CLINICAL PRACTICE GUIDELINES ON

TREATMENT OF NICOTINE DEPENDENCE AND TOBACCO USE DISORDER

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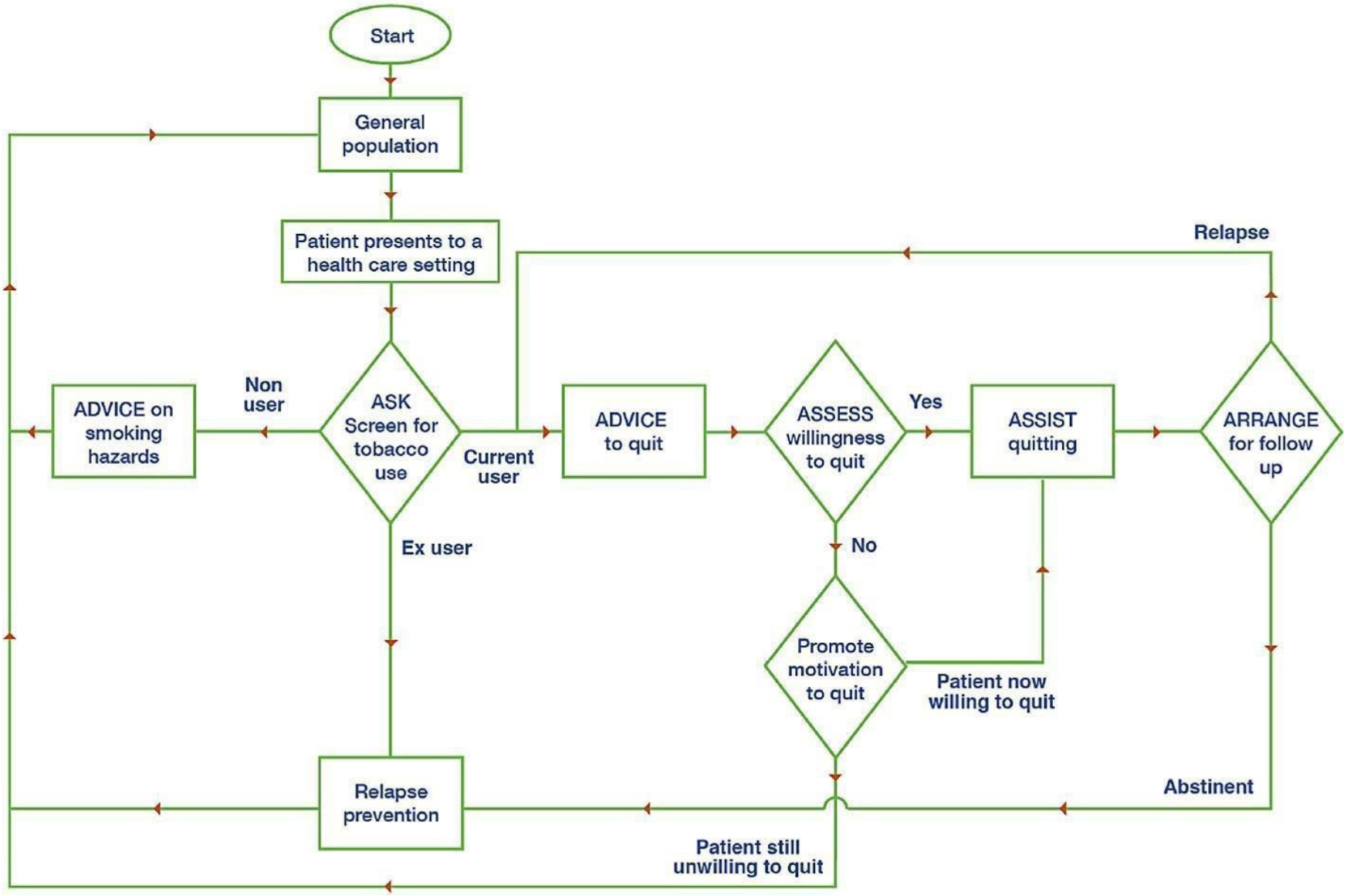
CLINICAL PRACTICE GUIDELINES ON TREATMENT OF NICOTINE DEPENDENCE AND TOBACCO USE DISORDER

ALGORITHM FOR TREATMENT OF TOBACCO USE DISORDER



STATEMENT OF INTENT

This CPG is an update of the CPG on Clinical Practice Guidelines on Treatment of Tobacco Use Disorder 2016. In this update, the CPG has been renamed as Treatment of Nicotine Dependence and Tobacco Use Disorder. This update is meant to be as guidelines for clinical practice, based on the best available evidence at the time of development. Adherence to these guidelines may not necessarily guarantee the best clinical outcome in every case. This CPG is not meant as a substitute for clinical judgement and clinicians are recommended to individualize the treatment strategy for every smoker. Every healthcare provider is responsible for the management of his/her unique patient based on the clinical picture such as nicotine addiction level, presented by the patient and the management options available locally.

This CPG will be reviewed every four years or sooner and updated with the most recent development as the need arises. Upon the time for next review, the CPG Secretariat will inform the Chairperson of the CPG Committee Members, who will initiate discussion on revision of the CPG. A multidisciplinary team will be formed and the latest systematic review methodology will be employed.

Every care is taken to ensure that this publication is correct in every detail at the time of publication. However, in the event of errors or omissions, corrections will be published in the web version of this document, which is always the definitive version. This version can be found on the Akademi Profesor Malaysia website: https://www.akademiprofesor.org.my/.

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GUIDELINE DEVELOPMENT AND OBJECTIVES

This guideline is based on a combination of two methods; firstly, clinical practice guidelines (CPGs) and report as mentioned below were used as main references and secondly, an updated literature review was incorporated in the development of this guideline.

The main references were from:

A. WHO Clinical treatment guideline for tobacco cessation in adults (2024)
B. Supporting smoking cessation: A guide for health professionals (2024)
C. U.S. Department of Health and Human Services. Smoking Cessation. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health (2020).

GUIDELINES DEVELOPMENT

The members of the Development Group (DG) for these CPG were from the Ministry of Health (MoH), Ministry of Higher Education, and other stakeholders from industry i.e. private medical hospitals and non-governmental organisations. There was active involvement of a multidisciplinary Review Committee (RC) during the process of the CPG development.

A literature search was carried out using the following electronic databases: Guidelines International Network (G-I-N); Medline via Ovid, PubMed and Cochrane Database of Systemic Reviews (CDSR) (refer to Appendix 1 for Example of Search Strategy). The inclusion criteria are all literature on treatment on tobacco use disorder regardless of study designs. The search was limited to literature published in the last 15 years, humans and English. In addition, the reference lists of all retrieved literature and guidelines were searched to further identify relevant studies. Experts in the field were also contacted to identify relevant studies. In certain situations, pivotal papers beyond the scope of search were used in the CPG. All searches were conducted from 30th July 2016 to 8th September 2023. Literature searches were repeated for all clinical questions at the end of the CPG development process allowing any relevant papers published before 2nd August 2024 to be included. Future CPG updates will consider evidence published after this cut-off date. The details of the search strategy can be obtained upon request from the CPG Secretariat.

Reference was also made to other CPG on treatment of Tobacco use disorder such as the World Health Organization (WHO), National Institute for Health and Care Excellence (NICE) and European Psychiatric Association (EPA). The CPG was evaluated using the Appraisal of Guidelines for Research and Evaluation (AGREE) II prior to them being used as references.

A total of 22 clinical questions were developed under six (6) different sections. Members of the DG were assigned individual questions within these sections. (Refer to Appendix 2 for Clinical Questions).

The CPG committee members met 4 times throughout the development of these guidelines. The literature retrieved was appraised by at least two DG members using Critical Appraisal Skill Programme checklist, presented in evidence tables and further discussed in each DG meetings. All statements and recommendations formulated after that were agreed upon by the DG. Where evidence was insufficient, the recommendations were made by consensus of the DG. Any differences in opinion were resolved consensually. The CPG was based largely on the findings of systematic reviews, meta-analyses and clinical trials, with local practices taken into consideration.

On completion, the draft of the CPG was reviewed by external reviewers. This CPG has been developed to serve as a useful tool for doctors and other health professionals and students in Malaysia to treat tobacco use in various settings, including hospitals, clinics or pharmacies.

LEVELS OF EVIDENCE SCALE AND GRADES OF RECOMMENDATION

The literature used in these guidelines was graded using the US/Canadian Preventive Services Task Force Level of Evidence (2001), while the grading of recommendation was based on the US Government Agency for HealthCare Policy and Research (AHCPR) ABC Grade of Recommendation. In formulating the recommendations, overall balances of the following aspects are considered in determining the strengths of the recommendations:-

- Overall quality of evidence
- Balance of benefits versus harms and side effects
- Values and preferences
- Resource implications
- Equity, feasibility and acceptability

LEVELS OF EVIDENCE SCALE

Level	Study Design
I	Evidence obtained from at least one properly randomised controlled trial.
II-1	Evidence obtained from well-designed controlled trials without randomization.
II-2	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one research group.
II-3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments.
III	Opinions of respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

Adapted from the US / Canadian Preventive Services Task Force 2001

GRADES OF RECOMMENDATION

A	Data derived from multiple randomized clinical trials or meta analyses
B	Data derived from a single randomized clinical trial or large non-randomized studies
C	Only consensus of opinions of experts, case studies or standard of care

Adapted from the US Government Agency for Health Care Policy and Research

(AHCPR)

KEY RECOMMENDATIONS

The following recommendations were highlighted by the CPG Development Group as the key clinical recommendations that should be prioritised for implementation.

OBJECTIVE

The objective of the CPG is to provide evidence-based recommendations to assist healthcare providers in the identification, assessment and management of nicotine dependant and tobacco use disorder in general and specific population to optimise cessation rate.

However, this CPG is not meant as a substitute for clinical judgement and clinicians are recommended to individualize their treatment strategies.

TARGET POPULATION

a. Inclusion criteria: Individuals with nicotine dependence and tobacco use disorder.

b. Exclusion criteria: Individuals with other substance disorders.

TARGET USERS

This CPG has been developed to serve as a useful tool for doctors and other health professionals and students in Malaysia, to treat nicotine dependent and tobacco use disorder in various settings, including hospitals, clinics, pharmacies or community settings.

MONITORING FOR TREATMENT OF TOBACCO USE DEPENDENCE

Definition of a quitter - A smoker is considered to have successfully quit smoking if he has been abstinent without even a single puff of cigarette for at least six months from the last cigarette (also quit date).

Six months is a typical period for measuring successful smoking cessation. A 'Quit Rate' for any treatment centre is defined as the proportion of tobacco users who managed abstinent from smoking for at least 6 months, among those who attempted to quit smoking.

A typical six-month quit rate for an institution is calculated using the following formula:

$$= \frac{Number\ of\ successful\ quitters\ in\ the\ current\ six\ months\ (e.g. Jan - June)\ x\ 100\%}{Number\ of\ smokers\ who\ have\ set\ their\ quit\ dates\ in\ previous\ six\ months\ (e.g. Jul - Dec)}$$

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The draft guideline was reviewed by a panel of experts from the public and private sectors. Local reviewers were asked to comment on the updates of this CPG, in comparison to the 2016 version and to concentrate on the comprehensiveness and accuracy of the interpretation of evidence supporting the recommendations in this CPG.

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LIST OF ABBREVIATIONS

1.	CDC	Centres for Disease Control and Prevention
2.	CI	Confidence interval
3.	CPG	Clinical practice guideline
4.	CTPR	Control of tobacco products and regulations
5.	EC	Electronic cigarette
6.	ETS	Environmental tobacco smoke
7.	FDA	Food and Drug Administration
8.	MAO	Monoamine oxidase
9.	MoH	Ministry of Health
10.	NRT	Nicotine replacement therapy
11.	OR	Odds ratio
12.	RACGP	The Royal Australian College of General
13.	RR	Relative risk
14.	SR	Sustained release
15.	TTS	Transdermal therapeutics system

LIST OF TABLES

1.0 INTRODUCTION

Tobacco use is the single greatest preventable cause of death in the world today and the World Health Organization has demonstrated that tobacco use is a contributing risk factor for 6 of the 8 leading causes of death, worldwide[1, Level III]. Tobacco products are responsible for the deaths of over 8 million people worldwide. More than 7 million of these deaths were caused by direct tobacco use. Furthermore, our country has been dealing with an issue with electronic cigarette use since 2013 and the problem became more visible in 2016. In 2018, the use of electronic cigarettes has risen alarmingly among teenagers and young children due to the evolution of their shape, which now includes a variety of flavours.

Malaysia is a party to the WHO Framework Convention on Tobacco Control (WHO FCTC) since its enforcement in September 2005. Article 14 of the WHO FCTC demands that "each Party shall develop and disseminate appropriate, comprehensive and integrated guidelines based on scientific evidence and best practices, taking into account national circumstances and priorities, and shall take effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence". Strengthening tobacco cessation is core to the 'O - Offer help to quit tobacco use' component of the MPOWER strategy of the WHO FCTC [2, Level I].

Malaysia is committed to achieve its WHO Global NCD Target 2025, which is to reduce national smoking prevalence by 15% by 2025. There are two main strategies to achieve this, which are to reduce smoking initiation among youths and to help existing smokers to beat their nicotine addiction.

A National Strategic Plan on Tobacco Control has been developed by the Ministry of Health in 2021, incorporating the MPOWER strategy for co-ordinating tobacco in Malaysia[3, Level III]. Strengthening tobacco cessation services is given priority, with development of a standardised services across the public and private practices – 'the mQuit Services' as one the activities. This Clinical Practice Guideline is essential for delivery of uniformed tobacco cessation services through the mQuit Services.

Nicotine is highly addictive and some researchers have placed nicotine dependence as comparable to the dependence caused by opiates, cocaine, or other illicit drugs[4, Level I]. Effective pharmacologic and counselling strategies are now the pillars of tobacco cessation programmes, and taken in combination can achieve the highest rates of smoking cessation[5, Level III]. Pharmacotherapy for smoking cessation aims primarily to reduce the intensity of urges to smoke and/or ameliorate the aversive symptoms while counselling or behavioural support aims to boost or support motivation to resist the urge to smoke and develop people's capacity to implement their plans to avoid smoking[6, Level III].

Most smokers believe that stopping smoking is purely a matter of willpower and remain unaware of effective treatments to promote quitting. It is important that health care providers whom often treat smokers to be familiar with available therapies to educate patients of their options for smoking cessation.

2.0 EPIDEMIOLOGY OF TOBACCO USE IN MALAYSIA

Tobacco use is still widespread in Malaysia. The prevalence of current smokers may have reduced from 23.1% in 2011 to 19.0% in 2023, nonetheless, the number of smokers has increased slightly from 4.7 million to 4.8 million smokers[7,8] (Figure 1). In addition to that, the prevalence of e-cigarette / vape use has increased 600% from 0.8% in 2011 to 5.8% in 2023. There is an estimate of 1.4 million e-cigarette/vape users in Malaysia in 2023.

The GATS 2023 survey found that a mere 9.0% of current tobacco smokers planned to quit in the next month, while 13.3% were thinking about quitting in the next 12 months[8]. Two-thirds (66.6%) of current smokers who had visited a healthcare provider had received advice or reminders to quit smoking.

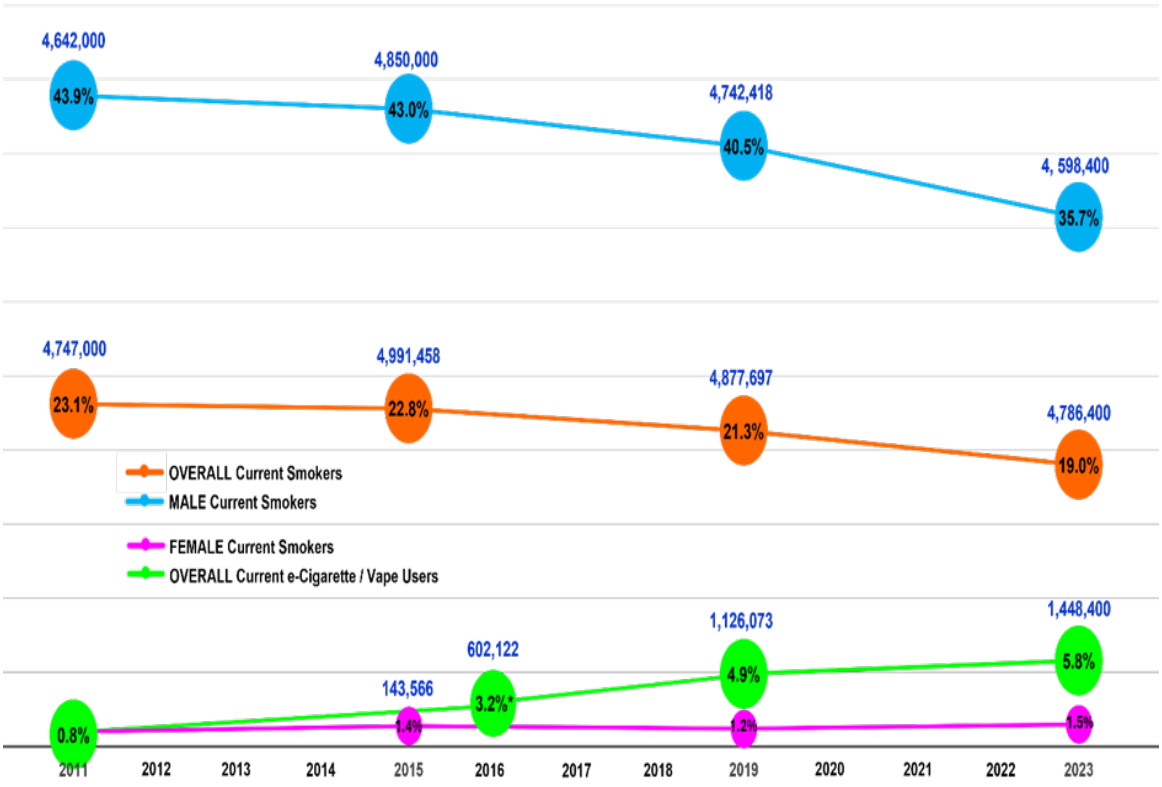


Figure 1 Trend of current smokers and e-cigarette / vape users among Malaysians aged 15 and above, from 2011 to 2023. Data is displayed as prevalence (%) and estimated population count.

Data from the Global School-based Student Health Survey (GSHS) series from 2012 to 2023 demonstrated that there is a decline in the prevalence of cigarette smoking among

Malaysian youths (Figure 2)[9,10]. Even though the prevalence of cigarette smoking has reduced from 11.5% to 6.2%, there is sharp rise of e-cigarette / vape use from 9.8% to 14.9% within 5 years. This 'switching' phenomenon was also previously seen among adolescents in the United States with the rapid surge of vaping popularity[11]. Alarmingly, vaping rates among Malaysian adolescents are high, with almost a quarter (23.5%) of boys and 6.2% of girls engaging in the habit.

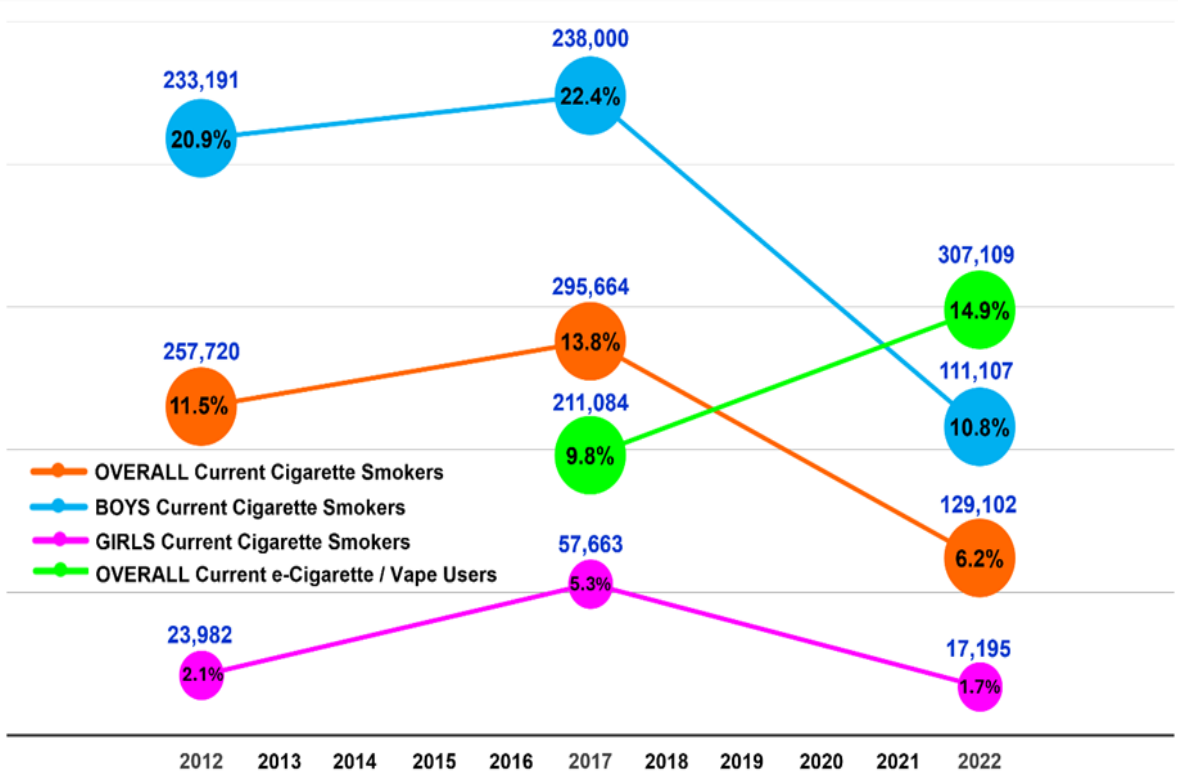


Figure 2 Trend of cigarette smoking and e-cigarette / vape use among Malaysian youths aged 13 to 17, from 2012 to 2022. Data displayed in prevalence (%) and estimated population count.

The statistics underscore Malaysia's double burden of nicotine use disorder: cigarette smoking and e-cigarette use. To effectively combat this crisis, comprehensive strategies are needed to deter initiation and promote cessation. Cessation services must be engaging and supportive, guiding users toward successful quitting. Enhancement of professional cessation services through evidence-based innovation and service delivery optimization is imperative to improve treatment reach, engagement, and cessation outcomes. This is particularly urgent given the increasing prevalence of nicotine dependence driven by electronic nicotine delivery systems (ENDS).

ASSESSMENT OF NICOTINE DEPENDENCE AND TOBACCO SMOKING

The first step in treating nicotine dependence and tobacco use disorder is to identify users. The identification of users in and of itself increases the likelihood of receiving clinician intervention. Effective identification of tobacco use status not only opens the

door for successful interventions (e.g., clinician advice and treatment) but also guides clinicians to identify appropriate interventions based on patients' tobacco use status and willingness to quit. This Guideline recommends that all healthcare providers use the opportunity at every encounter to assess and intervene all patients.

The assessments are to look for:

1. Level of nicotine dependence
2. Readiness to quit

Level of nicotine dependence for cigarette smokers can be assessed using the Modified Fagerström Test for Cigarette Dependence Questionnaire (See Appendix 3). Furthermore, smoking status can be verified with carbon monoxide (CO) in expired breath air. Exhaled CO level remains a useful parameter in predicting nicotine dependence, verification of smoking status and to motivate smokers to quit[13, Level I].

The Use of Spirometer

Simple dynamic spirometry is a useful healthcare tool to measure pulmonary function in smokers and help motivate them to quit smoking. Feedback on smoking-related harm, including nine studies testing spirometry with or without feedback on lung age and two studies on feedback on carotid ultrasound, also did not show a benefit (RR 1.26, 95% CI 0.99 to 1.61; I2 = 34%; n = 3314)[15, Level I]. However, a recent randomized clinical trial suggested that regular and detailed feedback of spirometry results with smokers increases smoking cessation. Specifically, the likelihood of quitting smoking in the intervention group is 1.42 times higher than in the control group (p = 0.018) [16, Level 1].

