acquisition

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Pharmacists' Perspectives on Nicotine Vaping Products (NVPs) for Smoking Cessation in Australia: A Qualitative Analysis

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Abstract: Vaping, particularly the use of nicotine vaping products (NVPs), has emerged as a public health concern. The regulatory environment surrounding NVPs in Australia has rapidly evolved, shifting from a prescription-only model to availability through community pharmacies. Pharmacists play a critical role in addressing vaping-related health concerns. This study explores Australian pharmacists' perspectives on their professional roles and the support needed to manage vaping-related enquiries. Qualitative semi-structured interviews were conducted with 25 practicing pharmacists using a topic guide developed from the current literature and team expertise. The interviews were transcribed verbatim and analysed thematically using an inductive approach to identify key themes. Key themes included *risk perception*, *professional vaping health-related services*, *professional practice* and *other support-related needs*. Pharmacists expressed significant uncertainty about the risks and harms associated with vaping. There was apprehension around the regulatory complexity of supplying NVPs, and participants called for greater education and support, particularly around NVP's place in smoking cessation and potential vaping cessation services. Effective public health messaging and risk communication about vaping are crucial. At the centre of recent legislative changes, pharmacists require training and professional support to address vaping-related scenarios and provide counselling that aligns with individual risk perceptions, ensuring NVP use is clinically appropriate.

Keywords: health services; nicotine vaping products (NVPs); perceptions; pharmacists; smoking cessation; vaping

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1. Introduction

Electronic nicotine delivery systems, known as e-cigarettes, vapes, e-hookahs, vape pens, mods, tanks or vaping products containing nicotine, referred to as simply nico-

tine vaping products (NVPs), are battery-operated devices that heat a liquid to produce a vapour/aerosol that users inhale in a process described as 'vaping'. The solutions used in vaping devices may contain high levels of nicotine and a range of chemicals used as flavourings, solvents and liquids required for aerosolization [1]. There is an increased uptake of vaping globally despite the limited evidence about the long-term safety of vaping [2]. A common perception is that vaping a nicotine solution is less harmful than smoking cigarettes, given vaping does not require the combustion of tobacco [3]. However, data compiled from a range of experimental studies indicates that NVP use has a wide range of toxic effects arising from the heat-based decomposition of chemicals in vaping solutions and the material of the vaping device, as well as from inhaling the nicotine-containing aerosol [3]. Nicotine exposure from NVPs has been shown to have an equivalent short-term health impact as conventional cigarettes, for example, on oxidative stress and immune function-mediated inflammatory responses, such as cough and mouth and throat irritation [4]. The long-term effects on respiratory health remain unclear [5]. Another issue is the mislabelling of nicotine content in NVPs, which is well documented across many countries, including in Australia, leaving consumers unknowingly exposed to nicotine content similar to or higher than conventional cigarettes in some cases [6,7].

The status of NVPs as an aid in smoking cessation is an ongoing topic of debate. An ongoing Cochrane review, for example, suggests that while there is evidence that NVPs may increase quit rates compared to conventional nicotine replacement therapies (NRTs), the data remain imprecise with few robustly conducted randomised controlled trials [8]. Most evidence summaries on this issue highlight the need for further research [9]. Regardless, from a clinical perspective, in 2023, Australian guidelines on smoking cessation were revised to include NVPs as a suggested method for trial only in a niche population of highly nicotine-dependent smokers who were unable to quit through conventional NRTs.

From a public health perspective, concerns have been expressed suggesting that while the 'therapeutic' benefits of NVPs in smoking cessation are publicised, the availability of NVPs will likely foster a new generation of nicotine-dependent persons [10]. Indeed, increasing vaping trends have been documented across all Australian age groups, particularly in the 18–24 group, in which a four-fold increase in prevalence from 1.6% (95% CI: 0.8–2.24) in 2019 to 9.3% (95% CI: 7.4–11.2) in 2022–23 is observed [11]. Concerns about the significant public health issues that may be a consequence of these trends, especially in younger adults, have prompted the Australian Federal Government to introduce restrictive legislation to regulate the supply and availability of NVPs (Figure 1) [12]. Initial regulatory changes saw NVPs restricted to a prescription-based supply (October 2021), followed by importation bans on nicotine (January 2024) and then all vaping products (March 2024), as well as the banning of sales of any vapes from any retailer except pharmacies (July 2024). These regulatory moves were based on allowing lawful access to therapeutic NVPs for those medically deemed likely to benefit from their use in terms of smoking cessation [13], whilst restricting any access to NVPs being used for non-clinical reasons [14]. However, in a recent legislative shift, access to NVPs for smoking cessation at a low dose of up to 20 mg/mL is possible for adult consumers from community pharmacies without a prescription [14]. NVPs are now placed in a class of medicines referred to as Schedule 3 in Australia, which requires pharmacist review prior to supply. This current landscape, therefore, imposes a duty of care for Australian pharmacists to ensure the safe supply of NVPs, whether dispensing a prescription or providing them over-the-counter (OTC).

Given that the dispensing or supply of NVPs should occur in line with the Therapeutic Goods Administration (TGA) standards and be subject to state and territory regulations, it is anticipated that pharmacists dispensing NVPs (or supplying NVPs) in a therapeutic paradigm would require them to undertake nicotine dependence assessments, gauge those

likely to benefit from using NVPs to support smoking cessation, provide appropriate smoking and vaping cessation counselling, and refer onwards for medical/specialist advice in highly nicotine-dependent patients [15]. While community pharmacists are at the forefront of primary care, it is unclear how Australian pharmacists should or do respond to queries about vaping-related risks and assess and monitor smokers likely to benefit from NVPs as a smoking cessation tool or provide vaping cessation support to those dependent on NVPs. A survey of pharmacy staff in Queensland, Australia, conducted before the 2021 legislative changes allowing the supply of NVPs in pharmacies, indicated that 91% of pharmacy staff felt uninformed and needed training in this area [16].

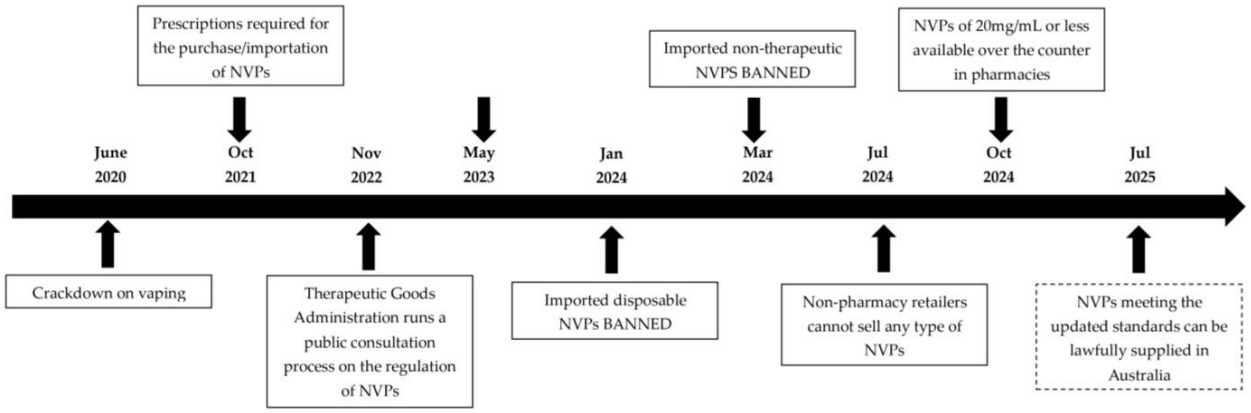

Figure 1. Timeline of Australian Vaping Regulations.

Other studies exploring health professionals' views on NVP supply have suggested the need for further training and for structured clinical resources for pharmacists supplying NVPs in the context of smoking cessation [17,18]. Pharmacy-based smoking cessation interventions have enabled trained pharmacists to contribute to a reduction in smoking rates in Australia and globally [19].

This study aimed to explore pharmacists' clinical awareness, professional support needs, and perceptions of vaping-related supply and counselling services. From 2021 to 2024, whilst these regulatory changes had been rolled out, there were no clinical practice guidelines to assist pharmacists in decision-making or counselling patients about vaping or vaping cessation. These were only very recently developed and published in September 2024. The findings of this study could therefore assist pharmacy educators and professional stakeholders in designing comprehensive training programs to implement practice guidelines for pharmacists.

2. Materials and Methods

Ethics approval for this project was obtained from The University of Sydney Human Ethics Committee [2023/748].

To ensure that the quality of the study was as rigorous as possible, the consolidated criteria for reporting qualitative research (COREQ) checklist was adhered to wherever applicable. A detailed description of procedural adherence to this checklist is provided in Appendix A [20].

2.1. Study Design

The Theory of Planned Behaviour, which posits that subjective norms, perceived behavioural control and attitudes of people influence professional behaviours, served as a reference for initiating this research [21]. This theory would suggest that the provision of vaping-related health services by pharmacists may depend on their perceptions regarding how peers/colleagues perceive such service delivery (subjective norms) and their own confidence in their capability to deliver such services (perceived behavioural control), as

well as attitudes towards vaping. There is robust evidence to suggest that this theory can 'predict' health professional behaviours [22], and therefore it was selected to underpin the exploration of pharmacists' likely vaping service provision behaviours. Pharmacists' planned behaviours around NVP provision were sought to understand the impact of the vaping regulatory changes [23]. Another theory, the 'Protection Motivation Theory', also informed specific lines of query in the interview guide [24]. This theory suggests that for a given 'risk' (with vaping services being a risky practice task), people evaluate the likely severity or impact from risk exposure and one's ability to cope with the risk or have access to effective 'coping' strategies [24]. This theory has been utilised in studies on consumers' vaping/smoking behaviours; hence, it was selected to understand the willingness of pharmacists to engage in practice activity (vaping service provision), which may have been deemed to be 'risky' in the current study [25].

2.2. Participant Recruitment

Registered Australian pharmacists were invited to participate in semi-structured interviews using a purposive convenience-based and passively snowballed sampling approach. Details of the research project were initially emailed to potential participants who were professional contacts of the research team or those known to researchers as being interested in smoking cessation or respiratory research. Written informed consent was obtained before interviewing participants, and reimbursement for their time was offered as $100 gift vouchers. The recruitment of pharmacists continued until thematic saturation was evident. Themes and codes were generated from data collected from the interviews until a stage where there was no relatively emergent information to inform further analysis [26].

2.3. Data Collection

Semi-structured interviews were conducted between February and May 2024 (prior to announcements of NVPs being downregulated to being available in pharmacies without a prescription, i.e., as Schedule 3 medicines). These interviews were conducted virtually via Zoom™ according to the participant's time preference. An interview guide (Appendix B) was designed based on literature research and the research team's expertise. The format of the questions was cognitively funnelled, beginning with demographic questions before moving onto in-depth questions that sought to explore the participants' views on professional roles and practice support needs. Probing questions were also used to capture a complete understanding of the issues discussed. All interviews were audio-recorded, transcribed and then reviewed by the first author.

2.4. Data Analysis

Interview transcripts were verified against the audio recordings to ensure accuracy. Each interview was then de-identified and assigned a unique alphabetical code. The interview transcripts were uploaded using NVivo™ 14 software and thematically analysed in an inductive paradigm using Braun and Clarke's six-step framework for qualitative analyses (Appendix C) [27].

Finally, a subjective analysis was undertaken to identify any differences in thematic derivation between transcripts, based on the participant's gender, years of experience as a registered pharmacist and pharmacy practice speciality.

3. Results

Pharmacists were interviewed until thematic saturation was achieved. Thematic saturation was based on informational redundancy when further interviews revealed no new information [28,29]. This occurred at about the 22nd interview. An amount of 3 further previously confirmed interviews were still conducted, with a total of 25 participants inter-

viewed with no dropouts. The interview duration ranged from 10 to 30 min. Participant demographics and pharmacy characteristics are depicted in Table 1.

Table 1. Participant Demographics and Pharmacy Characteristics.

Demographic Variables	Sample, *n* (*n* = 25) (%)
Gender	
Female	22 (88)
Male	3 (12)
Pharmacy Background	
Community	16 (64)
Hospital	9 (36)
Experience as a registered pharmacist (Years)	
<1–5	4 (16)
6–10	13 (52)
11–15	6 (24)
>16	2 (8)
Pharmacy Qualification	
BPharm	20 (80)
MPharm	5 (20)
Additional Study *	5 (20)
Pharmacy Characteristics	
Average number of prescriptions dispensed each day	
<50	1 (4)
51–100	3 (12)
101–250	12 (48)
251–400	4(16)
>401	5 (20)
Number of pharmacy staff on an average day	
1–5	4 (16)
6–10	10 (40)
11–19	7 (28)
>20	4 (16)
Type of pharmacy participants work in	
Banner Group	8 (32)
Independent	8 (32)
Private Hospital	6 (24)
Public Hospital	3 (12)
Pharmacy provides Smoking Cessation Services	
Yes	25 (100)
Consult Area for General Enquiries/Professional Services	
Yes	21 (84)
No	4 (16)
Average Smoking Cessation Consults by participants (Weekly)	
0–4	12 (48)
5–10	3 (12)
Unsure	10 (40)
Experience with Dispensing Vaping Products	
Yes	6 (24)
No	19 (76)

* BPharm: Bachelor of Pharmacy; MPharm: Master of Pharmacy. HMR: Home Medicines Review Accredited Pharmacist; Graduate Certificate of Pharmacy Practice; MPhil: Master of Philosophy; PhD: Doctorate of Philosophy; Graduate Diploma of Clinical Pharmacy.

Inductive analysis of the data collected during the interviews identified three main themes: (1) Risk Perception, (2) Professional Vaping Health-Related Services and (3) Professional Practice and Other Support Needs. Thematic derivations supported by additional participant exemplar quotes are presented in Figure 2. Most participants reported increasing presentations relating to requests for vaping products or advice in their workplaces.

Theme 1 - Risk Perception

- 'I feel like all the unknown chemicals once it's been inhaled and ignited, very unknown risk or toxins that you can inhale (…) So, I think it's a risk to the general public'
  - Participant E [Female, Hospital Pharmacist, Experience – 5 years]
- 'I don't want the pharmacy to turn into like a supermarket (…) We need to actually like, make sure the patient understands the risks'
  - Participant I [Female, Community Pharmacist, Experience – 10 years]
- 'My 2-year-old nephew picked it up (…) He put it in his mouth and started coughing. So, I think there is definitely a risk of having those around young children'
  - Participant M [Female, Community Pharmacist, Experience – 7 years]
- 'I had a customer, you know who has been vaping for over a year and he's actually an asthmatic, (…) the cough's absolutely horrendous. (…) and yet he still vapes'
  - Participant S [Female, Community Pharmacist, Experience – 13 years]

Theme 2 - Professional Vaping Health-Related Services

- 'I don't think that patients can do it purely on their own without possibly the help of a pharmacist. I think they're quite integral to that role, rolling out vaping as a smoking cessation aid'
  - Participant F [Female, Hospital Pharmacist, Experience – 16 years]
- 'I think it is an excellent idea to bring to the pharmacy only, too many kids are buying vapes from the corner shop at the moment'
  - Participant P [Male, Community Pharmacist, Experience -10 years]
- 'He was a very heavy smoker and the doctor basically said to him, if you continue, you're going to die. So, he resorted to the vapes, (…) He's not as aggressive whereas when he went, you know, on the nicotine replacement therapy, it wasn't working well for him at all. So, the vape really saved his life'
  - Participant S [Female, Community Pharmacist, Experience – 13 years]

Apprehension in providing NVP services

- 'I think I would be very put on the spot to be honest, just because I have no up-to-date knowledge about it'
  - Participant L [Female, Community Pharmacist, Experience – 10 years]

Regulatory Complexity

- 'The doctors did not even know what products were available and how to actually you know, gain access to prescribe some products, (…) we had to work together to figure it out, and it was like a tedious process'
  - Participant I [Female, Community Pharmacist, Experience – 10 years]

Theme 3: Professional Practice and Other Support Needs

- 'Helping pharmacists would be providing them with the most common questions that patients have about vaping products.(…) and they can better formulate the answers to that'
  - Participant F [Female, Hospital Pharmacist, Experience – 16 years]
- 'It comes down to whether the public is aware of like, whether pharmacists can provide these services, or even pharmacists have the knowledge to provide these services'
  - Participant H [Female, Community Pharmacist, Experience – 5 years]
- 'One of the big limiting factors is, of course, always going to be time and cost. Time allowed to the pharmacists to be able to conduct these services, who's going to be covering the cost of that?'
  - Participant K Female, Community Pharmacist, Experience – 6 years]

Figure 2. Patient Exemplar Quotes.

3.1. Theme 1: Risk Perception

Participants agreed that vaping is a risk to individual health and the wider public. Some participants reported this based on observations of consumers who were vaping and who presented to the pharmacy with shortness of breath or other respiratory symptoms. Many participants noted that there appeared to be a perception that vaping nicotine was harmless and safer than smoking cigarettes, especially among adolescents and young adults, who appeared to vape the most. Several participants opined that social media and peer pressure often influenced this.

There were mixed opinions about the comparative safety of NVP use versus cigarette smoking, with some participants believing nicotine vaping was 'as' or 'even more harmful' compared to cigarette smoking. A common impression of vaping trajectories was that whilst vaping commenced as a choice, it progressed into a habit among users. Some participants described this as a possible 'gateway effect' with vaping serving as a precursor to cigarette smoking behaviours. A few participants considered NVPs as a method to combat smoking cessation but acknowledged that the potential risk of nicotine addiction remained. These perceptions were based on participants' concerns about the uncertainty around the long-term effects of vaping. Participants were also concerned about the risk of second-hand vape exposure.

In addition, participants were unsure about the myriad ingredients within a vaping device, although there were some suggestions that pharmacy/prescription-based NVPs would gain the trust and confidence of consumers. Participants agreed that accessing a pharmaceutical-grade vaping product that has met stringent quality control requirements with accurate labelling of the nicotine and its excipients sounded more trustworthy.

> *"I think from a social perspective, society has normalised vaping. But I think that's also due to the fact that they've promoted it and marketed it as something that's quite harmless"*. Participant I [Female, Hospital Pharmacist, Experience—10 years]

3.2. Theme 2: Professional Vaping Health-Related Services

When asked about opinions around professional vaping-related services, either for the therapeutic provision of NVPs for smoking cessation or supporting the cessation of NVPs, a range of in-depth responses were obtained. Nearly all participants expressed that providing education and information to explain the risks and harms of vaping was a 'duty of care' and a 'harm-reduction' opportunity for their local community.

There were mixed views on whether NVPs should be used as a smoking cessation aid. Some participants were strongly against recommending NVPs, as they believed that current evidence supported only conventional nicotine replacement therapies, leaving these as the only viable alternative. While several other participants felt there could be a potential place for NVPs in smoking cessation, it would require more evidence. A few other participants also recognised that there may need to be situation-dependent scenarios for NVP provision to support smoking cessation if other avenues had been exhausted. When asked about NVP cessation services, participants suggested pharmacists could potentially assist by recommending lower doses alongside behavioural support.

> *"I don't think it's a good idea to use vaping as the strategy to quit smoking. But if it's easier, if it's a first step for someone, then maybe perhaps it's a solution. But I don't think that's the way to go"*. Participant H [Female, Community Pharmacist, Experience—5 years]

3.2.1. Subtheme 2.1: Apprehension in Providing NVP Services

When asked about practice experience, only a few participants recalled instances of patients who had come to the pharmacy with NVP prescriptions. Many participants had no

prior experience of dispensing NVPs. Participants felt that there was some public demand for NVPs; however, they felt apprehensive about NVP provision, despite the strong notion of having a duty of care to prevent or alleviate harm. This uneasiness appeared to stem from a lack of clinical confidence and clear guidelines to support professional practice.

> *"I personally can't give too much information on it, as I don't know too much about it"*. Participant G [Female, Community Pharmacist, Experience—10 years]

3.2.2. Subtheme 2.2: Regulatory Complexity

Apart from a reported uncertainty about the clinical/legal appropriateness of NVP supply, several participants reported being unable to keep up to date given the rapid changes in vaping-related legislation. Some reported that supply chains had not kept pace with regulatory changes; for example, whilst pharmacists had received NVP prescriptions, there were no products currently approved by the TGA that they could order from wholesalers; this necessitated them having to negotiate complex pathways for procurement of NVPs.

Concerning the regulatory policies, most participants supported the imposition of restrictive policies such as upgrading nicotine-containing vaping products to a therapeutic status, where NVPs would require a prescription for use in smoking cessation, rather than consumers sourcing it from illegal or non-pharmaceutical avenues. However, some participants reported difficulty navigating the regulatory framework to supply an NVP on prescription. A few participants reported that the regulatory process to prescribe, dispense and source NVPs was confusing and tedious, where collaboration between doctors and pharmacists had occurred in an attempt to provide a service to a patient requiring an NVP. Despite a willingness to provide smoking/vaping cessation services, the complex nature of the regulation at two levels (national and state/territory) rendered many participants hesitant.

> *"Because of like the fact that it's not approved by the TGA, you need a special authority. So that's like a bit of a burden"*. Participant N [Male, Community Pharmacist, Experience—1 year]

3.3. Theme 3: Professional Practice and Other Support Needs

All participants expressed an urgent need for education and training. Some participants suggested that workshops and online seminars run by pharmacy organisational bodies would be useful. Others suggested that technical detailing by industry representatives who could explain NVP device usage and discuss potential frameworks for NVP counselling on site would also be effective. Participants' overall needs appeared to be driven by pragmatism, e.g., how to communicate NVP risks/benefits to patients, how NVP devices operate and dosing and follow-up techniques. There was an expressed need for understanding the place of NVPs in conventional smoking cessation services. Most participants called for practical aids, such as patient education materials, to facilitate effective communication and allow pharmacists to address misconceptions.

Finally, participants were concerned that public perceptions needed to be shaped so that consumers could see pharmacies not just as a point of supply of NVPs but rather as providers of smoking/vaping cessation support. To provide these services viably, some participants raised the issue of remuneration for the time spent, which would acknowledge the training that the pharmacist had undertaken.

> *"The public health sector, they should in collaboration with pharmacists…decide how they're going to tackle this situation…with people who have experience in the community…it needs to be done on an integrative aspect"*. Participant W [Female, Community Pharmacist, Experience—13 years]

Notably, the generation of codes underpinning the themes did not subjectively differ based on participant attributes (age, gender, experience) in subjective analyses that compared the frequency of codes generated across transcripts. Based on a planned post-analysis reflective debrief by team members, it was acknowledged that as the main data analysts (DL, BS and MS) were all pharmacists, a professional lens may have influenced coding and theme derivation, leading to confirmatory bias.

4. Discussion

This study is the first to explore Australian pharmacists' perspectives on vaping-related health services since regulatory changes to make NVPs a prescription product were implemented. Participants expressed significant concerns about vaping, viewing it as a high-risk behaviour, particularly due to uncertainties about its long-term health effects, the role of NVPs in smoking cessation, and the increasing use of these products among adolescents. Though Australian vaping policies may be different from those of other countries, with restrictions around vape availability only in the context of clinical need, pharmacists worldwide will need to incorporate health services to combat vaping; the results of our study therefore have global relevance.

These results resonate with those reported in a recent opinion poll of the readership of the Australian Journal of Pharmacy, which is a professional journal (n = 1096 respondents, August 2024), where pharmacists indicated that vapes should be taxed and regulated (26%), banned entirely (29%), be prescription items (22%) or available OTC (7%)—reflecting the unease and risk perceptions voiced among our participants [30]. This poll was undertaken immediately after the regulatory position shift to allow pharmacists to supply Schedule 3 or non-prescription supplies for adult NVPs [31]. The willingness to supply NVPs without a prescription appears to be the least favoured option in this poll. Of course, our research was conducted prior to a change in the regulation, and even though 'prescription-based supply' appears to have more support, as indicated in the above poll, our participants were speculative even of this option. It is not surprising then that there has been a furore in professional pharmacy circles after the regulatory shift to NVPs being made available without prescription through pharmacies was announced in June 2024 [30]. Several key pharmacy organisations have suggested a lack of consultation by policymakers, leaving pharmacists trying to work out their required roles in an 'eleventh hour' regulatory change to allow NVPs as non-prescription pharmacist supply items. There is apprehension that political drivers may have motivated this change [30]. Interestingly, other Australian researchers have reported 'political interference' as being a rate-limiting factor in regulatory attempts to curb the uptake of NVPs in Australia [10]. However, some researchers had advocated for the non-prescription availability of NVPs in pharmacies, suggesting that many would likely resort to illicit use, likely to be more harmful, given such products would not be adherent to required quality standards. Our participants also emphasised that pharmaceutical-grade products legislated for pharmacist provision would offer people access to quality-assured products rather than purchasing products from illicit sources, which may be potentially harmful. Although tentatively, health economic modelling has portrayed that less restrictive access may afford higher public health gains [32]. These are valid points favouring non-prescription NVP supply by pharmacists; however, it would appear that pharmacist practitioners may not, in reality, be willing or ready to accept this role [18]. Similarly, public health researchers are also likely to have a different view, given the growing evidence of harm from NVPs and the notion that the downregulation/of NVPs from 'prescription only' to 'non-prescription' supply by pharmacists may signal to consumers that NVPs are safe [33].

It was evident in our thematic analysis that the introduction of a prescription-only regulatory model for NVPs (i.e., the regulation in place when interviews were conducted) had presented healthcare professionals with challenges. Other research studies have also reported that Australian health professionals find it difficult to grapple with the added burden of navigating the regulatory framework around NVPs. Similar experiences have been reflected in the legalisation of medical abortion drugs in NSW, where there have been varying degrees of uncertainty, complexity and concern expressed by doctors [34]. Likewise, pharmacists displayed an unwillingness to engage with the provision of the emergency contraceptive pill without a prescription, citing concerns about protocol and risk behaviours [35]. At the time of our research, there were no Therapeutic Goods Administration (TGA)-approved NVPs, which necessitated pharmacists researching products. This regulatory complexity packs an additional layer to the uncertainty evidently experienced by our participants around the supply of NVPs. Of course, this has been exacerbated with the unanticipated regulatory shift to allowing non-prescription availability.

The strong perception of risk voiced by our participants aligns with contemporary understanding of factors influencing risk assessment, such as *uncertainty* (e.g., of evidence of benefits versus harms) or *vulnerability* (more uptake by adolescents and young adults), which can negatively mediate risk perceptions [36]. Participants repeatedly expressed uncertainty around evidence for the safety of long-term NVP use or for NVP use in facilitating conventional smoking cessation [37]. Many were concerned about the increased uptake of vaping among adolescents, suggesting that this population would be very vulnerable to long-term health harms associated with vaping. Participants further noted the negative impact of social media platforms on their risk perceptions around vaping, which is an established determinant that can mould risk perceptions [38,39]. Certainly, in a content analysis of Australian pharmacy news sources, authors estimated that the 'representation' of vaping was portrayed negatively, with risk representations outweighing benefit representations, which is likely to build negatively influenced heuristics in pharmacist readers [40]. It has been proposed that given the clinical and regulatory reality of NVPs as non-prescription items that will require pharmacist interventions around judicious supply, be it upon prescription or without, accurate relative risk-based information may help pharmacists (and the public) arrive at a realistic decisional balance around providing or not providing NVPs to individuals [41].

The current public health debate and regulatory shifts may also swing the perceptions of current or potential NVP consumers. The Royal Australian College of General Practice (RACGP) has listed NVPs as a last resort for patients attempting to quit smoking after the failure of approved pharmacotherapies. Given this case, some patients who meet the medical criteria for NVP prescription may present to a pharmacy but hold a perception that NVP use is high risk, based on the current public debate, making them reluctant to try this approach. Community pharmacists filling the prescription would need to be able to provide clear benefits versus risks information. On the other hand, some patients request NVPs from pharmacies irrespective of any risks. These situations may place pharmacists in a clinical conundrum that requires skilful handling. Clinical hesitancy, as observed in our data, has also been observed in pharmacists when called upon to supply products to which public debate/controversy is linked, such as naloxone to prevent opioid overdose [42]. In an exploration of pharmacists' views on supplying naloxone over the counter, clinical hesitancy appeared to be based on under-confidence in clinical knowledge about opioid overdose as well as the impact on businesses where stigma may be attached to those using injectable opioids [42]. This was a clear observation in our data also.

Most participants recognised their duty of care in providing a professional, balanced overview of NVPs to minimise the risks and harms of vaping. Harm minimisation pro-

grams have been integral to the professional services that Australian pharmacists offer. Pharmacists have participated in needle exchange services as well as opioid substitution programs, which have benefitted the wider community [43]. Hence, moving forward, it may be useful to pinpoint harm reduction services; this is indeed the approach that has led professional organisations to construct practice guidelines (recently published in September 2024). Across various services, pharmacists have expressed a preference for collaborative service provision with general practitioners/physicians, and again, in advancing the pharmacy-based NVP supply model (prescription-based or non-prescription supply), a collaborative model is recommended [14].

For all healthcare professions, communication is a core skill taught in pre-registration curricula, but 'risk communication' is not specifically taught, and there is a paucity of research on how pharmacists undertake this [44]. Many models have been proposed to improve risk communication. The Extended Parallel Process Model (EPPM) is one such model. It suggests that risk perceptions can determine health behaviours, leading to a proactive, protective 'danger control' path or an avoidant, less useful 'fear control' path [45]. Protective actions are taken when there is a high perception of risk/threat and a firm belief in self-coping skills. Thus, pharmacists may need to gauge the risk stance of patients requesting NVPs and effectively transition patients towards undertaking danger control behaviours using targeted communication [46]. Models such as the EPPM are effective, for example, when used to gauge the responsiveness of public health workers in a potential pandemic through perceived risk communication, in which training programs could be developed to address these attitudes [47]. This can be replicated with pharmacists, where the apprehension observed can be minimised by structured training programs on risk communication training to enable confidence and the ability to assess risk in a vaping health-related service.

It was clear from our data that pharmacist participants strongly expressed a need for clinical guidelines, which have only recently been made available [48]. The next step in this timeline would be to facilitate pharmacists to translate the guidelines, which are couched from a harm minimisation approach, into a deliverable health service. For example, such service implementation training should outline the structures (S) and processes (P) required to provide the service and outcomes (O) necessary to demonstrate ongoing service provision to patients, where the SPO model is considered the framework for defining the quality of health services [49]. While participants suggested some structures and processes, it would be difficult to undertake without professional support and remuneration [50]. An end-to-end service involving nicotine addiction assessment, product selection, counselling, follow-up and referral/triage with specialist services would require time management, in addition to investment in resources such as staff training, space allocation (counselling room area and product shelf space) and rostering additional staff to cover pharmacist dispensing duties as depicted in Table 2. Remuneration for pharmacists providing these services is therefore important either via user-paid or health system-funded pathways. This will require practice research testing pharmacist-provided NVP supply in the context of smoking cessation as well as vaping cessation services for clinical impact and cost-effectiveness.

