CLINICAL PRACTICE GUIDELINES ON TREATMENT OF TOBACCO USE AND DEPENDENCE 2003

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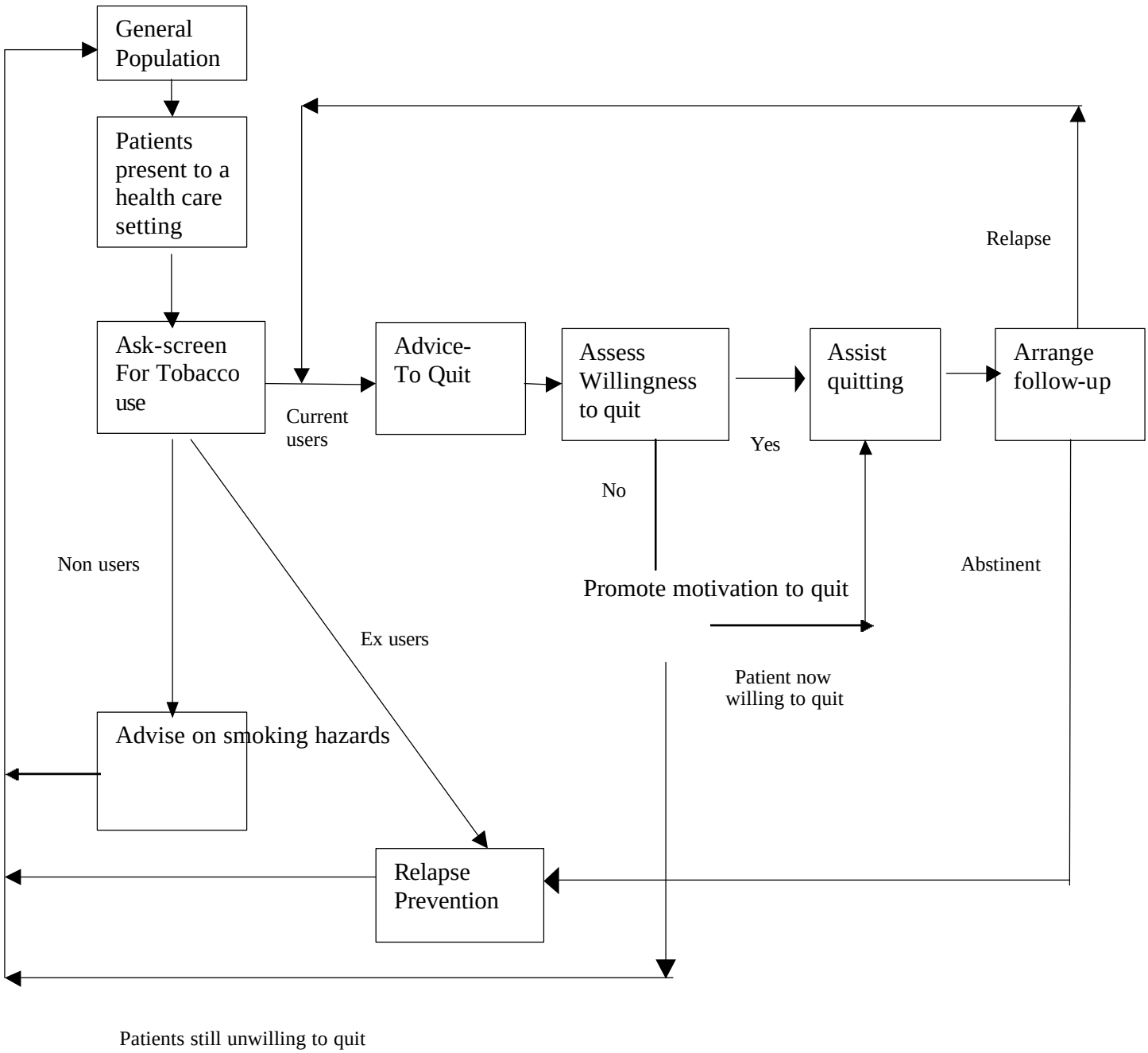

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FOREWORD

Smoking accounts for one out of every five deaths in Malaysia. It is the most important modifiable cause of premature death, responsible annually for an estimated 120,000 years of potential life lost. About 10,000 Malaysia die each year as a result of smoking. Since early studies in the 1950s and 1960s, a large body of epidemiological evidence has accumulated regarding the health effects of smoking. Major cohort studies, many case-control studies, and other data sources provide consistent, convincing evidence linking the use of tobacco with a variety of serious pulmonary, cardiovascular, and neoplastic diseases. A number of consistent findings from this body of evidence are well established.