There is no evidence or study showing the use of spirometry to assess smoking status in the literature. However, feedback on the spirometry results could be used as motivation to assist smokers quitting smoking.

Screening for current or past tobacco use will result in four possible responses:

A. The patient uses tobacco and is now willing to make a quit attempt;
B. The patient uses tobacco but is now not willing to make a quit attempt;
C. The patient once used tobacco but has since quit;
D. The patient never regularly used tobacco.

Assessment tools to measure electronic cigarette dependence

One of the primary tools for assessing dependence on electronic cigarettes is the Penn State Electronic Cigarette Dependence Index (PS-ECDI), developed by Foulds and colleagues (2015) (refer to Appendix 4). The PS-ECDI was adapted from the Penn State Nicotine Dependence Index[17] and consists of a 10-item scale designed to evaluate key dimensions of nicotine dependence as outlined in the DSM-V. These dimensions include

frequency of use, motivation, withdrawal symptoms, difficulty in cessation, and craving. The instrument incorporates elements from well-established nicotine dependence measures, including the Fagerström Test for Nicotine Dependence (FTND), the Heaviness of Smoking Index (HSI), and the Hooked on Nicotine Checklist (HONC). In addition, it includes specific items assessing nocturnal awakenings to vape and subjective cravings [17]. A PS-ECDI score of 13 or higher is indicative of a high level of dependence[18].

The e-cigarette Fagerström Test of Cigarette Dependence (e-FTCD) is an adaptation of the well-established and validated Fagerström Test of Cigarette Dependence (FTCD). In this adaptation, all references to “cigarettes” have been replaced with “e-cigarettes,” and all mentions of “smoking” have been substituted with “vaping.” This modification allows for the assessment of nicotine dependence specifically in the context of e-cigarette use. The scoring of the e-FTCD follows the same methodology as the original FTCD, where the total score is derived by summing the individual item responses. Higher scores on the e-FTCD correspond to greater levels of dependence on e-cigarettes[19].

The E-cigarette Dependence Scale (EDS) is adapted from the Patient-Reported Outcome Measurement Information System (PROMIS) Tobacco Dependence Bank (See Appendix 6). This scale is available in 22-item, 8-item, and 4-item versions, all of which have been validated as effective tools for assessing e-cigarette nicotine dependence in both adults and youth[20,21]. Higher scores on the EDS indicate a greater level of nicotine dependence.

This ten-item screening scale, the HONC is designed to identify the point at which an individual has lost full autonomy over their nicotine use and to assess the onset and severity of nicotine dependence. The scale evaluates the lifetime occurrence of cravings, withdrawal symptoms, and difficulties with cessation. It is applicable for use with individuals aged 12 and older[22,23] (See Appendix 7).

4.0 CLINICAL INTERVENTIONS FOR TOBACCO USE DISORDER

There are two types of clinical intervention depending on the intensity of intervention and level of service provided. They are:

1. Very brief intervention
2. Brief intervention
3. Intensive intervention

4.1 Very Brief Intervention for Tobacco Use Disorder

Very brief advice (VBA) refers to advice on quitting smoking delivered within 30 seconds to ⩽ 3 minutes, usually in primary healthcare settings. Examples of VBA interventions are the ABC (Ask about smoking, give Brief advice to quit, and offer Cessation assistance)[22] and the AAR (Ask, Advise, Refer)[23].

Results of thirteen randomized controlled trials (n = 26,437) indicated moderate-certainty evidence that VBA significantly increased self-reported tobacco abstinence at ≥ 6 months in the adjusted model (adjusted risk ratio ARR 1.17, 95% CI: 1.07-1.27) compared with controls. The sensitivity analysis showed similar results when abstinence was verified by biochemical validation (n = 6 studies, RR 1.53, 95% CI 0.98-2.40). There was high-certainty evidence that VBA significantly increased abstinence at < 6 months (ARR 1.22, 95% CI: 1.01-1.47). However, evidence of effect on quit attempts (ARR 1.03, 95% CI 0.97-1.08) was of very low certainty[24]. The WHO recommends that very brief advice should be routinely delivered to every tobacco user who accesses healthcare settings as a feasible, equitable, acceptable, and low-cost intervention[25].

4.2 Brief Intervention for Tobacco Use Disorder

4.2.1 For All Smokers

Brief intervention (BI) is an evidence-based intervention for smoking cessation aimed at identifying smokers and subsequently providing advice and assistance to quit smoking[26]. It is vital to change clinical culture and practice patterns to ensure that every patient who uses tobacco is identified and offered treatment.

The WHO recommends a form of BI for smoking cessation through the 5As (Ask, Advise, Assess, Assist, Arrange follow-up) and 5Rs (Relevance, Risk, Rewards,

Roadblocks, Repetition) model[25]. The five major steps (5 As) for intervention are described as follows and summarised in Table 1. The strategies are designed to be brief and minimal health care provider's time is required.

These brief opportunistic advice typically involve asking patients about their current smoking status, advising them to stop, offering assistance either by providing further advice, a referral to a specialist service or recommendation of or a prescription for pharmacotherapy or arranging a follow up wherever it is appropriate. The focus of this opportunistic advice is to increase smokers' motivation to quit in improving the success rate of quitting[18]. This brief intervention has been shown to increase overall tobacco abstinence rates regardless of whether he or she is subsequently referred to an intensive [19,20 Level I,21 Level III].

The steps involved in the delivery of brief intervention include:

Step 1: Ask about tobacco smoking

ALL patients should be **asked** about their smoking status and the findings should be documented in the patient's notes. This should be delivered opportunistically during routine consultations to all smokers regardless whether they are seeking help to stop smoking. For people who smoke or have recently stopped smoking, the smoking status should be checked and updated at every visit to prevent relapse. Systems should be in place in *all* health care settings to ensure that smoking status is accurately documented at every visit ([20, Level I; 6, Level I])

Step 2: Advice to quit

Advice to quit should be given clearly to all patients found to be smoking. Studies have shown that advice by health care providers (medical, dental, pharmacist, nurses, etc.) increases rates of abstinence. There is a strong dose-response relationship between the session length of person-to-person contact and successful treatment outcomes[20, Level I].

Multiple efforts by health care providers can increase these rates further. Every tobacco user should be offered at least a brief intervention which consists of brief cessation advice from the health care providers. However, intensive interventions are more effective than brief interventions and should be used whenever possible as smokers' motivation, beliefs and feelings about smoking and quitting may be conflicting18, Level III. Face - to - face treatment delivered for five or more sessions, lasting for at least 10 minutes per session, appears especially effective in increasing abstinence rates (WHO, 2024). Therefore, if feasible, treatment providers should strive to meet five or more times with individuals quitting tobacco use.

Health care workers should be provided with appropriate training to enable them to provide brief advice. This training should include providing the health care worker with information on available evidence-based smoking cessation treatments[19]. The

WHO offers a free e-learning course to train primary care providers to learn brief interventions delivery (https://campus.paho.org/en/node/30781).

Step 3: Assess readiness to make a quit attempt

Health care providers involved with tobacco treatment should **assess** the readiness to begin treatment to quit.

Though there is a lack of evidence for greater effectiveness of stage based approaches [27,23, Level I], stages of change model provides a useful framework to help health care providers to identify smokers and assist smokers in quitting[24, Level III].

There is some evidence that the likelihood of success in an attempt to quit is unrelated to the smoker's expressed interest in quitting in the period leading up to the attempt – unplanned attempts to quit are as likely (or even more likely) to be as successful as planned attempts[25, Level III; 26, Level III]. Thus, there is benefit in encouraging all smokers to consider quitting whenever the opportunity arises[20, Level I].

Step 4: Assist in quit attempt

All patients should be **assisted** to quit. Brief advice as short as 30 seconds and self-help material have been shown to help (Cheng et al., 2024)[14, Level I]. Brief advice (3-5 minutes) is effective and there is a dose response in treatment provision.

Setting a quit date has been shown to be effective. Ideally the quit date should be within 2 weeks on assessment to quit.

Step 5: Arrange follow up

Health care providers wanting to do more intensive counselling will require further appropriate training. Health care providers who are not confident in providing counselling interventions can still assist patients wanting to quit by **arranging** referrals to services that can assist.

Patients who are attempting to quit are at high risk of relapsing. Continuous abstinence is achieved when the patient has not smoked for at least 6 months. The highest risk of relapse is within the first 8 days of quitting. Hence the support has to be given the utmost importance in the first week of quitting cigarette smoking. Evidence has shown that abstinence of 12 months follow up is a good indicator for long term abstinence[31].

The evidence suggests that multiple treatment sessions increase smoking abstinence rate and its effectiveness. More intensive interventions (more than eight sessions in six months) may produce enhanced abstinence rate. However, these interventions may have limited reach (affect fewer smokers) and may not be feasible in some primary care settings[20, Level I].

The steps recommended by the NCSCT for evidence-based behaviour change techniques to assist health care providers in managing smokers who seek clinic help to quit smoking are[32, Level I]:-

Session 1: Pre-quit Assessment (1 or 2 weeks prior to Quit Date)
Session 2: Quit Date
Session 3: 1 week post Quit Date
Session 4: 2 weeks post Quit Date
Session 5: 3 weeks post Quit Date
Session 6: 4 weeks post Quit Date
(See Appendix 4 for details)

Table 2: The "5 A's" for brief intervention

1. Ask about tobacco use: ● Identify and document tobacco use status for every patient at every visit, including the adolescents. ● Where appropriate, ask the individual accompanying the patient about tobacco use or exposure to tobacco smoke. **What needs to be done?** Expand the vital signs to include tobacco use or use an alternative universal identification system (e.g. stickers on patient charts).

2. Advise to quit:

In a clear, strong and personalized manner, urge every tobacco user to quit.

Advice should be:

- Clear—"I think it is important for you to quit smoking now and I can help you." "Cutting down while you are ill is not enough."
- Strong—"As your clinician, I need you to know that quitting smoking is the most important thing you can do to protect your health now and in the future. The clinic staff and I will help you."
- Personalised —Tie tobacco use to current health/illness, and/or its social and economic costs, motivation level/readiness to quit, and/or the impact of tobacco use on children and others in the household.

3. Assess readiness to make a quit attempt:

Is the tobacco user ready to make a quit attempt at this time?

- If the patient is ready to make a quit attempt at this time, provide assistance.
- If the patient will participate in an intensive treatment, deliver such a treatment or refer to an intensive intervention.
- If the patient clearly states he or she is not ready to make a quit attempt at this time, provide a motivational intervention built around the “5 R’s”: relevance, risks, rewards, roadblocks, and repetition. (Refer to section Smokers not ready to quit, page 32)
- If the patient is a member of a special population (e.g., adolescent, pregnant smoker), consider providing additional information (refer to section Special Population, page 39).

4. Assist in quit attempt:

- For the patient ready to make a quit attempt, use counselling with pharmacotherapy (when indicated) to help him or her quit.

Preparations for quitting: (STAR)

- **S**et a quit date. Ideally, the quit date should be within 2 weeks. Reduce the number of cigarettes gradually before the set date.
- **T**ell family, friends, and co-workers about quitting and request understanding and support. Also, help patients obtain extra-treatment social support from self-help groups. Other smokers in the household. Patients should encourage household members to quit with them or not smoke in their presence to minimize risk of treatment failure and exposure to second-hand smoking.
- **A**nticipate challenges to planned quit attempts, particularly during the critical first few weeks. These include nicotine withdrawal symptoms. Discuss challenges/triggers and how patients will successfully overcome them. Provide patients with problem solving/skills training.
- **R**emove tobacco products from his or her environment. Prior to quitting, avoid smoking in places where a lot of patient's time is spent (e.g., work, home, car).
- Provide a supportive healthcare environment while encouraging the patient in his or her quit attempt.
- Abstinence. Total abstinence is essential. Not even a single puff after the quit date.
- Past quit experience. Identify what helped and what hurt in previous quit attempts.
- Alcohol. Since alcohol can cause relapse, the patient should consider limiting/abstaining from alcohol while quitting.
- Recommend the use of approved pharmacotherapies, if indicated. Explain how these medications increase smoking cessation success and reduce withdrawal symptoms.
- Provide supplementary materials.

5. Arrange follow-up:

Schedule follow-up, preferably within the first week after the quit date.

- **Timing**. Follow-up should occur soon after the quit date, preferably during the first week. Subsequent follow-ups are recommended weekly within the first month, and then every two weeks for the 2nd and 3rd month, and monthly after that up to 6 months.
- For those who successfully quit, schedule follow-up, either in person or via telephone. Actions during follow-up:
  - Congratulate success
  - If tobacco use has occurred, review circumstances and elicit commitment to total abstinence.
  - Remind patients that a lapse can be used as a learning experience. Identify problems already encountered and anticipate challenges in the immediate future.
  - Assess pharmacotherapy use and problems. Consider using more intensive treatment, if not available, referral is indicated.

Adapted from Fiore et al. 2008[20, Level I]*.*

Recommendation 1	Grade of Recommendation
Ask and document smoking status for **all** patients. Provide brief advice on quitting smoking at every visit to all smokers.	**C**
Use individual, group and telephone counselling approaches, or in combination for smoking cessation interventions.	**A**
Arrange a minimum of six to eight face to face follow-up sessions for smoking cessation interventions in six months.	**A**

4.2.2 ABC of Smoking Cessation

Alternatively, another approach is the ABC approach to help smokers to quit smoking (see Appendix 5). The ABC approach has been shown to be as effective as the 5As approach in encouraging quit attempts and abstinence in a randomized controlled trial (Kastaun et al., 2021, Level I).

The steps are as follows:

A. **Ask all people** about their smoking status and document this.
B. Provide **Brief advice to stop smoking** to all people who smoke, regardless of their desire or motivation to quit.
C. Make an offer of, and refer to or provide, evidence-based **Cessation treatment**.

Implementing the ABC Approach for Smoking Cessation Framework and work programme[19]

Physicians may be more effective in promoting attempts to stop smoking by offering assistance to all smokers than by advising smokers to quit and offering assistance only to those who express an interest in doing so[6]. Some facilitators that could aid a health professional to consistently carry out the ABC approach are training provision, system prompts, audits and feedback on the health professional's performance, and leadership assumption in advocating for systems-wide smoking cessation efforts (New Zealand Ministry of Health, 2021).

4.3 Intensive Interventions for Nicotine Dependence and Tobacco Use Disorders

Intensive interventions for nicotine cessation and tobacco use disorders include individual counselling, group counselling, and telephone counselling. Evidence shows that intensive tobacco dependence treatment is more effective than brief treatment (Lancaster & Stead, 2017, Level 1). This could be achieved by increasing the length of individual treatment sessions, the number of treatment sessions and specialized behavioural therapies. Intensive interventions could be provided by any suitably trained doctors and other health care providers who have the resources available to give intensive interventions and are appropriate for any tobacco user willing to participate in them [20, Level I].

Individual counselling is delivered by trained therapists in one-to-one sessions, typically involving an assessment of smoking history, identification of high-risk situations, and problem-solving strategies to minimise use and relapse (Hartmann-Boyce et al., 2022, Level 1). In a review of 33 trials (N = 13,762), high-certainty evidence of benefit for the provision of individual counselling compared to minimal support was found (1.48 (95% confidence interval (CI) 1.34 to 1.64, n = 13,762) (Lancaster & Stead, 2017, Level 1). Studies in Lower- and Middle-Income Countries

(LMICs) found that behavioural counselling was more effective than minimal interventions (OR = 6.87, 95% CI = 4.18–11.29, P < 0.001) (Akanbi et al., 2019, Level 1).

With regards to group counselling, thirteen trials compared a group programme with a self-help programme; there was an increase in cessation with the use of a group programme (N = 4,395, risk ratio (RR) 1.88, 95% confidence interval (CI) 1.52 to 2.33). Group therapy is better for helping people stop smoking than self-help, and other less intensive interventions. There is not enough evidence to evaluate whether groups are more effective, or cost-effective, than intensive individual counselling. Findings showed that individual delivery was less effective than delivery as part of a group (OR 0.78, 95% CrI 0.64–0.95) (Hartmann-Boyce et al., 2022).

Table 3: Components of an intensive nicotine dependence and tobacco use disorder intervention

Assessment	● Assessments should determine whether tobacco users are ready to make a quit attempt using an intensive treatment programme. ● Other assessments can provide information useful in counselling (e.g., stress level).
Programme clinicians	● Multiple types of clinicians are effective and should be used. ● One counselling strategy would be to have a medical/health care clinician deliver a strong message to quit and information about health risks and benefits and recommend and prescribe medications recommended in this Guideline update. ● Nonmedical clinicians could then deliver additional counselling interventions.
Programme intensity	There is evidence of a strong dose-response relation; therefore, when possible, the intensity of the programme should be: ● Session length – longer than 10 minutes for session or more ● Number of sessions – 5 or more

Programme format	● Either individual or group counselling may be used. ● Telephone counselling also is effective and can supplement treatments provided in the clinical setting. ● Use of self-help materials and cessation Web sites is optional. ● Follow up interventions should be scheduled.
Type of counselling and behavioural therapies	Counselling should include practical counselling (problem solving/skills training) and intra-treatment social support.
Medication	● Every smoker should be offered medications endorsed in this Guideline, except when contraindicated or for specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). ● The clinician should explain how medications increase smoking cessation success and reduce withdrawal symptoms. ● Combination of certain cessation medications increases success rate compared to monotherapy. ● Combining counselling and medication increases abstinence rates higher than either individual intervention.
Population	Intensive intervention programmes may be used with all tobacco users ready to participate in such efforts.

Adapted from Fiore et al. 2008 (Level I).

Another promising behavioural intervention is offering financial incentives are rewards in the form of vouchers or cash given to smokers if they said they quit smoking. Guaranteed financial incentives, in particular, had high-certainty evidence of effectiveness even six months beyond the intervention duration (OR 1.46, 95% CrI 1.15 to 1.85, 19 studies, n = 8877), and there was no significant difference between lower and higher amounts of incentivisation. Financial incentives delivered via SMS, with tailoring and a focus on how to quit, had an estimated OR of 2.94 (95% CrI 1.91–4.52) (Notley et al., 2019).

4.4 Pharmacological Intervention

All smokers attempting to quit should be offered pharmacotherapy unless contraindicated[21, Level I].

Agents recommended for pharmacotherapy are divided into:

1. Nicotine based – e.g. nicotine replacement therapies (NRT), e.g., gum, patch, lozenge, oral mouth spray and inhaler.
2. Non-nicotine based – e.g. varenicline, sustained release (SR) bupropion, cytisine and nortriptyline.

Choice of a specific first-line pharmacotherapy should be guided by four main factors; efficacy, safety, suitability and cost.

Nicotine replacement therapy

NRT helps to reduce withdrawal symptoms associated with stopping smoking by replacing the nicotine from tobacco products. NRT is available as skin patches that deliver nicotine slowly, and chewing gum, inhalers/inhalators, oral mouth sprays, microtabs, nasal sprays and lozenges, all of which deliver nicotine to the brain more quickly than from skin patches, but less rapidly than from smoking cigarettes or e-cigarettes.

Evidence shows that all forms of NRT made it more likely for a person's quit attempt to succeed. The chances of stopping smoking were increased by 50 to 60%. The evidence suggests no overall difference in effectiveness between different forms of NRT.[28, Level I]

NRT products work with or without additional counselling. NRT products in Malaysia do not require a doctor’s prescription as they are Group C or over-the-counter (OTC) medications. Heavier smokers usually need higher doses of NRT. People who use NRT during a quit attempt are likely to further increase their chances of success by using a combination of two NRT products. Combination NRT, compared to single-form NRT, as well as the use of 4 mg versus 2 mg nicotine gum, has been shown to enhance the likelihood of successful smoking cessation[29,Level I]. There was high-certainty evidence that combination NRT (a short-acting form plus a patch) results in higher long-term quit rates (17% to 37%) than single-form NRT (RR: 1.27; 95% CI: 1.17-1.37; 16 studies; 12,169 participants) [29,Level I]. Nicotine patch with short-acting nicotine- replacement therapy (e.g., NRT gum) appears safe and increases abstinence versus nicotine-replacement monotherapy (OR=1.63, 95% CI 1.06 to 3.03). [31,Level I]

Data suggest that starting to use NRT patches shortly before the planned quit date may increase the chance of success [32,Level I]. There is moderate-certainty evidence that neither reduction-to-quit nor abrupt quitting interventions result in superior long-term quit rates when compared with one another. Evidence comparing the efficacy of reduction-to-quit interventions with no treatment was inconclusive and of low certainty. There is also low-certainty evidence to suggest that reduction-to-quit interventions may be more effective when pharmacotherapy is used as an aid, particularly fast-acting NRT (such as gum or lozenge) or varenicline (moderate-certainty evidence).[30,Level I]

Adverse effects from using NRT are related to the type of product and include skin irritation from patches and irritation to the inside of the mouth from gum and lozenge. There is no evidence that NRT increases the risk of heart attacks.[28, Level I]

NRT provides some of the nicotine that a person would have otherwise received from tobacco, and in doing so reduces the person's urge to smoke.

All NRT products roughly double a person's chance of stopping compared with a placebo.

People should use NRT for at least eight to twelve weeks.

Using two NRT products (for example, patches and gum) is more effective than using one.

People who need NRT for longer than 12 weeks can continue to use it.

If the person is not ready to stop smoking straight away, NRT can be used to help reduce their smoking before they stop.

There are different NRT products available in Malaysia, including the patch, gum and oral spray.

Varenicline

Varenicline, a specific nicotine receptor partial agonist, may help people stop smoking by a combination of maintaining moderate levels of dopamine to counteract withdrawal symptoms (acting as an agonist) and reducing smoking satisfaction (acting as an antagonist). The odds of quitting were between two and three times higher with varenicline than that with placebo. Varenicline was about 50% more effective than any single formulation of NRT (patches, gum, lozenges, and inhalers), but similar in efficacy to combining two types of NRT. [33,Level I]

There is high-certainty evidence that varenicline helps more people to quit than placebo (RR 2.32, 95% CI 2.15 to 2.51, 41 studies, 17,395 participants). Varenicline at lower or variable doses was also shown to be effective, with an RR of 2.08 (95% CI 1.56 to 2.78).[35, Level I]

There is high-certainty evidence that varenicline helps more people to quit than bupropion (RR 1.36, 95% CI 1.25 to 1.49, 9 studies, 7560 participants), or a single

form of NRT (RR 1.25, 95% CI 1.14 to 1.37, 11 studies, 7572 participants). Quit rates of using varenicline might be similar to using more than one type of NRT at the same time (e.g., patches and gum together) (RR 1.02, 95% CI 0.87 to 1.20, 5 studies, 2344 participants). [33,Level I]

Trials which tested the use of varenicline beyond the 12-week standard regimen found the drug to be well-tolerated during long-term use. The number needed to treat with varenicline for an additional beneficial outcome, based on the weighted mean control rate, is 11 (95% CI 9 to 13).[35, Level I] Varenicline is indicated beyond three months treatment for relapse prevention.

The most reported adverse effect of varenicline was nausea, which was mostly at mild to moderate levels and usually subsided over time. Serious adverse events (SAE) such as neuropsychiatric occurring during or after active treatment suggests there may be a 23 % increase in the chance of SAEs among people using varenicline (RR 1.23; 95% CI 1.01 to 1.48, 26 studies, 14,356 participants). [33,Level I] There is no clear evidence of difference between varenicline and bupropion in rates of SAEs, neuropsychiatric, or cardiac SAEs.