Table 2. Handling of NVP requests and needs for service support.

Handling of a Patient/Consumer Request for a Vaping Product	Resources/Support Needs to Offer Vaping-Related Smoking Cessation Services
STRUCTURE ■ Counselling Room ■ Adequate Staffing ■ Stock Maintenance of NVPs ■ HONC/Fagerstrom Assessments ■ Guidelines ■ Placebo Devices ■ Pharmacy Staff Training ■ Pharmacist Training	**TRAINING (ALL)** ■ **Specific Training Topics** • Counselling/Nicotine addiction behaviours (Some) • Training specific to products (ALL) • Communication skills (Some) ■ **Training Formats** • Online (ALL) • Modules (ALL) • Hands-on (Most) • On the job (Some)
PROCESS ■ Information Gathering Phase • Smoking History • Nicotine Addiction • NRT Use • Quit Attempts ■ Action • Proactive support in GP referral • Referral to regular GP • Pros and Cons of vaping as smoking cessation discussed • Comprehensive consult • Counselling on device use Information provision	**RESOURCES** ■ Public risk/health messaging (Most) ■ Public/consumer messaging on evidence for vaping as a smoking cessation method (Few) ■ Specialised vaping cessation clinics/Quitline (Very Few) ■ NVP product information for patients (Some)
OUTCOME ■ Recommendation: Vaping prescription products are recommended only if prior attempts with NRT have been unsuccessful ■ Documentation of outcome ■ Follow-up support: Nicotine addiction review/success with smoking cessation ■ Referral to other support services [Quitline]	**SUPPORT (ALL)** ■ Local health district/PHN involvement with training (Some) ■ Government/Organisational bodies (ALL) ■ More GP training (Few) ■ Interprofessional collaboration (Very Few) ■ Public education campaigns (Most) ■ Industry-sponsored programs for pharmacists (Some) ■ Remuneration for vaping/smoking cessation services (Some)

NVPs: Nicotine Vaping Products. HONC: Hooked on Nicotine Checklist. NRT: Nicotine Replacement Therapy. GP: General Practitioner. PHN: Primary Health Network.

Strengths and Limitations

While the purposive convenience snowballing approach may have introduced a sampling bias, efforts were made to ensure participant diversity by recruiting pharmacists from various practice settings and with different experience levels to ensure a maximally varied sample. To further mitigate confirmation and researcher bias, regular peer debriefing sessions were held with the research team. Although participant validation was not feasible due to the participants' time constraints, methodological triangulation was employed by comparing the interview findings with the existing literature and related data sources to enhance the credibility of the results. The results may not be generalisable to all pharmacists; nonetheless, this robustly conducted qualitative study offers valuable insights into the experiences of a specific group of pharmacists, which may resonate with or inform similar contexts and stimulate future research in this important area. Survey instruments can now be designed to collect generalisable data from nationally representative samples of the pharmacist population, following the results of this study.

5. Conclusions

Vaping presents significant concerns, particularly among adolescents and young adults. Within an evolving regulatory landscape, Australian pharmacists are key to managing vaping-related risks. This study highlights their uncertainty, hesitancy and lack

of confidence in supplying NVPs for smoking cessation. Hence, effective public health messaging and risk communication about vaping are crucial. Pharmacists, being the most accessible primary healthcare professionals, require comprehensive training to address vaping-related scenarios and provide clinical counselling that aligns with individual risk perceptions, ensuring NVP use is clinically appropriate.

Author Contributions: Conceptualization, D.L., H.B., M.A.R., S.S. and B.S.; methodology, D.L.; software, D.L.; validation, D.L., H.B., M.A.R., S.S. and B.S.; formal analysis, D.L., M.S. and B.S.; investigation, D.L.; resources, D.L.; data curation, D.L.; writing—original draft preparation, D.L.; writing—review and editing, M.S., H.B., M.A.R., S.S. and B.S.; visualization, D.L. and B.S.; supervision, S.S. and B.S.; project administration, D.L.; funding acquisition, B.S. All authors have read and agreed to the published version of the manuscript.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The original contributions presented in this study are included in the article. Further inquiries can be directed to the corresponding author(s).

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Conflicts of Interest: The authors declare no conflicts of interest.

Appendix A

Table A1. COREQ Checklist.

Topic	Item Number	Researcher Report and reference to pages item described in the main manuscript.
Domain 1: Research Team and Reflexivity		
Personal Characteristics		
Interviewer/Facilitator	1	Mr David Le (DL) was the person who conducted the interviews and was the primary researcher for this study. Page 4.
Credentials	2	DL holds a Bachelors of Pharmacy and a Master of Public Health degree.
Occupation	3	DL is also a registered pharmacist, currently practicing as a hospital pharmacist as well as being enrolled as a Higher Degree Research student completing a Master of Philosophy.
Gender	4	Male.
Experience and training	5	Trained on interview skills, coding and theming primarily provided by a senior qualitative researcher, Professor Bandana Saini (BS), with support from Dr Maya Saba (MS). Others authors with prior experience in qualitative research e.g., Dr Habib Bhurawala/Prof Smita Shah and Prof Muhammad Aziz Rahman also provided relevant direction and training.

Table A1. *Cont.*

Relationship with Participants		
Relationship established	6	The seed participants were approached based on being professional contacts of DL or BS or those who had been previous research participants and expressed a desire for invitations to future research to BS. Other participants were snowballed from original contacts and researchers had no established relationship with these latter participants.
Participant knowledge of the interviewer	7	Participants were likely alerted about the credentials of the research team through the participant information sheet that was emailed to potential participants as per the approved ethics protocol. Page 4.
Interviewer characteristics	8	DL has qualifications in pharmacy and public health with an interest in harm reduction roles in pharmacy, given his Master of Public Health. DL is also an early career pharmacist with 10 years of experience as a pharmacist as well as 5 years of experience as a sessional academic tutoring pharmacy students at the University of Sydney.
Domain 2: Study Design		
Theoretical Framework		
Methodological orientation and Theory	9	As seen in Study Design. Page 4.
Participant Selection		
Sampling	10	A purposive convenience snowball sampling method was employed.
Method of approach	11	Potential participants were emailed an invitation on a professional email address known through them being 1) professional contacts of the research team (DL and BS) or 2) participants of prior respiratory research who had consented to be contacted about future research (BS).
Sample size	12	Twenty-five registered pharmacists.
Non-participation	13	None.
Setting		
Setting of data collection	14	Online, i.e., interviews were conducted on Zoom, a videoconferencing platform (Zoom.us).
Presence of non-participants	15	None.
Description of sample	16	As seen in Table 1 *Participant Demographics and Pharmacy Characteristics.* Pages 5–6.
Data Collection		
Interview guide	17	As seen in Appendix B.
Repeat interviews	18	None.
Audio/visual recording	19	Only the audio recordings were downloaded from Zoom™ onto a password protected laptop and then stored on the University's Research Data Storage to protect against data breaches.
Field notes	20	Field notes were taken where appropriate to aid in grasping the 'full picture' in data analysis. These notes were referred to during data analysis for clarification or for any nuances that may have been missed.
Duration	21	Interviews ranged from 10–30 min as highlighted in the Section 3 of the manuscript. Page 5.
Data saturation	22	As seen in Results. Pages 4–5.
Transcripts returned	23	No, this was a limitation of the study.

Table A1. *Cont.*

Domain 3: Analysis and Findings		
Data Analysis		
Number of data coders	24	There were three data coders DL, BS and MS. Of the transcripts 10% were coded by all three—BS MS, and DL. Team debriefs ensued to agree to a coding structure and then DL coded the remainder of the transcripts.
Description of the coding tree	25	**A summary of the coding tree** **Views on Vaping** - Risk/Harm to Youth - Evidence in smoking cessation - Lack of Education/Awareness - Impact on Health - Apprehension **Pharmacist Roles** - Counselling and Advice - Smoking Cessation - Vaping Cessation - Regulation **Support and Education Needed** - Resources and Training - Guidelines and Protocols - Patient Stimulated Scenarios
Derivation of themes	26	The research team reviewed transcripts and there were regular debriefs with the primary and senior researchers. DL and BS debriefed multiple times during the data analysis and thematic derivation process. MS an independent researcher also reviewed the data and assisted with the thematic derivation process. Discussion of the results of the analysis between the research team and using a consensus approach (DL, BS, SS and MS).
Software	27	NVivo™ 14 software as seen in the Section 2.4 of the manuscript. Page 4.
Participant checking	28	Participants did not provide feedback on the findings, but some have opted to receive the results of the study once completed.
Reporting		
Quotations presented	29	As seen in Figure 2 *Patient Exemplar Quotes.* Pages 6-7.
Data and findings consistent	30	Yes, as seen in the Section 3 of the manuscript. Page 9.
Clarity of major themes	31	Yes, as seen in the Section 3 of the manuscript. Pages 7–9.
Clarity of minor themes	32	Yes, as seen in the Section 3 of the manuscript. Pages 8–9.

Appendix B

Table A2. Semi-Structured Interview Guide for Pharmacists.

■ Interview Questions	Prompts to be Used Only if Needed	Aim of the Question
First, I would like to ask you about your background as a pharmacist. This is so we can see differing opinions between pharmacists *- What is the length in years of your total experience as a registered pharmacist?* *- Please would you tell me about your HIGHEST pharmacy qualification?* *- Was this degree completed in Australia?* *- How would you describe the pharmacy where you primarily work?* *- How many staff would there be in your pharmacy during regular opening hours?* *- Approximately how many prescriptions would your pharmacy dispense on a regular day?*	■ Not applicable	This question aims to establish participant characteristics and pharmacy demographics
■ **I would like to ask about the smoking cessation services your pharmacy provides. Would you describe them for me?**	■ Pharmacy area dedicated to this/visible displays? ■ Consult area options for smoking cessation ■ Any staff trained in smoking cessation ■ Average smoking cessation consults in a week? ■ Most common methods used by staff to offer smoking cessation (motivation/NRT/Rx) ■ Any collaborative experience with other healthcare professionals in the area	This question aims to determine the level/pattern/experience of smoking cessation by the pharmacist within their workplace
■ **In general, what are your opinions on vaping/vaping products?**	■ Vaping as a habit or choice ■ Relative risk of smoking versus vaping ■ Impact of vaping on health/public health ■ Vaping products and ingredients	Vaping is a recent phenomenon which has caused debate and controversy. This question seeks to understand how perspectives on vaping have been shaped.
Consider a patient who comes into your pharmacy; they are known to you as an ex-smoker. They ask you about your advice regarding vaping. How would you respond? Would you have different advice if this was a young adult?	■ Not applicable	This question aims to understand how pharmacists would manage a vaping-related health request.
■ **Finally, I would like to ask you about any practice support resources you feel pharmacists would need in order to implement vaping cessation services?**	■ Training (formats/courses/topics) ■ Practice guidelines ■ Support with specific services patients can be referred to ■ Resource materials for patient education	This question aims to elicit what pharmacists would feel to be confident in providing vaping-related health services.

Appendix C

1. Familiarisation with the data

After all the interviews were conducted, the primary researcher (DL) read through the transcripts several times to gain an understanding of the initial ideas. Similar or different responses were noted for further analysis.

2. Generation of initial codes

All interview transcripts were uploaded into NVIVO™ 14 software, in which coding took place by the primary researcher (DL). The coding was done also by two independent researchers (BS and MS), where 24% of the transcripts were analysed. Inter-coder discussion of the initial codes ensured where the primary researcher (DL) finalised the codes based on the team consensus.

3. Searching for themes

The finalised codes were then reviewed and then underwent thematic analysis to generate meaningful themes for the ideas/concepts presented in the codes.

4. Reviewing the themes

The themes underwent review to ensure consistency in the data gathered and were separated into subthemes when necessary. This allowed a comprehensive representation of the data in the form of representative themes references to coded concepts/ideas.

5. Defining and naming the themes

Further discussions about the themes and their implications were analysed at meetings between the primary researcher (DL) and two experienced qualitative researchers (BS and MS) to finalise the thematic framework appropriate for the data set.

6. Writing up the report

After agreement of the themes, the data was compiled into a report to ensure all overarching ideas/concepts were presented in the findings.

Figure A1. The Multi-Phased Thematic Analysis Process.

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Chapter 4

Quantitative Study

4.0 Chapter Overview

This chapter presents the findings of an educational module that aimed to address knowledge and skills gaps related to smoking and vaping in pharmacy students. A research manuscript entitled *No-To-Nicotine: Developing and Evaluating a Smoking and Vaping Cessation Module for Pharmacy Students* has been revised for resubmission to the *American Journal of Pharmaceutical Education*. The formatting style and references in the manuscript adhere to the publication guidelines.

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4.2 Author Contributions

The Authorship Contribution Statement will be described using the *Contribution Roles Taxonomy (CRediT)*

David Le: Conceptualisation, Data Curation, Validation, Investigation, Methodology, Visualisation, Formal Analysis, Writing – Original Draft
Maya Saba: Conceptualisation, Validation, Investigation, Methodology, Visualisation, Formal Analysis, Writing – Review and Editing
Emil Dan: Conceptualisation, Methodology, Validation
Jocelyn Bussing: Conceptualisation, Methodology, Validation
Renee Bittoun: Methodology, Writing – Review and Editing
Smita Shah: Conceptualisation, Methodology, Validation, Writing – Review and Editing
Bandana Saini: Conceptualisation, Methodology, Validation, Investigation, Visualisation, Formal Analysis, Writing – Review and Editing

No-To-Nicotine: Developing and Evaluating a Smoking and Vaping Cessation Module for Pharmacy Students

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Abstract

Objective:

With vaping emerging as a growing public health concern, pharmacists' training needs to address both smoking and vaping cessation. Pharmacy students, as future health professionals, require training that reflects current clinical guidelines and incorporates behavior change support techniques. This study aimed to develop and evaluate an educational module that addressed key knowledge and skill gaps related to smoking and vaping practices among pharmacy students.

Methods:

A pedagogical module, No-to-Nicotine, was implemented with second-year undergraduate pharmacy students at The University of Sydney. The module consisted of two lectures on smoking and vaping and a 2.5-hour interactive workshop to encourage active learning through

the application of content in practical activities. A pre-post module questionnaire was utilized to assess potential changes in knowledge and attitude scores.

Results:

There was a significant increase in knowledge (pre-mean total knowledge score 18.9±5.6; post-mean total knowledge score 25.4±5.0; $p<0.001$), demonstrating an improved understanding of smoking and vaping. Attitudinal shifts suggested greater awareness of the pharmacist's role in nicotine dependence management. Students' feedback reinforced the module's relevance and applicability to future pharmacy practice.

Conclusion:

An educational module with underlying pedagogical principles for pharmacy students can empower smoking and vaping cessation roles in professional practice. Incorporating knowledge and skills relevant to the current practices of smoking and vaping services is essential in pharmacy curricula.

1. Introduction

An essential feature of professional work for pharmacists situated in almost any healthcare setting is the ability to educate consumers to modify behaviors that adversely impact health. Behavior change techniques are required to help patients cope with substance use disorders such as nicotine dependence. Over the past century, the mass production of cigarettes led to their easy access, and influential marketing strategies swayed cultural and social norms, making smoking a prevalent and acceptable behavior.(2) When the impact of nicotine dependence and the harmful consequences associated with smoking and passive smoking were demonstrated, it prompted governments globally to introduce policies restricting tobacco use over the last few decades.(3) Whilst these policies have facilitated the decrease in smoking rates in some countries, in recent years, there has been a rise in the use of nicotine

containing electronic cigarettes, also known as nicotine vaping products (NVPs). The upward trend in vaping prevalence is being witnessed worldwide, with current prevalence estimated at 5.9% in the United States (US) and 3.5% in Australia,(4, 5) reflecting the pervasiveness of this newer form of nicotine delivery. Possibly, this rising prevalence has also been driven by promotional marketing strategies which have rendered vaping being perceived as a desirable and relatively safe activity.(6, 7) Indeed, Australian data indicate that many adolescents believe vaping to be socially acceptable and helpful in alleviating stress; indicating that this particular population has a reduced perception of harm related to NVP use.(8, 9) Further, recent data suggesting that NVPs may be useful as a nicotine replacement treatment to aid smoking cessation, has probably led to confusion and fueled the misperception that using NVPs may be relatively safer than smoking cigarettes.(10) However, data show that NVPs, while providing nicotine replacement to reduce cravings for those who smoke and are nicotine dependent, can themselves lead to ongoing dependence as well as cause a range of harmful effects.(11-13) Thus while NVPs may be used for a *therapeutic purpose* (to support smoking cessation), they still pose a *clinical problem* (nicotine dependence and other harms).(10)

Pharmacists have been regularly involved in smoking cessation services, with evidence suggesting high quit rates of smoking achieved through pharmacist-led interventions.(14),(15) These roles should now encompass vaping-related services, given there is currently some evidence to support the use of NVPs as smoking cessation aids where conventional pharmacotherapy, such as nicotine replacement therapy (NRT), and behavioral support have failed.(16) As NVPs themselves may be implicated in nicotine dependence, pharmacist provided vaping cessation services also need to be developed to support those using NVPs to quit.(11) Pharmacists, therefore, may be involved in vaping-related health services both in the context of *smoking cessation* or as part of *vaping cessation* plans, necessitating them to stock, dispense or supply therapeutic NVPs. In the US, each state has different legislation regarding the supply of NVPs for retailers, including within pharmacies; however, according to federal law, the minimum age of supply is 21 years.(17) While many pharmacies retail NVPs

worldwide, there has been opposition from professional organizations in the US, such as the American Pharmacists Association, calling for more evidence for their use.(18) Similarly, the Australian government has recently introduced regulatory measures restricting the use of NVPs as either prescription-only products or pharmacist-only, over-the-counter (OTC) products, depending on their nicotine concentration (i.e. NVPs containing ≤ 20mg/mL of nicotine can be supplied by a pharmacist without a prescription, while higher concentrations need to be prescribed by a physician).(19, 20) These rapidly evolving changes, amidst the uncertainty of evidence supporting NVPs for smoking cessation and the scarcity of guidelines on vaping cessation, have placed a regulatory burden on primary healthcare professionals.(21) Australian pharmacists, along with doctors, are being required to navigate the regulatory framework to meet the legalities of dispensing and/or prescribing clinically appropriate NVPs.

To enact these roles, pharmacists need to be familiar not only with the use of NVPs, the harms of smoking/vaping, clinical facts about NVPs and approved smoking cessation pharmacotherapies, but also have skills in preparing patients for behavioral change.(14) At the same time, there have been concerns about the minimal space in pharmacy curricula covering NVPs in countries such as the United States and Australia.(22, 23) Most vaping prevention education has been confined to secondary schools in the United States.(24) Although global data is lacking, in a recent systematic review reported by Barrett and colleagues, American pharmacy students have indicated a lack of confidence in providing counselling about NVPs compared to conventional smoking cessation.(25),(26) While this view may not be representative of pharmacy students or pharmacists worldwide, from an Australian perspective, this has been reflected in a previous survey of pharmacy staff in Queensland, which revealed that 91% of pharmacy staff felt uninformed and required more education and training within this area.(27) A recent poll of Australian pharmacists also reflected their unease about the regulatory changes which involved allowing NVPs to be provided without a prescription by a pharmacist.(28)

A realistic starting point to address clinical knowledge gaps and communication skills in response to the rise of vaping-related health enquiries and the availability of NVPs in pharmacies would be to educate future pharmacists. In general, pharmacy training should be able to provide students with an understanding of nicotine pharmacology, treatment of nicotine dependence, available NVP formulations, alternative treatments and avenues for referral, alongside essential skills required to facilitate behavioral change. Indeed, cross-sectional studies indicate that students with some NVP education have more informed opinions about the harms of long-term use of vaping.(29) Prior research suggests that multifaceted and pedagogically underpinned programs have enhanced knowledge, attitudes, and confidence among pharmacy students regarding conventional smoking cessation; this suggests that similar programs can be designed to include vaping-related topics that could potentially have similar outcomes.(30) This research study therefore aimed to develop and evaluate an educational module addressing key awareness and skill gaps among undergraduate pharmacy students around the impact of smoking and vaping on health, effective communication around these topics and evidence-based cessation strategies to assist patients who smoke and/or vape.

2. Methods

A constructivist approach was used in the pedagogical design of the ‘No-to-Nicotine’ or ‘N2N’ module.(31) Members of the research team, who have extensive experience in the design and delivery of innovative educational strategies, clinical pharmacy practice, and/or research in smoking and vaping cessation services, designed and developed the N2N educational module.

2.1 Pedagogical Principles

Using previous successful educational interventions around conventional smoking cessation training as a model,(32) a flipped classroom approach was used for N2N design and delivery.

Besides conventional smoking cessation education, the educational content designed specifically for vaping-related service provision, included information on NVP use patterns, therapeutic utility (as a potential aid for smoking cessation), benefits versus harms of NVP use, as well as vaping cessation techniques. Content delivery was initiated with conventional interactive lectures to explain key concepts, which provided the foundations of student learning during the 2.5-hour workshop later. Active engagement was encouraged through the use of authentic cases (Appendix A1) which is known to enhance student performance as applying theory into practice leads to greater retention of clinical knowledge.(33),(34) Skills building involved having students undertake a hands-on practice activity by demonstrating how to use placebo NRTs, measuring levels of carbon monoxide using a Bedfont® Smokerlyzer® CO monitor, and examining different vaping devices. Creativity and reflection activities involved designing an arts poster involving 5-7 students, participating in refusal strategies, self-assessment via pre-post N2N questionnaires and key take-home messages at the conclusion of the workshop. This gave the students an opportunity to reflect on the workshop content, in an attempt to foster collaboration and allow interpretation of practice while building student engagement.(35) The learning outcomes of the module were framed based on Blooms' Taxonomy of Learning Outcomes (Table 1).(36) Figure 1 showcases the content and format of activities of the N2N module.

2.2 Study Setting

The N2N module was designed for students enrolled in the second year of the Bachelor of Pharmacy (Honors)/Master of Pharmacy Practice and Bachelor of Pharmacy and Management (Honors)/Master of Pharmacy Practice, a five/six-year degree program offered at the Sydney Pharmacy School, Faculty of Medicine and Health, The University of Sydney. The module was embedded and aligned with the objectives of the 'Pharmaceutics and Professional Practice (PHAR2911) unit of study, a 12-credit-point core pharmacy subject. PHAR2911 covers pharmaceutics and professional practice components, focusing on

scientific and laboratory concepts, in-depth clinical knowledge and counselling skills. Communication, behavior change techniques, and culturally safe healthcare provision

Table 1: Learning Objectives and Constructive Alignment of N2N Workshop

Learning Category(36)	Learning Objective	Learning Activity	Assessment Approach
Knowledge	Understand the *pharmacology* of nicotine and the *pathophysiology* of *nicotine dependence*	Lectures, Pre-work Videos and Class Discussion	Formative evaluation of student participation in class discussion during the workshop, performance in post-module questionnaire (knowledge section)
Knowledge, Attitudes and Skills	Develop *skills* needed to address the different aspects of smoking and vaping cessation. These included skills in: • *assessing dependence* • *assessing readiness to quit* • *individualizing pharmacotherapy*	Clinical Cases in workshops, Lectures, Practical Demonstrations of NRT/ENDS/NVP devices	Formative evaluation of student engagement and participation during class discussions within the workshop, performance in the post-module questionnaire knowledge section

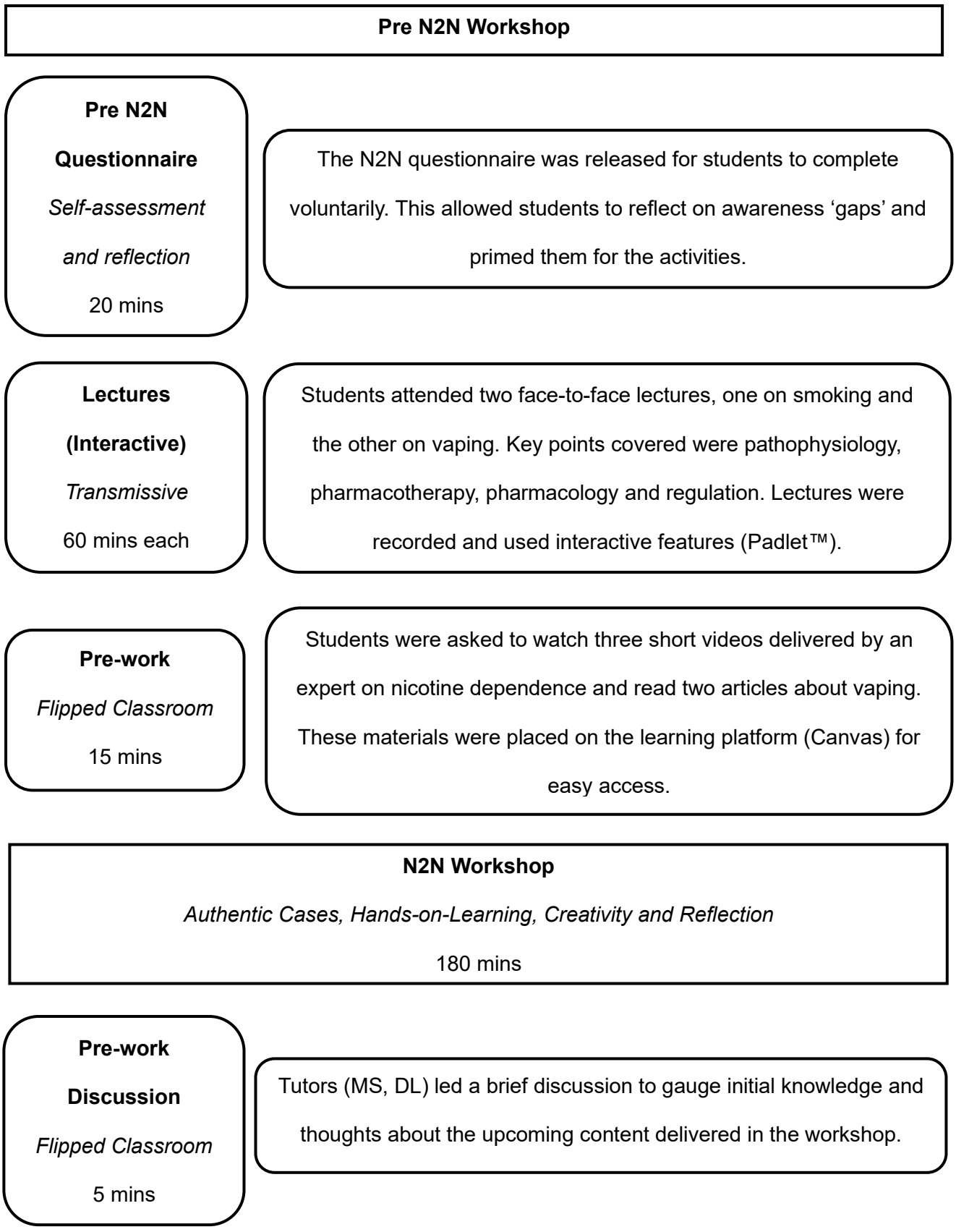
	• recommending *non-pharmacological measures* • providing *referral avenues*		
Attitudes	Recognise the *significant role of pharmacists* in implementing up-to-date smoking and vaping cessation interventions	Lectures Clinical Cases and Class Activity	Formative evaluation of student engagement and participation during class discussions within the workshop, performance in the post-module questionnaire knowledge section
Attitudes and Skills	Develop an *awareness of key sources of valid information* on smoking and vaping-related clinical issues.	Class Discussions and Poster creation activity and reflection at the workshop end	Formative evaluation of class discussion and participation during the workshop Review of poster themes and observation and reflection by tutors at the end of workshop delivery

NRT: Nicotine Replacement Therapy

ENDS: Electronic Nicotine Delivery Systems

NVP: Nicotine Vaping Products

Figure 1. Content and format of the N2N Module



Clinical Cases – Smoking and Vaping

Flipped Classroom, Authentic Cases

60 mins

Cases were developed in coloration by the author team which included experts in medical (SS), public health (SS, DL), nicotine addiction (RB, SS, MS), smoking and vaping cessation services (RB), pharmacy health services (BS, MS) and respiratory health (SS, BS).

Students were given a case about a clinical scenario related to smoking and vaping with the tutor role playing the case patient. There was time given for *initial information gathering* (e.g. asking questions of the case patient). Tutors provided feedback to students about communication skills required for appropriate counselling about smoking/vaping cessation. All students were provided with the Fagerstrom test and HONC(1) for assessing nicotine dependence in the case scenario. Discussion of the clinical scenario then led on to focus on current pharmacotherapy, device instruction (how to use NRT products), key counselling points, regulatory requirements and avenues of treatment support/referrals. The instructors facilitated the discussion and encouraged participation by asking further questions or stimulating probes.

Hands on Demonstration Activity

Skill Acquisition

15 mins

Students were given NRT products allowing a practical component connecting to the theory covered in the lectures and workshop. Two volunteers were selected to use a CO monitor to compare CO readings. Smoking/vaping status was either voluntarily disclosed by the student volunteers to the class or remained anonymous.

Refusal Strategies *Flipped Classroom, Authentic Cases, Behavioral Coaching* 10 mins	The instructors walked over to random students and presented the student being approached with either a demonstration cigarette or a vape. Each approached student was asked to state what they would accept or refuse the 'offer' and the reason for accepting/refusing the cigarette/vape. A brief discussion was held afterwards about highlighting the three key methods of avoid, refuse and exit.
Smoking/Vaping Pharmacy *Clinic Design Authentic Cases, Reflection* 15 mins	Students were asked to design a smoking/vaping cessation service in their pharmacy. A template was shown for another pharmacy service which students could draw from. Groups brainstormed ideas and delivered them via an online platform (Padlet™), where the instructors led the discussion. Tutors highlighted common service provision set up requirements, e.g., training, resources, systems to follow up with patients, and short and long-term goals of patient and service outcomes.
Post N2N Questionnaire *Reflection* 20 mins	Students were given an opportunity to participate in the research project by completing the questionnaire. This allowed the researchers to examine how students' knowledge, attitudes and skills have changed after completing the workshop.
Poster Group Work *Reflection* 15 mins	Students were asked to reflect on the learning content and design and present a poster targeting smokers/vapers of any demographic group.