Tobacco consumption had markedly reduced in most high-income countries. In the United States of America for instance, by 1997 the prevalence of smoking among Americans had dropped to 23% from 40% in 1964. In contrast, however, tobacco consumption in recent years has been rising in developing countries including Malaysia. The prevalence of smoking among Malaysian adults aged 15 years and above had increased from 21% in 1985 to 31% in 2000. Some 49% of all adult males and 5% of all adult females are now current smokers. Due largely to population increase, the number of smokers will continue to rise. Today there are about 5 million smokers in Malaysia, each consuming an average of 14 cigarettes per day. Of these smokers aged 15 years and above 90% are male. Half of these smokers alive today will eventually be killed by tobacco, and the number of annual deaths attributable to smoking will be triple over the next three decade from 10,000 in 1998 to 30,000 by the year 2030.

Nonetheless, as a result of our intensive anti smoking activities since 1991 in conjunction with our National Healthy Life Style Campaign, the level of awareness with regard to the hazard of smoking among the general public both smokers and non smokers alike have markedly increased. Among the current smokers, about 43% of them have attempted to quit on their own, but unfortunately most of them had been unsuccessful.

We know now that smoking is seriously difficult habit to break, and very few smokers succeed in their attempts to quit. Outside of individual strengths and willpower, various countries have proven that healthcare professionals can play an active role in helping smokers to break free of their tobacco addiction through a properly organized smoking cessation programs. Studies have found that a few minutes of firm advice from the doctor, supported by educational materials and the mutual understanding that there would be follow up, gave a 5% quit smoking rate which translated to about 25 ex-smokers per year per doctor. Other studies have shown that the greater the intensity of invention coupled with appropriate pharmacotherapy, the higher the success of smoking cessation.

Health Ministry recognized the need for doctors and other health professionals to participate in smoking cessation program. This Clinical Practice Guideline is timely produced to assist doctors and other health professionals to help smokers to quit smoking for good.

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(TAN SRI DATU DR. HJ. MOHD. TAHA BIN ARIF)
Director General of Health
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EXECUTIVE SUMMARY

Tobacco use is recognized as the main cause of premature and preventable death in our country. It is estimated that 10,000 deaths in Malaysia are attributed to smoking yearly. Tobacco dependency does not only cause physical withdrawal, it also causes life long addiction. Hence, due recognition should be given to it as a chronic disease. Malaysia has a high prevalence of smokers especially among the males and adolescents. However despite the high prevalence of tobacco use, healthcare providers are not well trained to manage this problem effectively. Furthermore health care providers lack the knowledge and awareness that treating tobacco dependence is more cost effective as compared to treating tobacco related diseases.

There is no clinical practice guideline available on treatment of tobacco use and dependence in Malaysia. Therefore it is imperative that the Ministry of Health produces a clinical practice guideline (CPG) which is for both public and private health care providers and best suited for Malaysians. With this in mind, the Division of Disease Control initiated and coordinated the preparation of this manual, enlisting the help of experts from the various medical fields relevant to tobacco cessation. This group collaborated for a year, going through the various local and international resources to produce this CPG. This includes the review of national statistics, The US Department of Health and Human Services, Public Health Service CPG on Treating Tobacco Use and Dependence, The Cochrane Collaboration and the New Zealand Smoking Cessation Guidelines. The preliminary draft of CPG was reviewed at a national level conference by independent experts and end-users.

The objective of this CPG is to provide the latest and updated treatment protocols to assist health care providers in managing tobacco use and dependence effectively.

This guideline is based on a combination of two methods, namely adaptation from the three leading and prominent CPGs on tobacco cessation in addition to the latest literature review based on a systematic search for evidence. All recommendations in this CPG are graded based on the appropriate level of evidence and are specific and unambiguous. The health benefits, adverse effects and risks of all recommended pharmacological agents are detailed in table forms. The overall treatment guideline is

provided in a clinical pathway format. Furthermore, the effectiveness and health benefits that are derived from each recommendation in this CPG are taken into consideration.

It is hoped that clinicians and other allied healthcare providers can adopt this evidence – based guideline to maximize the success rate of tobacco cessation. However, this CPG is not meant as a substitute for clinical judgement and clinicians are recommended to individualize their treatment strategies.

This CPG is planned for a review at every two-year interval by the committee and appropriately updated if the need arises.

Evaluation of this CPG would include an assessment of the number of smoking cessation services and the outcome of smokers treated throughout Malaysia. Studies to look at improvement in standard of practice regarding smoking cessation treatment will also be conducted.

During the development of this CPG it was realized that there was a lack of local data on tobacco use and dependence. Thus it is recommended that more research be conducted on a national level.