However, subsequent observational cohort studies and meta-analyses have not confirmed these fears. The findings of the largest trial to date on varenicline and bupropion in comparison with NRT and placebo in subjects with and without psychiatric disorders do not support a causal link between varenicline and neuropsychiatric disorders, including suicidal ideation and suicidal behaviour. [36, Level I]. Concerns have also been raised that varenicline may slightly increase cardiovascular events in people already at increased risk of those illnesses. Current evidence neither supports nor refutes such an association.[35, Level I]

Varenicline reduces a person's urge to smoke, as well as the 'reward' they get from smoking, and at least doubles a person's chance of stopping smoking.

Before prescribing or recommending varenicline, check the contraindications and cautions that apply.

Pregnant or breastfeeding women and people under the age of 18 cannot use varenicline.

Patients should use it for 12 weeks.

Common adverse effects include nausea, abnormal dreams and sleep disturbance. More serious adverse events – such as cardiovascular events, depression, suicidal ideation and suicide – have been reported, although these are uncommon.

If someone using varenicline experiences changes in mood or behaviour, advise them to stop taking varenicline and contact a health care provider immediately.

Cytisine

Cytisine increases the chances of successful smoking cessation by more than twofold compared with placebo and has no evidence of serious safety concerns. Cytisine can help people to stop smoking for at least 6 months (RR: 2.61; 95% CI: 1.50–4.67; 6 trials; 5194 participants). Studies showed that participants on cytisine were significantly more likely to have higher long-term abstinence rates than those who received NRT (RR: 1.36; 95% CI: 1.06–1.73; 2 trials; 1511 participants). There was no significant difference in the likelihood of quitting tobacco use between participants taking cytisine and varenicline (RR: 0.96; 95% CI: 0.63–1.45; 3 trials; 2127 participants)**.** There is moderate-certainty evidence that it may work as well as varenicline (RR 0.83, 95% CI 0.66 to 1.05, 2 studies, 2131 participants).[33, Level I]

Antidepressants

Bupropion and nortriptyline also aid long-term smoking cessation. There is high-certainty evidence that bupropion helps people to quit smoking for at least 6 months (RR 1.60, 95%CI 1.49 to 1.72, 50 RCTs, 18,577 participants). The odds of quitting were about 60% higher with bupropion than placebo. Evidence suggests that the mode of action of bupropion and nortriptyline is independent of their antidepressant effect and that they are of similar efficacy to nicotine replacement. Nortriptyline was more effective than placebo but did not offer any additional improvement when combined with NRT. Evidence suggests that neither selective serotonin reuptake inhibitors (e.g. fluoxetine) nor monoamine oxidase inhibitors aid cessation.[34,Level I]

People are 17% more likely to experience SAEs that could result in people stopping taking it or having to go to the hospital when taking bupropion. Nortriptyline appears to help people to quit smoking, but bupropion may be more effective. Bupropion may be as helpful as a single form of NRT in helping people to quit smoking, but less than combination NRT (a patch plus another form) and varenicline. [34,Level I]

The side effects of bupropion include insomnia, dry mouth and nausea and rarely (1:1000) seizures and perhaps psychiatric problems, but the last is unclear. There is also moderate quality evidence, limited by a relatively small number of included studies and participants, that the antidepressant nortriptyline increases quit rates (six trials, 975 participants). The side effects of nortriptyline include dry mouth, constipation, nausea, and sedation, and it can be dangerous in overdose.[37, Level I]

Bupropion is an atypical antidepressant that reduces the severity of tobacco withdrawal and approximately doubles a person's chance of stopping smoking.

People should start bupropion at least one week before their quit date and use it for at least seven weeks.

Before prescribing or recommending bupropion, check the contraindications and cautions that apply.

Pregnant or breastfeeding women and people under the age of 18 cannot use bupropion.

Common adverse effects include dry mouth, insomnia and headache. Seizure has been rarely reported and depression has been reported in some people.

Nortriptyline is an antidepressant medicine that also helps people stop smoking.

Nortriptyline reduces the severity of tobacco withdrawal symptoms and roughly doubles a person's chance of stopping smoking long term.

People should start nortriptyline at least one week before their quit date and use it for 12 weeks. The dose should be tapered at the end of treatment to avoid withdrawal symptoms that may occur.

Before prescribing or recommending nortriptyline, check the contraindications and cautions that apply.

Pregnant or breastfeeding women and people under the age of 18 cannot use nortriptyline.

Common adverse effects include drowsiness and dry mouth.

There are no fixed algorithms to guide optimal selection among these first-line medications. Cost may become the predominant factor when the smoker is paying out-of-pocket, as in buying the medication from a community pharmacist or private quit smoking cessation service. Suitability factors (e.g. nature of job, preference, etc.) should be considered to fit the medication to the lifestyle of the smoker. For instance, the NRT patch is the most discreet among the NRT products since it can be worn under the clothing. Conversely, some smokers prefer an oral form of the

NRT products (e.g., gum, lozenge or inhaler) since it addresses the hand and/or mouth fixation, to a certain extent, associated with smoking. Others prefer the simplicity of taking a tablet, as in the case of varenicline or bupropion.

Healthcare providers should discuss the pertinent details of the available medications with each smoker (Refer Appendix 6). Some smokers may prefer to sample a few preparations before finding the one most suitable for them. NRT preferences based on explanations have been shown to change after sampling. NRT sampling may also lead to better choice and treatment compliance.[38, Level II-2]

Prior successful experience (sustained abstinence with the medication) suggests that the medication may be helpful to the patient in a subsequent quit attempt, especially if the patient finds the medication to be tolerable and/or easy to use. However, some evidence suggests that retreatment of relapsed smokers with the same medication produces small or no benefit, while other evidence suggest that it may be of substantial benefit.[20, Level I]

The recommended duration of treatment is 12 weeks. The use of NRT for less than 4 weeks was associated with reduced likelihood of cessation. NRT use for longer periods of time has been associated with a higher likelihood of cessation. However, data suggest no overall benefit for using patches beyond eight weeks.[39, Level II-2]

Recommendation 2	**Grade of Recommendation**
All smokers who are attempting to quit should be offered pharmacotherapy, unless contraindicated.	**A**

4.4.1 Combination of pharmacological agents

Monotherapy of NRT provides lower levels of plasma nicotine as compared to that produced by cigarette smoking (Fig 1.) While monotherapy has been shown to be effective in most smokers, others, especially those who are hard-to-treat, may require combination strategy.

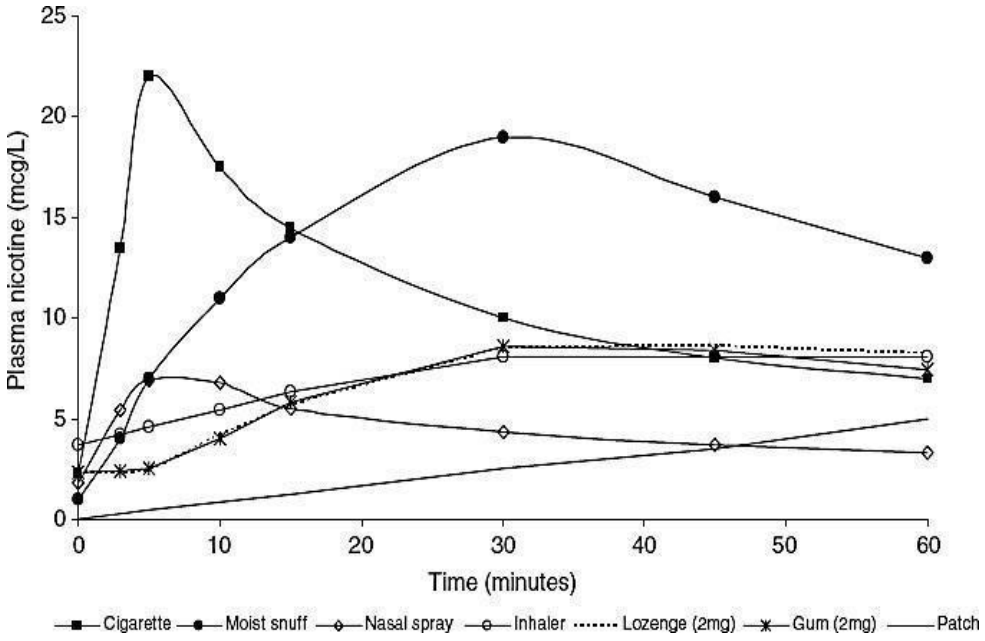


Figure 1. Plasma nicotine concentration for various nicotine containing products. Data from Fant et al. 1999[40]; Choi et al. 2003; Schneider et al. 2001[41]. (From Rx for Change: Clinician-Assisted Tobacco Cessation. The Regents of the University of California, University of Southern California and Western University of Health Sciences © 1999-2005: with permission)

Certain combinations of first-line medications have been shown to be effective smoking cessation treatment. Therefore, clinicians should consider using these combinations of medications in their patients who are willing to quit. Effective combination medications are[20, Level I]:

(1) Long-term (>14 weeks) nicotine patch + other NRT (gum and spray)
(2) Nicotine patch + nicotine inhaler
(3) Nicotine patch + bupropion SR

Strategies of combining agents available (e.g., two NRTs, a non-NRT, e.g. bupropion with an NRT) may be more efficacious. For example, combining the nicotine patch with a self - administered form of nicotine replacement therapy (either the nicotine gum or nicotine inhaler) is more efficacious than a single form of nicotine replacement, and patients should be encouraged to use such combined

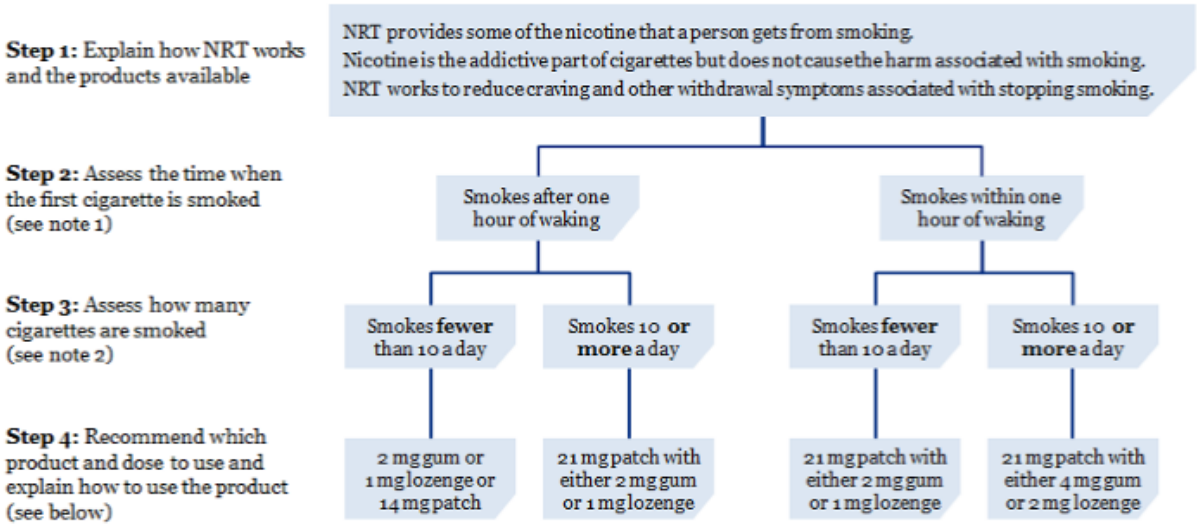
treatments if they are unable to quit using a single type of first-line pharmacotherapy[42 Level I; 43; 44].

Current literature indicates that combination therapy is statistically better than monotherapy in smoking cessation treatment. Adverse effects and adherence to combination therapy are similar to monotherapy and placebo[45].

Combination therapy may be most useful for those smokers at highest risk of relapse, e.g. heavy smokers, smokers who have relapsed multiple times, or smokers with psychiatric co-morbidities. However, cost is an important consideration [46].

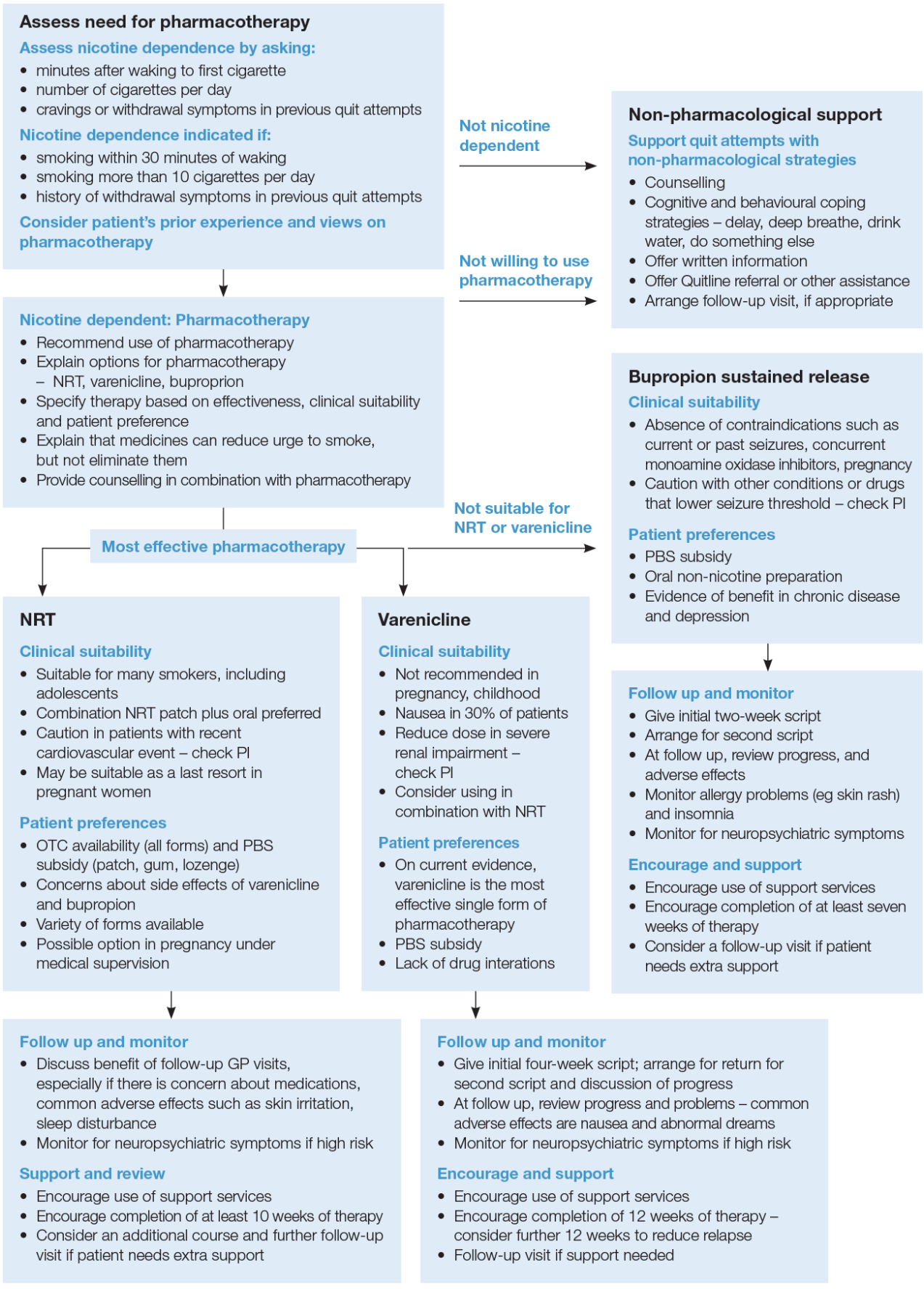
Combining varenicline with NRT agents has been associated with higher rates of side effects (eg nausea, headache)[20, Level I].

Algorithm of NRT use based on New Zealand 2021 CPG



Algorithm of NRT initial dosing

Adapted from RACGP 2024 Supporting smoking cessation: A guide for health professionals (https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/pharmacotherapy-for-smoking-cessation). [Accessed 9 November 2025].



Source: Supporting smoking cessation: A guide for health professionals (RACGP, 2024)

4.4.3 Combination of pharmacological agents with behavioural intervention

There is high quality evidence that using a combination of behavioural support and pharmacotherapy increases the chances of successfully quitting (RR 1.15, 95% CI 1.08 to 1.22). There is high-certainty evidence that providing behavioural support in person or via telephone for people using pharmacotherapy to stop smoking increases quit rates. Increasing the amount of behavioural support is likely to increase the chance of success by about 10% to 20%, based on a pooled estimate from 65 trials[48]. Level I

4.5 Traditional, complementary and alternative therapies

4.5.1 Digital smoking cessation interventions

Two studies have found that text message mobile phone support programmes are effective in the short term (6 weeks) and long term [55, Level I; 56, Level I]. Combined internet/ mobile telephone programmes can be effective for up to 12 months for assisting smokers to quit [57, Level I; 58, Level I].

Digital smoking cessation interventions are low cost and have the potential to reach a large number of smokers [59, Level I; 60, Level I]. Web based programmes are a promising delivery system for assisting smokers to quit, but further research is needed to identify their most effective use.

There are many other treatments and interventions that people may ask about or want to use, such as hypnosis and acupuncture. However, there is evidence that some of these interventions do not help people to stop smoking, and for other interventions, there is insufficient evidence as to their effectiveness

4.5.2 Hypnotherapy

There is not enough evidence to conclude whether hypnotherapy is more effective for smoking cessation compared to pharmacotherapies, other types of behavioral support, or quitting without assistance. In a meta-analysis of 14 studies, only one study was judged to be of low risk of bias, and most studies did not report significant results in favour of quitting smoking at six-month follow-up or longer (Barnes et al., 2019, Level I, Class A).

4.5.3 Exercise

Aerobic exercise has been found useful in aiding smoking cessation (associated with behavioural support and drug therapy) during the first 3 months of cessation (11 trials, risk ratio 0.79; 95% confidence interval, 0.66–0.94). However, there were no differences in aerobic exercises compared with usual care at medium- and long-term follow-ups. It should be noted that there was variability across included studies related to the intensity, duration, and frequency of exercise in the systematic review and analysis from which this recommendation derives[35,Level I]. Future programs should look to combining aerobic exercise and administering it in tandem with

behaviour change techniques to maintain abstinence.

4.5.4 Acupuncture

The recent updated meta-analysis found low certainty evidence that body filiform needle acupuncture, auricular acupressure, and acupoint catgut embedding appear to be safe and effective in achieving short-term smoking cessation. Traditional filiform needle acupuncture was more effective than sham acupuncture in achieving short-term smoking cessation (RR 1.44; 95% CI: 1.02–2.02; low certainty; n=1358); auricular acupressure was superior to both sham acupressure (RR=2.44; 95% CI: 1.13– 5.25; low certainty; n=210) and conventional therapy (RR=1.46; 95% CI: 1.14–1.87; low certainty; n=595); laser acupuncture appeared to be more effective than sham acupuncture (RR=2.25; 95% CI: 1.23–4.11; moderate certainty; n=160) and acupoint catgut embedding was comparable to bupropion or varenicline in improving short-term abstinence rate (RR=0.99; 95% CI: 0.70–1.40; low certainty; n=177)[36, Level 1].

However, evidence shows that body filiform needle acupuncture did not show effect on long-term smoking cessation. Compared with NRT, filiform needle acupuncture was less effective than NRT in achieving short-term smoking cessation. However, low certainty evidence suggested that body filiform needle acupuncture combined with auricular acupressure may be comparable to NRT patches in achieving short-term smoking cessation. More rigorously designed RCTs with larger sample size, biologically validated abstinence rate, and long-term follow-up data are warranted to further verify these effects.

4.5.5 Non-invasive brain stimulation

Non-invasive brain stimulation (NIBS), including transcranial magnetic stimulation (TMS) and transcranial direct current stimulation (tDCS), has gained interest as a therapeutic tool for various conditions such as chronic pain, obesity, alcohol use disorder, and depression. TMS uses magnetic pulses to stimulate brain regions, while tDCS delivers a low-intensity electrical current via scalp electrodes to modulate neuronal excitability. These techniques influence neural circuits related to cognitive and behavioural regulation.

In the context of smoking cessation, a systematic review and meta-analysis [37,Level 1] assessed 20 randomised controlled trials with a total of 899 participants. Most studies focused on stimulating the dorsolateral prefrontal cortex (DLPFC), a region involved in self-control and craving regulation. The results showed that NIBS produced a moderate reduction in daily cigarette use and a small-to-moderate reduction in cue-induced craving, with slightly stronger evidence for tDCS over TMS. While the impact on smoking frequency is less clear, tDCS is non-invasive, affordable, and generally well tolerated.

Although encouraging, the review noted limitations including inconsistent results for persistent craving and biological measures like carbon monoxide levels. Considerable variability across studies, small sample sizes, and potential publication bias were also highlighted. Despite these issues, NIBS—especially when combined with behavioural therapies—shows promise as a supportive approach to aid smoking cessation. It is recommended to standardising intervention protocols and conducting studies with longer follow-up durations. Further research in Malaysia should aim to refine stimulation protocols and examine the integration of tDCS with existing treatments to improve long-term outcomes for smokers, particularly those who have not succeeded with conventional methods.

Hypnosis, acupuncture, acupressure, laser therapy and electrostimulation do not improve the long-term abstinence rate in smoking cessation. More evidence is needed for non-invasive brain stimulation strategy.

4.5.6 Quitlines

Quitlines or helplines are often set up as telephone services that provide information and support for smokers to achieve nicotine abstinence. A 2019 Cochrane review of 104 trials concluded that there is moderate-certainty evidence that proactive telephone counselling aids smokers who seek help from quitlines, and moderate-certainty evidence that proactive telephone counselling increases quit rates in smokers in other settings[38, Level I] Telephone counselling was associated with greater effectiveness when provided as an adjunct to self-help written support ($p < 0.01$), or to a brief intervention from a health professional ($p = 0.02$). However, telephone counselling was less effective when provided as an adjunct to more intensive counselling. Quitline was more effective for people who were motivated to try to quit smoking ($p = 0.02$). Quit rates were higher for smokers receiving multiple sessions of proactive telephone counselling (RR = 1.38, 95% CI 1.19 to 1.61) compared with a control condition providing self-help materials or brief counselling in a single call.

A systematic review found that the evidence supporting telephone counselling for cessation is less clear when applied to smokers from the lower socioeconomic groups[39, Level I].

Another review assessed the effectiveness of quitline for people who were addicted to smokeless tobacco such chewing tobacco, snus or snuff[40, Level I]. Authors concluded that there are some probability for smokeless tobacco cessation through telephone quitline, but no proper evidence was found.

Despite their potential benefits, quitlines remain a largely untapped resource for smokers looking to quit. A review of GATS data from 31 countries has identified that

the majority of quit attempts were done without assistance, hence, very few reported using quitlines, partly because of the lack of quitlines in some countries[41, Level II-2].

These analyses suggest a robust effect of quitline counselling and are consistent with the guideline released by Centres for Disease Control and Prevention's: *Guide to Community Preventive Services* (CDC 2004).

4.5.7 Electronic cigarette / Vape

Electronic cigarette (EC) use for combustible tobacco smoking still generates considerable global debate. Since ECs appeared in the Malaysian market in 2006 smokers report using ECs to reduce risks of smoking and for quitting, but some healthcare organizations, tobacco control advocacy groups and policy makers have been reluctant to encourage smokers to switch to ECs, citing lack of evidence of efficacy and safety.