HONC: Hooked on Nicotine Checklist

NRT: Nicotine Replacement Therapy

CO: Carbon Monoxide

1. Wellman RJ, Savageau JA, Godiwala S, et al. A comparison of the Hooked on Nicotine Checklist and the Fagerström Test for Nicotine Dependence in Adult Smokers. *Nicotine & Tobacco Research.* 2006;8(4):575-80. https://doi.org/10.1080/14622200600789965.

services are threaded across the practice-based content of the unit (and relevant to smoking and vaping cessation content). The content of the unit is delivered in the format of lectures, hands-on laboratory sessions, online learning, tutorials and workshops.

2.3 Study Design

A pre-post intervention questionnaire was designed to assess potential changes in participants' knowledge and attitudes. The pre-post questionnaires served as a research instrument and allowed consenting students to reflect on learning gaps (pre-intervention) and learning achievements (post-intervention). The pre-post questionnaires comprised 38 True/False knowledge items (19 smoking- and 19 vaping-related items) which reflected, at the time, the currency of knowledge about smoking and vaping for pharmacy students. Participants were given 3 response options for each knowledge item, 'True', 'False' and 'Don't Know'. Both the pre- and post-questionnaires also included 15 items assessing attitudes towards smoking and vaping on a Likert Scale (1= Strongly Disagree to 5= Strongly Agree). Questions about knowledge and attitudes were based on a previously validated questionnaire on smoking for pharmacy students.(30) Demographic questions were incorporated into the pre-module questionnaire. The post-module questionnaire also had an additional 5 Likert Scale statements on the perceived impact of the module (1 = No Impact to 5 = A Large Impact) and 3 evaluation/feedback questions (improvements needed, valued activities and retention in PHAR2911) that sought student responses. The pre-post questionnaires (Appendix A2 and A3) were emailed to pharmacy students using the online platform REDCap® (Research Electronic Data Capture). Pre-post student data was linked by an independent REDCap® administrator and was then deidentified.

2.4 Participant Recruitment

Initial contact with students was made on the PHAR2911 Canvas site. Canvas is the university's online learning education design and delivery platform for students and instructors. Only students enrolled in a unit of study can access its Canvas site. Participating in the N2N

module was mandatory for all students as part of the unit of study. Students were informed that the embedded research study (requiring completion of a study questionnaire prior to and post N2N) was completely voluntary and was not linked to any assessments or marks. Allocated time was given in a previous PHAR2911 tutorial to complete the pre-module questionnaire, a week before the smoking and vaping lectures were delivered. An email with the REDCap® pre-module questionnaire link was sent to students. Consent was obtained via a checkbox at the beginning of the questionnaire, where the participant information statement was linked for students to access. Following the N2N module, the REDCap® post-module questionnaire link was emailed to students who had completed the pre-questionnaire. All deidentified questionnaire responses were stored on REDCap®.

2.5 Analytical Methods

Statistical Package for Social Sciences software (IBM SPSS™ Statistics for Windows, Version 29.0; IBM Crop, Armonk, NY) was used to analyze data generated from REDCap® using descriptive and repeated measures tests. The total knowledge score was derived from the 38 knowledge questions and mean total scores from pre-post module questionnaires were calculated and presented respectively as mean ± standard deviation. Each item with a correct answer was scored as 1, while incorrect answers were scored as 0. A paired samples t-test was used to compare student responses to the questions before and after completing the N2N educational module. The psychometric properties of the pre-post questionnaire were tested via reliability measures (Cronbach's alpha) and educational strength measures (difficulty and discrimination indices). Student feedback from post-N2N data was summarized using mean ± standard deviation for the 5 Likert statements. In addition, students' feedback on the N2N module from the post-module questionnaire was inductively analyzed and classified based on emergent common themes.

2.6 Peer observation

Three independent academic healthcare professionals observed the running of the N2N workshop component, evaluating its design and practicality. Feedback from the reviewers was collated through a standard peer observation of face-to-face teaching form that the university utilizes for evaluating teaching activities.

Ethics approval for this research study was obtained from The University of Sydney, Human Research Ethics Committee (2024/271)

The criteria for reporting on the development and evaluation of professional training interventions in healthcare (CRe-DEPTH) were followed where applicable.(37)(Appendix A4)

3. Results

A total of 267 were eligible to participate in the N2N module during semester 1, 2024. Of these a total of 175 students completed the pre-N2N questionnaire (overall participation rate = 65.5%). Automated post-N2N questionnaires were sent to all students who had completed the pre-N2N questionnaire upon completion of the workshop. A total of 147 students completed the post-N2N questionnaire (pre to post survey participation retention rate = 84.0%). Of the 147 participants who completed both questionnaires, 63.9% were females (age range 18-35 years, median age = 19.6 years). Over half of the participants (59.9%) indicated that they were currently working as pharmacy students/assistants in pharmacies. Most participants reported having no prior formal education in smoking cessation (94.6%) and vaping cessation (93.2%). Of these participants, 19 students (12.9%) stated they had smoked before, while 41 students (27.9%) indicated that they had vaped previously.

The mean total scores for the 38 knowledge questions improved from a baseline of 18.9 ± 5.6 to 25.4 ± 5.0 post-module ($p<0.001$). Students found the smoking questions to be more difficult than the vaping questions, as was evident from the difference in the mean total score of

Table 2: Knowledge and Attitudes Scores Pre/Post N2N Educational Module

Areas of Assessment (Score)	***Pre-N2N Scores, Mean (SD)***	***Post-N2N Scores, Mean (SD)***	***P-value***
Total Knowledge /38	**18.9 (5.6)**	**25.4 (2.7)**	<0.001
1. *Total Smoking Knowledge Score /19*	**7.6 (3.0)**	**11.2 (2.8)**	<0.001
2. *Total Vaping Knowledge Score /19*	**11.3 (3.1)**	**14.1 (2.7)**	<0.001
Total Attitude /5	**3.9 (0.5)**	**4.0 (0.6)**	0.0053
Comparison of Knowledge Pre/Post Difference Smoking/Vaping Related Items			
Knowledge Area	**Pre-N2N Scores, Average (SD)**	**Post-N2N Scores, Average (SD)**	**Mean Pre/Post N2N Score Difference (SD)**
A. General Knowledge			
Smoking			
(I # 2,4)	1.37 (0.65)	1.59 (0.59)	0.12 (0.78)
Possible score range 0-2			
Vaping			
(I # 1,3)	1.74 (0.53)	1.86 (0.40)	0.08 (0.56)
Possible score range 0-2			
B. Device Related Knowledge			
Smoking			
(I # 11,14,22)	0.78 (0.77)	1.15 (0.94)	0.27 (1.03)
Possible score range 0-3			

Vaping	3.06 (1.45)	4.17 (1.11)	0.74 (1.43)
(I # 10,12,13,15,16)			
Possible score range 0-5			
C. Pharmacology			
Smoking			
(I # 7,9,18,19,21)	3.24 (1.24)	3.9 (0.88)	0.35 (1.16)
Possible score range 0-5			
Vaping			
(I # 5,6,8,17,20,23)	4.46 (1.18)	4.88 (1.00)	0.10(1.09)
Possible score range 0-6			
D. Pharmacotherapy			
Smoking			
(I # 24,26,28,30,31,33,35,37,38)	2.20 (1.6)	4.57 (1.94)	2.10 (1.74)
Possible score range 0-9			
Vaping			
(I # 25,27,29)	1.02 (0.68)	1.25 (0.66)	0.14 (0.83)
Possible score range 0-3			
E. Regulation			
Vaping			
(I # 32,34,36)	1.01 (0.85)	1.96 (0.85)	0.85 (1.07)
Possible score range 0-3			

I = Item Number on N2N Study Questionnaire

Table 3: Knowledge Questions: Pre/Post-Module Item Difficulty and Discrimination Values

		Item Difficulty		Item Discrimination	
Question No	Topic	PreN2N	PostN2N	PreN2N	PostN2N
1	Vaping	0.83	0.87	0.27	0.17
2	Smoking	0.84	0.90	0.24	0.32
3	Vaping	0.91	0.97	0.24	0.05
4	Smoking	0.53	0.69	0.45	0.27
5	Vaping	0.85	0.95	0.29	0.10
6	Vaping	0.98	0.99	0.06	0.00
7	Smoking	0.87	0.91	0.37	0.17
8	Vaping	0.83	0.84	0.24	0.34
9	Smoking	0.16	0.28	0.10	-0.22
10	Vaping	0.79	0.88	0.35	0.12
11	Smoking	0.51	0.54	0.53	0.41
12	Vaping	0.59	0.84	0.51	0.24
13	Vaping	0.59	0.84	0.63	0.37
14	Smoking	0.17	0.34	0.33	0.37
15	Vaping	0.45	0.74	0.45	0.10
16	Vaping	0.64	0.88	0.71	0.34
17	Vaping	0.26	0.33	0.39	0.39
18	Smoking	0.75	0.86	0.51	0.24
19	Smoking	0.77	0.95	0.53	0.15
20	Vaping	0.82	0.95	0.43	0.15
21	Smoking	0.70	0.91	0.57	0.12
22	Smoking	0.11	0.27	0.16	0.37
23	Vaping	0.72	0.82	0.47	0.20

24	Smoking	0.77	0.91	0.49	0.15
25	Vaping	0.26	0.36	0.39	0.59
26	Smoking	0.12	0.27	0.14	0.29
27	Vaping	0.73	0.83	0.43	0.02
28	Smoking	0.07	0.10	0.10	0.17
29	Vaping	0.03	0.06	0.06	0.00
30	Smoking	0.15	0.42	0.29	0.63
31	Smoking	0.05	0.65	0.10	0.56
32	Vaping	0.48	0.85	0.37	0.15
33	Smoking	0.13	0.70	0.20	0.66
34	Vaping	0.42	0.64	0.39	0.56
35	Smoking	0.27	0.58	0.49	0.59
36	Vaping	0.11	0.47	0.22	0.51
37	Smoking	0.38	0.50	0.59	0.05
38	Smoking	0.25	0.45	0.37	0.54

smoking-related versus vaping-related items, respectively (Table 2). Item difficulty values were calculated to be 0.50 and 0.67 pre- and post-intervention, respectively, and item discrimination values were 0.35 pre-module and 0.27 post-module, where individual question values are highlighted in Table 3. The reliability of the knowledge questions was tested using Cronbach's alpha scores, and the pre- and post-values obtained were 0.83 and 0.79, respectively. The mean total score for the 15 attitude statements, after adjusting the negatively aligned items, increased from 3.9 ± 0.5 to 4.0 ± 0.6 (p=0.053).

Items in the N2N questionnaire were categorized into five key thematic topics (Table 2). There was minimal improvement in knowledge between the pre- and post-N2N questionnaire for items pertaining to general knowledge of smoking (items 2,4) and vaping (items 1,3), owing to reasonable scores at baseline. On the other hand, the concepts around pharmacology and pharmacotherapy of smoking (items 9, 26,28,30,31,33) appeared to be rather challenging for participants at baseline, where the pre-intervention results indicated lower knowledge levels, especially with respect to the use of NRT (items around this consequently had the most gains). Interestingly, there was a relatively larger gain in awareness around the knowledge of vaping devices as well as regulations surrounding NVP provision by pharmacists post-intervention.

Feedback provided by students on the learning impact of the N2N module was quite positive. Based on Likert scale responses, most students stated that the module had an impact on (1) their understanding of the public health impact of smoking and vaping (4.18 ± 0.86), (2) their clinical knowledge about smoking and vaping cessation services (4.41 ± 0.79), (3) their confidence in managing smoking and vaping related issues in the pharmacy setting (4.24 ± 0.84), (4) their confidence in checking nicotine prescription dose calculations (3.78 ± 1.08), and (5) their ability to counsel patients on smoking and vaping cessation to improve respiratory and overall health (4.20 ± 0.83). These responses were consistent with the fact that 89.1% of students (N=131 of 147 who completed the post-N2N questionnaire) agreed that the N2N

module should be retained in the pharmacy curriculum for future students. Four key themes were thematically analyzed, derived from open-ended comments: relevance to practice, knowledge gains, impact of the module and improvements to the module, with some exemplary quotes listed below. (Appendix A5)

"I enjoyed the hands-on experience of trying NRTs. I feel like that knowledge helps with my counselling if a patient asks."

"I liked that they tried to fill in the gaps in our knowledge that may not necessarily be addressed in professional settings (e.g. contraindications, how to use patches etc.) The little roleplays also made it more entertaining."

"I feel like the unit was overall well run and engaging, while still being informative and educational."

A total of 46 posters were created by student groups across all workshops run in the N2N training week, which were sorted as being in reference to smoking (24), vaping (11) or both (11). Exemplar posters are included in Appendix A6. The key themes depicted in the posters comprised risk communication, motivational messaging, refusal tactics, vulnerable populations and healthcare collaboration. These creative posters clearly illustrate the students' understanding of the health risks related to smoking and vaping. Tutors' observations highlighted that there was substantial collaboration within student groups who enthusiastically approached this activity.

Based on open-ended responses, most respondents appeared to find N2N to be relevant to their future practice and reported that it improved their knowledge and understanding. This demonstrates the practical impact of this educational module. Informal feedback from students provided directly to tutors and the unit of study coordinator flagged that the workshops were

held during the oral examination week of PHAR2911, a busy and stressful week for students, which could possibly explain the dropout rate from pre-post module data. In addition, there was a call for more interactive activities, such as role plays, as participants felt that the delivery of the clinical case was quite lengthy. This was reinforced by the three independent observers, noting that active participation could be enhanced by improving classroom logistics/table setups to promote further active engagement.

4. Discussion

Being at the forefront of primary care, pharmacists are well placed to facilitate smoking and vaping cessation, though this remains a challenging task. Several exploratory research efforts have defined the expressed requirements of pharmacists for training on nicotine dependence. This study represents, to the best of our knowledge, the first piece of scholarly inquiry testing the impact of a pedagogically sound educational intervention to train future pharmacists on smoking and vaping cessation services in Australia. The N2N educational intervention module led to a significant improvement in pharmacy students' knowledge of both smoking and vaping topics and enhanced their clinical awareness. While changes in attitudes were not statistically significant, learners conveyed high satisfaction and engagement with N2N. With the rapidly evolving nature of vaping in Australia, pedagogically informed interventions such as N2N can help future pharmacists build the necessary expertise for combating vaping from both a public health and an individual patient care aspect.

Analyzing the results of the knowledge gains from the N2N study questionnaire, it was noted that there was a higher degree of difficulty in answering smoking questions compared to vaping related questions, especially around pharmacology and pharmacotherapy (Table 2 and 3). These results also reflect the situational context as the participants were relatively within the age group where there has been the highest uptake of vaping. Reports suggest that vaping may be seen as a socially desirable and safe activity, noting that smoking prevalence in this age group has decreased.(6, 38) It is not surprising that participants in our study were more

likely to be familiar with vaping rather than smoking. Whilst being more aware of general issues about vaping, baseline (pre-N2N) awareness of key harms such as nicotine concentration, ingredients in vaping solutions, vaping device knowledge and regulatory measures was rather low. The N2N intervention was able to shift this pattern as post-intervention N2N study questionnaire scores demonstrated a significant improvement in clinical awareness surroundings. This was supported by higher mean item difficulty and a lower mean item discrimination indices post-module, with most students answering more items correctly. In a similar study involving high school adolescents, Chaplin and colleagues demonstrated the impact of educational interventions, where knowledge of vaping risks and harms increased after engaging in presentations.(39) Following the N2N intervention, study questionnaire results indicated gains across all knowledge sections, clearly highlighting participants' enhanced understanding post-N2N.

While the attitude scores indicated an improved alignment with evidence surrounding the harms of vaping and smoking, this score change was not statistically significant. This could possibly be because the risks and harms of smoking have been well established, and anti-smoking campaigns have conveyed strong public health messaging where smoking is seen as undesirable, and hence, baseline attitudes were already proactive.(40) Whereas for vaping, attitudes were mixed about the harms and benefits of NVPs, highlighting the need for more public health interventions.(6) It may also be the case, that similar to public opinion, the fact that NVPs have a ‘therapeutic use’ in smoking cessation may create a perception that they are safe, or at least safer than smoking. This issue needs to be better addressed in pharmacy student training in future iterations of the N2N module.(10)

Overall, the pedagogically aligned educational module served the aim of the study, where many participants appreciated the interactive aspect of the workshop, consolidating key learning outcomes. Educational approaches such as the use of flipped classrooms, authentic clinical cases, skills building and creativity and reflection were able to facilitate active

engagement. A systematic review by Akcayir and Akcayair (2018) on the impact of the flipped classroom approach highlighted improvements in student learning performance, with more confidence and better attitude perspectives towards the subject matter.(41) In the N2N, the flipped classroom model was reinforced through active engagement, where the use of authentic clinical cases empowered students with the necessary skills and confidence.(42, 43) Creativity was able to foster student experiences through their engagement in 'refusal strategies', 'smoking/vaping cessation clinic design' and 'poster activities' (Figure 1). Students were able to creatively address potential solutions to nicotine dependence; as reflection is known to improve a students' ability to form their own individual attitudes and perceptions.(44) The use of these pedagogical principles, we believe nurtured student learning and engagement, clearly highlighting the strength of the N2N educational module.

Teaching refusal skills to adolescents has been a strategy commonly used when educating school students about smoking.(45) The activity demonstrated the social challenge of refusing a vape/cigarette when offered by a close peer.(46) Our use of this activity in the N2N workshop was intended to allow students to reflect on this challenge, take note of refusal strategies used by peers, and apply this learning to combat social pressures around vaping. Of course, being close in age to adolescent groups, perhaps this activity could build refusal tactics among our students themselves, given that some participants reported smoking or vaping. Overall, we believe these cumulative opportunities for reflection allowed students to process information learnt, leading to the development of skills and positive attitudes.(47)

The interest in this topic within our student cohort was validated by the relatively higher response rate participating in the pre-intervention. This participation rate was much higher than that reported in any single institution-based survey of pharmacy students around vaping.(25, 29, 48, 49) Investing in a scholarly inquiry on this topic is important, given that many studies have demonstrated the effectiveness of pharmacist-led interventions targeting conventional smoking where cessation rates were significantly reduced through pharmacist

involvement.(50, 51) Further, our intervention development was based on initial exploratory research during which participating Australian pharmacists specifically expressed their needs for training,(20) given the uncertainty, hesitancy and lack of confidence.

Whilst time and resources were invested by authors to design this work, the details articulated in previous pages could now allow other educators to implement N2N with localized adaptations if required. The successful implementation of N2N can be adapted for other undergraduate health profession students. Vaping and its impact on communities globally require relevant training and education, where allied health students would benefit from nicotine-related knowledge and skills in primary practice.(52) Having tailored workshops in response to public health concerns allows students from any health discipline to develop strategies and preparedness to assist patients at risk or harm. For instance, integration of vaping into a post-graduate program for public health professionals facilitated learning and reflection, equipping them with the necessary attitudes, knowledge and skills for this public health concern.(53)

There were clearly some limitations to this research study; the smoking questions were derived from a previously validated questionnaire. However, the vaping questions that were developed have not been tested for validity e.g., using an exploratory/confirmatory factor analysis, although of course their validity as an assessment tool was indicated through the item difficulty/discrimination indices. As the pre- and post-module questionnaires utilized the same questions for the knowledge and attitudes section, test-retest bias was possible. Since this was the first time the N2N module was implemented, feedback from participants and observers about its delivery and design was obtained for future iterations, as the N2N module will be retained in the unit of study in future years given the results provided evidence of its utility. Finally, of course knowledge gains may not translate to practice, hence the real impact of the N2N module needs to be tested in actual clinical settings to determine whether trained students/pharmacists can affect behavior change such as smoking or vaping cessation.

5. Conclusion

Nicotine dependence is not a newly taught topic; however, pharmacy students, like other health professional students, need to develop the ability, confidence and skills to stay abreast of changes such as those of vaping. The N2N interventional study provides early evidence that a pedagogically informed, interactive educational module can significantly enhance pharmacy students' knowledge and preparedness to address nicotine dependence. It also highlighted the importance of empowering students with clinical expertise and communication skills for future professional practice. The N2N module is an innovative educational pilot package that can be possibly adopted in various pharmacy curricula. Refining the module, with evolving evidence of the role of NVPs in cessation, can prepare students for future practice. As pharmacists play an increasingly central role in supporting public health interventions related to tobacco harm reduction, investments in educational initiatives like N2N are both timely and essential.

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Appendix A1 : Clinical Case

Ms Fiona, a 20-year-old female comes into your pharmacy asking about how to quit smoking?

Class Discussion

What questions would you ask?

Ms Fiona comes back into your pharmacy three-months later with a prescription for *varenicline*.

Class Discussion

What would you do at this stage?

Ms Fiona, comes back into your pharmacy nine months later with a prescription for *Nicovape Q – Classic 20mg/mL*.

Class Discussion

What questions do you ask?

How would you dispense this prescription?

Appendix A2: Pre N2N Study Questionnaire

SECTION A: GENERAL DEMOGRAPHICS AND INFORMATION

Section A will ask you for information about yourself.

Please complete the following section by providing answers where indicated or by circling the most convenient answer where applicable.

1. **What is your age in years?**

   ___ years

2. **With which gender do you identify?**

   a. Female
   b. Male
   c. Non-binary
   d. Prefer not to respond

3. **Are you currently a full time second year student studying BPharm(Hons)/MPharm Practice or BPharm and Management(Hons)/MPharm Practice at the University of Sydney?**

   a. Yes
   b. No

[If respondents have answered ‘no’ Unfortunately you do not meet the relevant criteria to participate in this study; thank you for showing your interest in this research project]

4. Are you currently working as a pharmacy assistant?

a. Yes

b. No

5. Have you obtained a tertiary degree prior to admission to this course? If yes, please specify.

a. Yes

b. No

c. If yes, specify _____

6. Have you previously received any form of:

Smoking cessation training

a. Yes

b. No

Vaping cessation training

a. Yes

b. No

7. In your lifetime have you ever smoked a cigarette?

a. Yes
b. No
c. Don't Know
d. Can't Recall
e. Prefer Not to Say

8. In your lifetime have you ever vaped an e-cigarette containing nicotine?

a. Yes
b. No
c. Don't Know
d. Can't Recall
e. Prefer Not to Say

SECTION B: CLINICAL AWARENESS ABOUT SMOKING AND VAPING

Section B will ask you about your current clinical awareness of smoking and vaping from your perspective as a pharmacy student.

Statements in this section can be selected to be **TRUE or FALSE or DON'T KNOW.**

Please select an appropriate option selected from those presented after a statement.

	TRUE	**FALSE**	**DON'T KNOW**
Adolescents are most likely to take up vaping in Australia.			
Besides pulmonary effects, smoking causes cancer in various organs such as the bladder, intestines and cervix.			
Common side effects of vaping are mouth/throat irritation, headache, and cough.			
Deaths attributed to tobacco use in Australia outnumber those caused by AIDS, legal drugs, illegal drugs, road accidents, murder and suicide combined.			
Adolescents who vape are at greater risk of developing memory/attention deficient behaviours and mood disorders.			
Vaping may be harmful to the health of the user.			
In smoking mothers, neonatal death may occur secondary to tobacco smoke exposure.			
Vaping is safe during pregnancy.			
People with respiratory conditions, such as asthma, tend to smoke more.			

Regardless of nicotine content, vaping any solution may be associated with developing short term respiratory health effects.			
Rolling your cigarettes is safer than the packaged industrial brands.			
Disposable, Refillable and Pod Style are different kinds of vaping devices.			
Vaping devices may contain nicotine despite being labelled 'nicotine-free'.			
Nicotine is the most addictive and dangerous substance in a cigarette.			
The nicotine content in cigarettes and vapes is not comparable to each other due to different concentrations/method of administration.			
Acetone and arsenic have been found in vaping e-liquids.			
Adolescents who vape become addicted at the same rate as adults who vape.			
Nicotine dependence is a chronic relapsing disease.			
Nicotine dependence is mediated by dopamine within the reward system of the brain.			
Vaping nicotine containing e-cigarettes damages the brain areas controlling attention, learning, mood and impulse control			
Nicotine withdrawal symptoms are associated with increased noradrenergic outflow, secondary to deactivation of the reward system.			
A heavy smoker is defined as smoking who smokes a total of 15 or more cigarettes/day.			

In a young person who vapes, there is a strong likelihood of progressing to smoking cigarettes.			
In Australia, smokers can be referred to specialised smoking cessation clinics for treatment.			
There is robust evidence to suggest that vaping can be used as a strategy for smoking cessation.			
Younger smokers are easier to treat than older smokers who have been smoking for a longer time.			
Nicotine Replacement Therapy can be used for vaping cessation.			
Combinational behavioural and pharmacological therapy have been shown to be as effective as either alone in helping smoking cessation.			
Vaping nicotine solutions can alter drug metabolism by altering liver enzymes.			
Nicotine replacement sublingual tablets and patches are more effective than gums, lozenges and inhalers.			
A patient on nicotine replacement therapy (NRT) should warned not to smoke whilst on treatment.			
Nicotine containing vaping products supplied in Australia need a prescription.			
Combining different forms of NRTs for smoking cessation is contraindicated.			
Vaping products with or without nicotine can be supplied to anyone aged under 18 years with a prescription in Australia.			
Varenicline was proven to be safe in smokers younger than 18 years.			

Currently, there are nicotine containing vaping products approved by the Therapeutic Goods Administration (TGA).			
Some anti-depressants and anti-hypertensives can be used as therapeutic options for smoking cessation			
Relapse is uncommon if patients comply with their optimal smoking cessation plan.			

SECTION C: ATTITUDES TO SMOKING AND VAPING

Section C will ask you about your attitudes towards smoking and vaping from your perspective as a pharmacy student.

For each statement there are FIVE choices, only indicating your level of agreement/non-agreement. Please select the button located next to the answer choice you consider to best reflect your position.

	STRONGLY AGREE	**AGREE**	**NEITHER AGREE NOR DISAGREE**	**DISAGREE**	**STRONGLY DISAGREE**
If I am sharing a room/flat with a friend and they decide to smoke, I would ask them to smoke outside as I do not like to be exposed to smoke.					
If I am sharing a room/flat with a friend and they decide to vape, I would ask them to vape outside as I do not like to be					

exposed to vape smoke.					
Smoking on social occasions only is fine.					
Vaping is socially acceptable.					
Smoking for a year or so is okay, as long as you quit soon after that.					
Vaping is safer than smoking cigarettes.					
Tobacco sales to people younger than 18 years should be banned globally.					
Vaping is a public health issue.					
Smoking in public places should not be prohibited.					
Vaping in smoke-free is allowed.					
A patient's chances of quitting are increased if a health					

professional advises them to quit.					
All pharmacies should provide smoking cessation services.					
All pharmacies should provide vaping cessation services.					
Pharmacists require specific training on vaping clinical awareness.					
Smoking and vaping cessation training should be a key part of the pharmacy curriculum.					

Appendix A3: Post N2N Study Questionnaire

SECTION A: CLINICAL AWARENESS ABOUT SMOKING AND VAPING

Section A will ask you about your current clinical awareness of smoking and vaping from your perspective as a pharmacy student.

Statements in this section can be selected to be **TRUE or FALSE or DON'T KNOW.**

Please select an appropriate option selected from those presented after a statement.

	TRUE	**FALSE**	**DON'T KNOW**
Adolescents are most likely to take up vaping in Australia.			
Besides pulmonary effects, smoking causes cancer in various organs such as the bladder, intestines and cervix.			
Common side effects of vaping are mouth/throat irritation, headache, and cough.			
Deaths attributed to tobacco use in Australia outnumber those caused by AIDS, legal drugs, illegal drugs, road accidents, murder and suicide combined.			
Adolescents who vape are at greater risk of developing memory/attention deficient behaviours and mood disorders.			
Vaping may be harmful to the health of the user.			
In smoking mothers, neonatal death may occur secondary to tobacco smoke exposure.			
Vaping is safe during pregnancy.			
People with respiratory conditions, such as asthma, tend to smoke more.			

Regardless of nicotine content, vaping any solution may be associated with developing short term respiratory health effects.			
Rolling your cigarettes is safer than the packaged industrial brands.			
Disposable, Refillable and Pod Style are different kinds of vaping devices.			
Vaping devices may contain nicotine despite being labelled ‘nicotine-free’.			
Nicotine is the most addictive and dangerous substance in a cigarette.			
The nicotine content in cigarettes and vapes is not comparable to each other due to different concentrations/method of administration.			
Acetone and arsenic have been found in vaping e-liquids.			
Adolescents who vape become addicted at the same rate as adults who vape.			
Nicotine dependence is a chronic relapsing disease.			
Nicotine dependence is mediated by dopamine within the reward system of the brain.			
Vaping nicotine containing e-cigarettes damages the brain areas controlling attention, learning, mood and impulse control			
Nicotine withdrawal symptoms are associated with increased noradrenergic outflow, secondary to deactivation of the reward system.			
A heavy smoker is defined as smoking who smokes a total of 15 or more cigarettes/day.			

In a young person who vapes, there is a strong likelihood of progressing to smoking cigarettes.			
In Australia, smokers can be referred to specialised smoking cessation clinics for treatment.			
There is robust evidence to suggest that vaping can be used as a strategy for smoking cessation.			
Younger smokers are easier to treat than older smokers who have been smoking for a longer time.			
Nicotine Replacement Therapy can be used for vaping cessation.			
Combinational behavioural and pharmacological therapy have been shown to be as effective as either alone in helping smoking cessation.			
Vaping nicotine solutions can alter drug metabolism by altering liver enzymes.			
Nicotine replacement sublingual tablets and patches are more effective than gums, lozenges and inhalers.			
A patient on nicotine replacement therapy (NRT) should warned not to smoke whilst on treatment.			
Nicotine containing vaping products supplied in Australia need a prescription.			
Combining different forms of NRTs for smoking cessation is contraindicated.			
Vaping products with or without nicotine can be supplied to anyone aged under 18 years with a prescription in Australia.			
Varenicline was proven to be safe in smokers younger than 18 years.			

Currently, there are nicotine containing vaping products approved by the Therapeutic Goods Administration (TGA).			
Some anti-depressants and anti-hypertensives can be used as therapeutic options for smoking cessation			
Relapse is uncommon if patients comply with their optimal smoking cessation plan.			

SECTION B: ATTITUDES TO SMOKING AND VAPING

Section B will ask you about your attitudes towards smoking and vaping from your perspective as a pharmacy student.

For each statement there are FIVE choices, only indicating your level of agreement/non-agreement. Please select the button located next to the answer choice you consider to best reflect your position.