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LIST OF ABBREVIATION

1.	CDC	Centres for Disease Control and Prevention
2.	CPG	Clinical practice guideline
3.	CTPR	Control of tobacco products and regulations
4.	ETS	Environmental tobacco smoke
5.	FDA	Food and Drug Administration
6.	MAO	Monoamine oxidase
7.	NRT	Nicotine replacement therapy
8.	SR	Sustained release
9.	TTS	Transdermal therapeutics system

LIST OF TABLES

1. INTRODUCTION

Tobacco cessation strategy is a significant component of an overall tobacco control program to reduce morbidity and mortality due to tobacco-related diseases (CDC, 1984). Unfortunately quitting smoking is not easy. So many smokers have undergone the dilemma of wishing to quit and then been unsuccessful (CDC, 1990-1991; Hatziandreu et al., 1990). Therefore it seems obvious that there must be more to smoking than just a bad habit.

Today enough scientific evidence has been gathered to explain why some smokers had such difficulties with quitting. No matter how intellectually astute a smoker may be, no amount of rationalization will be able to curtail their craving for cigarette.

It is an accepted fact that cigarette smoking is an addiction. Within a few years of daily smoking, most smokers will become dependent, both physically and psychologically. This dependence is due to the neurobiological effects of nicotine on the brain. Nicotine receptors are found in the region of the brain involved in reward and emotion and in those areas associated with learning and memory, namely the hippocampus (Piccittio, 1998). The existence of these nicotine receptors which are directly connected to the reward system in the brain provides physical evidence of how nicotine found in tobacco exerts its addictive effects.

Most smokers attempt to quit at some point in their smoking lives and almost all fail on their first unaided attempt. The chance of success in a single unaided quit attempt is in the region of 1 in 100, and 98% of them relapsed within a period of 12 months (Fiore et al., 1995). It is not uncommon to see smokers who stopped for quite a while but slipped back into smoking and then quit again and then slipped back again, and the cycle continues. Research suggest that people who smoke go through a five stage tobacco addiction cycle that leads them from being non-smokers to new smokers, then to committed smokers, to smokers trying to stop and to finally reformed smokers (Prochaska & Goldstein, 1991). However only a few stay in that final stage. In reality the tendency is for recent or renewed quitters to relapse into nicotine addiction, and the overall cycle.

If smokers can be persuaded to not only quit smoking but also more importantly to stay clean of their addiction, they can benefit their own health and finance, as well as ease the burden on the society that must shoulder their healthcare costs.

We have now sufficient evidence-based treatment modalities that are both efficacious and effective ranging from behavioural therapy to pharmacotherapy. Several cost-effectiveness analyses have shown that cessation treatments compare quite favourably with routine medical interventions such as the treatment of hypertension and hypercholesterolemia, and with other preventive interventions such as periodic mammography (Eddy, 1986; Health and Human Service, 1991; Tengs et al., 1995; Lightwood & Glantz, 1997).

Objective

This CPG has been developed to serve as a useful tool for doctors and other health professionals in Malaysia to treat tobacco dependence in various settings, including hospitals, clinics or pharmacies. Adoption of this evidence-based guideline is hopes to maximize the success rate of tobacco cessation. However, this CPG is not meant as a substitute for clinical judgement and clinicians are recommended to individualize their treatment strategies.

This CPG will be reviewed every two years and updated with the most recent development if the need arises.

2. GUIDELINE DEVELOPMENT METHODOLOGY

This guideline is based on a combination of 2 methods, namely adaptation from the clinical practice guidelines (CPGs) as mentioned below and incorporation of the latest literature review.

The adaptation were from:

1. Treating Tobacco Use and Dependence 2000,US Department of Health and Human services (Fiore et al., 2000)
2. Guideline for smoking cessation 2001, New Zealand National Advisory Committee on Health and Disability.
3. American Psychiatric Association. Practice guideline for the treatment of patients with nicotine dependence 1996.

These reviewed CPGs provided data up to the year of 1999. Systematic search was done looking at the latest literature up to May 2001.The systematic search was on Medline database search, Cochrane review (up to early September 2001) and Yale search based mesh words on reports on nicotine or tobacco treatment, medications, and clinical management. Our search revealed 120 articles published in peer-reviewed journals.

The evidence level used is adapted from The US/Canada Preventive Services Task Force

Level of Evidence Scale

I	Evidence obtained from at least one properly randomised controlled trial
II-1	Evidence obtained from well-designed controlled trials without randomisation
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 (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence
III	Opinions of respected authorities, based on clinical experienced; descriptive studies and case reports; or reports of expert committees.

3. ASSESSMENT OF TOBACCO USE

The first step in treating tobacco use and dependence is to identify tobacco users. All patients should be asked if they use tobacco and should have their tobacco-use status documented on a regular basis. Evidence has shown that this significantly increases rates of clinician intervention (Fiore et al., 1995; Ahluwalia, 1997; Ahluwalia et al., 1999)(Level I).