There is evidence that e-cigarette are effective cessation aids and more effective than NRT.[28,Level 1] In the most recent evidence, nicotine e-cigarettes are more effective for smoking cessation compared to nicotine replacement therapy (NRT) and non-nicotine e-cigarettes. High-certainty evidence indicates that individuals using nicotine e-cigarettes are 59% more likely to quit smoking for at least six months compared to those using NRT (RR 1.59, 95% CI 1.29 to 1.93; 7 studies, 2544 participants). Moderate-certainty evidence shows a 46% increase in quit rates with nicotine e-cigarettes compared to non-nicotine e-cigarettes (RR 1.46, 95% CI 1.09 to 1.96; 6 studies, 1613 participants). Nicotine e-cigarettes may provide greater benefit for smoking cessation than no support or behavioral support alone.[50,Level 1]

While evidence suggests a benefit (RR 1.88, 95% CI 1.56 to 2.25; 9 studies, 5024 participants), this conclusion is less certain due to potential bias in the study design. Adverse events (AEs) reported include throat/mouth irritation, headache, cough, and nausea, typically resolving with continued use of e-cigarettes. There is no significant difference in the incidence of AEs between nicotine and non-nicotine e-cigarettes or between nicotine e-cigarettes and NRT. The overall incidence of serious adverse events (SAEs) was low across all study arms. No evidence of serious harm from nicotine e-cigarettes was detected, though the studies had a maximum follow-up of two years and a limited sample size.[50,Level 1]

4.5.7.1 Evidence of e-cigarettes for harm reduction

E-cigarettes generally exhibit reduced toxicity compared to traditional cigarettes, with lower levels of harmful chemicals due to the absence of combustion. [42,43,44] They are associated with reduced exposure to carcinogens and lower risks of severe health issues for smokers who switch from traditional cigarettes.[45,46]

Despite reduced toxicity, e-cigarettes are not without risks. They can cause significant cardiopulmonary alterations, including increased inflammatory responses, oxidative stress, and endothelial dysfunction.[42,45] Adverse events such as mouth or throat irritation, anxiety, and nausea are common.[47]

Meta-analyses show mixed results regarding the effectiveness of e-cigarettes for smoking cessation. Some studies report moderate benefits in smoking reduction and cessation, while others find no significant advantage over nicotine replacement therapy (NRT)[46,47,48,49]. The pooled efficacy rates for smoking reduction range from 48.3% to 58.7%, and for smoking cessation from 13.2% to 22.9%.[47]

4.5.7.2 Adverse effects of e-cigarettes use

E-cigarette use is associated with multiple adverse health effects. While exposure to combustion-related toxicants is generally lower than with conventional cigarettes, e-cigarettes are not without clinically relevant risks, and their long-term safety profile remains uncertain.

Respiratory effects have been documented in observational studies and clinical reports. Meta-analytic evidence indicates an increased likelihood of asthma (aOR ~1.39) and COPD (aOR ~1.49) among e-cigarette users compared with non-users.[51] Short-term e-cigarette use may cause airway irritation and has been associated with acute increases in diastolic blood pressure.[52] In addition, clinical case reports describe instances of acute lung injury linked to specific e-liquid constituents or contaminants.[57,58]

Commonly reported cardiovascular and neurological symptoms include mouth and throat irritation, nausea, headache, and dry cough[53,47]. Experimental findings also indicate that e-cigarette aerosol exposure may promote oxidative stress and potential DNA damage, which could contribute to longer-term cardiovascular and malignant risk, although current epidemiological evidence remains insufficient to confirm these outcomes.[54]

Nicotine toxicity remains a concern due to variability in product content. Systematic review findings show frequent mislabeling of nicotine concentration, with measured levels differing from stated labels by more than 10% in a substantial proportion of e-liquids[55]. Cases of acute intoxication and poisoning, including seizures and other severe systemic manifestations, have been reported in association with both intentional and accidental exposure.[56,57]

Device-related injuries have also been documented. Battery malfunction and thermal runaway can result in burns, soft tissue injury, and trauma to the oral and maxillofacial region. A review of clinical cases identified device explosions or self-combustion in approximately 53% of reported traumatic injury incidents.[56]

An emerging concern is the adulteration of e-liquids with psychoactive substances. Recent analyses report increasing detection of stimulant and opioid compounds in certain products, which introduces additional and unpredictable toxicological risks.[58]

Such adulteration may present clinically with tachycardia, agitation, altered mental status, and cardiovascular instability, and requires prompt medical evaluation.

5.0 FOR PATIENTS WHO ARE NOT READY TO QUIT

The 5 R's model (Relevance, Risks, Rewards, Roadblocks and Repetition) is a motivational strategy recommended in clinical guidelines for individuals not ready to quit smoking. It aims to enhance engagement and gradually build readiness to quit, especially in primary care settings. While the 5 R's are commonly used in behavioural support within clinical trials, they have not yet been formally evaluated in randomized controlled trials, highlighting the need for more robust evidence on their effectiveness[59]. (Appendix 10)

Recommendations 3	Grades of Recommendations
5R technique (Relevance, Risks, Rewards, Roadblocks & Repetition) should be used for patients who are unwilling to make a quit attempt.	**A**

6.0 RELAPSE PREVENTION INTERVENTION

There is evidence for the use of a combined approach (pharmacotherapy and behavioural). The Cochrane review by Livingstone-Banks et al.[60,Level I] suggests that combining drug and behavioural therapy for relapse prevention in smoking cessation is viable.

Comparative assessments of various interventional methods, encompassing general and motivational counselling, and carbon monoxide monitoring [61,Level I] highlight the importance of combining behavioral interventions such as general and motivational counseling with biochemical verification methods like carbon monoxide monitoring. While counseling enhances motivation and addresses psychological triggers, CO monitoring provides an objective measure of abstinence, together offering a comprehensive approach to sustaining cessation and preventing relapse.

There is also evidence to support the use of mindfulness training with realistic goal-setting, which demonstrates potential impact.[62,Level III] Davis et al. recommends the Exposure to Tips from Former Smokers campaign for its association with lower odds of cigarette smoking relapse. [63,Level II-2]

Overall, there is insufficient evidence to recommend the use of behavioural interventions alone to help smokers avoid relapse.[64]

For smokers who have recently quit, relapse prevention intervention may focus on

identifying and resolving tempting situations or smoking cues.[64, Level I] Most interventions have tried a skills-based approach, where recent quitters are taught to recognise high-risk situations and acquire the skills to withstand the temptation to smoke. However, trained health care providers should provide targeted and effective relapse prevention interventions due to the chronic relapsing nature of tobacco dependence .[65, Level III; 66, Level III; 67,Level III]

When clinicians encounter a patient who has quit tobacco use recently, they should:

a. Reinforce the patient's decision to quit
b. Review with patient the benefits of quitting
c. Assist the patient in resolving any residual problems arising from quitting.

Almost all lapses occur during the first 3 months after treatment and half of those who have their first lapse smoke their second cigarette within 24 hours of the first cigarette or immediately following treatment[68, Level I]. The annual incidence of relapse was around 20% to 25%[69, Level I].

Relapse prevention interventions can be delivered by means of scheduled clinic visits, telephone calls, use of quitline or any time the clinician encounters an ex- tobacco user. There are two practices of relapse prevention, either minimal or intensive.

Relapse prevention for most recent quitters can be addressed briefly during a coincident clinic visit or a scheduled follow-up visit. Similarly, the "5 R's" strategy should be used to prevent relapse. Patients should be encouraged to report difficulties promptly (e.g. lapses, depression, medication side-effects) while continuing efforts to remain abstinent. The simple D.E.A.D. pointer technique can be applied to refrain oneself from smoking:

Delay – Deliberately delay the act of lighting up cigarette by doing something else
Escape – Escape any situation / environment that induce smoking
Avoid – Plan to avoid situation / environment that induce smoking
Distract – Distract the intention to smoke by doing relaxation techniques, housework, spending time with family, etc.

Intensive relapse prevention components are individualized based on information obtained on what causes relapse and problems encountered by patients in maintaining abstinence. This intervention has place important in behaviour modification through imparting skills in counselling and monitoring[70, Level III]). These interventions may be delivered during a dedicated follow-up contact (in-person or by telephone) or through a specialized clinic or programme. Specific interventions recommended for problems related to maintaining smoking cessation are listed in the strategy table below. Long-term smoking cessation pharmacotherapy should be considered as a strategy to reduce the likelihood of relapse.

Relapse prevention strategies in smoking cessation may encompass behavioral support, extended use of smoking cessation medications, or a combination of both

approaches. According to the Cochrane review conducted by Livingstone-Banks et al. [60,Level I, Grade A] the integration of pharmacotherapy with behavioral therapy is a feasible strategy for relapse prevention in smoking cessation. The review highlights that among individuals who have achieved smoking cessation through pharmacotherapy, the efficacy of extending pharmacotherapy beyond the standard duration yields variable outcomes. Specifically, extended treatment with varenicline has been shown to be effective in mitigating relapse, while extended treatment with bupropion and nicotine replacement therapy (NRT) did not demonstrate significant benefits in preventing relapse among individuals who had already achieved abstinence. Livingstone-Banks et al.[60,Level I, Grade A] in the Cochrane review indicated that varenicline shows a significant benefit of extended varenicline with some heterogeneity with RR 1.23 (95% CI 1.08 to 1.41). Extended use beyond 12 weeks may further enhance its efficacy in preventing relapse with recommended maintenance dose for relapse prevention is 1 mg twice daily for an additional 12 weeks after achieving initial abstinence.[65,Level 1 Grade B]

A randomized clinical trial found that long-term NRT did not significantly reduce the risk of relapse compared to shorter-term NRT. The benefits of extending NRT were not substantiated by the trial results, suggesting limited additional benefit in preventing relapse beyond the standard treatment period. While extended NRT might alleviate cravings, the RCT concluded that it did not provide a significant advantage in preventing relapse compared to the standard duration of NRT[66,Level 1, Grade B]

Recommendation 4	Grades of Recommendations
Effective relapse prevention interventions should be provided to all smokers who have recently quit.	**A**
A combined approach should be considered the first line in relapse prevention of tobacco use.	**B**

7.0 SPECIFIC POPULATIONS

7.1 E-Cigarette/Vape Users Cessations

The 5A's approach is still applicable for e-cigarette treatment. However, currently no medication is approved for the indication of e-cigarette cessation in Malaysia[67,Level III]. Medications approved for conventional cigarette smoking cessation may later be used to address e-cigarettes, once more evidence is available.

Assessment of nicotine dependence among single e-cigarette users can utilize the Modified

Fagerstrom Test for Nicotine Dependence (mFTND). The mFTND is a useful tool for assessing nicotine dependence in e-cigarette users, with lower baseline scores linked to a higher likelihood of cessation over time.[68,Level III] Other instruments that can be used to measure e-cigarette dependence include Penn State Electronic Cigarette Dependence Index (PS-ECDI) and E-cigarette Wisconsin Inventory of Smoking Dependence Motives (e- WISDM).[69] (Refer Appendix 12)

7.1.1 Assist quitting among e-cigarette users

A pilot study used NRT to treat e-cigarette users using mFTND as a guide[70]. The results show that 3 out of 7 participants (42.9%) self-reported as having complete abstinence from nicotine. However, e-cigarette users may expose themselves to higher nicotine doses compared to conventional cigarette users, therefore a higher dose of NRT may be needed.[71]

In the United Kingdom, nicotine oral spray 1mg/spray has been registered for vaping cessation[72]. The spray is a short-acting NRT that is used when craving occur, up to two sprays every 30 minutes, with a maximum of 64 sprays per day or 2 sprays every half an hour over 16 hours. However, this indication is not yet registered in Malaysia.

Suggested treatment algorithm for e-cigarette cessation using NRT among adult single users and adolescents are available. [73] (Appendix 13)

A pilot study using vape-taper method has found that efficacy of the vape-taper method is comparable to NRT[70] (Appendix 14). However, the problem with vape-taper method is that some types of vapes are hard to taper as there are limited types of nicotine concentrations[74]. Another problem is that there are cases where the claimed concentration of nicotine on the label is not the same as its actual concentration. To circumvent these problems, the users can limit the usage by limiting the places where they vape by decreasing the number of sessions or reducing the amount of vape inhaled.[74]

According to a protocol drawn up for clinical trials involving varenicline for e-cigarette cessation, varenicline could be used similar to conventional smoking cessation – with one 0.5mg tablet for the first three days, followed by two 0.5mg tablets per day, one every 12 hours for 4 days, and four 0.5mg tablets, two every 12 hours for 12 weeks.[75] The doses should be given 7 days before the quit date, and behavioural support should be given. Subsequent visits should be at Week 1, 2, 4, 6, 8, 12 – where Week 1 is the week after the quit date. On every week including those without the visits, behavioural support should be given either face-to-face on weeks with visits, or telephone contact on weeks without visits.

7.1.2 Dual users (Conventional Cigarette + E-Cigarette/Vape)

Dual use of conventional cigarettes and e-cigarettes, often referred to as "dual users," is a growing phenomenon among smokers. This behaviour involves the concurrent use of both traditional tobacco products and electronic nicotine delivery systems. Understanding the implications of dual use is crucial for public health, as it may influence nicotine intake, health risks, and smoking cessation efforts.

Dual users tend to have a higher overall nicotine intake compared to exclusive e-cigarette users. This is due to the combined nicotine consumption from both e-cigarettes and conventional cigarettes, although they may consume less nicotine from e-cigarettes alone compared to exclusive e-cigarette users.[76] The intensity of use varies, with some dual users primarily smoking cigarettes, while others predominantly use e-cigarettes.[77]

Dual use is associated with increased health risks compared to exclusive use of either product. Studies indicate that dual users have a higher prevalence of non-communicable diseases (NCDs) such as liver failure, diabetes, hypertension, and gum diseases compared to single users of either product.[78] Cardiopulmonary symptoms and conditions, including arrhythmia and breathing difficulties, are also more prevalent among dual users[79]. Additionally, dual use is linked to higher cardiovascular risk factors, including metabolic syndrome, compared to cigarette-only smokers and never smokers.[83]

Dual use may serve as a transitional phase towards smoking cessation for some individuals. However, maintaining dual use can perpetuate smoking behaviors and associated health risks. Factors that positively influence cessation among dual users include employment status, previous quit attempts, low nicotine dependence, high motivation to quit, and receiving follow-up consultations[81]. Despite these challenges, dual users seeking cessation support can achieve abstinence rates similar to exclusive smokers.[81]

Dual use is associated with increased sleep latency and poorer sleep quality compared to non-smokers and non-vapers. This may be attributed to nicotine's stimulating effects, which can disrupt sleep patterns. Dual users also report higher incidences of cough and increased use of substances like marijuana and cocaine.[82]

Suggested treatment algorithm for dual users is available. (Appendix 15)

7.3 Economically Disadvantaged Smokers

Economically disadvantaged smokers experience higher rates of smoking compared to their economically privileged counterparts, highlighting the need to address this disparity through targeted interventions.

A Cochrane review found that financial incentives have shown promise in boosting engagement with quitline services among economically disadvantaged smokers.[84,Level I]Higher incentive amounts, of up to $40, increased re-engagement rates within 90 days. led to increased re-engagement within 90 days, and mailed invitation letters proved more effective than automated calls. Smokers from

backgrounds of economic privilege who received financial incentives had notably higher quit rates compared to those exposed only to smoking cessation campaigns.[85,Level I]However, the impact on economically disadvantaged smokers was less pronounced.

Behavioural interventions, particularly when combined with pharmacotherapy approaches have proven highly effective in smoking cessation efforts among women from economically disadvantaged backgrounds[86,Level II-3], with intervention groups being 1.68 times more likely to quit compared to control groups.

Integrating social needs navigation into Quitline services resulted in quit rates similar to standard Quitline services for economically disadvantaged daily smokers[87, Level I]. Nevertheless, it is worth noting that the standard Quitline plus social needs navigation showed lower quit rates compared to Quitline alone. Financial coaching and social services referrals for economically disadvantaged smokers led to a notable decrease in smoking rates and a significant reduction in economic stress.[88, Level I] It similarly targeted economically disadvantaged residents of New York City, combining smoking cessation coaching, nicotine replacement therapy, money management coaching, and referral to financial benefits and empowerment services[8..9, Level I]This intervention led to a substantial increase in abstinence rates and a reduction in financial stress among participants.

Boland (2019)[90, Level I] explored factors influencing Quitline and pharmacotherapy use among economically disadvantaged smokers, finding that self-efficacy and mental health conditions influenced Quitline utilization, while mental health conditions and alcohol consumption affected recent use of nicotine replacement therapy. Additionally, the study assessed the effectiveness of vaporized nicotine products compared to nicotine replacement therapy for daily smokers receiving government pensions or allowances, focusing on the impact on cessation rates, adherence, safety, and cost-effectivenes.[91, Level I] The study also highlighted how negative mood, motivation, and self-efficacy, with gender-specific variations, affect daily commitment to nicotine replacement therapy among economically disadvantaged smokers.[92, Level I]

Recommendation	Grades of Recommendations
The offer of financial incentives should be considered in programs to boost and maintain quit rates among economically disadvantaged smokers.	**A**

7.4 Female Smoker

Smoking cessation clinical trials reveal that the same treatments benefit both men and women.[71, Level II-2; 72, Level II-2] However, research suggests that some treatments are less efficacious in women than in men (e.g., NRTs)[73, Level I] due to lack of

documented data on smoking status among women and lack of intervention[74, Level I] as well as different brain system modulated by noradrenergic activity in women.[75, Level II-2]Women found to be less likely to stop[76, Level II-3], may have more difficulty to quit smoking[77, Level I] and less likely to be abstinent compared to men.[78, Level I]

Although research shows that women benefit from the same interventions as men, women may face different stressors and barriers to quitting that should be addressed in treatment. These stressors and barriers include greater weight control concerns[79, Level II-2], hormonal cycles[80, Level II-2] and stress smoking.[77, Level I] Women who are considering pregnancy may be especially receptive to tobacco cessation.

Other documented evidence which improved female smokers to quit are social support[81, Level I], physical activity[82, Level II-2; 83, Level II-3] and customised intervention programme for women especially pregnant smokers who are coming for antenatal follow up.[84, Level I]

Recommendation	Grades of Recommendations
Given the distinct psychosocial stressors that women often encounter, smoking cessation efforts should incorporate heightened attention and support. The development and implementation of tailored, gender-responsive interventions are strongly recommended for female smokers.	**A**

7.5 Pregnant and Lactating Women

Maternal smoking during pregnancy is an important and preventable major risk factor of adverse obstetrical and neonatal outcomes including placental abruption, miscarriage, stillbirth, preterm birth, and low birthweight.[96]

Meta-analysis of two studies established that the odds of discontinuation of any breastfeeding before six months were significantly increased in the second-hand smoke exposed women (pooled odds=1.07 [95%CI=1.01, 1.14], two studies, 1382 women). Therefore, second-hand smoke might be associated with discontinuing any breastfeeding before six months.[98,Level I]

Research indicates that a significant majority of women (96%) believe that they should be asked about each of the risk factors at least once (i.e. at first visit). The assessment should be included in the screening of risk factors during pregnancy.[101,Level III]

Healthcare professionals should ask at least once the smoking status of a pregnant mother and provide recommendations for smoking cessation interventions. When asking about smoking, questions on exposure to environmental smoke should be included as mothers who smoke are more likely to be exposed to environmental smoke. Pregnant women have expressed a preference for smoking cessation interventions delivered by healthcare professionals, with 29.1% favoring daily interventions and 59.8% preferring weekly sessions, implemented by health professionals such as doctors, nurses, or psychologists are the ones perceived as the most useful. 85.8% of pregnant mothers considered that the development of smoking cessation programs during pregnancy is important.[102, Level III]

A systematic review found that the majority of healthcare professionals ask about smoking and give advice to quit. However, less assess motivation and/ or dependence on smoking. The pooled percentages of studies reporting practices 'often/always' were: 'Ask' 91.6% (95% CI 88.2% to 95%); 'Advise' 90% (95% CI 72.5% to 99.3%), 'Assess' 79.2% (95% CI 76.5% to 81.8%), 'Assist (cessation support)' 59.1% (95% CI 56% to 62.2%), 'Arrange (referral)' 33.3% (95% CI 20.4% to 46.2%) and 'prescribing NRT' 25.4% (95% CI 12.8% to 38%).[104,Level I]

Healthcare professionals should encourage readiness to quit through identifying individual context, personalised support, and educational risk perception, and, supporting the process of quitting, and offering a range of options, underpinned by a personalised, non-judgemental approach[103, LevelI III]. On the whole healthcare professional knowledge may be insufficient about nicotine replacement therapy leading to hesitancy in providing smoking cessation advice. Poor understanding about the safety or efficacy of NRT in pregnancy compared with continued smoking may lead to underprescribing of NRT as a stop smoking aid.[104, Level I]

7.5.1 Psychosocial intervention

A Cochrane review concluded that psychosocial interventions increased the proportion of women who had stopped smoking in late pregnancy (by 35%) and mean infant birthweight (by 56 g), and reduced the number of babies born with low birthweight (by 17%) and admitted to neonatal intensive care immediately after birth (by 22%).[94, Level I] The level of evidence is considered moderate- to-high quality evidence.

Another meta-analysis of 63 RCTs (n = 19849 women) found that effective interventions pregnant smokers were: financial incentives (RR:1.77; 95%CI:1.21–2.58), counselling (RR:1.27; 95%CI:1.13–1.43) and long-term nicotine replacement therapy (NRT) (RR:1.53; 95%CI:1.16–2.01). Short-term NRT, bupropion, digital interventions, feedback, social support, and exercise showed no effectiveness. [100,Level I]

A meta-analysis including 12 trial arms from 12 studies was performed (n = 2306). The sample-weighted OR indicated that digital interventions significantly increased the odds of quitting smoking during pregnancy compared to control groups (OR = 1.44, 95% CI 1.04–2.00, p = 0.03).[97,Level I] Digital interventions include computer based applications and text messaging.

Effective psychosocial interventions for pregnant patients
Physician advice regarding smoking-related risks (2–3 minutes); video messages with information on risks, barriers, and tips for quitting; midwife counselling in one 10-minute session; self-help manual; and follow up letters.
Pregnancy-specific self-help materials (Pregnant Woman's Self-Help Guide to Quit Smoking) and one 10-minute counselling session with a health educator.
Counsellor provided one 90-minute counselling session plus bimonthly telephone follow up calls during pregnancy and monthly telephone calls after delivery.

Adapted from Fiore et al. 2008 [20, Level I]

A more recent meta-analysis found that digital health interventions had moderate certainty evidence to achieve continuous abstinence at late pregnancy (4 studies; 2049 women; RR=1.98, 95% CI 1.08 to 3.64, p=0.03) and low certainty evidence to achieve point prevalence abstinence postpartum (5 studies; 2238 women; RR=1.46, 95% CI 1.05 to 2.02, p=0.02).[99, Level I]

Smoking interventions utilizing long-term breastfeeding as a motivating factor may be successful in increasing smoking abstinence rates at least until the time of complete breastfeeding cessation.[105, Level III]

7.5.2 Use of NRT in pregnancy

Majority of pregnant smokers need assistance to stop smoking. Nicotine replacement therapy (NRT) has been demonstrated to help non-pregnant smokers to stop. NRT used for smoking cessation in pregnancy may increase smoking cessation rates in late pregnancy. However, this evidence is of low certainty, as the effect was not evident when potentially biased, non-placebo-controlled RCTs were excluded from the analysis (Claire *et al.*, 2020). [Level I]

NRT prescription seems to be associated with higher risk of infantile colic at 6 months as in case of smoking during pregnancy (aOR, 1.6, 95 CI 1.0–2.5), and with

risk of attention-deficit/hyperactivity disorder.[93, Level I] No association between NRT during pregnancy and other infant health disorders or major congenital anomalies has been reported. Health professionals should take note of FDA Pregnancy Class of NRT products. (Appendix 7)

7.5.3 Breastfeeding Pharmacology intervention

Due to the lack of safety and efficacy research among pregnant women, neither varenicline nor bupropion is recommended for use during pregnancy or while breastfeeding.[106, Level III] Healthcare professionals should be aware of these limitations and explore alternative smoking cessation methods.