	STRONGLY AGREE	**AGREE**	**NEITHER AGREE NOR DISAGREE**	**DISAGREE**	**STRONGLY DISAGREE**
If I am sharing a room/flat with a friend and they decide to smoke, I would ask them to smoke outside as I do not like to be exposed to smoke.					
If I am sharing a room/flat with a friend and they decide to vape, I would ask them to vape outside as I do not like to be					

exposed to vape smoke.					
Smoking on social occasions only is fine.					
Vaping is socially acceptable.					
Smoking for a year or so is okay, as long as you quit soon after that.					
Vaping is safer than smoking cigarettes.					
Tobacco sales to people younger than 18 years should be banned globally.					
Vaping is a public health issue.					
Smoking in public places should not be prohibited.					
Vaping in smoke-free is allowed.					
A patient's chances of quitting are increased if a health					

professional advises them to quit.					
All pharmacies should provide smoking cessation services.					
All pharmacies should provide vaping cessation services.					
Pharmacists require specific training on vaping clinical awareness.					
Smoking and vaping cessation training should be a key part of the pharmacy curriculum.					

SECTION C: NO-TO-NICOTINE IMPACT ON PHARMACY STUDENTS

Section C will ask you about your attitudes to gauge the extent to which you feel your clinical awareness and skills in smoking and vaping have been impacted through the NO-TO-NICOTINE learning module.

For each statement there are FIVE choices, only indicating your level of agreement/non-agreement. Please select the button located next to the answer choice you consider to best reflect your position.

	A LARGE IMPACT	**SOME IMPACT**	**A LITTLE IMPACT**	**VERY LITTLE IMPACT**	**NO IMPACT**
What impact, IF ANY, do you feel the *NO-TO-NICOTINE* module had on your understanding of the public health impact of smoking and vaping?					
What impact, IF ANY, did the *NO-TO-NICOTINE* module have on your clinical knowledge about smoking and vaping cessation services?					
What impact, IF ANY, did the *NO-TO-NICOTINE* module have on your confidence in managing smoking and vaping related issues in the pharmacy setting?					

What impact, IF ANY, did the *NO-TO-NICOTINE* module have on your confidence in checking nicotine prescription dose calculations?					
What impact, IF ANY, did the *NO-TO-NICOTINE* module have on your ability to counsel patients about smoking and vaping cessation to improve respiratory and overall health?					

What aspects of the NO-TO-NICOTINE module do you feel can be improved?

What aspects of the NO-TO-NICOTINE module do you feel you really enjoyed and valued?

Should the NO-TO-NICOTINE module be retained in PHAR 2911 or similar Units of Study in coming years?

YES ☐

NO ☐

UNSURE

Appendix A4 : The Criteria for Reporting on Development and Evaluation of Professional Training Interventions in Healthcare (Cre-DEPTH)

Criterion	Explanation
Development of Training	
Item 1: Description of the aim or objectives of the training	To develop and evaluate an educational module addressing key awareness and skill gaps in pharmacy undergraduate students around the impact of smoking and vaping. Please refer to Table 1.
Item 2: Description of the underlying theoretical framework	A constructivist approach was used to deliver pedagogical methods such as a flipped classroom, authentic clinical cases and reflection. Please refer to 'Pedagogical principles' on pages 5-6.
Item 3: Description of the developmental process	Vaping has become a public health issue, and governmental changes have affected pharmacists in the supply and provision of nicotine-containing vaping products (NVPs). Pharmacists are well versed in smoking cessation treatments, and NVPs have been proposed as an option despite limited evidence. Pharmacy students, as future pharmacists, need to be trained in the ability

	and confidence to handle smoking and vaping-related cessation enquiries.
Item 4: Description of target population and setting of the training	Pharmacy students in the second year of the Bachelor of Pharmacy (Honours)/Master of Pharmacy Practice or the Bachelor of Pharmacy and Management (Honours)/Master of Pharmacy Practice at the University of Sydney.
Item 5: Description of the educational resources	A pre-questionnaire was administered in tutorials before the lectures on smoking and vaping were given respectively, prior the commencement of the No-To-Nicotine Educational module. After the workshop, a post-questionnaire was given to participating students. Please refer to Figure 1.
Characteristics of the Training	
Item 6: Description of the content of the training	Please see 'Pedagogical Principles' on pages 5-6.
Item 7: Description of the format	The No-To-Nicotine educational module consisted of 2 lectures, a 2.5 hour workshop and 2 questionnaires. Please see Figure 1.
Item 8: Description of the didactic methods of training	Please see 'Pedagogical Principles' on pages 5-6.

Item 9: Description of tailoring of the training	The training was tailored towards pharmacy students who have learnt the foundations in the first year. It enhances the concepts of pharmacy practice to a more clinical setting by enabling them to demonstrate competence in risk communication and awareness.
Characteristics of the Providers/Trainers	
Item 10: Description of the providers of the training	Mr David Le (primary researcher) and Dr Maya Saba (smoking expert) facilitated the running of the workshops.
Assessment of the Training Outcomes	
Item 11: Description of the measured outcomes	The results of the pre-post questionnaires were analysed to determine the impact on students' knowledge and attitudes around smoking and vaping. Please see 'Results' on pages 8-11.
Item 12: Description of the applied assessment methods, including validity and reliability	Statistical Package for Social Sciences software (IBM SPSS™ Statistics for Windows, Version 29.0; IBM Crop, Armonk, NY) was used in the analysis of the pre-post questionnaires. Please refer to 'Analytical Methods' on pages 7-8.

Appendix A5: Student Feedback Thematic Analysis

Relevance to Practice

- ‘I enjoyed learning about how to counsel patients on how to undertake nicotine replacement therapy as it was, be useful for practice in the future.’
- ‘The case study effectively illustrated a patient's progression through different treatments and how progress is not linear.’
- ‘The education and the learning about a very vital topic.’
- ‘All the info provided was greatly informative and can be used in future to help patients.’

Knowledge Gains

- ‘I enjoyed making the posters as I find it very relevant and an effective way of communicating the messages about vaping and smoking to adolescents.’
- ‘I enjoyed making the poster with my friends and also the interactives. Being able to handle all the different products and learn how to use them was eye opening.’
- ‘The "Saying no" to the peer pressure activity we did was also enjoyable.’

Impact of N2N

- ‘I got a better understanding of vaping and smoking.’
- ‘I enjoyed the seminar as it was interactive and got everyone to reflect on the lectures and videos.’

Improvements to N2N

- ‘More videos, different table layout so you can actually work with your group.’
- ‘Unfortunately, the module was presented on the same week as the oral exam, and everyone is very restless because of this.’

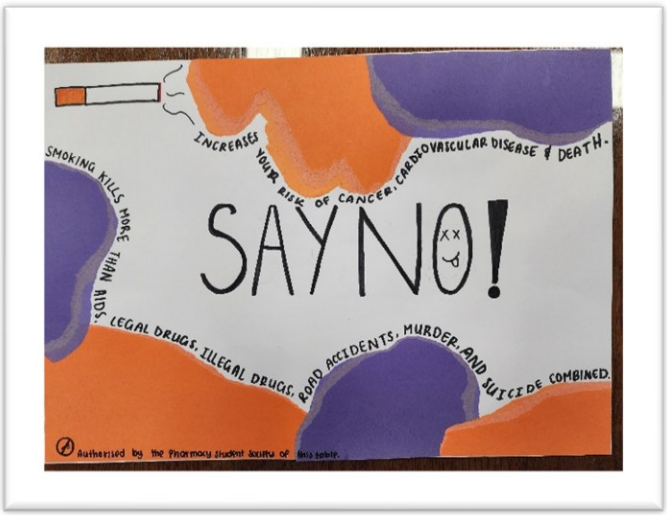
Appendix A6: Student Poster Group Work

Figure A6.1 Exemplar Posters (Theme: Risk communication)

Smoking

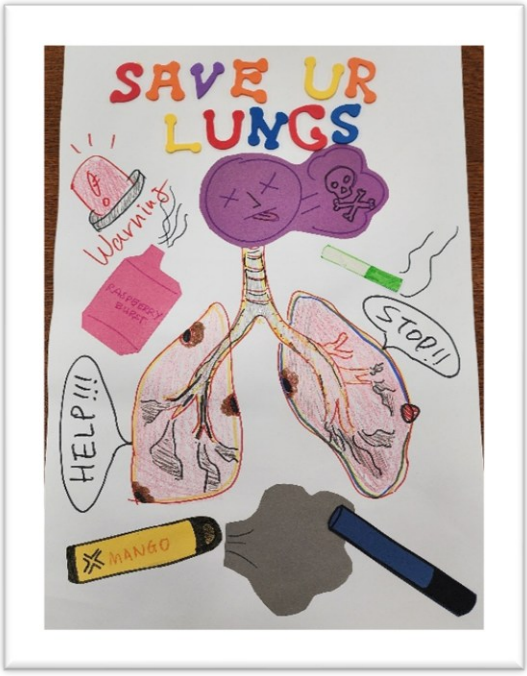
Vaping

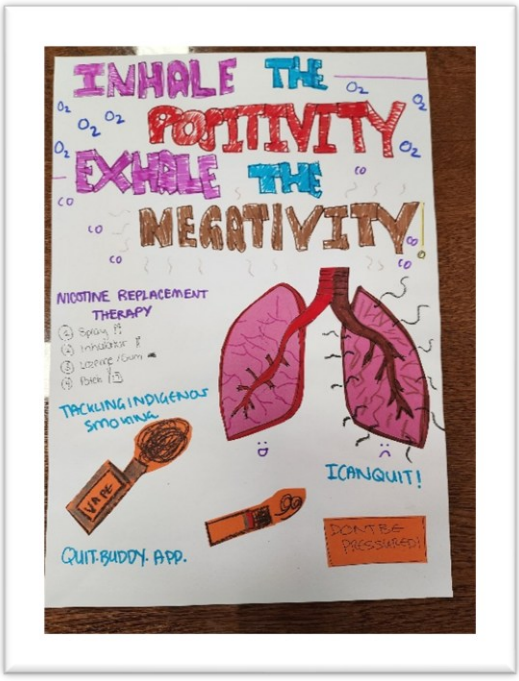
Figure A6.2 Exemplar Posters (Theme: Refusal Strategies)



Smoking

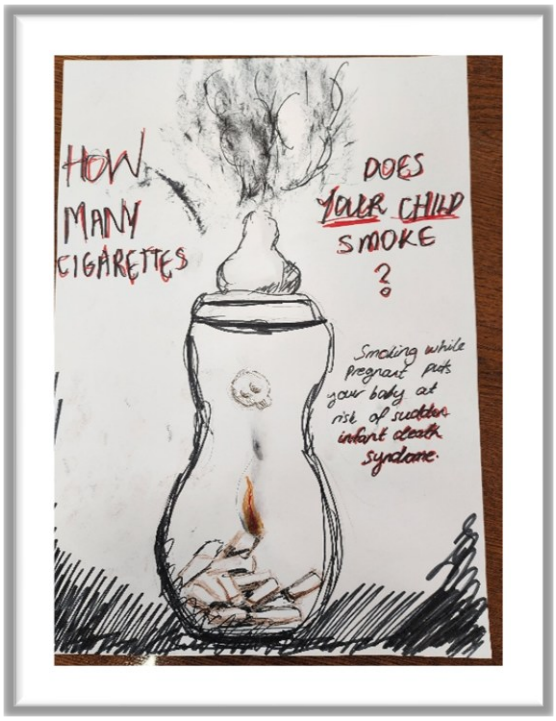
A6.3 Exemplar Posters (Theme: Motivational messaging)





Vaping and Smoking

A6.4 Exemplar Posters (Theme: Vulnerable populations)



Smoking

A6.5 Exemplar Posters (Theme: Health professional shared roles)

Smoking

Chapter 5

Discussion and Conclusion

5.0 Chapter Overview

This chapter provides a summary of the outcomes of the two phases of research reported on in this thesis, as well as a discussion of the implications of these outcomes. The strengths and limitations of both studies are highlighted, followed by an outline of potential future research directions, ending with concluding remarks.

5.1 Project Summary

Smoking and vaping have the potential for increased harm. Whilst public health emphasis in previous decades has been on smoking cessation, the increasing prevalence of vaping is an emergent issue for health professionals. As highlighted earlier in Chapter 1, the vaping prevalence in Australia is on the rise, fuelled by a variety of factors including influential marketing strategies, social acceptability of vaping, low awareness of potential risks and harms and consumer misperceptions about vaping being safe (or comparatively safer than smoking). The latter issue may have been stoked further through observations that therapeutic vapes can be 'prescribed' as an aid for smoking cessation. As such, there is a strong case for developing strategies to minimise the impact of harms from vaping, much before it reaches the epidemic proportions like those of smoking in past years (1).

Pharmacists are one of the most accessible primary healthcare professionals that can play a role in reducing harms from nicotine addiction, be that in the form of smoking or vaping. There is robust evidence supporting pharmacists' roles in smoking cessation, where such roles involve the supply of appropriate nicotine replacement therapies and providing behavioural coaching and referral avenues. Pharmacists' roles involving vaping came into sudden and sharp focus over the last two years, given that Australian regulatory changes shifted the availability of nicotine vaping products (NVPs) from local storefronts such as tobacconists to pharmacies either on a prescription to be dispensed by pharmacists or as pharmacist-only medications. This Master of Philosophy degree project, therefore, aimed to explore the needs of pharmacists around the provision of

NVPs and to improve clinical awareness for the effective implementation of vaping health-related services in pharmacies in the future.

5.2 MPhil Project Phases

The project plan involved two phases: the first, a qualitative study involving an exploration of the perspectives of ***Australian pharmacists*** around vaping and pharmacy-related services, and the second, a scholarly inquiry into the impact of a pedagogically informed intervention focused on ***pharmacy students*** around smoking and vaping cessation.

Phase 1

The rapid changes around vaping regulations introduced by the Australian government led to the regulated availability of NVPs at pharmacies. This issue became a subject of debate among health professionals, especially within the pharmacy profession. Given this debate, it was apparent that understanding the preparedness of pharmacists to supply NVPs was important. Several qualitative studies have explored the views of health professionals about the impact of these regulatory changes in Australia, but there have been no studies specifically focused on pharmacists and their viewpoints about therapeutic NVPs or their practice readiness for supplying these to consumers (2, 3). Therefore, the first phase of this MPhil research aimed to explore Australian pharmacists' perspectives about facilitating pharmacy-based vaping related services in-depth.

As outlined in Chapter 3, qualitative methods were employed and interviews with 25 practising pharmacists conducted. Interview audio recordings were transcribed verbatim and subjected to an inductive thematic analysis. Three key themes emerged from this exercise and included:1) *risk perception*, 2) *professional vaping health-related services*, 3) *professional practice* and *other support-related needs*.

Pharmacist participants raised concerns about the risks and safety of NVPs, given that long-term health impacts were still not known. Regardless, this apprehension about

NVPs overshadowed, in most cases, the pharmacists' recognition of having a duty of care to educate consumers about the risks and harms of vaping. Many pharmacist participants recommended a need for resources and guidelines for assessing and referring consumers requesting NVPs.

Phase 2

Given that pharmacist participants emphasised the need for training, the research team deliberated over '*how*' and '*to whom*' the training should be addressed. A pragmatic decision was taken to focus on undergraduate pharmacy students. As future pharmacists, if trained on the foundational aspects of nicotine dependence, vaping devices, vaping cessation resources and guidelines, these students could potentially implement successful vaping cessation services in the future. It was also deemed that training undergraduate students would be a powerful strategy, not just for future services, but for self-management and peer education, given that many students within the university age group were likely to have attempted vaping or have peers who actively used vapes. This phase, therefore, involved the development and implementation of an educational intervention module with second-year undergraduate pharmacy students.

This work was deemed relevant, given that while clear evidence about the positive impact of well-designed educational modules on pharmacy students' knowledge, skills and confidence in providing smoking cessation services exists (4-6), there are only a few studies which report on educational interventions around vaping services, and that too only overseas, not locally. For example, educational interventions conducted in high schools in Massachusetts and New Hampshire (2017) and Pittsburgh, US (2019-2022) were led by trained pharmacy students (i.e. outreach programs led by student pharmacists), and data collected clearly demonstrated that trained student pharmacists not only had an improved understanding of addiction to e-cigarettes but could effectively convey this information to younger students (7, 8). Such global studies highlighted the importance of developing and implementing a vaping focused educational module for pharmacist/pharmacy student education in Australia.

Our educational module, No-to-Nicotine (N2N), was underpinned by key pedagogical principles. The results of the N2N evaluation highlighted that pharmacy students participating in the N2N module demonstrated an improved understanding of clinical knowledge and displayed positive attitudes towards smoking and vaping cessation post-training (Chapter 4). Given that the N2N module implementation and analyses represented a pilot study, further refinement of the module is required to assess the clinical significance of successfully achieving smoking/vaping cessation by these students in future professional practice.

Note: In Chapters 3 and 4, the findings of the research in Phases 1 and 2 were discussed in depth. The following section is not a conventional discussion but aims to highlight the implications of the research findings as well as future directions research in this arena could embark on.

5.3 Implications of results from Phase 1

As mentioned earlier in Section 5.2, in our initial research exercise, pharmacists' views around NVP provision were explored using qualitative methods. Embedded within the themes derived from the analysis, there was a lack of confidence in clinical awareness and delivery of vaping-related health services reported by participating pharmacists. As discussed in Chapter 3, pharmacist participants highlighted that the changing landscape of the Australian government's introduction of measures to restrict the availability of NVPs was a key reason, among others, for this hesitancy.

To fully clarify why participants in Phase 1 of this MPhil research may have felt this uncertainty, a timeline of events and associated factors that influenced vaping reforms in Australia is provided in the section below.

5.3.1 *Evolution of Australian Vaping Reforms*

Period 1: *Up to 2017*

The access to and use of vapes in Australia have been the subject of interest from many stakeholders. Relevant stakeholder groups, including industry, consumer and healthcare bodies, have held and publicised widely differing views on NVP availability. Prior to the vaping reforms, NVPs were classified as Schedule 7 (Dangerous Poisons). This meant the sale or supply of NVPs was illegal in Australia; however, a prescription allowed the overseas procurement via the Therapeutic Goods Administration (TGA) personal importation scheme. The personal importation scheme gave authorisation from the TGA for an individual to import a maximum of three months' supply of a NVP for unapproved therapeutic use (9). These restrictions on NVPs were labelled as being a 'sensible harm reduction approach' by healthcare bodies such as The Royal Australasian College of Physicians (RACGP) and the Thoracic Society of Australia and New Zealand (10). In the lead up to the vaping reforms, industry and consumer groups attempted to influence the shaping of legislation around vaping in Australia (11). For example, consumer groups such as the New Nicotine Alliance applied to the Therapeutic Goods Administration in February 2017 to exempt nicotine in e-cigarettes from Schedule 7. The TGA at that point in time reached a decision that NVPs would remain as Schedule 7, thus rejecting the application (12). The tobacco industry, such as that represented by Philip Morris Ltd., is believed to have been involved over several preceding years in political lobbying through donations, meetings with policymakers and presentation of submissions for legislative review, pushing for the introduction of the retail sale of e-cigarettes and other heated tobacco products (11, 13).

Period 2: *2017-2021*

Leading up to this time, vaping behaviours in Australia followed global trends, raising concerns about an increasing national prevalence. The prevalence of ever use of NVPs among 14 years and older Australian smokers and non-smokers had nearly doubled from 4.5% in 2013 to 8.8% in 2016 (14). This increasing prevalence of vaping prompted the Minister for Health to call for an investigation of vaping trends in Australia. In October

2017, the Australian government commissioned an inquiry to investigate the use and marketing of e-cigarettes and personal vapourisers, led by the Standing Committee on Health, Aged Care and Sport (15). The tobacco industry and consumer groups favoured the relaxation of regulations; however, healthcare bodies supported the status quo (keeping NVPs on Schedule 7), leading to contrasting submissions being presented to the inquiry. The outcome of the inquiry was that the current regulatory model at the time of the inquiry was upheld, i.e. NVPs retained the classification as Schedule 7 medicines, with recommendations on developing frameworks and approaches to managing e-cigarette prevalence based on growing independent evidence on the public health impact of vaping (16). ***Interestingly, no peak pharmacy bodies participated in these submissions.***

In October 2021, following a notable increase in NVP use, particularly among adolescents and young adults, i.e., from 19.2% in 2016 to 26.1% in 2019, the Australian government announced further changes to vaping regulations, rescheduling NVPs from Schedule 7 to Schedule 4 (Prescription Medication) (14, 17). This meant that NVPs in Australia would be accessible in pharmacies with a valid prescription, with additional regulatory requirements for manufacturers to meet set product standards (18). Additionally, prescriptions would still allow for importation of NVPs in a quantity not to exceed three-months supply, as had been the case earlier when these products were listed on Schedule 7. Qualitative interviews, held in 2022 with 39 health professionals, including general practitioners and pharmacists, sought to examine the impact of Australia's prescription-based model of NVPs since the introduction of these changes (19). Healthcare professionals in this research study expressed confusion around either prescribing or dispensing NVPs amid the regulatory changes introduced by the Australian government (14). The study participants noted that the implementation of the prescription-based model could potentially inconvenience healthcare professionals amidst the uncertainty of evidence regarding the role of NVPs in smoking cessation (14), leaving them in a quandary about the appropriateness of prescription or benefit to users requesting NVPs. Research data from the study gathered from the very few pharmacist participants that had been included, particularly highlighted clinical uncertainty about

the benefits versus harms of vaping and hesitancy to supply NVPs (14). Notably, these data were evident prior to the down-scheduling of some NVPs (20mg/mL or less) as a pharmacist-only medication (Schedule 3), which later occurred in October 2024.

Period 3: *October 2024 to date*

The inclusion of some NVPs as Schedule 3 in October 2024 caused much heated debate among the pharmacy profession. Anecdotally, whilst some health professionals believed that the pharmacy profession itself had lobbied for this down-scheduling, this was not the case; more likely, political lobbying and negotiation influenced the loosening of restrictions on the Australian government's vaping reforms (20, 21). In fact, leading Australian pharmacy bodies, such as The Pharmacy Guild of Australia and The Pharmaceutical Society of Australia (PSA), opposed the provision of NVPs in pharmacies as Schedule 3. Both bodies issued statements stating that they were not involved in consultations with the government prior to the announcement of these changes (22-24). These statements were reinforced by major Australian pharmacy chains such as Chemist Warehouse, Priceline Pharmacy and TerryWhite Chemmart (25). The major reason for this opposition was the concern about the liability that pharmacy businesses would have to carry in the provision of NVPs (stock maintenance, consumer assessment, counselling and managing consumers not deemed suitable for NVP use) as well as the risks to individual health amid the limited evidence about the NVP Schedule 3 provision (25). Pharmacy professional organisations believed that this would diminish the pharmacists' professional role in promoting health due to the addiction potential of nicotine-containing vapes, along with other risks. ***These views and dissatisfaction with the current scenario were clearly reflected across the data we obtained from our pharmacist participants during our Phase 1 interviews.***

While there was significant opposition in the pharmacy profession to NVP provision as Schedule 3, there were some proponents of this change. These proponents proposed a *harm minimisation* stance and suggested that, while the prescription-only model was seen as inhibitory, consumers would more likely use the Schedule 3 pharmacist-provided NVP model, with the advantage that these patients would receive professional care and

support for smoking/vaping cessation. Meanwhile, the highly regulated environment of the pharmacy landscape would curtail access to NVPs for recreational use only. The shift from a prescription-only model would reduce medical burden for NVP-prescription related consults (26, 27).

Harm reduction services provided by pharmacists have been much discussed in the literature. For example, a 2016 systematic review and meta-analysis concluded that needle syringe programs provided by pharmacies were more effective in reducing patient risky behaviours among people who inject drugs compared to those who did not access such pharmacy services (28). Another harm reduction service available to Australian pharmacists is the supply of naloxone to reverse the effects of an opioid overdose. Similar to NVPs, naloxone was downregulated to a Schedule 3 medication for the same reasons of accessibility with pharmacist overview and prevention of harm (29). Similar models around pharmacist-led naloxone supply have been studied in other countries, for example, in Canada (30). Canadian pharmacists have been able to provide pharmacy-dispensed naloxone to prevent opioid overdose related deaths. Erku et al. (2021), in a systematic review of evidence, pointed out that since NVPs could potentially support smoking cessation, having them available through pharmacies as Schedule 3 would help enhance smoking cessation rates, though, of course, the onus would be on pharmacists supplying products to ensure that smoking cessation trajectories for those using NVPs for this purpose were progressed. These authors laid out practice recommendations for potential pharmacist interventions for this purpose (31). This viewpoint, which came to pass in October 2024, could well support pharmacists in becoming adopters for Schedule 3 provision with a vision of providing a harm minimisation service, much like the provision of nicotine replacement therapies already in place in pharmacy.

5.3.2 *Barriers in NVP Provision*

Hesitancy

Apart from the rapid changes and debate around the change of regulations allowing Schedule 3 access to NVPs, the lack of role clarity, self-reported by participants from our

qualitative interviews in Phase 1 of the MPhil also likely stemmed from, at least, in some part, the lack of robust evidence to support NVP use as a smoking cessation aid. Our participants preferred evidence-based treatments such as nicotine replacement therapy (NRT), varenicline and bupropion, which they were familiar with and could confidently counsel a patient with reference to appropriate guidelines. However, the clinical benefits of NVPs as smoking cessation aids versus the harms they could cause is what likely left our pharmacist-participants in Phase 1 in a difficult decisional balance.

Such perspectives may also be prevalent amongst consumers. A qualitative interview study reported from the United Kingdom (UK) focused on perceptions of risks and harms of vaping among 50 vapers (aged 16-26), comprising current cigarette smokers, non-smokers and never-smokers. These results implied that there were mixed community views on vaping, with some individuals perceiving it safer than smoking, while others acknowledged that vaping nicotine containing products could be risky as well (32). Similarly, in an Australian context, an online survey conducted in 2022 assessed the perceptions of vaping among adolescents and adults aged 12-25 years (26). Those who vaped had a more favourable view of vaping, as they perceived it to convey social benefits, while those who did not vape perceived it to be harmful, with mixed views on the role of NVPs for smoking cessation (33). This reflects the differing opinions on vaping, which pharmacists would need to dispel during counselling consumers about using NVPs. **Given the regulatory changes now allow the possibility of over-the-counter pharmacist-provided NVPs (i.e. Schedule 3) moving forward, pharmacists would certainly need to develop confidence in NVP provision. This requires professional organisations and training institutes to work together to help address barriers to this new role.**

These concerns, cited by participants in our Phase 1 interviews, were not dissimilar to the views of other health professionals reported in the literature. A scoping review between 2003 and 2024 examining the experiences of health professionals, including pharmacists, in offering vaping cessation support (34). The authors utilised the theoretical domains framework [TDF] to code barriers/facilitators evident in the collated

data [this TDF framework identifies 14 domains that can influence behaviour change, for example, regarding the implementation of interventions, such as vaping cessation support] (35). It was evident that health professionals reported more barriers than facilitators. Data identified by authors relating to the domains of '*social/professional role and identity'* and *'beliefs about capabilities'* indicated that healthcare professionals were motivated to help with NVP use despite their discomfort in addressing the issue (34). However, the review collated a range of commonly reported barriers, mainly related to *capabilities* and conflicting *motivations*. These were also evident in our own participants from the Phase 1 interviews of this MPhil research project

Administrative Burden

It was evident across our Phase 1 qualitative data that there was a clear confusion about the different NVPs available and the logistics of the procurement process (36). This was not surprising, given that the process of dispensing an NVP, as shown below in Figure 5.1, particularly in the absence of actual products readily available on shelves, is rather confusing, compared to the normal dispensing process in community pharmacies (which would have much fewer steps).

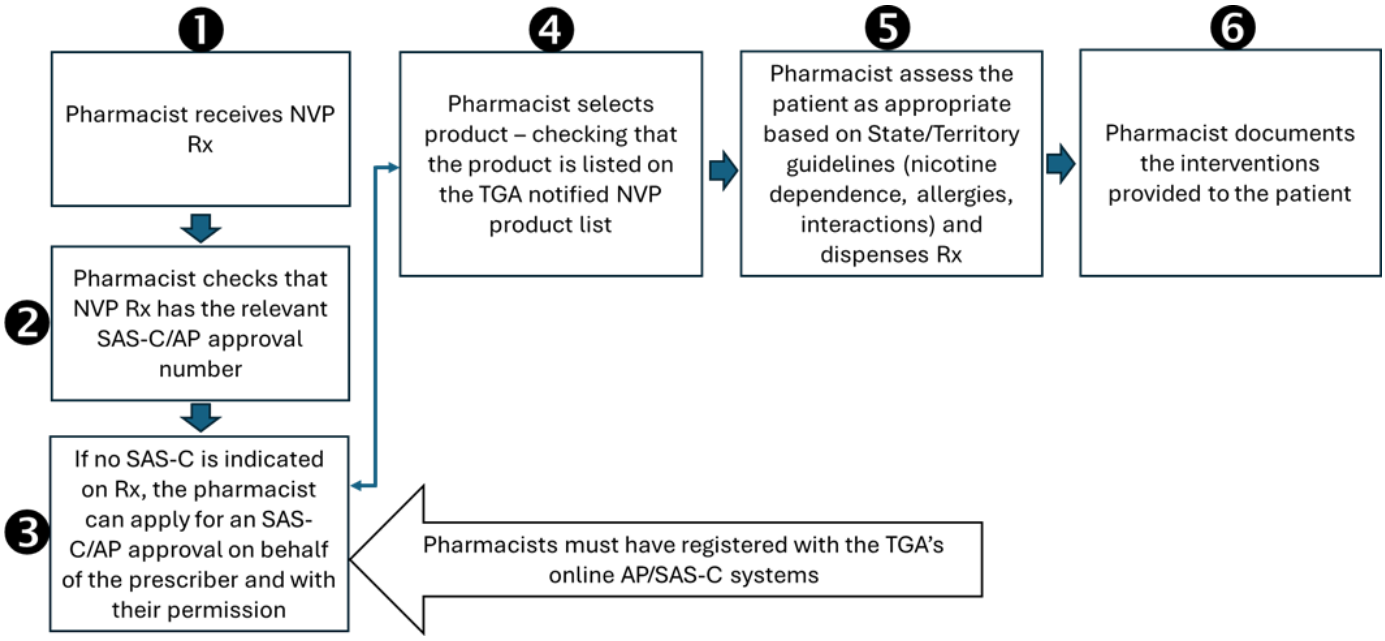


Figure 5.1: *Dispensing Process of an NVP Prescription*

AP: Authorised Prescriber

NVP: Nicotine Vaping Product

Rx: Prescription

SAS-C: Special Access Scheme C

TGA: Therapeutic Goods Administration

This administrative burden imposed by these processes was indeed one key issue discussed by participants in our Phase 1 interviews. Other Australian health professionals have raised the same procedural complexity as a barrier in the therapeutic use of NVPs. For example, in a study conducted with 13 Australian general practitioners at the point when NVPs were listed as Schedule 4, the administrative burden in NVP supply was raised by study participants. (19). Although our Phase 1 interviews were conducted ahead of the down-scheduling of some NVPs to Schedule 3, it may be hypothesised that this too would have led to the same level of additional administrative procedures for pharmacists regarding NVP provision (Figure 5.2) (36).

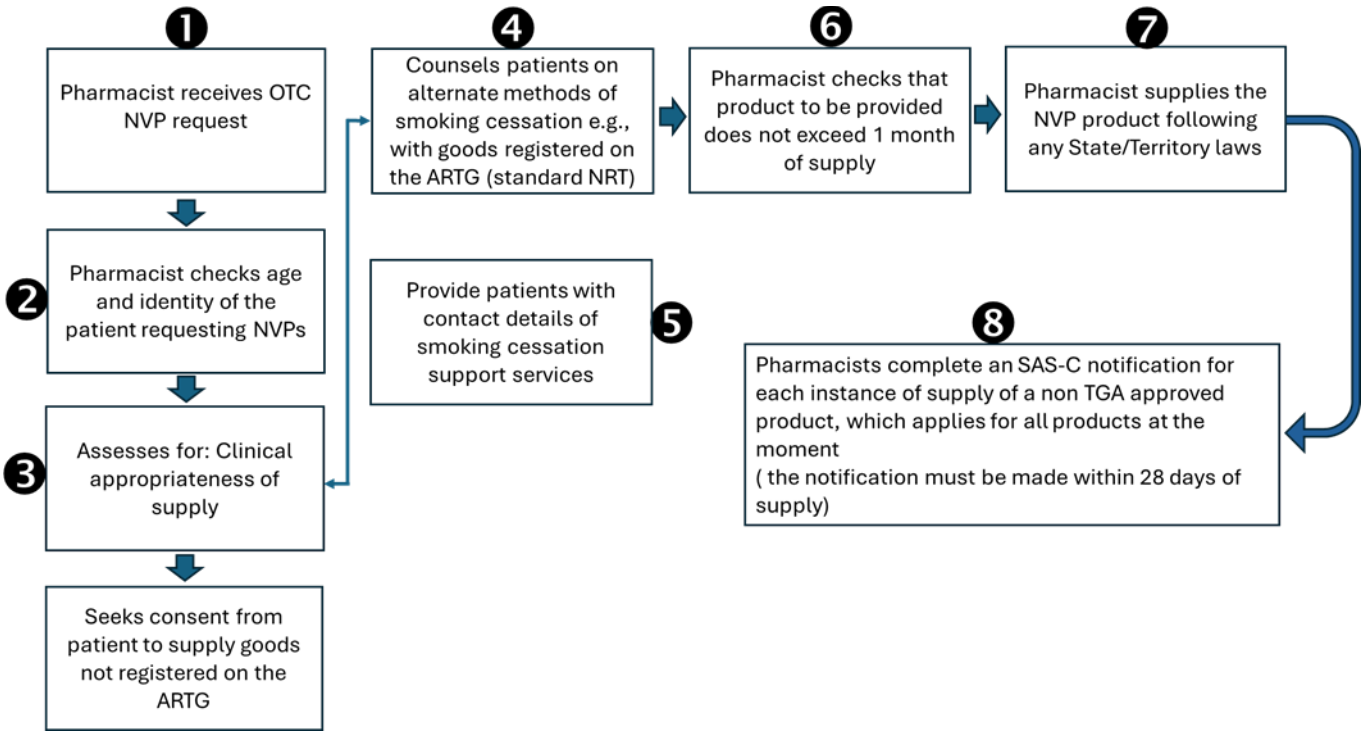


***Figure 5.2**: Schedule 3 NVP Provision Administrative Processes*

ARTG: Australian Register of Therapeutic Goods

OTC: Over The Counter

NRT: Nicotine Replacement Therapy

NVP: Nicotine Vaping Products

SAS-C: Special Access Scheme C

The Pharmaceutical Society of Australia has released guidance on how to handle pharmacist-only (i.e., Schedule 3) requests to help pharmacists navigate the professional and legal frameworks to ensure appropriate supply (37, 38). However, it is likely that the uptake and provision of NVP based non-prescription supply will still have burdensome administrative requirements. Notably, pharmacist participants in our Phase 1 study had already expressed process-related concerns about Schedule 4 supply; it is highly likely that Schedule 3 would increase this apprehension. Whilst of course this is yet to be explored (our Phase 1 occurred prior to the down scheduling timeline), ***a recommendation would be to provide pragmatic, translatable pocket-guides for pharmacists rather than formulaic process outlines.***

Clinical Complexity

Apart from the procedural issues, our participants in Phase 1 had also raised their lack of awareness or confidence in NVP product knowledge. Different emerging generations of vaping devices have been manufactured and have variable sizes, battery operations and customisation features (39). Compared to most conventional NRTs, especially patches, user vaping behaviours may determine bioavailability, for instance, the topography of the vape inhalation (40, 41). This implies that clinical prediction of required doses, treatment effect measurement and dose titration would be quite difficult and require expertise for clinicians to make appropriate decisions. Further, if NVPs are prescribed to a first-time user, pharmacists would need to check dosage levels and instruct on inhalation techniques. With the array of available devices, mastering these skills would be quite time consuming and require hands-on practical training.

Another clinical skill required in NVP-based smoking cessation services and consequent vaping cessation services would be accurate assessment. Pharmacists have been evidenced to provide effective smoking cessation services. In most cases, such services include an assessment of nicotine dependence, targeted NRT dosing, behavioural support and coaching and regular follow ups (42-44). This was demonstrated in a study which reviewed smoking cessation interventions delivered by pharmacists in eight community pharmacies in Portugal between 2009 and 2019 (36). In these pharmacies, pharmacists were trained to initiate smoking cessation services with nicotine dependence assessment, then provide treatment (NRT), use motivational and behavioural approaches and provide regular follow ups (45). It was evident from the review that pharmacists' interventions significantly improved quit rates, and the best results were observed when patients had been provided NRT as well as a higher number of consultations and regular follow ups (36). This data bodes well for pharmacists' provision of NVP based services, be that for smoking cessation support or vaping cessation. ***However, it must be recognised that NVP-based services to support nicotine addiction services would be much harder***. Compared to vaping, it is difficult to discern the nicotine concentration inhaled into the body (46). Pharmacists would need to determine the frequency of vaping and the depth of the puffs taken by the individual, as well as the NVP device used. This introduces a complexity affecting nicotine addiction and dependence to determine appropriate clinical use for NVP provision.

A validated tool, such as the modified Hooked on Nicotine Checklist (mHONC), could be a valuable resource for pharmacists to use with NVPs (47). The mHONC has been used to determine nicotine dependence and includes items such as time to first vape in adolescents, similar to the Fagerstrom checklist for nicotine dependence (48). Guidelines from the Royal Australian College of General Practitioners (RACGP) have been released on assessing nicotine dependence using mHONC (49).

Ethical concerns

Of course, we have focused on the current level of clinical hesitancy, expressed by study pharmacists in being able to supply NVPs based on a decisional balance of harms versus

benefits of NVPs in people who are current smokers willing to quit versus those simply seeking NVPs recreationally, as a training issue. However, it can be argued that some hesitancy to provide NVPs in the case of pharmacists may be appropriate.

From the principle of justice/equitable health care provision, it is likely that pharmacists may be worried about NVP provision in case it is not used as intended – i.e. used for nicotinic effect rather than as an aid to cease smoking; however, refusal to supply may withhold something that is potentially effective from a consumer who is motivated and keen to quit cigarette smoking.

Thus as highlighted above, pharmacists need to be provided with practical, hands-on training to improve their clinical skills in vaping support services including in ascertaining the suitability and appropriateness of consumers to whom NVPs should be supplied (e.g. when NVPs are requested without a prescription). Training on clinical skills should expressly cover ethical decision making and duty of care concepts in addition to the pharmacological, therapeutic and regulatory aspects.

5.3.3 *Precedents that may support NVP service roll out in pharmacies*

Interestingly, the circumstances around NVP supply can be paralleled to the Australian Health Care System regulation and access pathways for medicinal cannabis (MC). Notably, of course, MC use has been tried across several clinical conditions (unlike NVPs which are recommended for one issue only- i.e. nicotine dependence). Further NVPS are a modern formulation, however cannabis has been used as a traditional medicine or in sociocultural practices in some cultures for a long time. Nonetheless the implementation challenges around supply are quite comparable.

There is limited evidence for the use of MC in general; however, there is some data in the treatment of some specific medical conditions, such as multiple sclerosis and epilepsy and in refractory chronic non-cancer pain or nausea and vomiting in patients receiving

chemotherapy (50). In Australia, a general practitioner may prescribe MC as a treatment option when other conventional routes have been unsuccessful, in accordance with the protocols outlined by the TGA. The decision by the TGA to downregulate certain low-dose (to a maximum of 150mg/day) cannabidiol (CBD) products to Schedule 3 Pharmacists Only medicines in 2020 was prompted by efforts to improve accessibility. As such, pharmacists are tasked with managing access to the public. Despite these legislative changes, there is yet to be a low-dose CBD product successfully registered by the TGA for use in this manner, exactly similar to the current therapeutic NVP scenario (51). As in the case of NVPs, pharmacists expressed a lack of confidence and clinical uncertainty towards medicinal cannabis supply amidst the complex nature of the regulatory framework (52). A systematic review of 26 studies which focused on health professional perspectives surrounding MC, including general practitioners and pharmacists in 2018, highlighted similar issues (53). Participants expressed concerns about patient harm and risk for potential recreational abuse, and the authors concluded that there was a need for clarification of evidence-based guidelines for the provision of MC (54). A cross-sectional survey conducted in 2021 (n=217) also explored Australian pharmacists' perspectives towards MC and reported low levels of confidence from pharmacists handling MC enquiries (55). Health professionals, including pharmacists, have indicated that more education and training are needed to alleviate concerns and increase confidence when discussing the use of MC with patients (54). Similar to MC, the generation of evidence-based practices and guidelines for vaping would likely alleviate concern and improve pharmacists' confidence. Clearly, the qualitative data gathered with pharmacist participants in our Phase 1 study reflected the same need for building clinical competence with NVP supply.

Given that the down-scheduling of MC to Schedule 3 has preceded NVP down-scheduling, there may be key lessons to learn from the MC saga. The down-scheduling led to a high level of demand from consumers at pharmacies, where pharmacies/pharmacists did not have supply options, however this issue occurred only for a small period of time after MC down-scheduling was publicised by the media. Access from pharmacies without a prescription is still evidently the most frequent pathway

utilised by consumers. In general, though it appears that Australian consumers prefer higher accessibility but prefer prescription-based and evidence-supported use of MC (56, 57). This implies that, in the case of NVPs, pharmacists can refer patients to prescribers when there is clinical uncertainty, and this may be acceptable to consumers.

In the case of MCs, the emergence of specialised MC pharmacies has been a noticeable market model. In this model, a few specialised pharmacies within a geographic area (or even wider through use of digital technologies) choose to specialise in MC. These specialised services may comprise compounding formulations (as there are few TGA approved MC products available), as well as developing patient education materials (58, 59). Pharmacists may choose to use the services of these pharmacies for their patients who request MC products. Similar models can be foreseen for therapeutic NVP provision in pharmacies, and these were already evident in our Phase 1 interviews, where a few participants worked in pharmacies that had specialised in NVPs. Of course, there may be ethical dimensions in limiting the market to a few specialised pharmacies, particularly as patients may be regular customers at their pharmacy and have a working relationship of trust with their own pharmacist (56). Professional oversight and review for specialised pharmacies may be required in this case.

5.4 Implications of Results from Phase 2

Given the legislative development in the NVP space, it is likely that current undergraduate pharmacy students will manage NVP enquiries regularly in their practice as fully registered pharmacists. As such, this thesis explored the impact that educational initiatives would likely have on knowledge and confidence. As discussed in Chapter 4, a scholarly inquiry exercise, which involved the development and implementation of an educational intervention module, No-To-Nicotine (N2N), was undertaken. The N2N module was a pedagogically informed module which was carefully designed with strategic alignment between learning objectives and assessment of outcomes. The results of implementing this module with a cohort of second-year undergraduate students indicated, in a pre-post study, that the module increased knowledge, skills and

confidence among pharmacy students in providing smoking and vaping cessation services. Student participants highlighted the importance of learning about the pharmacy practice practicalities of nicotine addiction, cessation resources and guidelines with a focus on pharmacist roles in the provision of smoking and vaping cessation services.

5.4.1 *Currency of Pharmacy Practice Education*

One of the challenges in pharmacy curricula is the need to adapt to the dynamic healthcare environment. Pharmacy educators must stay current with the latest practice guidelines and regulatory frameworks that impact the pharmacy profession, as pharmacy students are expected to be proficient in these areas for future practice. Clearly, the regulatory framework developed and implemented by the Australian government aimed to curb the rates of NVP use, as a harm minimisation approach to support those who were using NVPs for smoking cessation or had become dependent on NVPs, so that could be safely supported to address this dependence. These policies (prescription-only and pharmacist-only access) have required pharmacists to practice in accordance with the guidelines and regulations regarding the handling of pharmacy-related vape requests.

While it is necessary to ensure pharmacy education encompasses topics such as the therapeutic use of vaping and pharmacist NVP provision, there should be a continual and balanced focus on the risks and harms of smoking combustible tobacco cigarettes. In the furore over NVPs, perhaps smoking cessation support for conventional smoking may be relegated to the background. Our data from participating students in Phase 2 of the pre-post educational intervention study clearly indicated that students were more knowledgeable about vaping compared to smoking, and the module allowed for ‘higher’ gains in the conventional smoking aspect as well as for NVPs. Smoking cessation or reduction has led to improved health outcomes, with evidence indicating benefits for both respiratory and cardiovascular health (60).

Pharmacy practice education in smoking cessation, aided by evidence-based pharmacotherapy and tailored to individual patient experiences, stimulates the delivery of practical pharmacist-led interventions. In the United Kingdom, a survey of pharmacy training programs examined the quality of smoking cessation education being delivered in 21 undergraduate pharmacy schools (49). While there was a focus on nicotine replacement therapy, behavioural support and pharmacotherapy, there was limited training of students with practical skills for smoking cessation (61). The practicality of providing smoking cessation interventions utilising the knowledge taught is an important skill for future pharmacists in professional practice settings. In other words, curricula need to be able to help future pharmacists in bridging the knowledge-practice gap. There has been a lack of formal smoking cessation training among overseas pharmacy students (Malaysia and Saudi Arabia), which has highlighted the absence of an adequately trained workforce to support patients in their smoking cessation journey (62, 63). This has led to pharmacy students in these settings being unprepared with sufficient clinical knowledge and practical skills to handle proficiently pharmacist-led interventions regarding smoking cessation.

5.4.2 *Adaptation into Education Curricula*

Given that nicotine-related education is recommended for implementation in pharmacy curricula, there is a need to incorporate interventional educational modules, such as the N2N module, across undergraduate healthcare disciplines. A systematic review of nicotine education and training for healthcare students, including medical, dental and nursing students, as well as healthcare practitioners, was conducted between 2006 and 2015 to analyse the inclusion of tobacco education and training. The analysis of 59 studies indicated an improvement in knowledge, attitudes, behaviours and skills through educational/training interventions for smoking cessation (64). These studies included quasi-experimental studies, cross-sectional studies and randomised controlled trials, some with a multidisciplinary scope, while others focused on a single healthcare discipline. The characteristics of education and training intervention studies involved the flipped classroom approach, self-directed learning and problem-based learning. This

highlighted the importance of maintaining and enhancing nicotine education across a multidisciplinary scope to address public health challenges of nicotine addiction and dependence.

Overall, though, there has been a scarcity of studies on the inclusion of vaping in nicotine education. In an online survey conducted with American medical students (n=259) in 2019-2020, to collate their views, experiences and perceptions of vaping and its impact on medical education, vaping medical education was regarded as inadequate. Students participating in this study reported that vaping knowledge was acquired from media outlets rather than the medical curriculum (65). This suggests that it would be important for vaping to be included in health curricula, so that students can gauge the accuracy of information publicised in the media compared to what has been learnt via pedagogical channels. Furthermore, a cross-sectional survey of 1406 nursing students from American nursing programs in 2020 revealed that there was no formal training on vaping in the nursing curriculum, with students being proficient in smoking cessation-related knowledge compared to managing vaping (66). This again highlights that the inclusion of vaping in relevant curricula is a crucial matter given the rising prevalence of vaping.

Current education on vaping, as evident in our scholarly inquiry effort, has been confined to pharmacy and respiratory educational programs; however, a module such as N2N can be adopted to varying healthcare disciplines, focusing on their professional educational needs and scope of practice. Nicotine education on vaping can broadly focus on a variety of areas in relevant disciplines. ***Differing perspectives on nicotine addiction and dependence, such as cardiovascular health, mental health, substance abuse, as well as efforts targeting vulnerable populations, such as culturally and linguistically diverse members of the community, can be added to the N2N as extensions.*** Of course, the N2N module focused primarily on respiratory health, given the limited scope of the Unit of Study it was embedded in.

Whilst the N2N targeted pharmacy students only, a strategic possibility would be to develop this program as an interprofessional learning activity. Interprofessional learning

would be important in portraying the management of nicotine addiction and dependence among healthcare professionals. In a pre-/post- test study design, pharmacy, nursing and social work students (n = 36) completed a training session on tobacco education in 2016. Based on student reflections post training, students reported improvement of knowledge and gained insight into the potential of collaborative multidisciplinary efforts (67). Indeed, other researchers have tested innovative teaching techniques such as escape rooms to solve nicotine dependence cases, with students reporting higher competencies post training on the topic (68). ***Thus, the adaptation of N2N to other areas of nicotine education and appropriate healthcare curricula could further enhance education and training around smoking and vaping cessation.***

It is clear that the implementation of the Schedule 3/Schedule 4 model for therapeutic NVP provision requires practice change. Pharmacists need to be able to view nicotine dependence as a whole, whether it involves conventional cigarette use or vaping products or other socio-culturally used formats (argileh, shisha, etc.). Whilst smoking cessation support services have been well established in Australian community pharmacies for a range of years, practice changes are required to include NVPs as a therapeutic modality to support nicotine replacement and be prepared to support NVP use cessation as well.

Practice change is always problematic. In the case of NVP provision and as reported by the participants in Phase 1, training, incentivisation, and reimbursement for services provided need to be thought through. There are only a few pharmacist-provided services that attract a reimbursement fee from Medicare (the Australian national insurance scheme funded by the government through tax levies), for example Home Medicine Reviews (69). Indeed, this point is a recurring theme across many practice-based exploratory studies across the spectrum of service provision. At the moment, for a pharmacy to provide NVP services, they would need to have an investment in training a range of staff including familiarity with the pragmatic aspects of the required administrative protocols. They would need to have agreements with suppliers when seeking NVP products and set aside space in the pharmacy consultation room for service

provision (assessment questionnaires for nicotine dependence and holding a range of demonstration products to demonstrate usage skills to consumers). While the provision of NVPs cannot be advertised, pharmacists will need to devise approved and legal methods of creating awareness of their services to support patients who are nicotine dependent. Finally, as part of this service re-think, strong collaborative relationships would need to be built with prescribers and other health professionals in the area. Of course, such investment is costly, hence pharmacy business owners would need to be able to make decisions about recouping costs – e.g. service fee or via pricing of the products supplied. This service re-think from conventional smoking services to an inclusive approach to nicotine addiction requires a high-level approach, for example as proposed by Aly et al. for minor ailment services by community pharmacies in Australia(70).

Given the difficulty of undertaking this practice change, it would be worth exploring models of behaviour change which can be used as frameworks to develop, implement and evaluate smoking and vaping cessation support services.

5.5 The COMB and BCW Model

Pharmacists can supply NVPs for appropriate clinical needs; however, it appears there has been little uptake. The COM-B model may offer a framework for diagnosing barriers in professional pharmacy practice in terms of NVP supply (71). This framework suggests that three primary factors influence behaviour (B): capability (C), opportunity (O) and motivation (M). To engage in such behaviour change, these three factors influence an individual's ability to perform this behaviour (B), such as pharmacist NVP provision (71). The application of the COM-B framework would enable an understanding of how pharmacists can be encouraged to adopt the provision of NVPs in a safe manner, while minimising nicotine exposure risk for individuals and successfully facilitating smoking and vaping cessation.

The Behaviour Change Wheel (BCW) is an extension of the COM-B model that enables

the development of effective behaviour change (72). The BCW consists of three layers: sources of behaviour, intervention function and policy categories (72). The sources of behavioural barriers stem from the COM-B model. The intervention function refers to the nine interventions that would be needed to address these sources of behavioural barriers. These intervention functions include coercion, education, enablement, environmental restructuring, incentivisation, modelling, persuasion, restrictions and training. The policy categories comprise 7 types of policies that can support these intervention functions. Such policy categories in the BCW are communication/marketing, environmental/social planning, fiscal measures, guidelines, legislation, regulation, and service provision (72). Table 5.1 outlines the factors related to COM-B, identifies the policies and interventions and suggests potential applications that can inform pharmacists on how to best deliver vaping-related professional services.

5.5.1 *Capability*

Capability refers to the physical and psychological components, including knowledge, skills and ability influencing behaviour (71). As mentioned by pharmacist participants, only very few of them have had experience dispensing NPVs due to limited exposure and availability in pharmacies. This lack of clinical confidence may be a *capability related barrier* to changing practice behaviours. Clarity of clinical and regulatory guidelines from professional bodies could potentially alleviate such concerns, with *education and training* on how pharmacists can best handle NVP requests, either on prescription or as pharmacist-only medication. As such, the implementation of workshops and seminars by pharmacy professional bodies would aid in the education and training of pharmacists. For example, the Pharmaceutical Society of Australia (PSA) has provided some guidance on the role of NVPs in cessation, which pharmacists can navigate through the training module about vaping (73). This training module could be a template for future workshops and seminars on vaping where intervention functions such as *education, training and modelling* could be used to address this capability.

The diverse range of vaping devices can be compared to inhaler devices used for asthma,

where there is evidence of pharmacist education on inhaler technique improving consequent patient inhaler use education by trained pharmacists. In a much-cited study reported by Basheti et al., a carefully designed workshop for pharmacists was implemented with 31 pharmacists. These pharmacists received training on asthma, inhaled medications and peak flow meter use to assess lung function. Pharmacists indicated that this skill-based training had a positive impact on their confidence and improved their ability to demonstrate the asthma inhalation technique to their patients (74). Similarly, training workshops on vaping targeted at pharmacists about dispensing NVPs on prescription or handling pharmacist-only requests could be developed to assist with the education and training of NVP provision. Additionally, guidelines and service provision policies would assist in the implementation of these intervention functions.

5.5.2 *Opportunity*

Opportunity refers to the external factors, including physical and social factors, prompting a specific behaviour (71). Physical opportunity barriers mentioned by participants in Phase 1 of the research suggested that a high workload and lack of consultation rooms, served to inhibit the actioning of NVP related services in many cases. The social norms around vaping being considered a trend, particularly among adolescents and young adults, warranted concern from pharmacist participants. Some pharmacist participants in Phase 1 of the research indicated that if they commenced NVP services, they would be viewed just as a retail point for NVPs. Hence, building public campaigns to challenge notions of the social acceptability of vaping would be useful. Another way of building social opportunities for pharmacists to provide meaningful clinical services would be to have promotional materials with well known and respected pharmacy professional leaders providing NVP services, serving to build a 'social opportunity' and perhaps as a 'modelling' type intervention. Having some pharmacies pilot *professional vaping services* and promote the initiative enables both pharmacists and members of society to see a shift towards pharmacists being promoters of smoking and vaping cessation.

Promoting models of pharmacy provided NVP services may also help other members of the profession shift forward in the adoption of this required service. The diffusion of innovations theory also serves this idea (75). When an intervention is first rolled out, there is often little uptake, except among early adopters who are comfortable with the newly proposed intervention (76). As this intervention is trialled and tested by these initial users, it encourages others to try it leading to a higher uptake , till it diffuses the entire population it was intended for, eventually becoming the status quo (75). This theory was used to frame process based data collection checking the barriers to implementing a pharmacist interventions (ask-advise-refer) to facilitate smoking cessation (76). The results indicated that the implementation of the intervention protocols to operational flows were a main impeding factor to implementation. By seeking to understand the factors affecting the diffusion of NVP services in pharmacies in Australia, it may be suggested that this theory could inform mixed methods research undertaken with early adopters of NVP service provision. Suggested policies that could be used to enable opportunity in pharmacist NVP provision could include the provision of pre-prepared communication/marketing toolkits.

5.5.3 *Motivation*

Motivation refers to automatic and reflective responses that are involved in driving the decision-making around the behaviour (71). Prior experiences of the down scheduling of naloxone supply caused pharmacist concerns about stigma, discomfort and unease, implying such behavioural responses may well impact uptake of NVP service provision through automatic motivation processes(77, 78). Again, promotional talks (webinars, panel discussions, etc) provided by early successful adopters of NVP and related services could help dispel this negativity.

A clear issue to address here to manage the 'automatic' motivation barrier to NVP service provision would be remuneration. In consultation with early adopters, a business case could be made to allow pharmacy proprietors to see how offering such services could be

cost effective at a systems level and also not cause financial loss at the individual business level. This could potentially allow pharmacist owners to allow the allocation of sufficient resources.

Reflective motivation involves a cognitive process of evaluation and decision making (71). Having early adopters talk throw their decision-making process and any resulting professionally satisfying cases (e.g. patients quitting smoking after commencing NVPs) may help motivate others through a reflective cognitive process.

Guidelines and clinical algorithms may also help pharmacy practitioners better reason through decisions to provide or not provide NVP services, highlighting the utility of the COM-B model as a behavioural diagnostic tool to identify and address barriers to change.

Table 5.1 highlights the application of this model to the pharmacy NVP service provision case study.

Table 5.1: *COM-B/BCW Adaptation of NVP Provision*

Behaviour	Barriers	Intervention	Policy	Application
Capability				
Physical	▪ Lack of availability of NVPs as stock for pharmacies ▪ Limited NVP prescriptions presented to pharmacies.	*Modelling* *Training*	*Communication* *Marketing*	▪ Having certain pharmacies providing NVPs as a pilot program and using their process to 'model' the service for other pharmacies ▪ Pharmacist training on NVP procurement/dispensing protocols
Psychological	▪ Confusion around evidence of the role of NVPs ▪ Unfamiliar with NVP regulations and guidelines	*Education* *Training* *Modelling* *Persuasion* *Incentivisation*	*Guidelines* *Service Provision* *Fiscal Measures*	▪ Workshops and seminars conducted by professional pharmacy bodies ▪ Inclusion of vaping in relevant curricula ▪ Professional framework for service provision of NVPs ▪ Government reimbursement for pharmacists for NVP services
Opportunity				
Physical	▪ Allocation of resources ▪ Lack of time	*Modelling* *Training*	*Environmental/Social Planning* *Regulation*	▪ Pilot trial of NVP provision in pharmacies ▪ Structural changes in pharmacy design/resources
Social	▪ Perceptions of pharmacy as a retail point for NVPs ▪ Clarity on professional guidelines on NVP provision	*Enablement* *Modelling*	*Guidelines* *Communication/Marketing* *Regulation* *Environmental/Social Planning*	▪ Collaboration among government and professional healthcare bodies ▪ Public health messaging, building image of pharmacists and pharmacy services ▪ Development of professional guidelines and resources

Motivation				
Reflection	▪ Concerns about the risks of NVP supply ▪ Prior experiences of pharmacy services (methadone)	*Education* *Training*	*Service Provision* *Guidelines*	▪ Educating pharmacies on the expanded scope of practice
Automatic	▪ Remuneration	*Incentivisation*	*Legislation*	▪ Introduction of a rewards system

NVP: Nicotine Vaping Product

5.6 Strengths and Limitations

The strengths and limitations of the two studies conducted in Phase 1 and Phase 2 of the project are presented in the manuscripts in Chapters 3 and 4, alongside the rationale behind the methodology in Chapter 2; some of the strengths and limitations are detailed briefly below.

In the qualitative study, a purposive convenience snowballing approach was used to recruit pharmacist participants, which may have introduced sampling bias. However, efforts were made to ensure a selection of pharmacists from diverse working backgrounds and experiences to provide a range of differing perspectives on the topic of interest. The interviews were conducted, and data analysis was carried out by the primary researcher, which may have introduced confirmation and researcher bias. However, the transcripts were generated from audio recordings and were double checked by the primary researcher for accuracy. Participating pharmacists did not confirm or validate finalised transcripts; this was mainly because of time constraints and busy work environments. Data analysis was repeatedly discussed with members of the research team, during which the final codes and themes were agreed upon, alleviating some of the confirmation and researcher bias. In addition, the findings of this study from a small sample of 25 pharmacist participants are not generalisable to the views of the pharmacist profession. Future studies would be needed to confirm the initial findings in this study relating to NVP provision.

In the quantitative study, a pre-/post-study design was used for pragmatic purposes, despite being a weak study design. The vaping questions in the N2N questionnaire were not previously validated, which could have influenced the validity of the questionnaire used in the study. However, evaluating the discrimination index values of the question items developed may help in assessing the validity of the questionnaire. While the post-N2N questionnaire was administered directly after the completion of the workshop, the knowledge retention results could potentially influence the outcome of the study. Hence, it would be important to assess sustained knowledge retention and application of information, such as in exams and practice provisions, to gauge the impact of this

educational intervention. In addition, the preliminary outcome of N2N was not reflective of all pharmacy students globally, being only tested in a single cohort at one university, despite being currently retained in the pharmacy curriculum.

A strength of both studies was that the research team had a diverse background with experiences in education, pharmacy, medicine, public health and research, all with expertise in smoking and vaping services. This assisted in limiting the subjective bias when approaching study design, data analysis and collection, which may have influenced study outcomes. Also, two checklists, COREQ and Cre-DEPTH, were utilised to establish trustworthiness in the studies and were adhered to where applicable.