Other forms of NRT, such as gum and lozenge are recommended to deliver a lower total daily nicotine dose. For lactating woman, using intermittent, short-acting forms of NRT are preferable and the woman should be advised to avoid using the products for at least one hour before breastfeeding.[94, Level I]

Recommendation 5	Grades of Recommendations
Offer multi-sessions behavioural smoking cessation interventions to all pregnant and breastfeeding women who smoke.	**A**

7.6 Hospitalised Smokers

Hospitalisation provides a powerful opportunity to quit smoking. It is vital that they attempt to quit smoking, as smoking may interfere with their recovery. Augmented smoking cessation treatments e.g. self-help via brochure or audio/videotape, chart, prompt reminding physician to advise smoking cessation, pharmacotherapy, hospital counselling, and post-discharge counselling telephone calls have been shown to be effective. Among cardiac patients, second heart attacks are more common in those who continue to smoke[95]. Lung, head, and neck cancer patients who are successfully treated, but who continue to smoke, are at higher risk for a second cancer.[96, Level I; 97, Level II-3; 98, Level I; 99, Level I; 100; 99, Level I] Additionally, smoking delays bone and wound healing.[101; 102; 103]

Hospitalised patients may be particularly motivated to make a quit attempt for two reasons. Firstly, the illness causing the hospitalisation may have been due to or exacerbated by smoking, highlighting the patient's personal vulnerability to the

health risks of smoking.[104; 105] Secondly, all hospitals in Malaysia are designated smoke-free areas.[106] Patients in long-term care facilities such as mental health institution, old folks' home, rehabilitation centres should also receive tobacco cessation interventions.

Suggested interventions for hospitalised patients include:

a. Ask each patient on admission if he or she uses tobacco and document tobacco use status.
b. For current tobacco users, record tobacco use status on the admission problem list and as a discharge diagnosis.
c. Use counselling and pharmacotherapy to assist all tobacco users to maintain abstinence and to treat withdrawal symptoms accordingly.
d. Provide advice and assistance on how to quit during hospitalisation and remain abstinent after discharge.

Recommendation	Grades of Recommendations

7.7 Psychiatric Patients

It is estimated that 11.2% of Malaysians have some form of mental illness[107, Level II-3]). Studies have shown that the prevalence of smoking amongst psychiatric patients can be as high as two to three times that of the general population[108, Level II-3; 109, Level II-1]. Often, these same smokers smoke at higher rates, on average 25 cigarettes per day[110, Level II-1]; are highly addicted and it is estimated that they consume 43.9% of all cigarettes sold in the US[111, Level II-2]. These same patients have higher health morbidity and mortality, dying 25 years earlier compared to the persons who do not smoke. [112, Level II-2]

Despite these startling numbers, psychiatric patients often do not receive advice or treatment to quit smoking[19, Level II-3]. In a study, a total of 105 psychiatric patients who were identified as current smokers, only 1 patient was encouraged to quit smoking, referred for cessation treatment, and provided with nicotine replacement therapy on discharge.[113, Level II-2]

Studies have shown that psychiatric patients can quit and want to quit [114; 115, Level II-3] and those who do quit often receive similar health benefits as those without psychiatric illness. The American Psychiatry Association (APA) also recommends that psychiatrists assess the smoking status of all patients, including readiness to quit, previous quitting history and level of nicotine dependence.[116, Level II-2] Therefore, it is important that **ALL** patients be asked to quit when seen in psychiatric services.

Despite the very good and extensive database on the safety and efficacy of pharmacological treatment of tobacco dependence, only a few studies have examined their use in mentally ill patients. Depression and schizophrenia have been the most studied amongst the various mental illnesses. The combination of pharmacological and behavioural measure is deemed to be the gold standard in the treatment of tobacco dependence.

A recent recommendation from the European Psychiatric Association (EPA),[117, Level III] for all patients with mental illness who smoke, include:

1. Record the smoking status:
   Smoking status should be evaluated and documented for every psychiatric patient and the degree of dependence should be documented (preferentially with the FTND).

2. Set the time of the intervention
   The best time for cessation would be when the patient is in a stable phase, with no recent or planned changes in medications and no urgent problems take precedence

3. Give counselling
   '5 A's Intervention' is recommended for the short-term intervention by physicians. To increase the quit rate, established programmes (individual therapy, group therapy, telephone coaching) should be employed wherever available

4. Offer drug treatment with a first-line product
   NRT, varenicline, bupropion should be given for even a mild degree of tobacco dependence. Attention must be paid on the severity of tobacco dependence, possible psychiatric side effects, drug-drug interactions and contraindications.

5. Contact within first days after quit day

6. Perform follow-up visits

7. Relapse prevention and management
   The patient should be made aware that lapses and relapses are fine and a new attempt with different procedures (e.g. psychotherapy, medication) should be discussed with the patient.

7.7.1 Schizophrenia

There are limited smoking cessation pharmacological clinical trials conducted on persons suffering from schizophrenia. The most investigated smoking cessation pharmacological treatments are nicotine replacement therapy (NRT), sustained release bupropion (bupropion SR) and varenicline.

The effectiveness of NRT in this group of patients is unclear owing to the few trials with small sample size. One trial compared the use of high dose transdermal nicotine patch (42 mg) with regular dose transdermal nicotine patch (21 mg) in 51 patients with schizophrenia who wanted to quit smoking. In this trial, seven-day point prevalence abstinence rates at eight weeks were not significantly different between the high dose group (32%) and the regular dose group (23%).[118 , Level II-1]

Bupropion has been found to be effective for smoking cessation in schizophrenia patients. A meta-analyses[119, Level I] reported that the cessation rates after using bupropion was significantly higher than placebo at the end of treatment (seven trials, N = 340; RR=3.03; 95% CI 1.69 to 5.42) and after six months (five trials, N = 214, RR=2.78; 95% CI 1.02 to 7.58). At the end of treatment, smokers with schizophrenia who received bupropion smoked about 11 fewer cigarettes per day than those who took placebo. There were no significant differences in positive, negative and depressive symptoms between bupropion and placebo groups. There were no reports of major adverse events such as seizures with bupropion.

The effectiveness of combination of different smoking cessation treatments is unclear in treating schizophrenia. Nevertheless, a 10-week, double-blind, placebo-controlled trial of bupropion (300 mg/day) in combination with transdermal nicotine patch (21 mg/24h) for 58 outpatient smokers with schizophrenia found that the combination of bupropion and transdermal nicotine patch was well-tolerated and significantly improved short-term smoking abstinence in this group of patients.[120, Level II-2]Another small randomized controlled trial found that patients taking bupropion and NRT had a significant increase in smoking reduction at 3 and 6 months (60% vs. 31%; P = 0.036), and a greater continuous abstinence rate at week 8, (52% vs. 19%; P = 0.014) over patients taking placebo and NRT. [121, Level II-1]

For varenicline, the information that varenicline increased smoking cessation rates higher than placebo in individuals with schizophrenia was based on two studies. These studies found that smokers with schizophrenia were nearly 5 times more likely to quit compared to placebo at the end of the treatment (N = 137; RR=4.74, 95% CI 1.34 to 16.71).[119, Level I] This information, however, need to take into consideration that it was based on only two studies. There is no sufficient direct evidence presently to know whether the benefit of varenicline is maintained for six months or more. Nevertheless, there were no significant differences in reported psychiatric symptoms between the varenicline and placebo groups.[122, Level I]

7.7.2 Depression

Depression is one of the commonest mental health conditions worldwide and is estimated to be the second leading cause of health morbidity by 2020[123, Level II-3]. Smoking and smoking cessation has been linked to both depressed mood and depression, however, the relationship is unclear.

A review looking at smoking cessation interventions for patients with depression identified only 3 RCT's out of the 16 studies reviewed which included patients with current depression. This review found small, but positive findings for the use of antidepressant (RR=1.31; 95% CI 0.73 to 2.34), NRT and addition of behavioural mood management (RR=1.41; 95% CI 1.01 to 1.96).[124, Level I]

The Cochrane group reviewed the use of antidepressants and smoking cessation and found positive results for both bupropion (44 trials and almost 13,000 participants, RR=1.62, 95% CI 1.49 to 1.76) and nortriptyline (9 trials, 975 participants, RR=2.03, 95% CI 1.48 to 2.79).[37, Level I] Both medications increase the likelihood to quit, however, for bupropion this is seen for at least six weeks. This review did not find any added advantage of the serotonin selective reuptake inhibitors (SSRIs) as a quit smoking agent (RR = 0.93, 95% CI 0.71 to 1.22). International guidelines have suggested that individuals with depression and wanting to quit smoking can be started on these two treatments.

Varenicline has been found to be the most effective agent for smoking cessation (RR=2.31) and probably equally effective for both individuals with and without depression. Risk of suicidal behaviour has not been found to be true in the community.[37, Level I] However, caution is still recommended as a result of previous concerns.

Anxiolytics have not been found to be useful for smoking cessation.

7.7.3 Bipolar Disorder

There are only four published controlled smoking cessation treatment studies in smokers with bipolar disorder using pharmacological agents such as nicotine replacement therapy, bupropion, and varenicline.

An open-label, pilot study suggested that NRT (nicotine patch) may be an effective treatment for tobacco dependence in bipolar smokers.[125, Level II-3]

One small study on smoking cessation using sustained-release bupropion involved only five patients. In this randomized, double-blind, placebo-controlled trial study, two smokers in the bupropion group either quit or reduced their smoking compared to placebo treatment which was associated with early dropout from the study and occurrence of symptoms of hypomania.[126, Level I]

In a recent randomized, double-blind, placebo-controlled, parallel-group, relapse-prevention clinical trial conducted in 10 community mental-health centres, 247 smokers with schizophrenia or bipolar disorder were enrolled. Two hundred and three received 12-week treatment with varenicline and cognitive behavioural therapy or cognitive behavioural therapy alone. After a period of a year, the point-prevalence abstinence rate was 60% with varenicline treatment and 19% with placebo (OR = 6.2; 95% CI 2.2 to 19.2). Varenicline was also found to be efficacious for maintenance treatment in the study and furthermore there was no impact on psychiatric symptoms reported.[127, Level I]

In another study by Chengappa et al. (2014) varenicline added to CBT, tripled 4-week continuous abstinence rates at the end of a standard 12-week course of treatment in smokers with bipolar disorder. [128, Level I] There were significantly more subjects with bipolar who quit smoking with varenicline (n/n = 15/31, 48.4%) compared to placebo (n/n = 3/29, 10.3%) (OR=8.1; 95% CI 2.03 to 32.5) at 3 months. At 6 months, 6 of 31 varenicline-treated subjects (19.4%) remained abstinent compared to 2 of 29 (6.90%) assigned to placebo (OR=3.2; 95%CI 0.60 to 17.6). Psychopathology scores remained stable throughout the study. Ten serious adverse events occurred (N = 6, varenicline; n = 4, placebo) with the most common reported as abnormal dreams occurred significantly more often in varenicline- treated subjects (n/n = 18/31, 61.3%) than in those receiving placebo (n/n = 9/29, 31%; P = .04). Eight people treated with varenicline and 5 placebo-assigned subjects expressed fleeting suicidal ideation, a non-significant difference.

With only two published RCT adequately powered to detect treatment efficacy in this population, the data is currently inadequate to form a consensus guideline for treating nicotine dependence in people with bipolar disorder. However, as currently available treatments have been reported to be safe, all patients with bipolar should be given pharmacological aid should they want to quit smoking.

7.7.4 Substance use disorder

7.7.4.1 Alcohol use disorder

In an open trial of the transdermal nicotine replacement therapies for smoking cessation on 49 alcohol and drug-dependent patients (39/49 were alcohol dependent) who entered inpatient treatment, seven subjects (14.3%) self-reported tobacco abstinence at 21 days, and 5 (10.2%) self-reported abstinence as outpatients at 6 weeks.[129, Level II-2]

There was evidence that bupropion – sustained release (bupropion-SR) is effective in helping alcohol dependent smokers to quit smoking. In an open-label, naturalistic study among alcohol dependent smokers, participants who received bupropion-SR were more likely to abstain from smoking than controls at any of the follow-up time points, reduced their smoking and smoked less cigarettes per day (CPD) at baseline, 30 days and 180 days post-baseline, compared to controls.[130, Level I]

A double-blind, placebo-controlled smoking cessation study involving heavy-drinkers found that varenicline produced a sustained decrease in alcohol consumption in addition to a significant decrease in the number of cigarettes smoked.[131, Level I]

An open-label, pilot study suggested that varenicline may be an effective treatment for tobacco dependence in recovering alcohol-dependent smokers.[132, Level II-1]

The combination of two smoking cessation treatments had no added benefit in smokers with a dependence to alcohol based on current evidence. In a double-blind placebo-controlled study of sustained-release bupropion with NRT as a smoking cessation aid in 58 alcohol dependent smokers, it was found that the addition of bupropion to NRT (nicotine patch) did not improve smoking outcomes. One third of participants on bupropion reported discontinuing the drug during weeks 1 to 4. All study participants however, significantly reduced cigarette use.[133, Level I]

7.7.4.2 Cannabis use disorder

The co-occurrence of tobacco and cannabis use is high, however, treatments of tobacco use in this population is lacking.[134, Level I] A case series reported the use of a 12-week, 9 session computer-assisted version of Motivational Enhancement Therapy (MET), Cognitive Behavioral Therapy (CBT), and Contingency Management (CM), i.e., abstinence-based incentives aimed at both tobacco and cannabis use in those with cannabis use disorder. This programme included an optional tobacco intervention that comprised of five computer modules in a tailormade programme and NRT. All participants initiated the tobacco intervention but 50% opted to use NRT. Five out of six participants made self-reported reduction attempts during treatment (i.e., reduced cigarette use lasting at least 24 h in

duration), with a mean of 4.8 attempts (range 1–8), and cigarettes per day decreased from intake to end of treatment.[135, Level II-3]

Studies on co-occurring drug use and tobacco use, however, did not report worsening of symptoms when using NRTs, bupropion or varenicline and therefore all available treatments can be used.[20, Level I]

7.7.4.3 Opioid use disorder in methadone maintenance treatment

In general, smoking cessation rates in methadone-maintained smokers is low. To date, only two RCTs have been conducted on this group of patients. This study used a three-group randomized design, whereby it attempted to study the efficacy of varenicline versus placebo, in comparison with nicotine replacement therapy (NRT), in 315 persons methadone-maintained smokers (varenicline =137, placebo=45 and combination nicotine replacement =133). This study found that the 7-day abstinence at 6-months was 5.4% overall, with varenicline 3.7% compared to placebo 2.2%, and NRT 8.3% (p> .05). Between baseline and 6-months there was an overall self-reported mean reduction of 8.3 cigarettes/day. This study reported that quitting using NRTs to be comparable to other studies and the use of varenicline did not increase quit rates in this population.[136, Level I]

In another study, 383 methadone-maintained smokers were assigned randomly to nicotine patch (8– 12 weeks) plus either (1) a baseline tailored brief motivational intervention, a quit date behavioural skills counselling session and a relapse prevention follow-up session or (2) brief advice using the National Cancer Institute's 4 As model. In this study, a tailored behavioural intervention did not increase quit rates over NRT and National Cancer Institute's 4 As model treatment.[137, Level I]

Recommendation 6	Grade
For psychiatric and substance abuse disorder patients:	
● Record the smoking status of ALL patients (preferable with the Fagerstrom Test for Nicotine Dependence or carbon monoxide smokerlyzer)	**A**
● Set the time of intervention (quit date) when the patient's mental status is stable	**C**
● Provide "5 A's intervention" by trained health care providers	**C**
● Offer pharmacotherapy to ALL smokers with psychiatric condition o Caution should be taken when using varenicline and bupropion–NRT, bupropion, nortriptyline or varenicline	**A-B**
● Behavioural support should be provided where applicable and available	**A**

7.8 Children and Adolescents

Although most smoking-related disease burden is in adults, youth-focused cessation is crucial: ~70% of Malaysian smokers start before 18, and earlier quitting limits life-expectancy loss.[124, Level II-3] Early initiation accelerates disease and dependence, making unassisted quitting harder[112, Level II-3], and many youths want to quit smoking/vaping but are unsuccessful[123, Level I]. Youth vaping in Malaysia is rising, with concerns about illicit drug delivery[114, Level III], local data show high psilocybin-via-vaping exposure among ATS users [116, Level II-2] and adolescent vaping increases later drug use risk such as marijuana[115, Level III]. Trials in adolescents emphasize prevention/education; effective quit supports include group counselling, mixed-delivery, and computer/messaging interventions, while pharmacotherapy shows no clear benefit and only mild adverse effects[111, Level I], and no cessation medications are FDA-approved for this group.[123, Level I]

For ages 18–24, effective options include text messaging, quit-and-win contests, and multicomponent behavioural programs[126, Level I]; tailored primary-care education from early childhood through adolescence is also effective beyond school settings[117, Level II-2]. Interpersonal discussions and tech-based tools should be leveraged[110, Level I], and booklets with booster calls and in-person counselling aid quitting[120, Level I]. Parental cessation lowers youths' smoking risk[122, Level I], and embedding cessation in respiratory/paediatric follow-ups reduces cigarettes smoked using simple screening and motivational interviewing[119, Level II-2]. Clinician advice prompts quit attempts even in pre-contemplative users.[107, Level II-2]

Despite limited pharmacologic evidence overall, the American Academy of Pediatrics allows consideration of off-label NRT for moderate/severe dependence108, Level III and promotes the repeat-visit ACT model—Ask, Counsel, Treat121, Level III, aligning with NSW guidance to Ask, Advise, and Help with tailored plans, behavioural strategies, pharmacotherapy when indicated, and follow-up113, Level III. Nicotine replacement therapy delivers measured nicotine to reduce withdrawal and cravings without exposure to other harmful smoke/vape constituents and is safe for those ≥12 years where no contraindications exist109, Level III, 113, Level III. NRT should be considered for adolescents ≥12 with daily smoking, withdrawal, cravings, or TTFV within 30 minutes of waking, following assessment by healthcare professionals and paired with behavioural support and a sustainable quitting plan.

Assessment of nicotine dependency for vapers can be done utilizing both short and long form of evaluation.[113, level III] (Appendix 16). Behavioural strategies to support adolescents to quit smoking are available[Level III] (Appendix 17)

Strategy 1 Alternative dopamine reward	This strategy uses dopamine release as a reward. Dopamine is a 'feel-good' chemical released in the brain. Research has shown that nicotine increases the level of dopamine in the brain. Suggest: Instead of using an e-cigarette, the young person should carry a snack. (nuts, flavoured sugar-free gum) for a dopamine release.
Strategy 2 Think of yourself as someone who does not use e-cigarettes	This strategy is based on motivational interviewing so the young person can imagine themselves as someone who does not use e-cigarettes. To exercise this strategy, the young person can say to themselves: “I am not a vaper” “I don’t vape/smoke” This can include asking the young person to imagine an example of being offered an e-cigarette and role-playing their response.
Strategy 3 Use the ¨stray cat¨ metaphor.	This strategy uses the metaphor that the craving is like a stray cat. If you feed the cat, it will keep coming back, but if you don't, the cat will eventually go away. Practise: ask the young person to rehearse the metaphor when they have no cravings mindfully. Use the image of the cat when the craving begins.
Strategy 4 Distraction	Suggest the young person distract themselves by doing something else e.g., Playing a video game, going for a walk, looking at Instagram / Snapchat (if all dealers/vape material has been deleted or blocked), listen to music. Advanced technique: distraction with imagery. When experiencing a craving, the young person learns to visualize something completely different, like being on a beach or cows grazing in a paddock. If stuck, it may help them to focus on an aversive image, e.g.,

	vomiting. Practise: Mindfully rehearse a simple distracting visualization when there is no craving.
Strategy 5 Rewards or incentives (contingency management)	Suggest the young person set measurable goals to reduce or cease their e-cigarette use, including positive reinforcement (rewards or incentives) for periods of abstinence.
Strategy 6 Making a promise (either committing to one or more of the above behavioural strategies or to not using e-cigarettes)	Studies have shown that people are more likely to comply when they promise to do something. Example 1: Ask the young person to promise to commit to using one or more of the behavioural strategies in this guide. This can also be used when the health professional or worker asks the young person to promise not to use e-cigarettes for a specific time or number of days. Example 2: Do you promise me that you won't use e-cigarettes (vape) during school hours? The young person may agree with a handshake (if appropriate).

Recommendation	Grade
For adolescents and children: ● Use early screening, motivational interviewing, and digital tools like text messaging, following the 2A+H model—Ask, Advise, and Help ● Assess nicotine dependence with short-form tools like Time to First Vape (TTFV) and long-form tools like the Modified Hooked on Nicotine Checklist (M-HONC), Penn State E-Cigarette Dependence Index, and the E-cigarette Dependency Scale (EDS). ● Consider NRT for adolescents 12 and above with high nicotine dependency, combined with behavioural support, while carefully assessing the benefits and risks. ● Implement school-based and primary care educational initiatives, focusing on early prevention and repeated engagement across various stages of childhood and adolescence.	C C C C

7.9 Elderly

A randomised control trial among older adults living in rural area found that both text-based schedule gradual reduction (SGR) intervention plus support messages and text-based support messages only were useful in for quitting smoking (SGR = 57%, Control = 63%). Although not statistically significant, the SGR group had a higher rate of biochemically validated cessation (SGR = 15%, Control = 5%, Cohen *d* = 0.67).[127, Level1]

A Cochrane review found inconclusive evidence that using e-Health nutritional interventions which provided multicomponent health interventions, which aimed to improve nutrition and other health behaviors (eg, exercise, smoking cessation, medication adherence) to be useful for smoking cessation.[128, Level1]

Recommendation	Grades of Recommendations
Text-based schedule gradual reduction (SGR) intervention	A
Counselling interventions, physician advice, buddy support programmes, age-tailored self-help materials, telephone counselling, and the nicotine patch	A

7.10 Incarcerated People

Individuals released from prison or discharged from mental health and substance use treatment facilities often relapse to smoking shortly after their release. A systematic review found that while smoking bans alone do not effectively encourage cessation. A multi-component intervention combined is recommended to enhance cessation rates after release, provided that participants receive adequate support during this transition period[131,, Level III]

A multi-component tobacco control intervention which included prisoners and prison staff showed a reduction and cessation in smoking. This multicomponent intervention resulted in high abstinence rates, had high acceptability among both staff and prisoners, and was associated with wider health benefits across the prison settin.[129, Level III]

An RCT of people released from smoke free prison randomised to a single session of motivational interview or usual care. There was no significant

between-group difference in continuous abstinence between MI (8.6%) versus usual care (7.4%) with risk ratio = 1.16, 95%CI 0.67□2.03[130, Level I].

Recommendation: A multicomponent tobacco control intervention is recommended for incarcerated people in smoking cessation.

Recommendation	Grades of Recommendations
A multicomponent tobacco control intervention	A
Single session of motivational interview	B

8.0 MANAGEMENT OF WEIGHT GAIN / OBESE SMOKERS

Concerns about weight gain after stopping smoking are a commonly cited barrier to stopping smoking. For smokers who are greatly concerned about weight gain, it may be most appropriate to prescribe or recommend bupropion SR (MD −1.01 kg, 95% CI −1.35 to −0.67; 10 studies, 1098 participants; I2 = 3%) or NRT MD −0.52 kg, 95% CI −0.99 to −0.05; 21 studies, 2784 participants; I2 = 81%), in particular nicotine patch or gum, which have been shown to delay weight gain after quitting[149, 150, Level I].

Quitting smoking is often followed by weight gain hence, health professionals involved should:

i. Note that the health risks of weight gain are small when compared to the risks of continued smoking
ii. Recommend physical activities and a balanced, healthy diet to control weight
iii. Recommend that patients should concentrate primarily on smoking cessation, not weight control, until ex-smokers are confident that they will not return to smoking.