5.7 Future Directions

The exploratory findings from the studies conducted provide the foundational work for future research around pharmacy and vaping related services. Initially, surveys about vaping perspectives and professional practice roles with pharmacy students and pharmacists were planned to be held after the qualitative interviews. However, due to time constraints, the semester's allotted time for MPhil study curtailed the administration of a national survey. The materials for the surveys have ethics approval and could form the basis of either an Honours or a PhD project, as seen in the Appendix Section D. This would enable a larger sample size to capture diverse perspectives of pharmacists around NVP provision and knowledge of vaping, building on the initial findings from the qualitative and quantitative study.

Another potential direction for this area of research would be to conduct another phase of qualitative interviews with pharmacists, given that some NVPs are now on Schedule 3. This would allow pharmacists with more experience in NVP provision to share their insights, as the participants in the interviews had limited experience with NVPs as Schedule 4. The findings from this future qualitative study would be able to clarify the perspectives of pharmacist participants in the initial qualitative study.

Of course, designing and testing a pharmacy based NVP service provision model in hybrid implementation-effectiveness study designs may be a useful future research direction.

The role of pharmacists around vaping could be investigated by developing standardised Consumer Medicines Information (CMI) leaflets about NVPs which are based on up-to-date evidence. Such CMIs would allow pharmacists an opportunity to provide current information about NVPs to the general public who use them, whether OTC or via prescription. Apart from this public health education mechanism, other public health approaches, such as harm minimisation, could be applied. For example, as done effectively in the case of conventional cigarette smoking, health warnings on NVP packages, and legislatively requiring plain packaging, may assist pharmacists, supplying or dispensing NVPs, to effectively synergise public health messaging about the harms and risks of vaping.

N2N could be conducted in other Australian universities with other pharmacy students, which would assist in the validation of the questionnaire. In addition, with evolving information, the educational module should be updated accordingly, tailored to the learning outcomes of the relevant year level and be incorporated as part of interprofessional learning. Pharmacy students who have participated in N2N previously could be tested again when they are practising as health professionals about vaping-related health requests.

In terms of training, while the N2N module indicated preliminary evidence of being effective in improving knowledge of university students surrounding vaping, the module itself could be separated logically and embedded in relevant Unit of Studies across the duration of the pharmacy degree. Knowledge and skills would be built gradually by exposing students to the harms and risks of lifestyle choices, leading on to the clinical impact of NVP exposure and subsequent application of this knowledge in practice while on placement. Of course, this planning requires curricular consultation and the 'buy- in' from a range of educators teaching into the BPharm Honours and Masters in Pharmacy Practice Degree. Future studies could

entail a longitudinal cohort design, where initial education provided, e.g. in the first year, could be assessed year on year, with 'gaps' then addressed in subsequent teaching exercises.

The future directions for this area of research should reflect the growing needs of pharmacists and pharmacy students regarding NVP provision. With regulatory changes and evolving information about vaping at the time of these studies, it is essential to stay up to date with current guidelines and protocols.

5.8 Conclusion

The qualitative research (Phase 1 of the MPhil) uncovered key barriers to the provision on pharmacy provided NVP services. Given that changed regulations permit pharmacists to supply NVPs either as a non-prescription or prescription product, such services will be an important public health-harm minimisation type service pharmacists will need to and should certainly offer. Whilst hesitant, a clear paradigm of 'duty of care' was apparent within pharmacist participants in Phase 1 of this work. This suggests that investments in this area of pharmacists' scope of practice are worth the effort. Clearly, many of the barriers evident from the qualitative phase of this MPhil work can be addressed by applying behaviour change models and designing strategic interventions to facilitate practice change using implementation science informed approaches.

The MPhil Phase 2 research undertook to address one of the barriers to pharmacy based NVP service provision i.e. education/training. The N2N model which was informed by robust pedagogical principles clearly demonstrated an improvement in knowledge in participating student learners. The N2N can be scaled to a national delivery level with minor modifications and readied for training not only for pharmacy students but pharmacists also. Of course this is one, but not the only solution to encouraging NVP service provision in pharmacies.

To conclude, this MPhil research has uncovered key barriers to practice change in terms of NVP service provision, identified several strategies to address them as well as developed and tested one such strategy with positive impacts. Further research to design and test service models for pharmacist delivered NVP related services are a much-needed direction for the profession. This would allow the generation of evidence based NVP service models that could be adopted nationally. Given the expanding harm reduction portfolio that pharmacists across professional settings in Australia deliver upon, NVP services would fit well within this realm of practice and add to their well-established roles in chronic disease management

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Appendices

Appendix A

Ethics Approvals

Appendix A1

Qualitative Study Ethics Approval

Research Integrity & Ethics Administration
Human Research Ethics Committee

Thursday, 21 December 2023

Dr Bandana Saini
Pharmacy; Faculty of Medicine and Health
Email: bandana.saini@sydney.edu.au

Dear Bandana,

The University of Sydney Human Research Ethics Committee (HREC) has considered your application.

After consideration of your response to the comments raised your project has been approved.

Approval is granted for a period of four years from **21/12/2023to 21/12/2027**

Project No.: **2023/748**

Project Title: **Exploring perspectives on professional roles and practice support needs of pharmacists and pharmacy students for vaping related health services**

Authorised Personnel: **Saini Bandana; Le David; Shah Smita; Bhurawala Habib; Rahman Muhammad Aziz;**

First Annual Report due: 21/12/2024

Documents Approved:

Date Uploaded	Version number	Document Name
27/11/2023	Version 2	Attachment A - PSA and Guild Clean Version
27/11/2023	Version 2	Attachment B - Project Advert Clean Version
27/11/2023	Version 2	Attachment G - PIS_Phase2(Surveys_PharmacyStudents) Clean V
27/11/2023	Version 2	Attachment K - Participant Consent Form Pharmacists Clean V
27/11/2023	Version 2	Attachment C - Interview Invitation Email Clean Version
27/11/2023	Version 2	Attachment E - PIS_Phase1(Interviews) Clean Version
27/11/2023	Version 2	Attachment F - PIS_Phase2(Surveys_Pharmacists) Clean Version
27/11/2023	Version 2	Attachment H - Pharmacist Vaping Interview Questions Clean V
27/11/2023	Version 2	Attachment D - Canvas Annoucement Clean Version
27/11/2023	Version 2	Attachment I - Questionnaire for Pharmacists Clean Version
27/11/2023	Version 2	Attachment J - Questionnaire for Pharmacy Students Clean V
25/09/2023	Version 1	External Declaration - Aziz
25/09/2023	Version 1	External Declaration - Habib

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Condition/s of Approval

- Research must be conducted according to the approved proposal.
- An annual progress report must be submitted to the Ethics Office on or before the anniversary of approval and on completion of the project.
- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:
  - Serious or unexpected adverse events (which should be reported within 72 hours).
  - Unforeseen events that might affect continued ethical acceptability of the project.
- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).
- Personnel working on this project must be sufficiently qualified by education, training and experience for their role, or adequately supervised. Changes to personnel must be reported and approved.
- Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.
- Data and primary materials must be retained and stored in accordance with the relevant legislation and University guidelines.
- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures and governance requirements.
- The Ethics Office may conduct audits on approved projects.
- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.
- The Clinical Trials Support Office has been notified as outlined in the University's Clinical Trials Policy where a clinical trial is being undertaken.

This letter constitutes ethical approval only.

Please contact the Ethics Office should you require further information or clarification.

Sincerely,

[redacted]

Associate Professor Helen Mitchell
Chair
Human Research Ethics Committee (HREC 1)

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The University of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council's (NHMRC) current National Statement on Ethical Conduct in Human Research (2018) and the NHMRC's current Australian Code for the Responsible Conduct of Research (2018).

Appendix A2

Quantitative Study Ethics Approval

Research Integrity & Ethics Administration
Human Research Ethics Committee

Wednesday, 20 March 2024

Dr Bandana Saini
Pharmacy; Faculty of Medicine and Health
Email: bandana.saini@sydney.edu.au

Dear Bandana,

The University of Sydney Human Research Ethics Committee (HREC) has considered your application.

I am pleased to inform you that your project has been approved.

Approval is granted for a period of four years from **20/03/2024** to **20/03/2028**.

Project No.: **2024/271**

Project Title: **Building skills in pharmacy students for delivering smoking and vaping public risk education and cessation services in future practice**

Authorised Personnel: **Saini Bandana; Shah Smita; Bittoun Renee; Le David; Saba Maya;**

First Annual Report due: **20/03/2025**

Documents Approved:

Date Uploaded	Version number	Document Name
02/02/2024		ATTACHMENT A - NO-TO-NICOTINE PIS_STUDENTS
02/02/2024		ATTACHMENT B - CANVAS ANNOUCEMENT
02/02/2024		ATTACHMENT C -NO-TO-NICOTINE Workshop Introduction Slides
02/02/2024		ATTACHMENT F -PRE-NO-TO-NICOTINE Survey
02/02/2024		ATTACHMENT G-POST-NO-TO-NICOTINE Survey

Special Condition/s of Approval

- Please consider the possibility that the cohort may contain students who are not yet 18 years, and consider if you need to amend data storage requirements accordingly.
- PIS - Please correct the reference to Animal Ethics in section 11.

Condition/s of Approval

- Research must be conducted according to the approved proposal.
- An annual progress report must be submitted to the Ethics Office on or before the anniversary of approval and on completion of the project.
- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:

- Serious or unexpected adverse events (which should be reported within 72 hours).
- Unforeseen events that might affect continued ethical acceptability of the project.

- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).

- Personnel working on this project must be sufficiently qualified by education, training and experience for their role, or adequately supervised. Changes to personnel must be reported and approved.

- Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.

- Data and primary materials must be retained and stored in accordance with the relevant legislation and University guidelines.

- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures and governance requirements.

- The Ethics Office may conduct audits on approved projects.

- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

- The Clinical Trials Support Office has been notified as outlined in the University's Clinical Trials Policy where a clinical trial is being undertaken.

This letter constitutes ethical approval only.

Please contact the Ethics Office should you require further information or clarification.

Sincerely,

Eszter Kalman
Chair
Low Risk Human Ethics Research Committee

The University of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council's (NHMRC) current National Statement on Ethical Conduct in Human Research (2018) and the NHMRC's current Australian Code for the Responsible Conduct of Research (2018).

Appendix B

Qualitative Study

Appendix B1

Email Invitation

Email Invitation for potential participants professionally known to researchers/interested in smoking/vaping cessation research

Dear 'name'

My name is David Le and I am completing a Masters of Philosophy at the University of Sydney under the supervision of Professor Bandana Saini (Sydney Pharmacy School) and Professor Smita Shah (affiliated with the School of Public Health at the University of Sydney). My MPhil research aim is to explore the perspectives of Australian pharmacists regarding vaping and vaping cessation services.

We would like to invite you to participate in an interview to explore your views on vaping related health services within the pharmacy setting. If you would like to take part in this interview, please fill in the attached participant consent form and email it to d.le@sydney.edu.au. A member of the research team will contact you to organise a suitable time to conduct the interview.

Of course, participating in this study is completely voluntary and non-participation will in no way affect your relationship with the research team members or the University of Sydney. We would also like to highlight that interview data will be de-identified prior to analysis and will not bear any links to you or your pharmacy. In appreciation of your time and commitment to the topic, we would like to offer you a 100 dollar Coles/Myer Gift voucher as a small token of appreciation for taking part in the interview. If you have any questions, please feel free to contact d.le@sydney.edu.au.

Kind regards,

David Le

Appendix B2

Participant Information Sheet: Pharmacists (Interviews)

Participant Information Statement – Pharmacists Phase 1 (Interviews)

Research Study: Exploring perspectives on professional roles and practice support needs of pharmacists for vaping related health services (Phase 1)

Professor Bandana Saini (Responsible Researcher)
School of Pharmacy, Faculty of Medicine and Health
Phone: +61 2 93516789 | Email: bandana.saini@sydney.edu.au
Mr David Le B.Pharm MPH (Student) | Email: d.le@sydney.edu.au

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1. What is this study about?

Evidence suggests that there is an increasing use of vaping products or e-cigarettes in Australia. Currently, discussions about the safety and use of vaping as a strategy for smoking cessation in established smokers attempting to quit are taking place in clinical, professional, and public health domains of Australian health care. Pharmacists have been important in the delivery of smoking cessation services and need to now consider vaping and vaping cessation support services. The professional, clinical information and practice support needed to undertake this new role are not yet established, nor are clear pharmacy-based practice guidelines for vaping cessation available. Therefore, we are conducting a research study to explore pharmacists' perspectives on vaping, and their practice support or information needs relating to vaping related health services. The findings of the study can be used to develop professional resources for practising pharmacists.

Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

2. Who is running the study?

The study is being carried out by the following researchers:

- Bandana Saini, Professor, School of Pharmacy, Affiliate Staff and Research Leader, Woolcock Institute of Medical Research
- Smita Shah, Clinical Professor, Faculty of Medicine and Health, Fellow of the Thoracic Society of Australia and New Zealand, Associate of the Woolcock Institute of Medical Research, Director, Prevention Education and Research Unit (PERU), Western Sydney Local Health District

- Muhammad Aziz Rahman, Professor, Research Adviser and Discipline Leader of Public Health, Institute of Health and Wellbeing, Federation University of Australia
- Habib Bhurawala, Doctor, Head of Paediatrics, Senior Specialist Staff, Nepean Hospital
- David Le, Pharmacist, School of Pharmacy, Student, Woolcock Institute of Medical Research

David Le is conducting this study as the basis for the degree of Masters of Philosophy at The University of Sydney.

This study has no funding; however, Mr David Le is being supported by a small scholarship based on a philanthropic donation to the Woolcock Institute of Medical Research. This donation specified scholarship support for a research student working in the health services area of smoking/vaping cessation in pharmacies.

3. Who can take part in the study?

The study involves exploring the awareness about and perceptions of participants around vaping to better understand how appropriate resources can assist in developing evidence based vaping related health services in the pharmacy context. We are therefore seeking registered and practising pharmacists to participate in this study.

4. What will the study involve for me?

If you decide to take part in this study, you will be invited to an interview which will take roughly 30 minutes. Participants will be asked to turn off their cameras for the duration of the interview, following initial introductions. These interview questions will focus on your perceptions about pharmacist roles in vaping cessation, clinical experience of handling vaping related queries from consumers, your opinion about vaping specific services in pharmacies and, information or resource needed to provide vaping related health services in pharmacies.

5. Can I withdraw once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision will not affect your current or future relationship with the researchers or anyone else at The University of Sydney.

If you decide to take part in the study and then change your mind you can withdraw during the interview by informing the researcher interviewing you. In this case, the interview recording will be erased and not used in the data. You may also choose not to answer specific questions during the interview. All interviews and interview transcripts will be stored using a code which will be maintained by one member of the

research team not actively involved in interviewing. Once the data collection is complete, the coding key will be destroyed, rendering the interview/transcripts unidentifiable after this point. It is expected that data collection will be completed within 6 months after your interview. Withdrawing after that time will not be possible, as your interview/transcript would have been completely de-identified.

6. Are there any risks or costs?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

7. Are there any benefits?

The research findings will help professional organisations and pharmacy educators to develop meaningful professional learning activities and practice guidelines on this topic and thus will be of indirect benefit to a current or future pharmacist professional.

Whilst not commensurate with your expertise or skills, we would like to offer you a 100 Coles-Myers gift voucher as a small token of appreciation for the time you would spend in participation.

8. What will happen to the information that is collected?

Any information you provide us will be stored securely and we will only disclose it with your permission unless we are required by law to release information. We are planning for the study findings to be published. You or the pharmacies you work in will not be individually identifiable in these publications. Only the de-identified interview transcripts will be used for analysis; the recording will not be used in any form in publications/presentations. Your interview recording and transcript will be stored electronically on a highly secure platform accessible to the University of Sydney staff/students only, using codes rather than individually identified file names. Only the research team members listed on this information sheet will have access to the folder where these materials are stored.

9. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. Please provide your contact details at the end of the interview if you are interested in receiving feedback. This feedback will be in the form of a brief summary of key findings.

10. What if I would like further information?

When you have read this information, the following researcher/s will be available to discuss it with you further and answer any questions you may have:

- David Le, d.le@sydney.edu.au

11. What if I have a complaint or any concerns?

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney Project Number: 2023/748 according to the *National Statement on Ethical Conduct in Human Research (2007)*.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the University:

Human Ethics Manager
human.ethics@sydney.edu.au
+61 2 8627 8176

This information sheet is for you to keep

Appendix B3

Participant Consent Form:

Pharmacists (Interviews)

Participant Consent Form – Pharmacist Interviews (Phase 1)

Research Study: Exploring perspectives on professional roles and practice support needs of pharmacists for vaping related health services (Phase 1)

Professor Bandana Saini (Responsible Researcher)
School of Pharmacy, Faculty of Medicine and Health
Phone: +61 2 93516789 | Email: bandana.saini@sydney.edu.au
Mr David Le B.Pharm MPH M.Phil Candidate (Student) | Email: d.le@sydney.edu.au

---

Participant Name _____

I agree to take part in this research study. In giving my consent, I confirm that that:

- The details of my involvement have been explained to me, and I have been provided with a written Participant Information Statement to keep.
- I understand the purpose of the study is to investigate risk perceptions and attitudes about vaping among pharmacists.
- I acknowledge that the risks and benefits of participating in this study have been explained to me to my satisfaction.
- I understand that in this study I will be required to complete an online interview via Zoom.
- I understand that being in this study is completely voluntary.
- I am assured that my decision to participate will not have any impact on my relationship with the research team or the University of Sydney.
- I understand that I am free to withdraw from this study at any time and that I can choose to withdraw any information I have already provided (unless the data has already been de-identified or published).

- I have been informed that the confidentiality of the information I provide will be protected and will only be used for purposes that I have agreed to. I understand that information identifying me will only be told to others with my permission, except as required by law.

- I understand that the results of this study may be published, and that publications will not contain my name or any identifiable information about me.

- I understand that after I sign and return this consent form it will be retained by the researcher and that I may request a copy at any time.

- I confirm the following:

  I consent to recordings (audio) Yes ☐ No ☐

  I would like a summary of the overall results of this study Yes ☐ No ☐

  If you answered **yes**, please provide your preferred contact details (email/telephone/postal address):

  _____

  _____

  _____

  _____

- I understand that after I sign and return this consent form it will be retained by the researcher and that I may request a copy at any time.

- Signed paper-based consent forms will be uploaded digitally and destroyed once they have been scanned and backed up and stored in the Research data store (RDS).

Participant Name _____

Signature _____

Date _____

Appendix C

Quantitative Study

Appendix C1

CANVAS Announcement

Canvas Announcement: Student Invitation

Dear students,

Do you know **everything about smoking**? What about **vaping**? **Are you confident in your ability to counsel a patient in the pharmacy about smoking/vaping cessation?**

This research project linked to your PHAR 2911 unit of study will be run by Mr David Le alongside Professor Bandana Saini and Dr Maya Saba. The focus of this project is to help you ***build clinical decision making*** and ***effective communication skills*** regarding ***smoking and vaping cessation services*** in order to ***assist patients*** with smoking and vaping-related requests presenting within community pharmacy settings.

The **smoking and vaping cessation module**, called **NO-TO-NICOTINE** will cover a suite of activities and resources including lectures, a hands-on workshop and self-assessment opportunities.

The researchers are very interested in finding out if this interactive module can make a positive impact in this important health area, therefore, your participation in this study would be very valuable to us and to the future of smoking and vaping cessation services in pharmacy practice.

Participation in the research project is ***voluntary and anonymous***. Whilst the **NO-TO-NICOTINE module** will be offered to all students as a **compulsory element** of your learning in **PHAR 2911**, for the purposes of the research project we will invite you to **complete and submit two online questionnaires before (Week 9) and after you sit the NO-TO-NICOTINE educational module (Week 10)**. You are to complete the questionnaires within class time; your tutors will allow 15-20 minutes for you to complete them. The questionnaires will be posted on Canvas with a link to complete them on an **online platform called REDCap**. The REDCap administrator will build an anonymising algorithm into the survey so that your student email is converted to a code

that can be matched between your responses at the two time points. This way none of the researchers will be able to identify any of the participants.

Participation by completing the questionnaires is NOT related to and will have NO impact on any assessment outcomes.

For more detailed information, please refer to the Participant Information Statement on Canvas.

If you have any questions, please email d.le@sydney.edu.au

We appreciate you taking the time to complete this survey and thank you for contributing to our study.

Appendix C2

Introduction to N2N Workshop

PHAR 2911- Pharmaceutics and Professional Practice

Invitation to participate in a research project -
Improving knowledge and attitudes about smoking, vaping and relevant cessation interventions among pharmacy students

THE UNIVERSITY OF SYDNEY

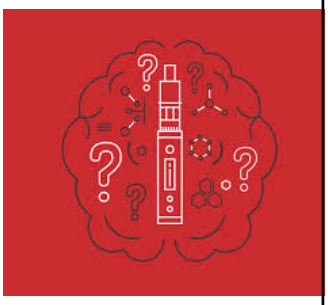
USER NOTE:
It is mandatory to include an 'Acknowledgement of Country' in your presentation. Please include this slide in your presentation.

We recognise and pay respect to the Elders and communities – past, present, and emerging – of the lands that the University of Sydney's campuses stand on. For thousands of years they have shared and exchanged knowledges across innumerable generations for the benefit of all.

THE UNIVERSITY OF SYDNEY

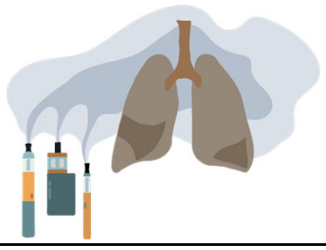
What is the project about?

- Do you know everything about smoking?
- What do you know about vaping?
- Can you counsel a patient on smoking/vaping cessation?
- **NO-TO-NICOTINE** Workshop.
- **TWO** questionnaires (Week 9 and 10)
- Participation has **no impact** on assessment outcomes.
- Participant Information Sheet QR Code.



Smoking and Vaping Importance

- Smoking is bad for your health.
- Pharmacists provide advice and support for patients who smoke to quit smoking.
- Vaping is on the rise. What are the health effects?
- What do pharmacy students know about smoking/vaping?
- Pharmacist's role in vaping education/cessation support?



Appendix C3

Participant Information Sheet

Participant Information Statement

Second Year BPharm(Hons)/MPharm Practice and
BPharm and Management (Hons)/MPharm Practice students.

Research Study: Building skills in pharmacy students for delivering smoking and vaping public risk education and cessation services in future practice

Professor Bandana Saini (Responsible Researcher)
Sydney Pharmacy School, Faculty of Medicine and Health
Phone: +61 2 93516789 | Email: bandana.saini@sydney.edu.au
Mr David Le B.Pharm MPH (Student) | Email: d.le@sydney.edu.au

1. What is this study about?

Given evidence of the harmful effects of smoking on human health, pharmacists currently provide health education and dispense prescription and non-prescription treatments to assist consumers who smoke to quit smoking. Vaping or the use of electronic cigarettes (e-cigarettes) involves the inhalation of vapourised nicotine and/or non-nicotine containing solutions through a vaping device. Whilst being a newer phenomenon compared to smoking, data on the impact of vaping on health is rapidly emerging. Similar to the case of smoking, pharmacists will be required to provide vaping-related health education, vaping cessation support and/or monitor the use of prescribed nicotine vape solutions. *It is important that pharmacy education programs effectively train learners to provide evidence-based services for people who smoke and/or vape.*

We are conducting a research study to assess the impact of an educational module for pharmacy students on their awareness of and confidence in providing smoking and vaping related health services. The module, named 'NO-TO-NICOTINE' will be offered in the PHAR2911 Unit of Study within the current undergraduate pharmacy degrees in the Sydney Pharmacy School to all students enrolled in the Unit of Study. The learning objectives cover health promotion, communication skills and over-the-counter treatment provisions. The module will include a 2-hour lecture and a 2.5-hour workshop supported by a range of clinically relevant resources.

Participation will involve completing a questionnaire both before and after you have participated in the NO-TO-NICOTINE module.

This participant information sheet outlines what you need to know about this research project. Knowing what it involves will help you decide whether you want to participate or not. By agreeing to fill in the questionnaire you would have:

- ✓ Provided consent to participate in this research project.
- ✓ Understood what this research project involves.

- ✓ Agreed to our use of the information you provide in the manner outlined within this participant information sheet.

Please read this sheet carefully and feel free to ask questions.

2. Who is running the study?

The study is being carried out by the following researchers:

- Bandana Saini, Professor, Sydney Pharmacy School, the University of Sydney, Affiliate Staff and Research Leader, Woolcock Institute of Medical Research
- Smita Shah, Clinical Professor, Faculty of Medicine and Health, the University of Sydney, Fellow of the Thoracic Society of Australia and New Zealand, Associate of the Woolcock Institute of Medical Research, Director, Prevention Education and Research Unit (PERU), Western Sydney Local Health District
- Maya Saba, Associate Lecturer, Sydney Pharmacy School, the University of Sydney
- Renee Bittoun, Professor, Nicotine Addiction Unit, Lifestyle Medicine Avondale University, Medical School University of Notre Dame; and Tobacco Treatment Specialist Consultant
- David Le, MPhil Candidate, Sydney Pharmacy School, the University of Sydney, and Woolcock Institute of Medical Research; and Pharmacist

Mr David Le is conducting this study as the basis for their degree of Master of Philosophy (MPhil) at The University of Sydney. Mr David Le will be involved in inviting you to participate and later collecting anonymous data from the online completed questionnaires for those who choose to participate. Mr Le is in no way involved in any assessment aspect of this Unit of Study (PHAR 2911) and does not hold an academic position within the Sydney Pharmacy School.

3. Who can take part in the study?

We are seeking students enrolled in the PHAR 2911 Unit of Study in Semester 1, 2024.

You have been invited to take part in this study because you are a Bachelor of Pharmacy (Honours)/Master of Pharmacy Practice or a Bachelor of Pharmacy and Management(Honours)/Master of Pharmacy Practice student currently enrolled in the PHAR 2911 Unit of Study. Invitations to take part in this study are being made available on your student Canvas site which is accessible only to enrolled students.

Participation in this research study is completely voluntary. Participation or non-participation is in no way linked to any assessable components of the Unit of Study. The 'NO-TO-NICOTINE' module will be offered to ***all*** enrolled students as a key part of PHAR 2911, ***regardless of your participation in the research.***

4. What will the study involve?

If you decide to take part in this study, you will be asked to fill out a study questionnaire twice, in Weeks 7 and 10 of the academic semester(Semester 1, 2024). The questionnaire will ask you some demographic questions about yourself, document your clinical awareness around and confidence in providing smoking and vaping cessation services. This will involve answers to some questions (True/False/Don't Know or Multiple Choice or Likert scale). It will take about 15-20 minutes to complete each questionnaire (30-40 minutes altogether to complete both questionnaires) and this will be carried out in your normal tutorial time within an online platform called REDCap that is independent to Canvas. You will be emailed a unique link to complete the questionnaire by Mr David Le prior to your scheduled tutorial class. If you choose to participate and use this link to complete and submit the questionnaire, the submitted questionnaire will be assigned an automatic code for de-identification (by REDCap) so your email is not visible. The coding key will not be visible to the researchers – only a REDCap administrator independent to the research team will be able to access this. The purpose of using your student email is so that the same code can be assigned to your surveys in Week 7 and 10 by REDCap, allowing us to compare data prior to and after the delivery of the NO-TO-NICOTINE module. This will allow us to see if there were any changes in students' awareness about or confidence in providing smoking and vaping health services after participating in this clinical module.

The questionnaire will not require you to reveal your name or Student Identification Number (SID). Researchers will only see the de-identification code generated for any completed survey. Your coordinator or facilitators/tutors will not be present in the room during this data collection process and will not access any data collected during the study, except in a summary form provided to them by the researchers. ***This questionnaire is not an assessment and will not affect your marks in this Unit of Study in any way.***

5. Can I withdraw once I've started?

Being in this study is completely voluntary and you do not have to take part. If you decide to take part in the study and then change your mind later, you are free to withdraw at any time by not completing either of the questionnaires. Submitting your completed questionnaire is an indication of your consent to participate in the study. You can withdraw at any time before you have submitted the questionnaire in Week 10. Once you have submitted the questionnaire the second time (Week 10), your responses cannot be withdrawn because the code created for you by REDCap will not be stored in any way beyond this point, rendering the responses completely unidentifiable - therefore, we will not be able to tell which questionnaire is yours. Your

decision will not affect your current or future relationship with the researchers or anyone else at The University of Sydney.

6. Are there any risks or costs?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

7. Are there any benefits?

The research findings will help professional organisations and pharmacy educators to develop meaningful professional learning activities and practice guidelines on this topic and thus will be of indirect benefit to a current or future pharmacist professional.

8. What will happen to information that is collected?

By providing your consent, you are agreeing to us collecting information about you for the purposes of this study. Your information will only be used for the purposes outlined in this Participant Information Statement. Any information you provide us will be stored securely and we will only disclose it with your permission, unless we are required by law to release information. We are planning for the study findings to be published. However, you will not be individually identifiable in these publications.

9. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. Answers to questions you answered in the questionnaire will be posted on the Canvas site for your cohort. Further, when available, a summary of the study results will be posted on a relevant Canvas site, this may occur when you have progressed to the next semester/next year. The results of the study will also be shared through a brief commentary in a professional pharmacy journal. You may, at any stage, reach out to the Chief Investigator to know more.

10. What if I would like further information?

When you have read this information, the following researcher/s will be available to discuss it with you further and answer any questions you may have:

- Mr David Le, d.le@sydney.edu.au
- Professor Bandana Saini, bandana.saini@sydney.edu.au

11. What if I have a complaint or any concerns?

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of the University of Sydney [2024/271] according to the *National Statement on Ethical Conduct in Human Research (2007)*.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the University:

Human Ethics Manager
human.ethics@sydney.edu.au
+61 2 8627 8176

This information sheet is for you to keep

Appendix C4

N2N Tutor Workshop Slides

NO-TO-NICOTINE
PHAR2911 Workshop

Dr Maya Saba
Email: maya.saba@sydney.edu.au

Mr David Le
Email: d.le@sydney.edu.au

THE UNIVERSITY OF SYDNEY

https://www.raymondgeddes.com/blogs

We recognise and pay respect to the Elders and communities – past, present, and emerging – of the lands that the University of Sydney's campuses stand on. For thousands of years they have shared and exchanged knowledges across innumerable generations for the benefit of all.

THE UNIVERSITY OF SYDNEY

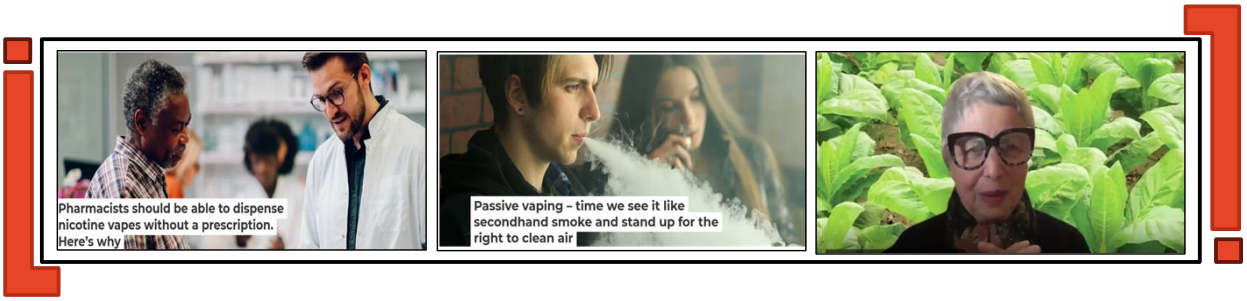
Learning Objectives

- Understand the ***pharmacology*** of nicotine and ***pathophysiology*** of ***nicotine dependence***
- Develop ***skills*** needed to address the different aspects of smoking and vaping cessation in terms of ***assessing dependence***, ***assessing readiness to quit*** and ***individualising pharmacotherapy*** alongside ***non-pharmacological measures*** and ***referral avenues***
- Recognise the ***significant role of pharmacists*** in implementing up-to-date smoking and vaping cessation interventions
- Develop an ***awareness of key sources of valid information*** on smoking and vaping-related clinical issues.

Workshop Activities

- **Activity 1:** Pre-work discussion (5 min)
- **Activity 2:** Smoking and vaping cessation cases (60 min)
- **Activity 3:** Hands-on demo activity for CO monitor and NRT (15 min)
- **Activity 4:** Say 'NO' to smoking/vaping activity (10 min)
- **Activity 5:** Setting up a smoking/vaping cessation clinic (15 min)
- **Activity 6:** POST No-To-Nicotine survey (20 min)
- **Activity 7:** Post-work art activity (15 min)

ACTIVITY 1 Prework Discussion



Activity _1

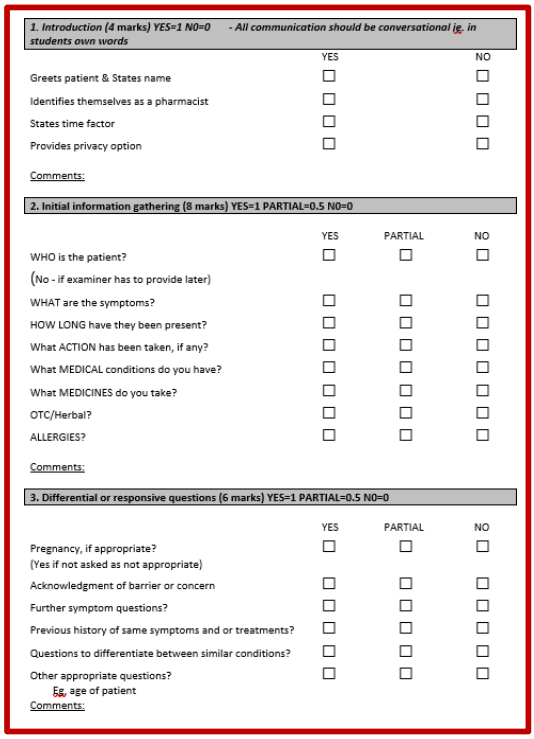
ACTIVITY 2 Clinical Case

Prompt

Ms Fiona, a 20-year-old female comes into your pharmacy asking about how to quit smoking.

What questions would you ask?

Activity _2



1. Introduction (4 marks) YES=1 NO=0 - All communication should be conversational ie. in students own words

	YES	NO
Greets patient & States name	☐	☐
Identifies themselves as a pharmacist	☐	☐
States time factor	☐	☐
Provides privacy option	☐	☐

Comments:

2. Initial information gathering (8 marks) YES=1 PARTIAL=0.5 NO=0

	YES	PARTIAL	NO
WHO is the patient? (No - if examiner has to provide later)	☐	☐	☐
WHAT are the symptoms?	☐	☐	☐
HOW LONG have they been present?	☐	☐	☐
What ACTION has been taken, if any?	☐	☐	☐
What MEDICAL conditions do you have?	☐	☐	☐
What MEDICINES do you take?	☐	☐	☐
OTC/Herbal?	☐	☐	☐
ALLERGIES?	☐	☐	☐

Comments:

3. Differential or responsive questions (6 marks) YES=1 PARTIAL=0.5 NO=0

	YES	PARTIAL	NO
Pregnancy, if appropriate? (Yes if not asked as not appropriate)	☐	☐	☐
Acknowledgment of barrier or concern	☐	☐	☐
Further symptom questions?	☐	☐	☐
Previous history of same symptoms and or treatments?	☐	☐	☐
Questions to differentiate between similar conditions?	☐	☐	☐
Other appropriate questions? Eg. age of patient	☐	☐	☐

Comments:

4. Analysis and Advice (12 marks) YES=2 PARTIAL=1 NO=0 NB: Appropriate non-supply = full marks, patient harm (inappropriate advice/referral) is ZERO OVERALL. Inappropriate advice not causing harm = ZERO for section

	YES	PARTIAL	NO
Identifies PROBLEM (document)	☐	☐	☐
RECOMMEND appropriate therapy/advice (document).....	☐	☐	☐
Counsels on USE (dose, frequency) (document).....	☐	☐	☐
Counsels on BENEFITS	☐	☐	☐
Counsels on RISKS (interactions, side effects)	☐	☐	☐
Counsels on appropriate FOLLOW-UP (who, when and for what symptoms if relevant) (document).....	☐	☐	☐

Comments:

5. Verbal Communication (6 marks)

	YES	PARTIAL	NO
Uses open ended questions in a logical order	☐	☐	☐
Uses appropriate pace, pitch and volume of speech	☐	☐	☐
Uses appropriate language	☐	☐	☐
Demonstrates active listening (repeats back or uses appropriate response words)	☐	☐	☐
Confirms patient understanding (via dialogue)	☐	☐	☐
Concludes with a summary and closes interaction	☐	☐	☐

6. Non-Verbal Communication (4 marks)

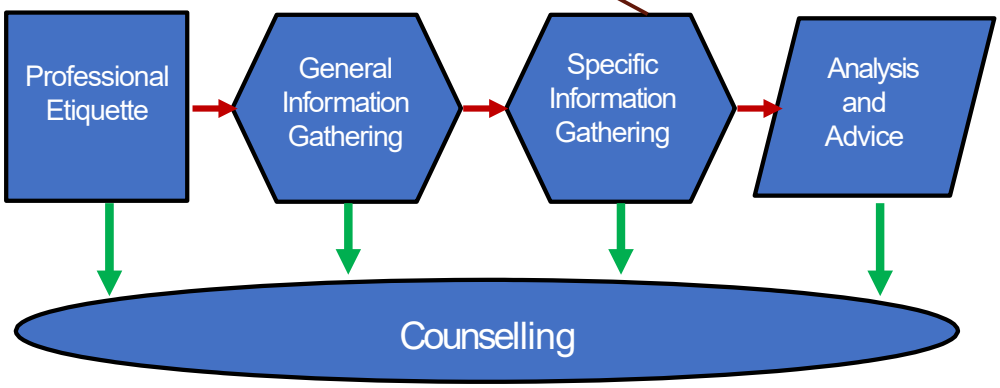
	YES	PARTIAL	NO
Demonstrates appropriate level of empathy	☐	☐	☐
Maintains eye-contact	☐	☐	☐
Maintains open posture and appropriate body movement	☐	☐	☐
Maintains appropriate facial expression eg. smiles appropriately, facial movement	☐	☐	☐

Comment section 4 & 5

Total Mark

Communication Skills - Breakdown

- Nicotine dependence
- Triggers
- Previous action/ response
- Readiness to quit



Activity _2

Fagerström Test for Nicotine Dependence

	PLEASE TICK (✓) ONE BOX FOR EACH QUESTION	
How soon after waking do you smoke your first cigarette?	Within 5 minutes 5-30 minutes 31-60 minutes	☐ 3 ☐ 2 ☐ 1
Do you find it difficult to refrain from smoking in places where it is forbidden? e.g. Church, Library, etc.	Yes No	☐ 1 ☐ 0
Which cigarette would you hate to give up?	The first in the morning Any other	☐ 1 ☐ 0
How many cigarettes a day do you smoke?	10 or less 11 – 20 21 – 30 31 or more	☐ 0 ☐ 1 ☐ 2 ☐ 3
Do you smoke more frequently in the morning?	Yes No	☐ 1 ☐ 0
Do you smoke even if you are sick in bed most of the day?	Yes No	☐ 1 ☐ 0
	Total Score	

SCORE		
	1- 2 = low dependence 3-4 = low to mod dependence	5 - 7= moderate dependence 8 + = high dependence

Activity _2

Clinical Case – Key Points from Information Gathering

Specific info

- *Smokes 20 cigarettes a day for 5 years*
- *TTFC is within 15-20 minutes of waking up with a large cup of coffee to kick start the day*
- *Loves the first cigarette the most*
- *Smokes more frequently in the morning*
- *Finds it hard to avoid smoking in smoke-free public places*
- *Smokes even if sick or unwell*
- *Triggers are stress, university/workload, smoking friends*
- *Tried quitting cold turkey on her own last month but did not manage*

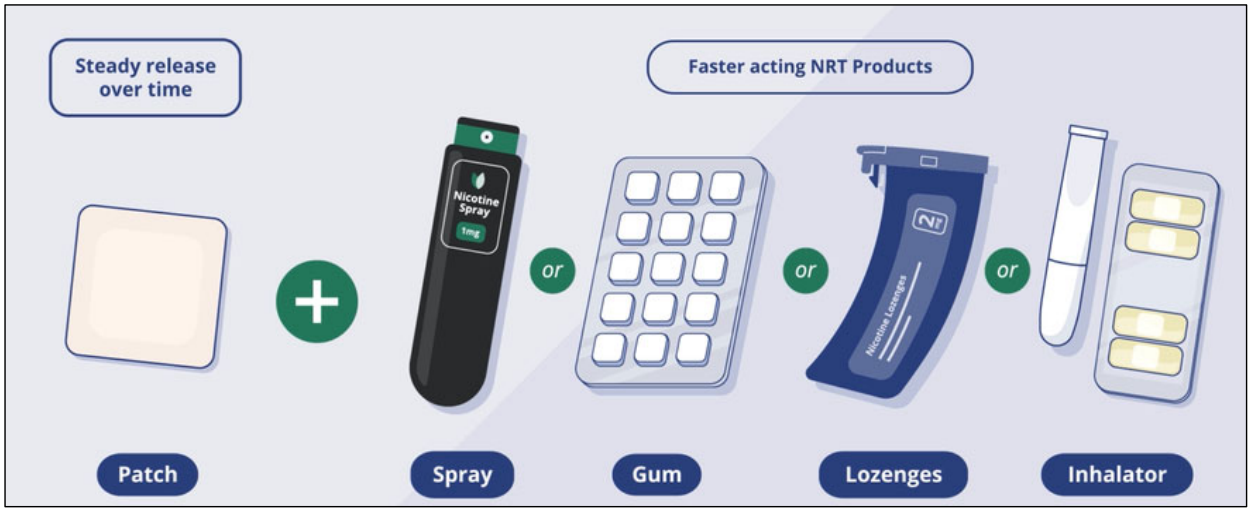
$$\text{Number of pack years} = \frac{\text{cigarettes smoked per day} \times \text{number of years smoked}}{20}$$

General info

- **Occupation:** University Student
- **Allergies:** No known allergies
- **Conditions:** Mild asthma and depression
- **Medications:** *Escitalopram 20mg once daily, Fluticasone propionate 125mcg/salmeterol 25mcg/dose 1 puff twice daily (pMDI), Salbutamol 100mcg (pMDI) 1 puff when required*

Activity _2

Clinical Case – Key Recommendations



https://www.quit.org.au/articles/nicotine-replacement-therapy-frequently-asked-questions

Activity _2

Clinical Case – Key Counselling Points

- 21mg/24hr patch daily + 4mg gum/lozenge/mini or inhalator or spray *prn* for craving
- Side effects
- Instructions for use
- Avoidance of triggers/non-pharmacological measures/referral avenues
- Smoking with NRT??

Activity _2

Nicotine Replacement Therapy

Dosage Form	Benefits	Adverse Effects	Precautions/ Contraindications	Comments
Over-the-Counter ❑ 2 & 4 mg gum ❑ 2 & 4 mg lozenge ❑1.5 & 4 mg mini lozenge ❑ 15 mg inhalator ❑ 21, 14 & 7 mg 24-hour patch ❑ 25, 15, 10 mg 16-hour patch ❑ 1 mg/spray quickmist	• Slow delivery of lower doses of nicotine as compared to a cigarette (1/3-1/2) • Decrease in the intensity of cravings and withdrawal symptoms • Reduction in the reinforcing effects of tobacco-delivered nicotine • Minimal addictive potential • Absence of toxic chemicals in cigarettes • Double successful quit rates as compared to placebo • 50-70% increase in the rate of long-term quitting	• Safe with no serious side effects with short and long-term use • Patch: Skin rashes on site of application, sleep disturbances, vivid dreams (apply before bed to minimise incidence) • Oral Products: irritation of mouth or throat, headaches, dizziness, hiccups, indigestion, nausea, coughing, tingling of lips	• Recent heart attack within the past 48 hours • Patch: Allergy to any of its components, generalised skin disorders such as sun burn or broken skin • Lozenge/mini lozenge: Phenylketonuria • Inhalator: Menthol sensitivity	• 8 weeks minimum duration of therapy • Safe in smokers as young as 12 years • May be used in pregnancy and lactation after failure of non-pharmacological interventions (start with oral products at lower dosages) • Safe in patients with ***stable*** chronic cardiovascular diseases • Safe in renal/hepatic diseases • Patches subsidised on Pharmaceutical Benefits Scheme

Activity _2

Clinical Case - continued

Prompt

Ms Fiona, comes back into your pharmacy three-months later with a prescription for *varenicline.*

What would you do at this stage?

Activity _2

Clinical Case – Key Points

- Suitability of varenicline??
- Dosage
- Duration
- Side effects -- nausea??
- Avoidance of triggers/non-pharmacological measures/referral avenues
- Smoking with varenicline? Quit date?

Activity _2

Varenicline

Dosage Form	Benefits	Adverse Effects	Precautions/ Contraindications	Comments
Prescription Only ❑ 0.5 & 1 mg oral tablets ✓ Day1-3: 0.5 mg daily ✓ Day4-7: 0.5 mg twice daily ✓ Day 8-week 12: 1 mg twice daily	• Partial agonist acting centrally on α4β2 nicotine receptors, stimulating dopamine release, thus reducing cravings and withdrawal symptoms • Antagonist preventing stimulation of receptors by nicotine, thus decreasing the pleasurable effects achieved from smoking and the risk of full relapse after temporary lapse • 3-fold increase in odds of successful long-term quitting as compared to pharmacologically unassisted attempts	• Mild to moderate nausea in 30% of patients, generally diminishing with time • Headache • Insomnia • Vivid dreams • Reports of serious neuropsychiatric symptoms and suicidal ideations	• Caution in patients with underlying psychiatric illnesses – Monitor closely • Dose adjustment in severe renal impairment • Not recommended in pregnancy, breastfeeding and in smokers under the age of 18 due to lack of conclusive evidence • Contraindicated in hypersensitivity to any ingredient	• Recommended 12-week course of therapy for increased chances of success • No significant increase in CV adverse effects • Equally effective to combination NRT • Available on PBS

Activity _2

Clinical Case - continued

Prompt

Ms Fiona, comes back into your pharmacy nine months later with a prescription for *Nicovape Q – Classic 20mg/mL.*

What questions do you ask?
How would you dispense this prescription?

Activity _2

The Modified Hooked on Nicotine Checklist (M-HONC)

Questions	Yes	No
1. Have you ever tried to stop vaping but could not?		
2. Do you vape now, because it is hard to quit?		
3. Have you ever felt like you were addicted to vaping?		
4. Do you ever have strong cravings to vape?		
5. Have you ever felt like you really needed a vape?		
6. Is it hard to keep from vaping in places where you are not supposed to (e.g. University classes)		
7. When you tried to stop vaping… (or when you have not vaped for a whlile..)		
a. Did you find it hard to concentrate because you couldn't vape?		
b. Did you feel more irritable because you couldn't vape?		
c. Did you feel a strong need or urge to vape?		
d. Did you feel nervous, restless or anxious because you couldn't vape?		

Activity _2

Clinical Case – Key Points

- No approved nicotine vaping products by TGA
- Prescription required
- Evidence of AP or SAS B/C approval + subject to state/territory restrictions
- NSW Health needs to be notified prior to supply by pharmacists
- Unapproved nicotine vaping products sourced from overseas

Activity _2

STEP 1

Step 1 – Ask

1. Ask screening questions to determine e-cigarette use	"Do you vape?" "Do you use any other products containing tobacco, like cigarettes, shisha, or cannabis?" (If the young person responds yes to the above question, ask subsequent questions for both vaping and other tobacco product/s they use) "In the last month, how many times have you vaped?" If struggling to initiate conversation, try an open-ended question: "Some people use vapes to manage their stress, what has your experience been?" If the young person says no to all the above, ask: "Have you ever used vapes or tobacco products (like smokes, shisha or cannabis)?" If young person has never used e-cigarettes or other tobacco products, affirm their choice. If young person answers yes to any of the above, continue.
2. Ask screening questions to determine dependence and understand nicotine withdrawal symptoms	Screen for nicotine dependence. Short form: Time to First Vape (TTFV). Use TTFV by asking: "How long after waking do you vape?" Long form: Modified-Hooked on Nicotine Checklist (M-HONC) or PENN State E-Cigarette Dependence Index Refer to Appendix 1 for M-HONC and Appendix 2 for Penn State. Ask about nicotine withdrawal symptoms, such as: • Irritability, frustration, anger • Cravings • Anxiety • Difficulty concentrating • Increased appetite • Restlessness • Depressed mood • Difficulty sleeping (insomnia) Ask about what they are vaping: • Brand • Type (e.g., disposable, rechargeable, refillable) • Flavour • With/without THC (tetrahydrocannabinol)
3. Ask about the immediate needs of the individual	Determine and agree with the young person what their immediate priorities are, e.g.: Managing nicotine withdrawal symptoms • Supporting long-term cessation

See Lecture on vaping

Activity _2

Step 2 – Advise

1. Advise young person to quit vaping	Ask permission to advise about the harms and risks of vaping. In a non-judgmental way, advise the young person to quit vaping, and inform them of the most effective ways to do so. "One of the best things you can do for your health is to quit vaping, I can help you with this"
2. Advise on harms and risks associated with e-cigarette use and benefits of quitting	"Would you like me to give you some information about vaping?" If yes, some examples of harms to discuss include: "Most vapes contain nicotine, which is highly addictive and can harm your brain development." (noting the brain continues to develop until the age of 25) "Vaping has been linked to serious lung disease, and many of the other long-term health effects are not yet known" "Vape aerosol is not water vapour. Vapes can contain the same harmful chemicals found in cleaning products, nail polish remover, weed killer and bug spray"
3. Provide information and NSW Health factsheets to support AYA quit	Provide the young person information about e-cigarettes and NSW Health factsheets about quitting: • '**Do you know what you're vaping?**' (36)

Activity _2

STEP 2

Step 3 – Help

1. Discuss behavioural strategies	Discuss barriers and opportunities for cessation that the young person may experience (see Appendix 6). Consider: "What are some challenges to quitting?" "What are some good reasons to quit?" Discuss suitable behavioural strategies to support the young person with cessation, e.g.: • Using an alternative dopamine reward such as nuts or flavoured sugar-free gum • Thinking of yourself as someone who does not vape • Using the "stray cat" metaphor • Trying distraction • Establishing rewards or incentives • Making a promise (either committing to try one or more of the above behavioural strategies, or to not using vapes for a certain time) Assist the young person to develop a plan to quit vapes (and tobacco if a dual user) and strategies for coping with high-risk situations (Appendices 3,4,5). Document in records / notes, the young person's decision to quit.

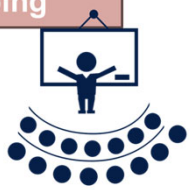
Activity _2

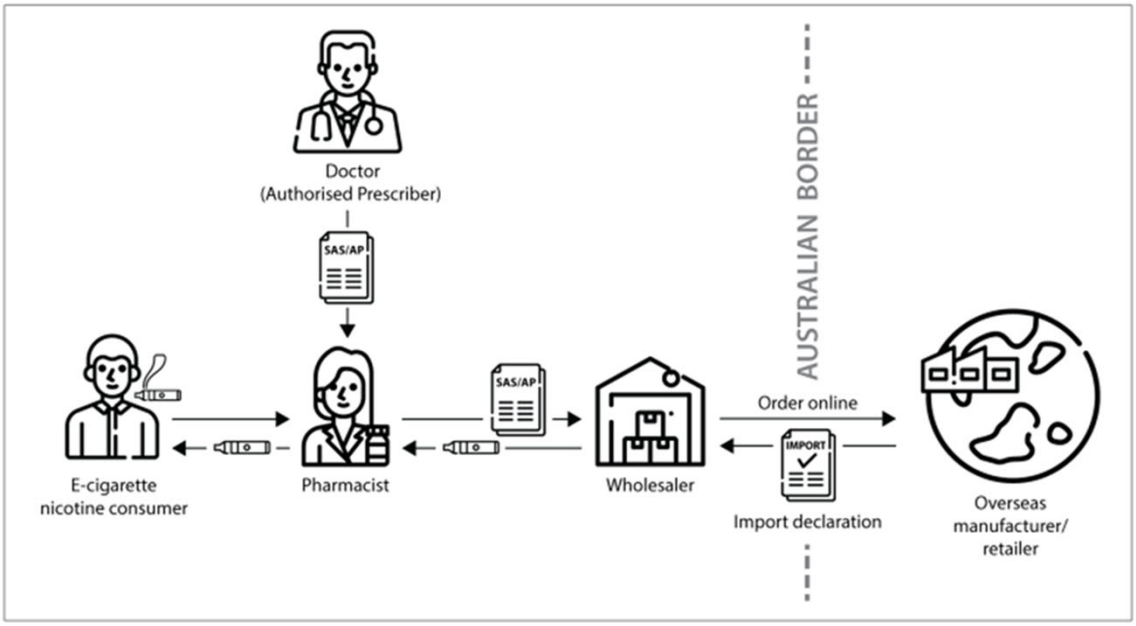
STEP 3

Step 3 – Help (cont.)

2. Consider whether pharmacotherapies are appropriate	Depending on nicotine dependence levels and whether the young person is a dual user of tobacco and vapes, NRT or Varenicline may be appropriate to help manage cravings and nicotine withdrawals. For more information, refer to the Pharmacotherapy section of this Guide or other resources (such as SCHN Guide, RACGP, NSW Health tools, etc.). Pharmacotherapies should always be combined with behaviour change support (e.g., Quitline). It is recommended young people discuss pharmacotherapy options with their doctor or other suitably qualified health professional.
3. Refer to other cessation services	Refer the young person to: • iCanQuit website (**www.iCanQuit.com.au**) • Quitline 13 7848 • Aboriginal Quitline 13 7848 • Quit apps (iCanQuit, etc.) • Other e-cigarette cessation programs (where available)
4. Refer to other services, if appropriate	Depending on the circumstances (for example if the young person is dual using vapes and other drugs), some young people may require referral to more specialised services, such as smoking/nicotine cessation clinical nurse consultants (CNCs), Mental Health services and Alcohol and other Drug services. These services can support the young person to quit vaping whilst addressing their other health needs.
5. Arrange follow up calls or appointments	Offer ongoing support to check in. Arrange follow up appointments to review progress and motivate the young person to continue quit attempts if possible or refer young person to their GP or other health professional. Review effectiveness of pharmacotherapy. *If required:* acknowledge that slip-ups are expected and a young person should not be discouraged, support the young person to re-commit to their goals and try again.

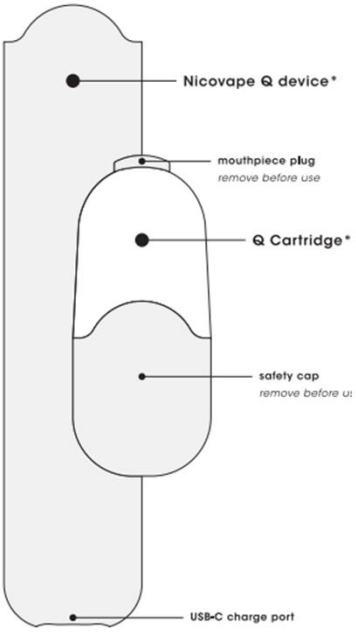
See Lecture on vaping





Activity _2

Welcome to your Nicovape Q

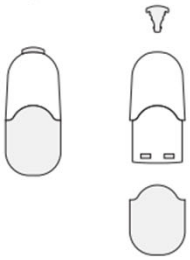


*sold separately

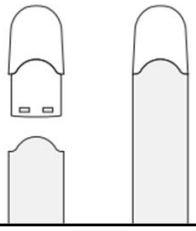
Getting started

1. Remove the coloured safety cap and mouthpiece plug from your Q cartridge

♻ Please recycle



2. Insert the Q cartridge into the top of your Nicovape Q device. It will secure itself automatically via the magnets



Getting started

3. For the best experience, ensure your device is fully charged by using the USB-C charger provided

The light ring around the charge port will indicate your device's current charge level

- **No charge**
- **Running low**
- **Normal charge**
- **Fully charged**

A flashing white light ring means your Q Cartridge may be empty, or there may be a connection error. Try removing it and re-inserting, or replace with a new cartridge if it appears to be empty.

4. Once your device is fully charged, please refer to the reverse side of this booklet for important guidance on how to start using your new device

Activity _2

How to get the best experience

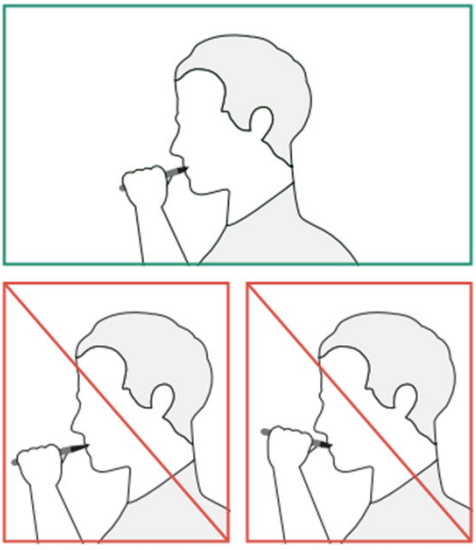
The Nicovape Q is simple and familiar to use, and activates only when you draw through the mouthpiece.

1. To start, place the mouthpiece between your lips as shown on the right, about halfway along the mouthpiece.
2. Draw firmly on the mouthpiece for 2 to 3 seconds – Aim to draw enough air through the device to fill your mouth.
3. Immediately inhale deeply and exhale slowly.

Wait at least 20 seconds before your next puff. This will enable you to see if you've had enough to satisfy your cravings and will allow the device to reset for the next puff.

It's not unusual to cough when you first start, but this will ease with continued use.

Just stick with it!



Ensure half of mouthpiece is between lips

Ensure device is pointing downwards

Activity _2

Peak Body Guidelines and Recommendations

RACGP
Interim Guidelines on Vaping Cessation Jan '24

At present, medicines approved for smoking cessation are not approved for vaping cessation, and so prescribing for vaping cessation is off label. This may change as new regulations come into effect

Adults who vape
For adults who vape, approved nicotine replacement therapy (NRT) with behavioural support is a reasonable pathway

Titration of NVPs
There is currently a lack of evidence about the optimal length of NVP use, or how to titrate NVP's down in order to achieve nicotine cessation

Suggested approaches include:
- Attempting a weaning or cessation of NVPs after 12 weeks of use
- Transitioning from NVP's to NRT – form of nicotine less associated with long-term use
- Consideration of other approval oral smoking cessation pharmacotherapies; however, further research is needed before these can be recommended

A maximum duration of 12 months' use of NVPs is a reasonable consideration.

PSA
For Pharmacists providing Smoking Cessation '21

Pharmacists should reinforce the vaping cessation plan agreed to between the patient and prescriber. This may include weaning or ceasing the nicotine vaping product after 12 weeks of use or transition to NRT. If the patient is continuing to use nicotine vaping products for longer than the plan agreed to between the patient and prescriber, the pharmacist should confirm any changes to the vaping cessation plan with the prescriber and
patient. Offer behavioural support (brief advice tailored to vaping cessation and referral to Quitline for multi-session behavioural intervention).

PBS
Eligibility for NRT- Dec 2023

Are patients eligible for subsidised NRTs for vaping cessation under the Pharmaceutical Benefits Scheme (PBS)

'The PBS restriction for NRT aims to provide an affordable intervention to support nicotine cessation. Where clinically appropriate, a patient may be eligible for PBS subsidised NRTs provided they are nicotine dependent from the inhalation of any nicotine containing product'

Activity _2

Sources:
RACGP Link
PSA Link
PBS Link

UK Experience

MHRA Approved Indication for Vaping Cessation on Nicorette® QuickMist

Approved Indication[1]:

Nicorette® QuickMist relieves and/or prevents craving and **nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes.** It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

Pack Claim and Directions for Use

Directions: For adults and children 12 years and over. It is important to use enough nicotine spray to control cravings. Use one spray first when you would normally smoke/vape, or have cravings to smoke/vape. If your cravings do not disappear within a few minutes use a second spray. If 2 sprays are required to control cravings, future doses may be delivered as 2 consecutive sprays.

Do not use more than 2 sprays per dose or 4 sprays per hour or 64 sprays per day.