A majority of smokers gain weight after they quit smoking. In a meta-analysis including 35 cohorts, the subjects who stopped smoking gained 4.10 kg (95% CI, 2.69-3.60) on average.[132, Level I] It has been reported that about 10% of quitters gain up to 15 kilograms.[150, Level I] However, weight gain that follows smoking cessation is a negligible health threat compared with the risks of continued smoking.[151, Level I]

Weight gain that follows smoking cessation is a negligible health threat compared with the risks of continue smoking. Post-cessation weight gain appears to be caused

both by increased intake and by metabolic adjustments. The involvement of metabolic mechanisms suggests that even if smokers do not increase their caloric intake upon quitting, they will, on average, gain some weight.[152, Level II-1; 153, Level II-2; 154, Level II-1]

Some smoking cessation pharmacological treatments may also have limited weight gain. Bupropion, fluoxetine, NRT and varenicline all limit weight gain during treatment however, the effects on weight gain reduction were smaller after the treatment had stopped and there was insufficient evidence to be sure that these effects persisted in the long-term.

9.0 IMPLEMENTING THE GUIDELINES

It is essential to manage the treatment of nicotine dependant and tobacco use disorder at all healthcare levels in Malaysia by using an evidence-based CPG. This aims to increase the success rate for nicotine dependant and tobacco users to beat their nicotine addiction.

9.1 Facilitating and Limiting Factors

Existing facilitators for application of the recommendations in the CPG include:-

i. wide dissemination of the CPG to healthcare providers (hardcopies and softcopies
ii. training and regular update for healthcare providers
iii. public awareness campaigns related to nicotine dependant especially using electronic e-cigarette

Existing barriers for application of the recommendations of the CPG are:-

i. inadequate understanding of evidence-based treatment of nicotine dependant and Tobacco Use Disorder
ii. insufficient resources especially trained personnel, pharmacotherapy and infrastructure
iii. variation in treatment practice and preferences
iv. lack of awareness among patients, families/carers and community to handling nicotine dependants and tobacco users among youngster

9.2 Potential Resource Implications

To implement the CPG, there must be strong commitment to:-

i. ensure widespread distribution of the CPG to healthcare providers
ii. initiate training (with adequate funding) of healthcare providers ensuring information is up-to-date
iii. ensure availability of dedicated management team and trained including multidisciplinary team at different levels of healthcare where appropriate
iv. ensure widespread distribution of updated patient education materials

Implementation strategies such as Quick Reference and Training Module will be developed following the approval of the CPG by MoH.

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GLOSSARY - Secretariat

Abstinence. Smokers who remain smoking free at follow-up of at least 6 months after quitting date.

Bupropion SR (bupropion sustained-release). A non-nicotine aid to smoking cessation originally developed and marketed as an antidepressant. It is chemically unrelated to tricyclics, tetracyclics, selective serotonin re-uptake inhibitors, or other known antidepressant medications. Its mechanism of action is presumed to be mediated through its capacity to block the re-uptake of dopamine and norepinephrine centrally.

Clinician. A professional directly providing health care services.

Extra-treatment social support component. Interventions or elements of an intervention wherein patients are provided with tools or assistance in obtaining social support outside of treatment. This category is distinct from intra-treatment social support, in which social support is delivered directly by treatment staff.

First-line pharmacotherapy for tobacco dependence. First-line pharmacotherapies have been found to be safe and effective for tobacco dependence treatment and have been approved by the FDA for this use. First-line medications have established empirical record of efficacy, and should be considered first as part of tobacco dependence treatment except in cases of contraindications.

Intensive Clinical Intervention. Refers to interventions that involve extended contact between clinicians and patients. It was coded based on the length of contact between clinicians and patients (greater than 10 minutes). If that information was unavailable, it was coded based on the content of the contact between clinicians and patients.

Intra-treatment social support. Refers to an intervention component that is intended to provide encouragement, a sense of concern, and interested empathic listening as part of the treatment.

Low-intensity counselling. Low-intensity counselling refers to interventions that involve contact between clinicians and patients and that last between 3 and 10 minutes. If the information on length of contact was unavailable, it was coded based on the description of content of the clinical intervention.

Brief Clinical Intervention. Brief clinical intervention refers to interventions that involve very brief contact between clinicians and patients. It was coded based on the length of contact between clinicians and patients (3 minutes or less). If that information was unavailable, it was coded based on the content of the clinical intervention.

Motivation. A type of intervention designed to bolster patients' resolve to quit through manipulations such as setting a quit date, use of a contract with a specified quit date, reinforcing correspondence (letters mailed from clinical/study staff congratulating the patient on his or her decision to quit or on early success), providing information about the health risks of smoking, and so on.

Nicotine replacement therapy (NRT). Refers to a medication containing nicotine that is intended to promote smoking cessation. There are a few nicotine replacement therapy delivery systems currently approved for use in Malaysia. These include nicotine chewing gum, nicotine inhaler and nicotine patch, nicotine nasal spray.

Person-to-person intervention. In-person, or face -to-face, contact between a clinician and a patient(s) for the purpose of tobacco use intervention or assessment.

Practical counselling (problem solving/skills training). Refers to a tobacco use treatment in which tobacco users are trained to identify and cope with events or problems that increase the likelihood of their tobacco use. For example, quitters might be trained to anticipate stressful events and to use coping skills such as distraction or deep breathing to cope with an urge to smoke. Related and similar interventions are coping skill training, relapse prevention, and stress management.

Primary care clinician. A clinician (e.g., in medicine, nursing, psychology, pharmacology, dentistry/oral health, physical, occupational, and respiratory therapy) who provides basic health care services for problems other than tobacco use per se. Primary care providers are encouraged to identify tobacco users and to intervene, regardless of whether tobacco use is the patient's presenting problem.

Proactive telephone counselling. Treatment initiated by a clinician who telephones and counsels the patient over the telephone.

Psychosocial interventions. Refers to intervention strategies that are designed to increase tobacco abstinence rates due to psychological or social support mechanisms. These interventions comprise such treatment strategies as counselling, self-help, and behavioural treatment like rapid smoking and contingency contracting.

Quit date. The date of a given cessation attempt during which a patient tries to abstain totally from tobacco use. Also, refers to a motivational intervention, whereby a patient commits to quit tobacco use on a specified day.

Randomised controlled trial. For the purposes of this guideline, a study in which subjects are assigned to conditions on the basis of chance, and where at least one of the conditions is a control or comparison condition.

Second-hand smoke is a combination of side-stream cigarette smoke and the exhaled main-stream smoke. Those who are exposed to second hand smoke for 15 minutes in two days within a week is defined as second-hand smokers.

Second-line pharmacotherapy for tobacco dependence. Second-line medications are pharmacotherapies for which there is evidence of efficacy for treating tobacco dependence, but they have a more limited role than first-line medications because: (1) the FDA has not approved them for a tobacco dependence treatment indication, and (2) there are more concerns about potential side effects than exist with first-line medications. Second-line treatments should be considered for use on a case-by-case basis after first-line treatments have been used or considered.

Self-help. An intervention strategy in which the patient uses a non-pharmacologic physical aid to achieve abstinence from tobacco. Self -help strategies typically involve little contact with a clinician, although some strategies (e.g., hotline/helpline) involve patient-initiated contact. Examples of types of self-help materials include: pamphlets / booklets / mailings / manuals; videos; audios; referrals to 12-step programmes; mass media community-level interventions; lists of community programmes; reactive telephone hotlines/helplines; and computer programmes/Internet.

Smokeless tobacco. Any used form of unburned tobacco, including chewing tobacco, snuff and also electronic cigarette.

Specialized assessments. Refers to assessment of patient characteristics, such as nicotine dependence and motivation for quitting, that may allow clinicians to tailor interventions to the needs of the individual patient.

Weight/diet/nutrition component. An intervention strategy designed to address weight gain or concerns about weight gain. Interventions that teach diet/weight management strategies, incorporate weekly weight monitoring (for reasons other than routine data collection), require or suggest energy intake maintenance/reduction, and/or convey nutritional information/counselling.

Appendix 1

EXAMPLE OF SEARCH STRATEGY

The following MeSH terms or free text terms were used either singly or in combination, search was limit to English and human:

Pubmed:

((((((((((nicotine) OR tobacco) AND nicotine replacement) OR varenicline) OR Nortriptyline) OR bupropion) OR brief advice) OR motivational interviewing) AND smoking cessation) AND ((Clinical Trial[ptyp] OR Review[ptyp]) AND Humans[Mesh]))) AND brief intervention

Ovid:

1 nicotine.tw.

2 tobacco.tw.

3 nicotine replacement.tw.

4 varenicline.tw.

5 bupropion.tw.

6 Nortriptyline.tw.

7 brief advice.tw.

8 motivational interviewing.tw.

9 brief intervention.tw.

10 smoking cessation.tw.

11 1 or 2

12 3 or 4 or 5 or 6 or 7 or 8 or 9

13 10 and 11 and 12

14 limit 13 to English

15 limit 13 to human

Cochrane Database of Systemic Reviews (CDSR):

#1 MeSH descriptor: [Nicotine] explode all trees

#2 MeSH descriptor: [Tobacco] explode all trees

Appendix 2

CLINICAL QUESTIONS

Population level interventions

1. Are any current interventions aimed at the general population effective in reducing the number of people who smoke and the harms linked to tobacco use? If so, which ones?
2. Which pharmacological intervention provides effective and cost-effective cessation?
3. Which behavioural intervention provides effective and cost-effective cessation?
4. Do interventions which aim to change tobacco related social norms reduce the demand for tobacco?
5. What are the most effective stop smoking interventions for smokers who are part of a hard-to-reach group?
6. Which interventions reduce the difference in the number of smokers in low socioeconomic compared with high socioeconomic groups most effectively?
7. Which interventions are the most effective to help people stop smoking in communities where smoking as a group has cultural and social value?
8. What are the most effective strategies for relapse prevention?
9. What is the evidence on effectiveness of digital technology in tobacco use cessation?

Electronic cigarettes

10. How effective and safe are e-cigarettes, and are they as effective and safe as other cessation products?
    How can we educate people effectively about the risks and benefits of using e-cigarettes?
11. Are e-cigarettes an effective and cost-effective aid to help people to stop smoking, and are they as effective as other products?

Pregnancy

12. How safe are e-cigarettes when used during pregnancy, and are they as safe as other products?
    What are the most effective and cost-effective methods pregnant smokers can use to give up smoking?
    Are e-cigarettes an effective and cost-effective aid to help people to stop smoking during pregnancy, and do they have cultural and social value?

Mental health and substance abuse

13. How can we encourage and help mental health workers to offer stop smoking services to their patients with mental illness?
14. What is the most effective and cost-effective way to help people with mental health problems to quit smoking inside and outside of mental health treatment settings?
15. What is the most effective and cost-effective way to help people who also have drug and alcohol problems to quit smoking?
16. Can include treatment patient with autism or ADHD?

Young people

17. What is the most effective and cost effective way to stop young people from starting to smoke, in particular those in hard-to-reach groups?
18. Are there effective interventions to stop early trials of smoking from turning into tobacco use disorder?
19. How can we stop the children of smokers from starting to smoke themselves?

Treatment delivery

20. How can we ensure all healthcare providers provide cessation treatment that has been found to be effective, safe & cost-effective?
21. What type of health providers provide the most effective support to help people to quit smoking, and how much training do they need to be most effective?
22. What are the most effective interventions that can be used in primary care (e.g. doctors' and dentists' surgeries, pharmacies) to encourage more people to use stop smoking services and to give up smoking?

Appendix 3

Modified Fagerström Test for Cigarette Dependence (English version)

1. How soon after you wake up do you smoke your first cigarette?

	Within 5 minutes	(3 points)
	5 to 30 minutes	(2 points)
	31 to 60 minutes	(1 point)
	After 60 minutes	(0 points)

2. Do you find it difficult not to smoke in places where you shouldn't, such as in church or school, in a movie, at the library, on a bus, in court or in a hospital?

□ Yes (1 point)
□ No (0 points)

3. Which cigarette would you most hate to give up;which cigarette do you treasure the most?

□ The first one in the morning (1 point)
□ Any other one (0 points)

4. How many cigarettes do you smoke each day?

	10 or fewer	(0 points)
	11 to 20	(1 point)
	21 to 30	(2 points)
	31 or more	(3 points)

5. Do you smoke more during the first few hours after waking up than during the rest of the day?

□ Yes (1 point)
□ No (0 points)

6. Do you still smoke if you are so sick that you are in bed most of the day, or if you have a cold or the flu and have trouble breathing?

□ Yes (1 point)
□ No (0 points)

Scoring: 7 to 10 points = highly dependent; 4 to 6 points = moderately dependent; less than 4 points =minimally dependent.

Modified Fagerström test for evaluating intensity of physical dependence on nicotine. Adapted with permission from Heatherton TF, Kozlowski LT, Frecker RC, Fagerström KO. The Fagerström test for nicotine dependence: a revision of the Fagerström Tolerance Questionnaire. Br J Addict 1991;86:1119-27.

Versi Bahasa Malaysia

Ujian Fagerstrom Untuk Ketagihan Nikotin

Adakah merokok “hanya satu tabiat” atau “adakah anda ketagih?” Sila jalani ujian ini untuk mengetahui tahap ketagihan nikotin anda.

1. Selepas bangun dari tidur, bilakah anda menghisap rokok pertama anda?

☐	Dalam masa 5 minit	(3 mata)
☐	6-30 minit	(2 mata)
☐	31 – 60 minit	(1 mata)
☐	Selepas 60 minit	(0 mata)

2. Adakah anda berasa sukar untuk menahan diri dari merokok di kawasan larangan merokok?

□ Ya (1 mata)

□ Tidak (0 mata)

3. Waktu merokok yang mana satu paling sukar untuk dielakkan ?

□ Yang pertama pada waktu pagi (1 mata)

□ Yang lain (0 mata)

4. Berapa batang rokok yang anda hisap dalam sehari?

☐	10 atau kurang	(0 mata)
☐	11 - 20	(1 mata)
☐	21 - 30	(2 mata)
☐	31 atau lebih	(3 mata)

5. Adakah anda merokok lebih kerap semasa beberapa jam pertama selepas bangun dari tidur berbanding pada waktu lain?

□ Ya (1 mata)

□ Tidak (0 mata)

6. Adakah anda merokok meskipun ketika anda sakit dan terlantar di katil sepanjang hari

□ Ya (1 mata)

□ Tidak (0 mata)

Tandakan markah dan jumlahkan kesemuanya

Markah kurang daripada 5:
“Tahap ketagihan nikotin anda masih rendah. Anda perlu bertindak sekarang sebelum tahap ketagihan meningkat.”

Markah ialah 5:
“Tahap ketagihan nikotin anda adalah sederhana. Jika anda tidak berhenti segara, tahap ketagihan nikotin anda akan meningkat sehingga anda mungkin mengalami ketagihan yang serius. Bertindak sekarang untuk menghentikan ketagihan nikotin anda.”

Markah lebih daripada 7:
“ Tahap ketagihan anda adalah tinggi. Anda tidak dapat mengawal tabiat merokok anda-sebaliknya ia mengawal anda! Apabila anda membuat keputusan untuk berhenti, mungkin anda mahu bertanya kepada doktor anda mengenai terapi penggantian nikotin atau ubat-ubatan lain untuk membantu anda mengatasi ketagihan anda.”

Adapted with permission from: Anne Yee HA, Ng CG, Rusdi AR. 2011. Validation of the Malay version of Fagerstrom test for nicotine dependence (FTND-M) among a group of male staffs in a University Hospital. Malaysian Journal of Psychiatry 20(1).

Appendix 4

NCSCT CLINICAL CHECKLISTS

Introduction

The National Centre for Smoking Cessation and Training (NCSCT) has identified the knowledge and skills that smoking cessation practitioners need for effective behavioural support during individual face-to-face smoking cessation interventions.

Using the clinical checklists

The NCSCT clinical checklists have been divided into sections, which correspond to the sessions outlined in the Standard Treatment Programme. They are designed to allow practitioners to 'build' their portfolio of skills, and can be used as a memory aid when seeing smokers or as a learning tool when observing other practitioners.

Standard Treatment Programme

Clinical Checklist: Pre-quit Assessment (Session 1)

- Assess current readiness and ability to quit
- Inform the client about the treatment programme
- Assess current smoking
- Assess past quit attempt
- Explain how tobacco dependence develops and assess nicotine dependence
- Explain and conduct carbon monoxide (CO) monitoring
- Explain the importance of abrupt cessation and the 'not a puff' rule
- Inform the client about withdrawal symptoms
- Discuss stop smoking medication
- Set the Quit Date
- Prompt a commitment from the client
- Discuss preparations and provide a summary

Communication skills used throughout this session:

- Boost motivation and self-efficacy
- Build rapport
- Use reflective listening
- Provide reassurance

This session also covers general preparations for quitting and it should aim to enhance motivation and boost self-confidence throughout.

Clinical Checklist: Quit Date

- Confirm readiness and ability to quit
- Confirm that the client has sufficient supply of medication and discuss expectations of medication
- Discuss withdrawal symptoms and cravings / urges to smoke and how to deal with them
- Advise on changing routine
- Discuss how to address the issue of the client's smoking contacts and how the client can get support during their quit attempt
- Address any potential high risk situations in the coming week
- Conduct carbon monoxide (CO) monitoring
- Confirm the importance of abrupt cessation
- Prompt a commitment from the client
- Discuss plans and provide a summary
- Boost motivation and self-efficacy
- Build rapport
- Use reflective listening
- Provide reassurance

Communication skills used throughout this session:

This session also covers strategies for avoiding smoking and should aim to enhance motivation and boost self-confidence throughout.

Clinical Checklist: 1, 2, 3 weeks' post Quit Date

- Check on client's progress
- Measure carbon monoxide (CO)
- Enquire about medication use and ensure that the client has a sufficient supply
- Discuss any withdrawal symptoms and cravings / urges to smoke that the client has experienced and how they dealt with them
- Discuss any difficult situations experienced and methods of coping
- Addressing any potential high risk situations in the coming week
- Confirm the importance of the 'not a puff' rule and prompt a commitment from the client
- Provide a summary
- Boost motivation and self-efficacy
- Build rapport
- Use reflective listening
- Provide reassurance

Communication skills used throughout this session:

This session also covers strategies for avoiding smoking and it should aim to enhance motivation and boost self-confidence throughout.

Clinical Checklist: 4 weeks' post Quit Date

- Check on client's progress
- Measure carbon monoxide (CO)
- Advise about continued medication use and ensuring that the client knows where to obtain further supplies
- Discuss any withdrawal symptoms and cravings / urges to smoke that the client has experienced and how they dealt with them
- Discuss any difficult situations experienced and methods of coping and address any potential high risk situations in the future (i.e. stressful situations that they have not experienced over the past four weeks)
- Confirm the importance of the 'not a puff' rule and prompt a commitment from the client
- Advise about how to access additional support if needed
- Advise about what to do if the client lapses (i.e. before relapsing)
- Provide a summary

Communication skills used throughout this session:

- Boost motivation and self-efficacy
- Build rapport
- Use reflective listening
- Provide reassurance

This session also covers strategies for avoiding smoking in the long term and it should aim to enhance motivation, boost self-confidence and promote the ex-smoker identity throughout (McEwen, A. 2012).

Appendix 5

ABC for Smoking Cessation

Ask	Ask about and document smoking status for all people (for those who smoke or have recently stopped smoking, smoking status should be checked and updated on a regular basis). For example, you could ask: 'Do you currently smoke cigarettes?'

Brief Advice	1. Provide advice to all people who smoke. For example, you could say: 'You may know the risks involved with smoking, but do you realise how harmful it is? I cannot stress enough how important it is to stop smoking. Stopping is the best thing that you can do to improve your health. I understand that it can be hard to stop smoking, but if you want to, I can help you.' 2. Personalise the advice (for example, if relevant explain how smoking is related to existing health problems and how stopping smoking might help). Highlight the benefits of quitting. 3. Acknowledge that some people make several attempts to quit before stopping for good. 4. Document that advice was given.

Cessation Support	There are two options for providing cessation support. 1. Refer: Health care workers *without* the expertise or time to help people to stop smoking should refer smokers to smoking cessation services. 2. Provide support: Health care workers who are able to provide support should do so. Support can include setting a quit date; advising the smoker that complete abstinence from smoking is best; arranging medication to aid the quit attempt and arranging for a follow-up consultation within a week. Assessment of the degree of nicotine dependence helps guide treatment.

Adapted from: New Zealand Smoking Cessation Guidelines 2007

Appendix 6

Clinical Use of Pharmacotherapy in Treatment of Tobacco Use Disorder

Table 6: Clinical Use of Nicotine Gum

Patient selection	Appropriate as a first-line pharmacotherapy for smoking cessation.
Precautions	Pregnancy: Pregnant smokers should be encouraged to quit first without pharmacologic treatment. Nicotine gum should be used during pregnancy only if the increased likelihood of smoking abstinence, with its potential benefits, outweighs the risk of nicotine replacement and potential concomitant smoking. Similar factors should be considered in lactating women (FDA Class D) – see Appendix 7. Cardiovascular diseases: NRT is not an independent risk factor for acute myocardial events, but it should be used with caution among certain cardiovascular patient groups: those in the immediate (within 1 to 2 weeks) post myocardial infarction period, those with serious arrhythmias, and those with serious or worsening angina pectoris.
Side effects.	Common side effects of nicotine chewing gum include mouth soreness, hiccups, dyspepsia, and jaw ache. These effects are generally mild and transient, and often can be alleviated by correcting the patient's chewing technique (see prescribing instructions below).
Dosage	Nicotine gum is available in 2 mg and 4 mg (per piece) doses. The 2 mg gum is recommended for patients smoking less than 20 cigarettes per day, while the 4 mg gum is recommended for patients smoking 20 or more cigarettes per day. Generally, the gum should be used for up to 12 weeks with no more than 24 pieces/day. Clinicians should tailor the dosage and duration of therapy to fit the needs of each patient.
Availability	Nicorette 2 and 4 mg

Prescribing instructions	Chewing technique: Gum should be chewed slowly until a peppery or minty taste emerges, then parked between cheek and gum to facilitate nicotine absorption through the oral mucosa. Gum should be slowly and intermittently chewed and parked for about 30 minutes or until the taste dissipates. – see Appendix 8. Absorption: Eating and drinking anything except water should be avoided for 15 minutes before and during chewing as acidic beverages (e.g., coffee, juices, and soft drinks) interfere with the buccal absorption of nicotine. Scheduling of dose: Patients often do not use enough gum to get the maximum benefit: they chew too few pieces per day and they do not use the gum for a sufficient number of weeks. Do not eat or drink while gum is in the mouth. Instructions to chew the gum on a fixed schedule (at least one piece every 1-2 hours during waking hours) for at least 1-3 months may be more beneficial than when necessary.

Table 7: Clinical Use of Nicotine Patch

Patient selection	Appropriate as a first-line pharmacotherapy for smoking cessation.
Precautions	Pregnancy: Pregnant smokers should be encouraged to quit first without pharmacological treatment. The nicotine patch should be used during pregnancy only if the increased likelihood of smoking abstinence, with its potential benefits, outweighs the risk of nicotine replacement and potential concomitant smoking. Similar factors should be considered in lactating women. (FDA Class D) Cardiovascular diseases. As per gum
Side effects	Skin reactions. Up to 50% of patients using the nicotine patch will have a local skin reaction. Skin reactions are usually mild and self-limiting, but may worsen over the course of therapy. Local treatment with hydrocortisone cream (1%) or triamcinolone cream (0.5%) and rotating patch sites may reduce such local reactions. In less than 5% of patients, such reactions require the discontinuation of nicotine patch treatment. Other side effect: Insomnia.