Activity _2

Sources:
RACGP Link
PSA Link
PBS Link

Cessation Resources/Referral Avenues

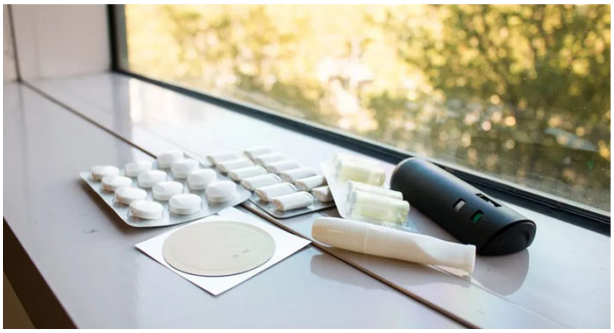
- iCanQuit website (*www.iCanQuit.com.au*)
- Quitline 13 78 48
- Quit Apps e.g. My QuitBuddy, Nicorette®
- Tackling Indigenous Smoking
- Koori Quitline Facebook Page
- NSW Health
- Cancer Institute NSW
- Alcohol and other Drug Services
- Mental Health Services

Quitline 137848

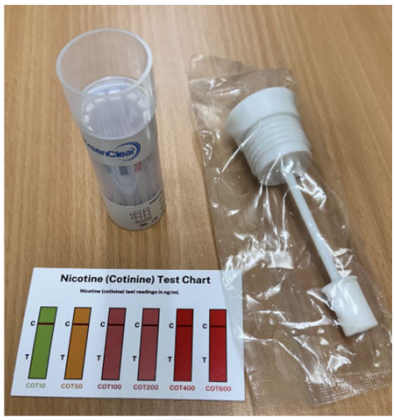
Activity _2

ACTIVITY 3 Hands-on Demo

- Any volunteers ?!



https://www.quit.org.au



https://www.nichemedical.com.au/bedfont-smokerlyzer

Activity _3

ACTIVITY 4 How Would You Say 'NO'?

Avoid **Refuse** **Exit**

Activity _4

ACTIVITY 5 Smoking and Vaping Cessation Clinic

- You have been asked, by the pharmacist you work with, to assist in the design of a new smoking and vaping cessation clinic based at the community pharmacy.

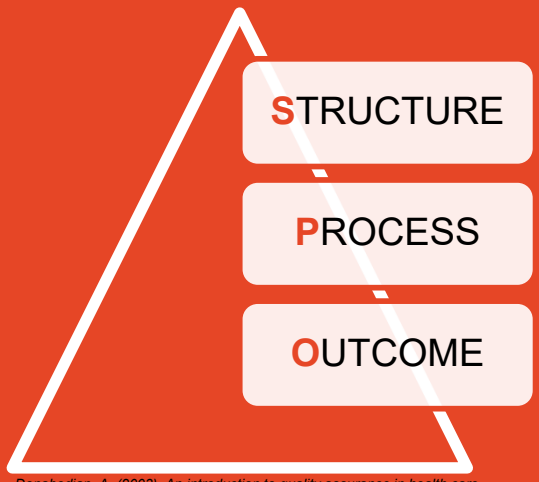
What would you include in your proposal?

https://www.freshtherapeutics.com.au

Structure **Process** **Outcome**

Activity _5

Developing a "Quality Service"



Donabedian, A. (2003). An introduction to quality assurance in health care. (1st ed., Vol. 1). New York, NY: Oxford University Press

EXAMPLE:
Let's say you were considering a SABA (short-acting beta-2 agonist for asthma) stewardship service in your pharmacy….

Activity _5

STRUCTURE

- Training pharmacy staff about SABA overuse risks
- Training pharmacy staff on risk communication
- Training staff on FAFA (first aid for asthma)
- Sourcing good educational materials on SABA overuse and asthma related risks
- Sourcing placebo inhalers/spacers to demonstrate SABA inhaler use
- Having digital/paper versions of asthma control tests
- Ensuring a private sit-down area in the pharmacy is available for the service

PROCESS

- Setting a process flow for referral of SABA requests to pharmacists only
- Using a **standard process** to provide stewardship service
  - Maintaining a system of recording the no of SABA inhalers a patient is using.
  - Recording Asthma Control and checking preventer use per NAC guidelines
  - Completing a referral plan for patients GP
  - Setting a follow up appointment
  - Documenting everything

OUTCOME

- Summing how many people you offered the service to and how many accepted
- Evaluating change in SABA inhaler use
- Evaluating change in asthma control
- Checking patient satisfaction with their asthma
- Checking patient satisfaction with your service
- Getting feedback from GPs in your area if your referrals helped

Activity _5

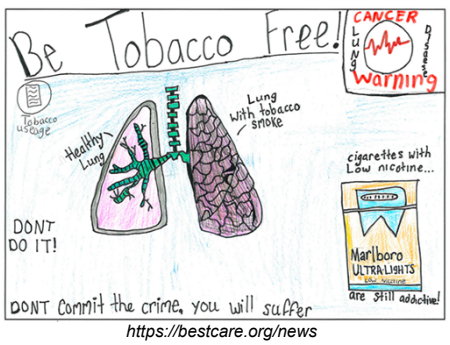
ACTIVITY 6 POST No-To-Nicotine Survey

- Please check your student email
- Post survey sent at 4pm on 29/4/24

Activity _6

ACTIVITY 7 Post-Work Art Activity

- You are to design a poster using the material provided to raise awareness about smoking and vaping cessation to a particular target population.
- Please submit at the end of the workshop.
- Be creative and have fun!

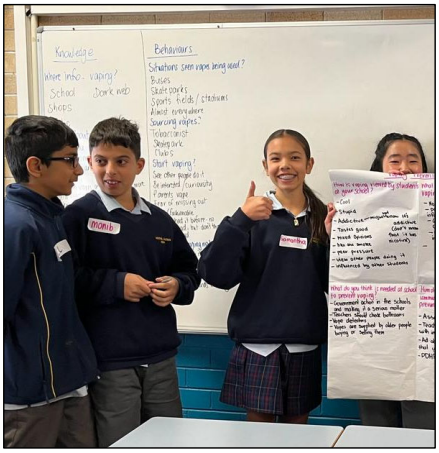


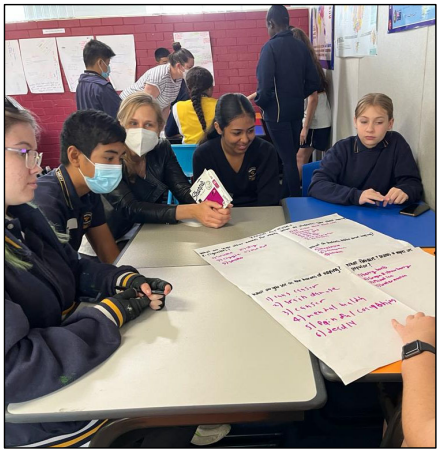
https://bestcare.org/news

https://www.timeslive.co.za/news

Activity _7

Unpacking Vaping in Schools: Youth Voices





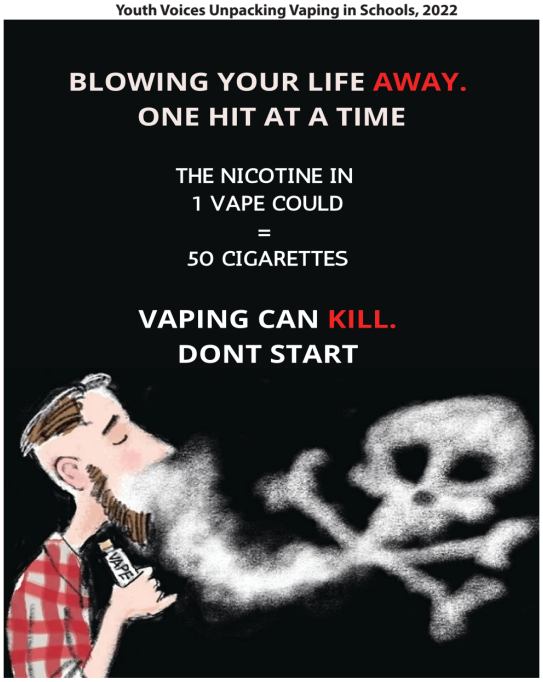
Youth Voices Unpacking Vaping in Schools, 2022

William Clarke College

Be Smart Don't Start
For more information

"Not a high"

Youth Voices Unpacking Vaping in Schools, 2022



Model Farms High School

Be Smart Don't Start
For more information

"Blowing your life away"

Youth Voices Unpacking Vaping in Schools, 2022

Colyton High School

Be Smart Don't Start
For more information

"Health impacts of Vapes"

Youth Voices Unpacking Vaping in Schools, 2022

Redbank School

Be Smart Don't Start
For more information

"Genie in a vape"

Questions?

https://www.raymondgeddes.com/blogs

Appendix D

Future Research

Appendix D1

Email Invitation

Email Invitation for PSA/The Guild

To whom it may concern,

My name is David Le and I am completing a Master of Philosophy at the University of Sydney under the supervision of Professor Bandana Saini (from the Sydney Pharmacy School) and Professor Smita Shah (affiliated with the School of Public Health at the University of Sydney). My research topic is about exploring the perspectives of Australian pharmacists regarding professional roles around the dispensing of prescribed nicotine solutions for vaping or providing specific vaping cessation services. We are releasing a short survey to explore the above issues and hope that you may be able to help us disseminate information about this timely study and a survey link to pharmacists across Australia to encourage participation. We also have an e-poster to advertise the project attached to this email. Please let us know if you would like further information or have any questions. We hope that the survey findings will help us understand pharmacists' practice support needs around vaping services and help organisations such as the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia, work towards building resources that can help pharmacists play an active role in vaping and smoking cessation support.

Please reach out to me or Bandana Saini (copied in the email) if you have any queries or would like to clarify anything.

Kind regards,

David Le

Appendix D2

Study Advertisement

Pharmacy and Vaping

We are seeking pharmacists to participate in a short 15-minute online survey

This anonymous survey will explore pharmacist perspectives around vaping and support needs for vaping related health services

Criteria

- Practising pharmacist
- Current general or provisional registration
- Residing in Australia
- Over 18 years old

Significance

- Provide data on vaping knowledge and attitudes
- Development of vaping education and training resources
- Support pharmacists' role in the area of vaping education and cessation

To take the survey, please click on the link below:

For further information, email our student researcher:
d.le@sydney.edu.au

Survey respondents can go in a draw for a chance to win one of fifteen 75 dollar vouchers

Appendix D3

CANVAS Announcement

Canvas Announcement

Dear students,

How much do you know about vaping? What would you like to learn about vaping? We would like to invite you to participate in a short survey exploring your views on vaping. This study is run by David Le alongside Professor Bandana Saini who seeks to understand your perspectives as pharmacy students about vaping. If you are interested, please click on the following link to the survey. We appreciate you taking the time to complete this survey and contribute to this study.

Appendix D4

Participant Information Sheet: Pharmacists (Surveys)

Participant Information Statement – Pharmacists Phase 2 (Survey)

Research Study: Exploring perspectives on professional roles and practice support needs of pharmacists and pharmacy students for vaping related health services (Phase 2) – Pharmacists

Professor Bandana Saini (Responsible Researcher)
School of Pharmacy, Faculty of Medicine and Health
Phone: +61 2 93516789 | Email: bandana.saini@sydney.edu.au
Mr David Le B.Pharm MPH (Student) | Email: d.le@sydney.edu.au

1. What is this study about?

There is increasing discussion about the use of vaping or e-cigarettes in Australia. Whilst vaping grows in popularity, many discussions about its safety and use as a strategy for smoking cessation in established smokers attempting to quit are taking place in clinical, professional, and public health domains of Australian health care. Pharmacists have been important in the delivery of smoking cessation services and need to consider vaping and vaping cessation support. The professional clinical information and practice support needed to undertake this new role are not yet established. Therefore, we are conducting a research study to explore pharmacists' and pharmacy students' perspectives on vaping, and their practice support or information that needs to be related to vaping related health services. Taking part in this study is voluntary.

Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

2. Who is running the study?

The study is being carried out by the following researchers:

- Bandana Saini, Professor, School of Pharmacy, Affiliate Staff and Research Leader, Woolcock Institute of Medical Research
- Smita Shah, Clinical Professor, Faculty of Medicine and Health, Fellow of the Thoracic Society of Australia and New Zealand, Associate of the Woolcock Institute of Medical Research, Director, Prevention Education and Research Unit (PERU), Western Sydney Local Health District

- Muhammad Aziz Rahman, Professor, Research Adviser and Discipline Leader of Public Health, Institute of Health and Wellbeing, Federation University of Australia
- Habib Bhurawala, Doctor, Head of Paediatrics, Senior Specialist Staff, Nepean Hospital
- David Le, Pharmacist, School of Pharmacy, Student, Woolcock Institute of Medical Research

David Le is conducting this study as the basis for the degree of Master of Philosophy at The University of Sydney. This study has no funding; however, Mr David Le is being supported by a small scholarship based on a philanthropic donation to the Woolcock Institute of Medical Research. This donation specified scholarship support for a research student working in the health services area of smoking/vaping cessation in pharmacies.

3. Who can take part in the study?

We are seeking pharmacists to participate in this study. The study involves a survey exploring the awareness about and perceptions of participants around vaping to better understand how appropriate resources can assist in developing evidence-based vaping-related health services in the pharmacy context.

4. What will the study involve for me?

If you decide to take part in this study, you will be asked to fill in an online survey, which will take roughly 15 minutes to complete. This online survey consists of closed and open-ended questions about vaping related health facts, perceptions about pharmacist roles and information needed to provide vaping related health services in pharmacies.

5. Can I withdraw once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision will not affect your current or future relationship with the researchers or anyone else at The University of Sydney.

By submitting your survey, you consent to take part in the study. You can withdraw any time before you submit however once your responses are submitted, they cannot be withdrawn. This is because they are anonymous, and we will not be able to tell which one yours is.

6. Are there any risks or costs?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

7. Are there any benefits?

The research findings will help professional organisations and pharmacy educators to develop meaningful professional learning activities and practice guidelines on this topic and thus will be of indirect benefit to a current or future pharmacist professional. Further, after completing the survey, we would like to offer you the option of choosing to enter a draw for fifteen vouchers valued at 75 dollars in appreciation of your time and interest.

8. What will happen to the information that is collected?

By providing your consent, you are agreeing to us collecting information about you for the purposes of this study. As responses to the survey are anonymous, we will be unable to identify you. The study findings may be presented and published in academic journal articles and be presented at conferences. If there is any identifiable information, we will only disclose this with your permission, unless we are required by law to release information.

9. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. Please provide your contact details at the end of the survey if you are interested in receiving feedback. This feedback will be in the form of a brief summary of key findings.

10. What if I would like further information?

When you have read this information, the following researcher/s will be available to discuss it with you further and answer any questions you may have:

- David Le, d.le@sydney.edu.au

11. What if I have a complaint or any concerns?

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney [INSERT HREC Approval No. once obtained] according to the *National Statement on Ethical Conduct in Human Research (2007)*.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the University:

Human Ethics Manager
human.ethics@sydney.edu.au
+61 2 8627 8176

This information sheet is for you to keep

Appendix D5

Participant Information Sheet: Pharmacy Students (Surveys)

Participant Information Statement - Pharmacy Students Phase 2 (Survey)

Research Study: Exploring perspectives on professional roles and practice support needs of pharmacists and pharmacy students for vaping related health services (Phase 2) – Pharmacy Students

Professor Bandana Saini (Responsible Researcher)
School of Pharmacy, Faculty of Medicine and Health
Phone: +61 2 93516789 | Email: bandana.saini@sydney.edu.au
Mr David Le B.Pharm MPH (Student) | Email: d.le@sydney.edu.au

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There is increasing discussion about the use of vaping or e-cigarettes in Australia. Whilst vaping grows in popularity, many discussions about its safety and use as a strategy for smoking cessation in established smokers attempting to quit are taking place in clinical, professional, and public health domains of Australian health care. Pharmacists have been important in the delivery of smoking cessation services and need to consider vaping and vaping cessation support. The professional clinical information and practice support needed to undertake this new role are not yet established. Therefore, we are conducting a research study to explore pharmacy students' perspectives on vaping, and their practice support or information that needs to be related to vaping related health services. Taking part in this study is voluntary.

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- Bandana Saini, Professor, School of Pharmacy, Affiliate Staff and Research Leader, Woolcock Institute of Medical Research
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- Muhammad Aziz Rahman, Professor, Research Adviser and Discipline Leader of Public Health, Institute of Health and Wellbeing, Federation University of Australia
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4. What will the study involve for me?

If you decide to take part in this study, you will be asked to fill in an online survey, which will take roughly 10 minutes to complete. This online survey consists of closed and open-ended questions about vaping related health facts, perceptions about pharmacist roles and information needed to provide vaping related health services in pharmacies.

5. Can I withdraw once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision will not affect your current or future relationship with the researchers or anyone else at The University of Sydney.

By submitting your survey, you consent to take part in the study. You can withdraw any time before you submit however once your responses are submitted, they cannot be withdrawn. This is because they are anonymous, and we will not be able to tell which one yours is.

6. Are there any risks or costs?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

7. Are there any benefits?

The research findings will help professional organisations and pharmacy educators to develop meaningful professional learning activities and practice guidelines on this topic and thus will be of indirect benefit to a current or future pharmacist professional. Further, after completing the survey, we would like to offer you the option of choosing to enter a draw for one of two iPad mini(s) in appreciation of your time and interest.

8. What will happen to the information that is collected?

By providing your consent, you are agreeing to us collecting information about you for the purposes of this study. As responses to the survey are anonymous, we will be unable to identify you. The study findings may be presented and published in academic journal articles and be presented at conferences. If there is any identifiable information, we will only disclose this with your permission, unless we are required by law to release information.

9. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. Answers to questions in the survey will be posted on the Canvas site for your cohort. Further, when available, a summary of the study results will be posted in a relevant Canvas site, this may occur when you have progressed to the next year/next semester. The results of the study will also be shared through a brief commentary in a professional pharmacy journal. You may, at any stage, reach out to the Chief Investigator to know more.

10. What if I would like further information?

When you have read this information, the following researcher/s will be available to discuss it with you further and answer any questions you may have:

- David Le, d.le@sydney.edu.au

11. What if I have a complaint or any concerns?

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney [INSERT HREC Approval No. once obtained] according to the *National Statement on Ethical Conduct in Human Research (2007)*.

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This information sheet is for you to keep

Appendix D6

Questionnaire for Pharmacists

Questionnaire for Pharmacists

Thank you for participating in this survey, which explores the roles of pharmacists in smoking and vaping cessation.

For the purposes of the survey, vaping implies the act of using an e-cigarette, or a 'vape'. These lithium battery-powered devices use cartridges filled with liquids, or 'juice.'

The survey is divided into FIVE sections and should take 15 minutes to complete. All your responses are anonymous. Please note completion and submission of this form signifies your consent to participate in the research.

SECTION 1: GENERAL INFORMATION

Section 1 will ask you for information about yourself so that we can compare across different pharmacist practice settings and experiences.

1. **What is your age in years?**

   ___ years

2. **With which gender do you identify with?**

   a. Female
   b. Male
   c. Transgender
   d. Non-binary
   e. Prefer not to respond

3. **Currently are you a pharmacist registered on the APHRA register with?**

   a. General registration
   b. Provisional registration
   c. Not registered

[If respondents have answered 'not registered' Unfortunately you do not meet the relevant criteria to participate in this study, thank you for showing your interest in this research project]

4. **In what pharmacy environment do you mainly work in Australia?**

   a. Community pharmacy
   b. Hospital pharmacy
   c. Industry
   d. Academia
   e. Other

SECTION 2: GENERAL PERCEPTIONS OF VAPING AND VAPING PRODUCTS

Section 2 will ask you about your current awareness about vaping/vaping products/vaping health effects. Your responses will help the development of suitable training modules for pharmacists.

There are FIVE choices for each question/statement, only one of which is correct. Please select to the best of your knowledge, the button next to the answer choice you consider most appropriate or correct.

1. **Of the following age groups, which group are most likely to take up vaping in Australia?**

    a. Children (6 – 12 years)
    b. Teenagers to Adolescents (13 – 24 years)
    c. Young Adults (25 – 34 years)
    d. Adults (35 – 54 years)
    e. Older Adults (55 + years)

2. **What kind of vaping devices are available in Australia?**

    a. Disposable Vape
    b. Pod Style Vape
    c. Refillable Vape
    d. All of the above
    e. Don’t know

3. **How often do you think vaping products, even if not labelled, might have nicotine?"**

    a. Always
    b. Sometimes
    c. Rarely
    d. Never
    e. Don’t know

4. **Which of the following ingredients have been found in vaping products?**

   Formaldehyde
   Heavy metals (Arsenic, lead, nickel)
   Volatile Organic Compounds (Found in paint/cleaning products)
   Pesticides

   a. All of the above
   b. Some of the above
   c. One of the above
   d. None of the above
   e. Don't know

5. **Which of the following statement(s) is true:**

   a. Cigarettes are more addictive than vaping.
   b. Cigarettes are less addictive than vaping.
   c. Nicotine content in cigarettes and vapes is not comparable to each other.
   d. Vaping nicotine solutions is as addictive as smoking cigarettes.
   e. Don't know.

6. **A consumer purchases a vaping solution pack containing 10 mL bottles labelled as containing 5 mg/mL of nicotine each. If the consumers vape an entire 10 mL bottle in one day (50 mg nicotine), the amount of nicotine vaped would be <u>approximately</u> equivalent to:**

   a. 5 cigarettes
   b. 15 cigarettes
   c. 25 cigarettes
   d. 50 cigarettes
   e. Don't know

SECTION 3: PERCEPTIONS ABOUT VAPING WITHIN THE PHARMACY CONTEXT

Section 3 is split into TWO sections and will ask you about vaping and vaping cessation support from your perspectives personally and as a pharmacist. Vaping in this context refers to nicotine containing solutions.

SECTION 3A

Statements in this section can be selected to be True or False or Don't Know. Please select to the best of your knowledge, an appropriate option selected from those presented after a statement.

	True	False	Don't Know
Currently, there are nicotine containing vaping products approved by the Therapeutic Goods Administration (TGA).			
Consumers require a prescription for all purchases of nicotine vaping products from pharmacies, such as nicotine e-cigarettes, nicotine pods and liquid nicotine.			
Vaping products with nicotine can be supplied to anyone with a prescription by outlets selling vapes in Australia.			
The maximum concentration of nicotine in vaping products as per Australian legislation is 100mg/mL.			
'Avoid contact with skin' is a warning statement that must be labelled when supplying nicotine containing vaping products.			
Common side effects of vaping are mouth/throat irritation, headache, and cough are likely to arise from propylene glycol.			
Common symptoms of withdrawal from nicotine containing vapes include anxiety, insomnia, and weight gain			
Adolescent vapers become addicted to nicotine containing vaping devices at the same rate as adult vapers			
Adolescents who vape nicotine-containing solutions are more at risk of developing memory/attention deficient behaviours and mood disorders			
Vaping nicotine containing solutions may interact with some medications such as the contraceptive pill			

Can vaping nicotine solutions also cause changes in drug metabolism enzymes like smoking does with enzymes such as Cytochrome P450 (CYP) 1A2 and 2B6, which might affect drug doses?			
Research strongly indicates that using nicotine solutions for vaping might be helpful for smokers who want to quit.			

SECTION 3B

For each statement there are FIVE choices, only indicating your level of agreement/non-agreement. Please select the button located next to the answer choice you consider to best reflect your position.

	Strongly Agree	Agree	Neither agree or disagree	Disagree	Strongly Disagree
Vaping a nicotine containing or non-nicotine containing product may be harmful to the health of the user.					
Vaping solutions, either containing or not containing nicotine, may be associated with developing short term respiratory health effects.					
Vaping solutions, containing, or not containing nicotine, may be associated with developing respiratory disease in the long term.					
In a young person who uses any vaping product, there is a strong likelihood of progressing to smoking cigarettes.					
Vaping is a public health concern.					
For a person who wants to quit, I am confident about providing support and counselling to someone who is actively smoking.					
As a pharmacist, I am confident about dispensing prescription medication for smoking cessation in accordance with TGA guidelines.					
As a pharmacist, I am confident about dispensing a nicotine-containing vaping product/solution in accordance with TGA guidelines.					
As a pharmacist, I am confident about providing counselling about a nicotine-containing vaping product/solution					
As a pharmacist, I am confident about providing support to a person actively vaping nicotine-containing products who wants to quit.					

Whilst there are no guidelines, offering Nicotine Replacement Therapy would be a clinically appropriate alternative for vaping cessation.					
There are sufficient resources from Professional Pharmacy Bodies about vaping and vaping cessation that pharmacists can access.					
Pharmacists need to be (either appropriately or formally) trained about vaping and vaping cessation.					
I believe that the pharmacy curriculum at the university should include the topic of vaping and vaping cessation.					

Thank you for providing your responses to this questionnaire!

SECTION 4: SURVEY PRIZES, ANSWERS AND RESULTS

Section 4: is optional and is related to the outcome(s) of the study.

Please indicate what you would like to receive at the end of the study.

- Correct answers to the factual questions in this survey
- Outcomes of this study
- Entry into a competition to win one of **FIFTEEN 75 dollar vouchers** (Winners randomly selected and notified at the close of the survey date)

Please note that if you have selected yes to any of the above responses, you will be taken to a separate web page and asked to provide your email address. Your survey responses will remain anonymous.

Appendix D7

Questionnaire for Pharmacy Students

Questionnaire for Pharmacy Students

Thank you for participating in this survey, which explores the roles of pharmacists in smoking and vaping cessation among pharmacy students.

For the purposes of the survey, vaping implies the act of using an electronic cigarette ‘e-cigarette’, or a ‘vape,’. These are lithium battery-powered devices that use cartridges filled with liquids, or ‘juice.’

The survey is divided into FIVE sections and should take you 10 minutes to complete. All your responses are anonymous. Please note completion and submission of this form indicate your consent to participate in the research.

SECTION 1: GENERAL INFORMATION

Section 1 will ask you for information about yourself.

1. **What is your age in years?**

   ___ years

2. **With which gender do you identify with?**

   a. Female
   b. Male
   c. Transgender
   d. Non-binary
   e. Prefer not to respond

3. **Currently are you a full time student studying pharmacy at the University of Sydney?**

   a. Yes
   b. No

[If respondents have answered 'no' Unfortunately you do not meet the relevant criteria to participate in this study, thank you for showing your interest in this research project]

4. **Have you ever vaped before?**

   a. Yes
   b. No
   c. Prefer not to respond

5. **Do you currently vape?**

   a. Yes
   b. No
   c. Prefer not to respond

6. **Do you know someone who vapes?**

    a. Yes
    b. No
    c. Prefer not to respond

SECTION 2: GENERAL PERCEPTIONS OF VAPING AND VAPING PRODUCTS

Section 2 will ask you about your current knowledge of vaping from your perspective as a pharmacy student

For each question/statement, there are FIVE choices, only one of which is correct. Please select to the best of your knowledge, the button located next to the answer choice you consider most appropriate or correct.

7. **Which group is most likely to take up vaping in Australia?**

    a. Children (6 – 12 years)
    b. Teenagers to Adolescents (13 – 24 years)
    c. Young Adults (25 – 34 years)
    d. Adults (35 – 54 years)
    e. Older Adults (55 + years)

8. **What kind of vaping devices are available in Australia?**

    a. Disposable Vape
    b. Pod Style Vape
    c. Refillable Vape
    d. All of the above
    e. Don't know

9. **How often do you think vaping products, even if not labelled, might have nicotine?**

    a. Always
    b. Sometimes
    c. Rarely
    d. Never
    e. Don't know

10. Which of the following ingredients have been found in vaping products

Acetone (Nail polish remover)
Heavy metals (Arsenic, lead, nickel)
Volatile Organic Compounds (Found in paint/cleaning products)
Pesticides

a. All of the above
b. Acetone and Heavy Metals
c. Volatile Organic Compounds and Pesticides
d. None of the above
e. Don't know

11. Which of the following statement(s) is true:

a. Cigarettes are more addictive than vaping.
b. Cigarettes are less addictive than vaping.
c. Nicotine content in cigarettes and vapes is not comparable to each other.
d. Vaping nicotine solutions is as addictive as smoking cigarettes.
e. Don't know.

12. A consumer purchases a vaping solution pack containing 10 mL bottles labelled as containing 5 mg/mL of nicotine each. If the consumers vape an entire 10 mL bottle in one day (50 mg nicotine), the amount of nicotine vaped would be <u>approximately</u> equivalent to nicotine absorbed from smoking :

a. 5 cigarette
b. 15 cigarettes
c. 25 cigarettes
d. 50 cigarettes
e. Don't know

SECTION 3: PERCEPTIONS ABOUT VAPING WITHIN THE PHARMACY CONTEXT

Section 3 is split into TWO sections and will ask you about vaping and vaping cessation support from your perspectives, personally and as a pharmacy student. Vaping in this context refers to nicotine containing solutions.

SECTION 3A

Statements in this section can be selected to be True or False or Don't know. Please select to the best of your knowledge, an appropriate option selected from those presented after a statement.

	True	False	Don't Know
Currently, there are nicotine containing vaping products approved by the Therapeutic Goods Administration (TGA).			
Nicotine containing vaping products supplied in Australia need a prescription.			
Vaping products with or without nicotine can be supplied to anyone aged under 18 years with a prescription in Australia.			
The maximum concentration of nicotine in vaping products as per Australian legislation is 100mg/mL.			
The following warning statements as per Australian legislation need to be labelled on vaping products containing nicotine. *Keep reach out of children*. *Avoid contact with eyes*. *Avoid contact with skin*.			
Common side effects of vaping are mouth/throat irritation, headache, and cough.			
Common symptoms of withdrawal from nicotine containing vapes include anxiety, insomnia, and weight gain.			
Adolescents who vape become addicted at the same rate as adults who vape.			
Adolescents who vape are more at risk of developing memory/attention deficient behaviours and mood disorders.			
Smoking cigarettes can lead to changes in required doses for drugs such as Clozapine. Does vaping nicotine solutions have the same effect?			

SECTION 3B

For each statement there are FIVE choices, only indicating your level of agreement/non-agreement. Please select the button located next to the answer choice you consider to best reflect your position.

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
Vaping may be harmful to the health of the user.					
Vaping solutions either containing or not containing nicotine, may be associated with developing short term respiratory health effects.					
Vaping solutions either containing or not containing nicotine may be associated with developing of respiratory disease in the long term.					
In a young person who vapes, there is a strong likelihood of progressing to smoking cigarettes.					
Vaping can be used as an aid for smoking cessation.					
Nicotine Replacement Therapy can be used for vaping cessation.					
Vaping is a public health issue.					
Pharmacy students need to be trained about vaping and vaping cessation.					

Thank you for providing your responses to this questionnaire!

SECTION 4: SURVEY PRIZES, ANSWERS AND RESULTS

Section 4: is optional and is related to the outcome(s) of the study.

Please indicate what you would like to receive at the end of the study.

- Correct answers to the factual questions in this survey
- Outcomes of this study
- Entry into a competition to win one of **TWO iPad minis** (Winners randomly selected and notified at the close of the survey date)

Please note that if you have selected yes to any of the above responses, you will be taken to a separate web page and asked to provide your email address. Your survey responses will remain anonymous.