Dosage	Treatment of a t l e a s t 8 weeks has been shown to be as efficacious as longer treatment p e r i o d s . 16- and 24-hour patches are of comparable efficacy. Clinicians should consider individualizing treatment based on specific patient characteristics such as previous experience with the patch, amount smoked, degree of addictiveness, etc. Finally, clinicians should consider starting treatment on a lower patch dose in patients smoking 10 or fewer cigarettes per day.
Availability	Niquitin (21, 14 and 7 mg, respectively), Nicorette 25,15 and 10 mg

Niquitin®	If smoking 10 cigarettes or more a day, start with Step 1 (21 mg) and gradually move to step 2 (14 mg) after 6 weeks and then step 3 (7 mg) for 2 weeks, as directed on pack over 10 weeks. If smoking less than 10 cigarettes a day, start at Step 2 and follow the 8 week programme described on the pack.
Nicorette®	15 mg x 8 weeks, then 10 mg x 2 weeks and finally 5 mg x 2 weeks
Prescribing instructions	Location. The patient should place a new patch on a relatively hairless location, typically between the neck and waist, usually upper arm or shoulder. Rotate and avoid using the same site of application for about 1 week (see **Appendix 9**). Activities : No restriction while using the patch Time: Patches may be applied as soon as the patient wakes up. In patients who experience sleep disruption, advise the patient to remove the 24- hour patch prior to bedtime or use the 16-hour patch. Smokers with time-to-first cigarette (TTFC) of 30 minutes or less may benefit from putting the patch immediately before sleeping, so that the plasma nicotine level is highest upon waking up 6 to 8 hours post application of the patch. Remove the patch after 16 or 24 hours.

Table 8: Clinical Use of Nicotine Inhaler

Patient selection	Appropriate as a first-line pharmacotherapy for smoking cessation.
Precautions	Pregnancy and cardiovascular diseases. As for nicotine gum.
Side effects	Local irritation reactions: Local irritation in the mouth and throat was observed in 40% of patients using the nicotine inhaler. Coughing and rhinitis occur in 32% and 23%, respectively. Severity was generally rated as mild, and the frequency of such symptoms declined with continued use.

Dosage	A dose from the nicotine inhaler consists of a puff or inhalation. Each cartridge delivers 4 mg of nicotine over 80 inhalations. Recommended dosage is 6-16 cartridges/day. Recommended duration of therapy is up to 6 months. Instruct patient to taper dosage during the final 3 months of treatment.

Availability	4 mg/cartridge
Prescribing	Ambient temperature: The inhaler and cartridges should be kept at room temperature. Duration: Use is recommended for up to 6 months with gradual reduction in frequency of use over the last 6-12 weeks of treatment. Absorption: Acidic beverages (e.g., coffee, juices, and soft drinks) interfere with the buccal absorption of nicotine, so eating and drinking anything except water should be avoided for 15 minutes before and during inhalation. Best effects: Best effects are achieved by frequent puffing.

Table 9: Clinical Use of Nicotine Lozenge

Patient selection	Appropriate as a first-line pharmacotherapy for smoking cessation. As an aid to smoking cessation, by treatment of tobacco dependence through the relief of nicotine withdrawal symptoms, including cravings.
Precautions	DM, MI, severe dysrhythmia or CVA. Active oesophagitis, oral or pharyngeal inflammation, gastritis, gastric or peptic ulcer. Moderate to severe renal/hepatic impairment. Children <18 yr. Pregnancy
Side effects	Nausea, vomiting, dyspepsia, upper abdominal pain, diarrhoea, dry mouth, constipation, hiccups, stomatitis, flatulence, oral discomfort; headache, dizziness, tremor; sleep disorders eg insomnia & abnormal dreams, nervousness; palpitations; pharyngitis, cough, pharyngolaryngeal pain, dyspnoea; increased sweating; arthralgia, myalgia; application site reactions, chest pain, pain in limb, asthenia, fatigue.
Dosage	*2 mg and 4 mg*

Prescribing instruction	Up to 2 mg (smoker of <20 cigarettes/day) or 4 mg (smoker of ⩾20 cigarettes/day). **Stepwise treatment for abrupt cessation:** Week 1-6: 1 lozenge 1-2 hourly. Min: 9 lozenge/day. Week 7-9: 1 lozenge 2-4 hourly. Week 10-12: 1 lozenge 4-8 hourly. Max: 15 lozenge/day. Max duration: 24 wk.

	Gradual cessation: Use a lozenge when there is a strong urge to smoke. Max: 15 lozenge/day. Lozenge should not be chewed or swallowed. Do not eat or drink while lozenge is in the mouth.

Table 10: Clinical Use of Nicotine Oral Spray

Patient selection	Appropriate as a first-line pharmacotherapy for smoking cessation. As an aid to smoking cessation, by treatment of tobacco dependence through the relief of nicotine withdrawal symptoms, including cravings.
Precautions	Do not use this product if patients have serious heart disease, are pregnant or breastfeeding. Not to be used by non-smokers.
Side effects	Headache, hiccups, throat irritation, nausea, dysgeusia, cough, abdominal pain, dry mouth, diarrhoea, dyspepsia, stomatitis, vomiting, burning sensation.
Dosage	*1 mg/spray x 150 sprays*
Prescribing instruction	At the beginning of treatment, device should be primed/loaded properly to be used effectively. Prime the spray pump if it has not been used for 2 days. To do this, point the spray safely away and press firmly the top of the dispenser with index finger 3 times until a fine spray appears. Users should use one or two sprays whenever they would normally smoke a cigarette, or whenever they experience cravings. Up to 4 sprays per hr/ 64 sprays in any a day. If cravings do not disappear within a few minutes of using a single spray, *a second spray may be used*. Some subjects may consistently need to use two consecutive sprays for optimal control of cravings. Up to 3 sprays/hr or 48 sprays/day. Acidic beverages (e.g., coffee, juices, and soft drinks) interfere with the buccal absorption of nicotine, so eating and drinking anything except water should be avoided for 15 minutes before and during administration. Note: It contains a small amount of ethanol, at (9.7% w/v) and

	7.1mg per dose.

Table 11: Clinical Use of Varenicline

Patient selection	Appropriate as a first-line pharmacotherapy for smoking cessation. Use in pregnancy: There are no adequate data from the use of varenicline in pregnant women. Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown. Varenicline should not be used during pregnancy (FDA Category C)

Precautions	Effect of Smoking Cessation: Physiological changes resulting from smoking cessation, with or without treatment with varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary (examples include theophylline, warfarin and insulin). As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. Smoking cessation, with or without pharmacotherapy, has been associated with the exacerbation of underlying psychiatric illness (e.g. depression). Care should be taken with patients with a history of psychiatric illness and patients should be advised accordingly. There is no clinical experience with varenicline in patients with epilepsy. At the end of treatment, discontinuation of varenicline was associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients. The prescriber should inform the patient accordingly and discuss or consider the need for dose tapering. Depressed mood may be a symptom of nicotine withdrawal. Depression, rarely including suicidal ideation and suicide attempt, has been reported in patients undergoing a smoking cessation attempt. These symptoms have also been reported while attempting to quit smoking with varenicline. Clinicians should be aware of the possible emergence of significant depressive symptomatology in patients undergoing a smoking cessation attempt, and should advise patients accordingly. Effects on the Ability to Drive or Operate Machinery: Varenicline may have minor or moderate influence on the

	ability to drive and use machines. Varenicline may cause dizziness and somnolence and therefore may influence the ability to drive and use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether varenicline affects their ability to perform these activities. Use in lactation: It is unknown whether varenicline is excreted in human breast milk. Animal studies suggest that varenicline is excreted in breast milk. A decision on whether to continue / discontinue breastfeeding or to continue / discontinue therapy with varenicline should be made taking into account the benefit of breastfeeding to the child and the benefit of varenicline therapy to the woman.

Side effects	In general, when adverse reactions occurred, onset was in the 1st week of therapy; severity was generally mild to moderate and there were no differences by age, race or gender with regard to the incidence of adverse reactions. In patients treated with the recommended dose of 1 mg twice daily following an initial titration period, the adverse event most commonly reported was nausea (28.6%). In the majority of cases, nausea occurred early in the treatment period which was mild to moderate in severity and seldom resulted in discontinuation. The treatment discontinuation rate due to adverse events was 11.4% for varenicline compared with 9.7% for placebo. In this group, the discontinuation rates for the most common adverse events in varenicline-treated patients were as follows: Nausea (2.7% vs 0.6% for placebo), headache (0.6% vs 1% for placebo), insomnia (1.3% vs 1.2% for placebo) and abnormal dreams (0.2% vs 0.2% for placebo). In the following text, all adverse reactions, which occurred at an incidence greater than placebo are listed by system organ class and frequency [very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100) and rare (≥1/10,000 to <1/1000)]. Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness. Infections and Infestations: Uncommon: Bronchitis, nasopharyngitis, sinusitis, fungal infection, viral infection. Metabolism and Nutrition Disorders: Common: Increased appetite. Uncommon: Anorexia, decreased appetite, polydipsia. Psychiatric Disorders: Very Common: Abnormal dreams, insomnia. Uncommon: Panic reaction, bradyphrenia, abnormal thinking, mood swings. Nervous System Disorders: Very Common: Headache. Common: Somnolence, dizziness, dysgeusia. Uncommon:

	Tremor, abnormal coordination, dysarthria, hypertonia, restlessness, dysphoria, hypoaesthesia, hypogeusia, lethargy, increased or decreased libido. Cardiac Disorders: Uncommon: Atrial fibrillation, palpitations. Eye Disorders: Uncommon: Scotoma, scleral discolouration, eye pain, mydriasis, photophobia, myopia, increased lacrimation. Ear and Labyrinth Disorders: Uncommon: Tinnitus. Respiratory, Thoracic and Mediastinal Disorders: Uncommon: Dyspnoea, cough, hoarseness, pharyngolaryngeal pain, throat irritation, respiratory tract congestion, sinus congestion, postnasal drip, rhinorrhoea, snoring. Gastrointestinal Disorders: Very Common: Nausea. Common: Vomiting, constipation, diarrhoea, abdominal distension, stomach discomfort, dyspepsia, flatulence, dry mouth. Uncommon: Haematemesis, haematochezia, gastritis, gastroesophageal reflux disease, abdominal pain, change in bowel habit, abnormal faeces, eructation, aphthous stomatitis, gingival pain, coated tongue. Skin and Subcutaneous Tissue Disorders: Uncommon: Generalised rash, erythema, pruritus, acne, hyperhidrosis, night sweats. Musculoskeletal and Connective Tissue Disorders: Uncommon: Joint stiffness, muscle spasms, chest wall pain, and costochondritis. Renal and Urinary Disorders: Uncommon: Glycosuria, nocturia, polyuria. Reproductive System and Breast Disorders: Uncommon: Menorrhagia, vaginal discharge, sexual dysfunction. General Disorders and Administration Site Conditions: Common: Fatigue. Uncommon: Chest discomfort, chest pain, pyrexia, feeling cold, asthenia, circadian rhythm sleep disorder, malaise, cyst. Investigations: Uncommon: Increased blood pressure, electrocardiogram ST-segment depression, decreased electrocardiogram T-wave amplitude, increased heart rate, abnormal liver function test, decreased platelet count, increased weight, abnormal semen, increased C-reactive protein, decreased blood calcium. Post-marketing cases of myocardial infarction, depression and suicidal ideation have been reported in patients taking varenicline.

Dosage	The recommended dose is 1 mg varenicline twice daily following a 1-week titration as follows: Days 1-3: 0.5 mg once daily; Days 4-7: 0.5 mg twice daily; Day 8-end of treatment: 1 mg twice daily. Patients who cannot tolerate adverse effects of varenicline may have the dose temporarily or permanently lowered to 0.5 mg twice daily. Patients with Renal Insufficiency: No dosage adjustment is necessary for patients with mild (estimated creatinine clearance >50 mL/min and ⩽80 mL/min) to moderate (estimated creatinine clearance ≥30 mL/min and ≤50 mL/min) renal impairment. For patients with moderate renal impairment who experience adverse events that are not tolerable, dosing may be reduced to 1 mg once daily. For patients with severe renal impairment (estimated creatinine clearance <30 mL/min), the recommended dose is 1 mg once daily. Dosing should begin at 0.5 mg once daily for the first 3 days then increased to 1 mg once daily. Based on insufficient clinical experience in patients with end-stage renal disease, treatment is not recommended in this patient population. Patients with Hepatic Impairment: No dosage adjustment is necessary for patients with hepatic impairment. Elderly: No dosage adjustment is necessary for elderly patients. However, since elderly patients are more likely to have decreased renal function, prescribers should consider the renal status of an elderly patient. Children: varenicline is not recommended for use in children or adolescents <18 years due to insufficient data on safety and efficacy.

Prescribing instruction	The patient should set a date to stop smoking. Dosing should start 1-2 weeks before this date. Tablets should be swallowed whole with water, can be taken with or without food, but incidence of nausea increases when taken on an empty stomach. Patients should be treated for 12 weeks. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment with 1 mg twice daily may be considered. No data are available on the efficacy of an additional 12 weeks course of treatment for patients who do not succeed in stopping smoking during initial therapy or who relapse after treatment.

	In smoking cessation therapy, risk for relapse to smoking is elevated in the period immediately following the end of treatment. In patients with a high risk of relapse, dose tapering may be considered. When varenicline and transdermal NRT were co-administered to smokers for 12 days, there was a statistically significant decrease in average systolic blood pressure (mean 2.6 mmHg) measured on the final day of the study. In this study, the incidence of nausea, headache, vomiting, dizziness, dyspepsia, and fatigue was greater for the combination than for NRT alone.

Table 12: Clinical Use of Cytisine

Patient selection	Appropriate as a first-line pharmacotherapy for smoking cessation.
Precautions	Hypersensitivity to the active substance or to any of the excipients. Others: Unstable angina, A history of recent myocardial infarction, Clinically significant arrhythmias, A history of recent stroke, Pregnancy and breastfeeding. A lack of clinical experience or safety data means that cytisine is not recommended for patients: ■ with renal impairment ■ with hepatic impairment ■ over 65 years of age ■ under 18 years of age Cytisine should not be used with anti-tuberculosis drugs.
Side effects	Very common: dry mouth, diarrhea, nausea, changes flavour, heartburn, constipation, vomiting, abdominal pain (especially in the upper abdomen). Others: sleep disorders (insomnia, drowsiness, lethargy, abnormal dreams, nightmares), headaches, dry mouth and fatigue.
Dosage	1.5mg per tablet.

Prescribing instruction	Each tablet contains **1.5 mg of cytisine**. One pack of Cytisine contains 100 tablets which is a complete treatment course (25 days). Cytisine should be taken with water according to the following schedule with **the quit date no later than the fifth day of treatment:**

Days of treatment	Recommended dosing	Maximum daily dose
From the 1st to the 3rd day	1 tablet every 2 hours	6 tablets
From the 4th to the 12th day	1 tablet every 2.5 hours	5 tablets
From the 13th to the 16th day	1 tablet every 3 hours	4 tablets
From the 17th to the 20th day	1 tablet every 5 hours	3 tablets
From the 21st to the 25th day	1–2 tablets a day	2 tablets

Table 13: Clinical Use of Bupropion

Patient selection	Appropriate as a first-line pharmacotherapy for smoking cessation.
Precautions	Pregnant smokers should be encouraged to quit first without pharmacologic treatment. Bupropion SR should be used during pregnancy only if the increased likelihood of smoking abstinence, with its potential benefits, outweighs the risk of bupropion SR treatment and potential concomitant smoking (FDA Category C). Similar factors should be considered in lactating women (FDA Class B). Cardiovascular diseases: Generally well tolerated; infrequent reports of hypertension. Side effects: The most common side effects reported by bupropion SR users were insomnia (35-40%) and dry mouth (10%). Contraindications: Bupropion SR is contraindicated in individuals with a history of seizure disorder, a history of an eating disorder, who are using another form of bupropion (Wellbutrin SR) or who have used an MAO inhibitor in the past 14 days. Close monitoring of patients for clinical worsening, emergence of suicidality, agitation, irritability & unusual changes in behaviour. Patient with history of seizure, cranial trauma or other predisposition toward seizure, or patients taking seizure threshold-lowering agents.

	Excessive use or abrupt discontinuation of alcohol or sedatives. Renal or hepatic impairment including mild to moderate & severe liver cirrhosis. Patients w/ a recent history of MI or unstable heart disease. False +ve urine immunoassay screening tests for amphetamines. May affect ability to drive or operate machinery.
Dosage	Patients should begin with a dose of 150 mg q AM for 3 days, then increase to 150 mg b.i.d. Dosing at 150 mg b.i.d. should continue for 7-12 weeks following the quit date. Unlike nicotine replacement products, patients should begin bupropion SR treatment 1-2 weeks before they quit smoking. For maintenance therapy, consider bupropion SR 150 mg b.i.d. for up to 6 months.
Prescribing instructions	Scheduling of dose: if insomnia is marked, take the PM dose earlier (in the afternoon, at least 8 hours after the first dose) may provide some relief.

Appendix 7

FDA Pregnancy Class

Category	Description
A	Medicines are considered safe to be used throughout pregnancy. Medicines have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus.
B	Medicines which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus. Studies in animals have not shown evidence of an increased occurrence of foetal damage, or are inadequate or may be lacking, but available data show no evidence of an increased occurrence of foetal damage, or there are evidence of an increased occurrence of foetal damage, but the significance of which is considered uncertain in humans.
C	Medicines which have caused or may be suspected of causing harmful effects on the human foetus or newborn infant without causing malformations. These effects may be reversible. Medicines must only be given only if the potential benefits justify the potential risk to the foetus.
D	Medicines that have caused, are suspected to have caused or may be expected to cause an increased incidence of human foetal malformations or irreversible damage. The use is warranted only in life-threatening situation or for a serious disease for which safer medicines cannot be used or ineffective.
X	Medicines which have such a high risk of causing permanent damage to the foetus that they should not be used in pregnancy or when there is a possibility of pregnancy.

Appendix 8

NICOTINE GUM CHEWING TECHNIQUE

CORRECT WAY TO USE THE GUM

CHEW

Chew the gum slowly until peppery/minty taste becomes strong after about 10 chews

REST

Rest the gum between your gum and cheek

CHEW

Start chewing again when taste has faded

After about 30 minutes discard it properly

Adapted with permission from Johnson & Johnson Sdn. Bhd.

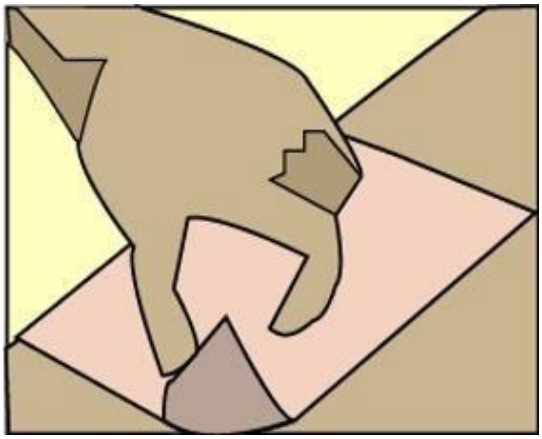
Appendix 9

HOW TO USE THE NICOTINE PATCH

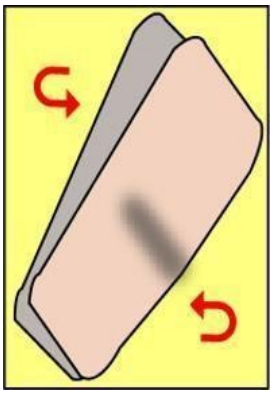
1. **Remove seal at the back of the nicotine patch**

2. **Put the patch on your arm or hip (non-hairy area). Rotate and avoid using the same site of application for at least 1 week**

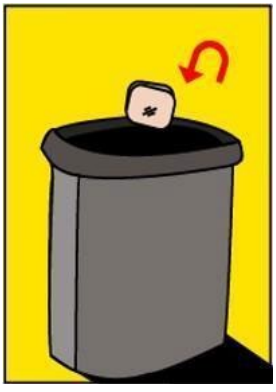
3. **Leave it on for about 16 hours (during waking hours)**



4. **Peel off the patch**



6. **Fold it before discarding it safely**



5. **Next day, put the patch on a different side (DO NOT use the same side for at least 1 week)**

Appendix 10: Enhancing motivation to quit tobacco—the "5 R's"

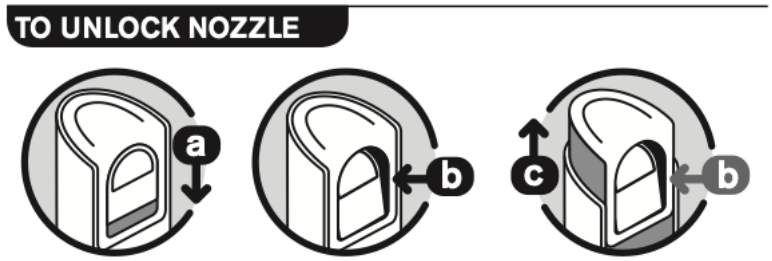
Relevance	● Encourage the patient to indicate why quitting is personally relevant, being as specific as possible. ● Motivational information has the greatest impact if it is relevant to a patient's disease status or risk, family or social situation (e.g. having children in the home), health concerns, age, gender, and other important patient characteristics (e.g. prior quitting experience, personal barriers to cessation).
Risks	The clinician should ask the patient to identify potential negative consequences of tobacco use. The clinician may suggest and highlight those that seem most relevant to the patient. The clinician should emphasize that smoking low-tar/low-nicotine cigarettes or use of other forms of tobacco (e.g., smokeless tobacco, cigars, and pipes) will not eliminate these risks. Examples of risks are: **Acute risks**: Shortness of breath, exacerbation of asthma, increased risk of respiratory infections, harm to pregnancy, impotence, and infertility. **Long-term risks**: Heart attacks and strokes, lung and other cancers (e.g., larynx, oral cavity, pharynx, oesophagus, pancreas, stomach, kidney, bladder, cervix, and acute myelocytic leukemia), chronic obstructive pulmonary diseases (chronic bronchitis and emphysema), osteoporosis, long-term disability, and need for extended care. **Environmental risks**: Increased risk of lung cancer and heart disease in spouses; increased risk for low birth-weight, sudden infant death syndrome (SIDS), asthma, middle ear disease, and respiratory infections in children of smokers.

Rewards	The clinician should ask the patient to identify potential benefits of stopping tobacco use. The clinician may suggest and highlight those that seem most relevant to the patient. Examples of rewards follow: • Improved health • Food will taste better • Improved sense of smell • Saving money • Feeling better about oneself • Home, car, clothing, breath will smell better • Setting a good example for children and decreasing the likelihood that they will smoke • Having healthier babies and children • Feeling better physically • Performing better in physical activities • Improved appearance, including reduced wrinkling/aging of skin and whiter teeth
Road-blocks	The clinician should ask the patient to identify barriers or impediments to quitting and provide treatment (problem solving counselling, medication) that could address barriers. Typical barriers might include: • Withdrawal symptoms • Fear of failure • Weight gain • Lack of support • Depression • Enjoyment of tobacco • Being around other tobacco users Limited knowledge of effective treatment options
Repetition	The motivational intervention should be repeated every time an unmotivated patient visits the clinic setting. Tobacco users who have failed in previous quit attempts should be told that most people make repeated quit attempts before they are successful.

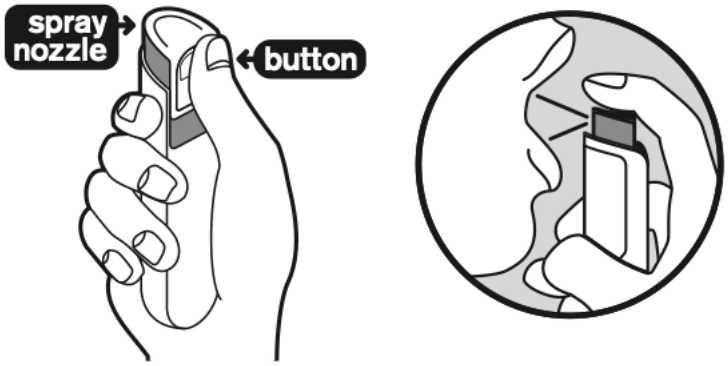
Adapted from Fiore et al. 2008[20, Level I].[1, Grade B].

Appendix 11

HOW TO USE THE NICOTINE OROSPRAY



1. Use your thumb to slide down the button *(a)* until it can be pushed lightly inwards *(b)*. Do not push too hard.
2. While pushing in, slide upwards *(c)* to unlock the top of the dispenser. Then release the button.



3. Point the spray nozzle towards your open mouth and hold it as close to your mouth as possible.
4. Press the top of the dispenser to release one spray into your mouth. Do not inhale while spraying to avoid getting spray down your throat. For best results, do not swallow for a few seconds after spraying.

TO LOCK NOZZLE

Strategy: Addressing problems encountered by former smokers

A patient who previously smoked might identify a problem that negatively affects health or quality of life. Specific problems likely to be reported by former smokers and potential responses follow:	
Problems	Responses
Lack of support for cessation	● Schedule follow-up visits or telephone calls with the patient. ● Help the patient identify sources of support within his or her environment. ● Refer the patient to an appropriate organization that offers counselling or support.
Negative mood or depression	● If significant, provide counselling, prescribe appropriate medication, or refer the patient to a specialist.
Strong or prolonged withdrawal symptoms	● If the patient reports prolonged craving or other withdrawal symptoms, consider extending the use of an approved medication or adding/combining medications to reduce strong withdrawal symptoms.

Weight gain	● Recommend starting or increasing physical activity. ● Reassure the patient that some weight gain after quitting is common and usually is self-limiting. ● Emphasize the health benefits of quitting relative to the health risks of modest weight gain. ● Emphasize the importance of a healthy diet and active lifestyle. ● Suggest low-calorie substitutes such as sugarless chewing gum, vegetables, or mints. ● Refer the patient to a nutritional counsellor or programme.
Smoking lapses	● Suggest continued use of medications, which can reduce the likelihood that a lapse will lead to a full relapse. ● Encourage another quit attempt or a commitment to total abstinence. ● Reassure that quitting may take multiple attempts, and use the lapse as a learning experience. ● Provide or refer for intensive counselling.

Adapted from Fiore et al. 2008[20], Level I

Modified Fagerstrom Test for Nicotine Dependence (mFTND) is used in the Malaysian Clinical Practice Guideline for EVALI (Ministry of Health Malaysia, 2021a).

Nicotine dependence characteristics	Score	
1. How soon after waking do you vape your electronic cigarette.	Within 5 min = 3	☐
	5–30 min = 2	☐
	31–60 min = 1	☐
	After 60 min = 0	☐
2. Do you find difficulty to refrain from vaping in places where it is forbidden such as mosque, church, library?	Yes = 1	☐
	NO = 0	☐
3. Which vaping would you hate to give up?	The first in the Morning = 1	☐
	Any other = 0	☐
4. How many times a day do you vape?	10 or less = 0	☐
	11–20 = 1	☐
	21–30 = 2	☐
	31 or above = 3	☐
5. Do you vape more frequently in the morning?	Yes = 1	☐
	NO = 0	☐
6. Do you vape even if you are sick in bed most of the day?	Yes = 1	☐
	NO = 0	☐
Total		

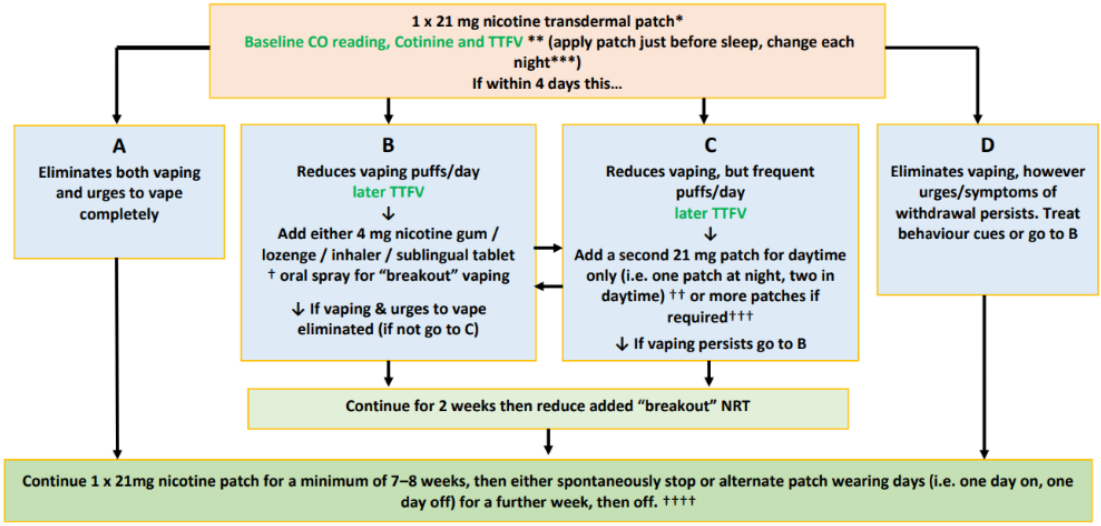
Score: 1–3 = low dependence, 4–6 = moderate dependence, 7–10 = high dependence

Figure 5.4 shows the mFTND that has been developed and tested for use in Malaysia (Rahman et al., 2020).

Guideline for EVALI (Ministry of Health Malaysia, 2021)

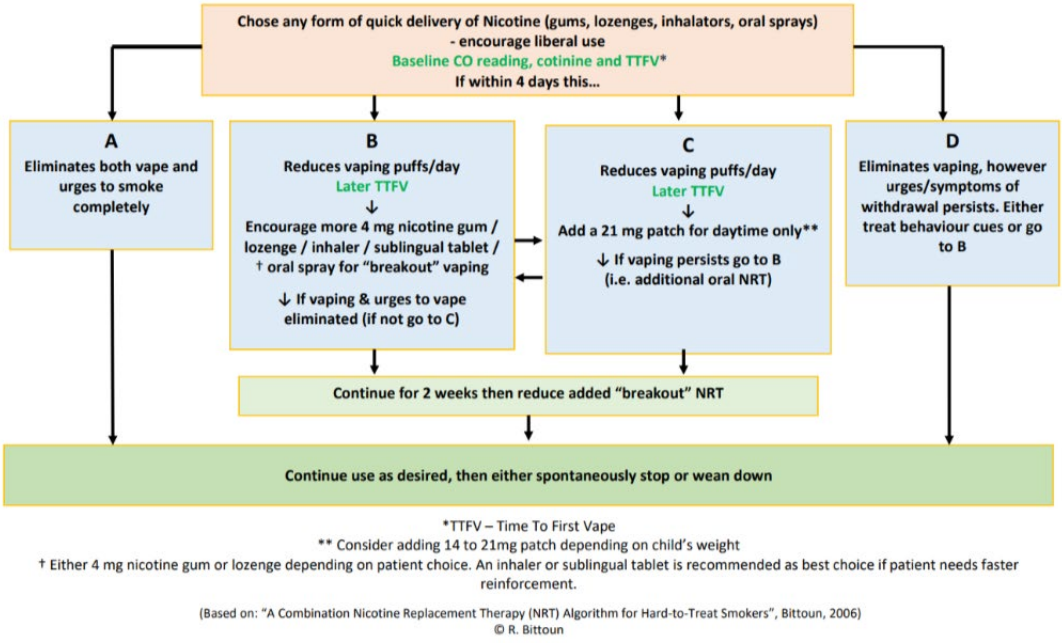
Appendix 13

1. Adult single user



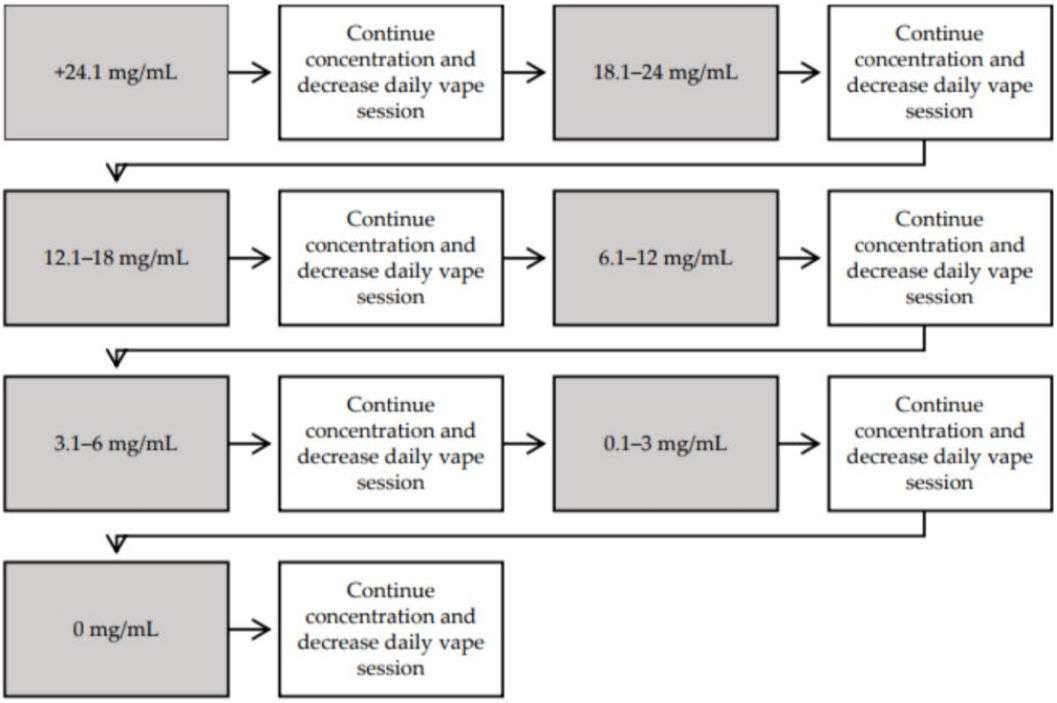
*CONTRAINDICATION: RECENT CARDIOVASCULAR EVENT (within 48 hours)
**TTFV– Time To First Vape
*** Applying patch last thing before sleep allows the slow rise of nicotine overnight — the likelihood of first vape of the day 'urge' is strongly diminished.
† Either 4 mg nicotine gum or lozenge depending on patient choice. An inhaler, oral spray or sublingual tablet is recommended as best choice if patient needs faster reinforcement.
†† No evidence in the literature or in our experience of toxicity. Consider reducing concentrations if nausea occurs.
††† (Przulj et al, 2019)
††††There is no evidence in the literature for weaning (or reduction) of patch strengths.
(Based on: "A Combination Nicotine Replacement Therapy (NRT) Algorithm for Hard-to-Treat Smokers", Bittoun, 2006)

2. Adolescents



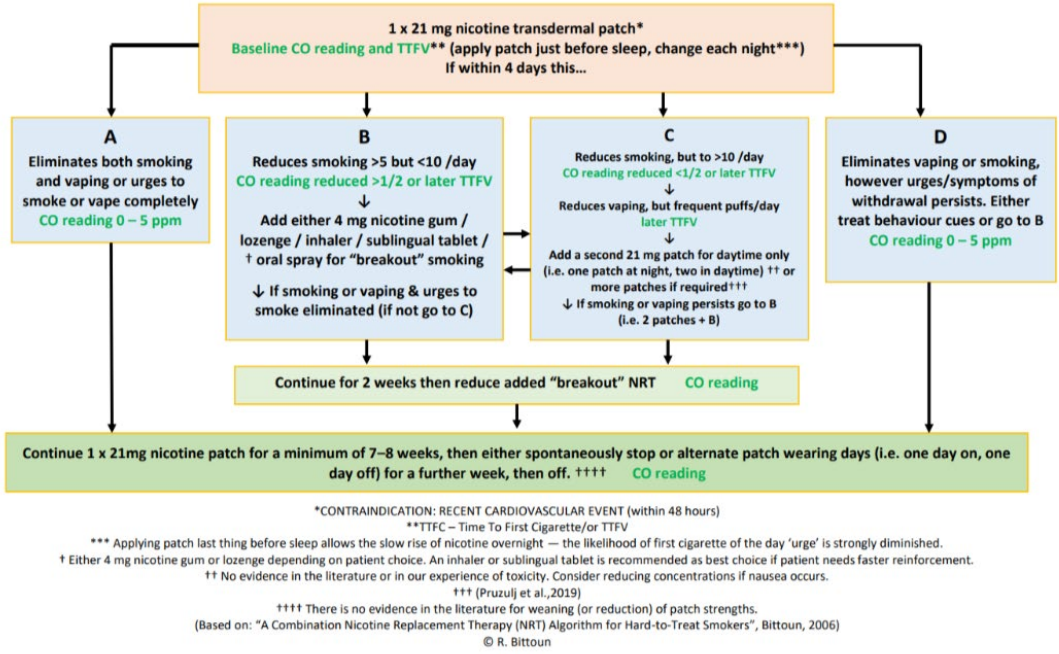
Bittoun, Renee. "Managing Vaping Cessation: A Monograph for Counselling Adult Managing Vaping Cessation: A Monograph for Counselling Adult and Adolescent Vapers and Adolescent Vapers," 2021. https://nwmphn.org.au/wp-content/uploads/2023/07/Managing-Vaping-Counselling-Adult-and-Adolescent.pdf.

Appendix 14



Sahr et al., 2019

Appendix 15



Bittoun, Renee. "Managing Vaping Cessation: A Monograph for Counselling Adult Managing Vaping Cessation: A Monograph for Counselling Adult and Adolescent Vapers and Adolescent Vapers," 2021. https://nwmphn.org.au/wp-content/uploads/2023/07/Managing-Vaping-Counselling-Adult-and-Adolescent.pdf.

Appendix 16

Short form: Time to First Vape (TTFV)

1. Ask ¨How long after waking do you first vape¨
2. Vape usage within 30 minutes of waking up and, presence of cravings or withdrawals are associated with high nicotine dependency.

Long form:

1. Modified-Hooked on Nicotine (M-HONC) checklist
2. Penn State E-Cigarette Dependence Index
3. E-cigarette Dependency Scale (EDS) (Morean et al., 2019)

Appendix 17

Strategy 1 Alternative dopamine reward	This strategy uses dopamine release as a reward. Dopamine is a 'feel-good' chemical released in the brain. Research has shown that nicotine increases the level of dopamine in the brain. Suggest: Instead of using an e-cigarette, the young person should carry a snack. (nuts, flavoured sugar-free gum) for a dopamine release.
Strategy 2 Think of yourself as someone who does not use e-cigarettes	This strategy is based on motivational interviewing so the young person can imagine themselves as someone who does not use e-cigarettes. To exercise this strategy, the young person can say to themselves: “I am not a vaper” “I don’t vape/smoke” This can include asking the young person to imagine an example of being offered an e-cigarette and role-playing their response.
Strategy 3 Use the ¨stray cat¨ metaphor.	This strategy uses the metaphor that the craving is like a stray cat. If you feed the cat, it will keep coming back, but if you don't, the cat will eventually go away. Practise: ask the young person to rehearse the metaphor when they have no cravings mindfully. Use the image of the cat when the craving begins.
Strategy 4 Distraction	Suggest the young person distract themselves by doing something else e.g., Playing a video game, going for a walk, looking at Instagram / Snapchat (if all dealers/vape material has been deleted or blocked), listen to music. Advanced technique: distraction with imagery. When experiencing a craving, the young person learns to visualize something completely different, like being on a beach or cows grazing in a paddock. If stuck, it may help them to focus on an aversive image, e.g., vomiting.

	Practise: Mindfully rehearse a simple distracting visualization when there is no craving.
Strategy 5 Rewards or incentives (contingency management)	Suggest the young person set measurable goals to reduce or cease their e-cigarette use, including positive reinforcement (rewards or incentives) for periods of abstinence.
Strategy 6 Making a promise (either committing to one or more of the above behavioural strategies or to not using e-cigarettes)	Studies have shown that people are more likely to comply when they promise to do something. Example 1: Ask the young person to promise to commit to using one or more of the behavioural strategies in this guide. This can also be used when the health professional or worker asks the young person to promise not to use e-cigarettes for a specific time or number of days. Example 2: Do you promise me that you won't use e-cigarettes (vape) during school hours? The young person may agree with a handshake (if appropriate).

Health, C. f. P. (2024). Guide to Support Young People to Quit E-Cigarettes. In N. M. o. Health (Ed.), (pp. 29). Retrieved from https://www.health.nsw.gov.au/tobacco/Pages/e-cigarette-young-people-guide.aspx

Appendix 13

The Penn State Electronic Cigarette Dependence Index

Taken from: Foulds, J., Veldheer, S., Yingst, J., Hrabovksy, S., Wilson, S.J., et. al, (2015). Development of a questionnaire for assessing dependence on electronic cigarettes among a large sample of ex-smoking e-cigarette users. *Nicotine & Tobacco Research, 17*(2), 186-192.

1	How many times per day do you usually use your electronic cigarette? (Assume that one "time" consists of around 15 puffs or lasts around 10 minutes.)	O 0-4 times/day (0) O 5-9 (1) O 10-14 (2) O 15-19 (3) O 20-29 (4) O 30+ (5)
2	On days that you can use your electronic cigarette freely, how soon after you wake up do you first use your electronic cigarette?	O 0-5 mins (5) O 6-15 (4) O 16-30 (3) O 31-60 (2) O 61-120 (1) O 121+ (0)
3	Do you sometimes awaken at night to use your electronic cigarette?	O Yes (1) O No (0)
4	If yes, how many nights per week do you typically awaken to use your electronic cigarette?	O 0-1 nights (0) O 2-3 nights (1) O 4+ nights (2)
5	Do you use an electronic cigarette now because it is really hard to quit?	O Yes (1) O No (0)
6	Do you ever have strong cravings to use an electronic cigarette?	O Yes (1) O No (0)
7	Over the past week, how strong have the urges to use an electronic cigarette been?	O None/Slight (0) O Moderate/Strong (1) O Extremely Strong (2)
8	Is it hard to keep from using an electronic cigarette in places where you are not supposed to?	O Yes (1) O No (0)
9	Did you feel more irritable because you couldn't use an electronic cigarette?	O Yes (1) O No (0)
10	Did you feel nervous, restless, or anxious because you couldn't use an electronic cigarette?	O Yes (1) O No (0)

PS-ECDI Scoring: Sum the items. Total scoring: 0–3= not dependent, 4–8 low dependence, 9–12 medium dependence, 13+ = high dependence.

Appendix 14

The E-cigarette Fagerström Test of Cigarette Dependence

Tool taken from: Piper, M.E., Baker, T.B., Benowitz, N.L., Smith, S.S., & Jorenby, D.E. (2020). E-cigarette dependence measures in dual users: reliability and relations with dependence criteria and e-cigarette cessation. Nicotine and Tobacco Research, 22(5), 756-763.

Scoring taken from: Johnson, J. M., Muilenburg, J. L., Rathbun, S. L., Yu, X., Naeher, L. P., & Wang, J. S. (2018). Elevated Nicotine Dependence Scores among Electronic Cigarette Users at an Electronic Cigarette Convention. Journal of community health, 43(1), 164–174. https://doi-org.myaccess.library.utoronto.ca/10.1007/s10900-017-0399-3

1	How many times per day do you usually use your electronic cigarette? (Assume that one "time" consists of around 15 puffs or lasts around 10 minutes.)	O 0-4 times/day (0) O 5-9 (0) O 10-14 (1) O 15-19 (1) O 20-29 (2) O 30+ (3)
2	Do you find it difficult to refrain from vaping in places where it is forbidden (e.g. in church, at the library, in the cinema)?	O Yes (1) O No (0)
3	When would you hate most to give up e-cigarette use?	O In the morning (1) O During or after meals (0) O During or after stressful situations (0) O None of the above (0)
4	On days that you can use your electronic cigarette freely, how soon after you wake up do you first use your electronic cigarette?	O 0-5 mins (3) O 6-15 (2) O 16-30 (2) O 31-60 (1) O 61-120 (0) O 121+ (0)
5	Do you use your e-cigarette more frequently during the first two hours of the day than during the rest of the day?	O Yes (1) O No (0)
6	Do you use your e-cigarette when you are so ill that you are in bed most of the day?	O Yes (1) O No (0)

Scoring eFTND: Sum the items. Total score: 0-2 = low dependence, 3-4 = low to moderate dependence, 5-7 = moderate dependence, 8+ = high dependence

Appendix 15

E-cigarette Dependence Scale

Taken from: Morean, M.E., Krishnan-Sarin, S., Sussman, S., Foulds, J., Fishbein, H., Grana, R., & O'Malley, S.S. (2019). Psychometric Evaluation of the E-cigarette Dependence Scale. Nicotine and Tobacco Research, 21(11), 1556-1564.

4-item EDS = Items 1 – 4 **8-item EDS = Items 1 – 8** **22-item EDS = Items 1 – 22**

Item	Instructions. Please respond to each question marking one box per row.	Never (0)	Rarely (1)	Sometimes (2)	Often (3)	Almost Always (4)
1	I find myself reaching for my e-cigarette without thinking about it.					
2	I drop everything to go out and buy e-cigarettes or e- juice.					
3	I vape more before going into a situation where vaping is not allowed.					
4	When I haven't been able to vape for a few hours, the craving gets intolerable.					
5	When I'm really craving an e-cigarette, it feels like I'm in the grip of some unknown force that I cannot control.					
6	I crave vaping at certain times of day.					
7	My urges to vape keep getting stronger if I don't vape.					
8	After not vaping for a while, I need to vape in order to avoid feeling any discomfort.					
9	My desire to vape seems overpowering.					
10	Cravings for an e-cigarette					
	make it difficult for me to quit.					
11	It is hard to ignore urges to vape.					
12	When I go without vaping for a few hours, I experience cravings.					
13	I frequently crave e-					

	cigarettes/vaping.					
14	**The idea of not vaping causes me stress.**					
15	**When I run out of e-cigarettes or e-juice, I find it almost unbearable.**					
16	**I get a real gnawing hunger for an e-cigarette when I haven't vaped in a while.**					
17	**I vape even when I am so ill that I am in bed most of the day.**					
18	**When I go too long without vaping I feel impatient.**					
19	**It is hard for me to go without vaping for a whole day.**					
20	**When I go too long without vaping, I get strong urges that are hard to get rid of.**					
21	**Vaping is a large part of my daily life.**					
22	**I am tempted to vape when I realize I haven't vaped for a while.**					

Scoring : Sum the items. Greater scores signify greater dependence.

Appendix 16

The Hooked on Nicotine Checklist

Taken from:

American Academy of Pediatrics. (2019). Assessing nicotine dependence in adolescents [PowerPoint slides]. Retrieved from E-cigarette Curriculum: https://downloads.aap.org/AAP/PDF/2D_Assessing_Nicotine_Dependence_in_Adolescents.pdf

Carroll, D.M, Wagener, T.L, Thompson, D.M, Stephens, L.D, Peck, J.D, Campbell, J.E, et al. (2017). Electronic nicotine delivery system use behaviour and loss of autonomy among American Indians: results from an observational study. *BMJ Open*, *7*(12): e018469.

		Yes	**NO**
1	Have you ever tried to stop vaping, but couldn't?		
2	Do you vape now because it is really 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 to vape?		
6	Is it hard to keep from vaping in places where you are not supposed to, like school?		

When you tried to stop vaping (or, when you haven't vaped for a while…)

7	Did you find it hard to concentrate because you couldn't vape?		
8	Did you feel more irritable because you couldn’t vape?		
9	Did you feel a strong need or urge to vape?		
10	Did you feel nervous, restless or anxious because you couldn’t vape?		

HONC Scoring: Sum the number of ‘yes’ responses. Any score greater than zero indicates that the client has lost some degree of autonomy over their vaping.

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