This clinical practice guideline is organized to provide the clinician with simple, but effective interventions for all of these patients.

The assessments are to look for:

i. Level of addiction (using Fagerstrom Questionnaires + number of cigarette smoked) -*Appendix 1*
ii. Readiness for quitting (Miller & Rollnick, 1991)

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

i. the patient uses tobacco and is now willing to make a quit attempt;
ii. the patient uses tobacco but is not now willing to make a quit attempt;
iii. the patient once used tobacco but has since quit;
iv. the patient never regularly used tobacco.

4. PATIENTS WILLING TO QUIT

There are 2 types of clinical intervention depending on the intensity of intervention and level of service provided. They are:

i. Brief clinical intervention
ii. Intensive clinical intervention

4.1 Brief Clinical Intervention

Brief clinical intervention by the physician increases quit rates effectively (Fiore et al., 2000) (Level I). It is vital to change clinical culture and practice patterns to ensure that

every patient who uses tobacco is identified and offered treatment. Brief intervention can be divided into treatment either non-pharmacological, pharmacological or combined.

4.11 Non-pharmacological intervention

Every tobacco user should be offered at least a brief intervention whether or not he or she is referred to an intensive intervention as this has been proven to increase overall tobacco abstinence rates (Robinson et al., 1995; Ahluwalia et al., 1999). There is a strong dose-response relationship between the session length of person-to-person contact and successful treatment outcomes (Fiore et al., 2000). Intensive interventions are more effective than brief interventions and should be used whenever possible (Fiore et al., 2000). Person-to-person treatment delivered for four or more sessions appears especially effective in increasing abstinence rates. Therefore, if feasible, clinicians should strive to meet four or more times with individuals quitting tobacco use.

Individual and group counselling formats are effective and should be used in smoking cessation interventions. Smoking cessation interventions that are delivered in multiple formats increase abstinence rates and should be encouraged. Studies have shown that individual counselling resulted in higher abstinence rates as compared to group or phone counselling and self-help (Fiore et al., 2000) (Level I).

The five major steps (the “5 A’s”) to intervention in the primary care setting are described below. The strategies are designed to be brief and minimal clinician’s time is required (Glynn & Manley, 1989; Glynn et al., 1990).

Table 1. The “5 A’s” for brief intervention

1. Ask about tobacco use: • Identify and document tobacco use status for every patient at every visit. 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 willingness to make a quit attempt: Is the tobacco user willing to make a quit attempt at this time? • If the patient is willing 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 unwilling to make a quit attempt at this time, provide a motivational intervention. Refer page 15-16. • If the patient is a member of a special population (e.g., adolescent, pregnant smoker), consider providing additional information.
4. Assist in quit attempt: For the patient willing to make a quit attempt, use counselling with pharmacotherapy (when indicated) to help him or her quit. Preparations for quitting: • Set a quit date. Ideally, the quit date should be within 2 weeks. Reduce the number of cigarettes gradually before the set date. • Tell family, friends, and co-workers about quitting and request understanding and support. Also,

help patient 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.
- Advice patient to remove 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.
- Anticipate challenges to planned quit attempt, particularly during the critical first few weeks. These include nicotine withdrawal symptoms. Discuss challenges/triggers and how patient will successfully overcome them. Provide patients with problem solving/skills training.
- 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 contact, preferably within the first week after the quit date.

- Timing. Follow-up contact 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 contact, either in person or via telephone.
- Actions during follow-up contact. Congratulate success. If tobacco use has occurred, review circumstances and elicit recommitment to total abstinence. Remind patient 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., 2000.

Who Should Deliver The Service?

Abstinence rate is better when smoking cessation interventions are delivered by health care providers as compared when there is no clinician involved (e.g., self-help interventions). However, studies have shown that interventions by doctors are cost-effective and their non-pharmacological interventions produced better abstinence rates than those by other healthcare personnel (Silagy et al, Cochrane Library 2001; US Department of Health and Human Services, Nov 2000)(Level 1). Therefore, doctors should take the lead role in tobacco cessation programs involving a multidisciplinary team.

4.1.2 Pharmacological Intervention

Our expert committee have reviewed research papers and also from our clinical experience in Malaysia we are in the opinion that all smokers attempting to quit with scores from Modified Fagerstrom's questionnaire (Appendix 1) of ≥ 4 should be offered pharmacotherapy (Level II). If and smoking > 10 cigarettes per day pharmacotherapy is considered in smokers with Fagerstrom's score < 4 or smokes < 10 cigarettes/day, clinicians may use a lowered dose.

Agents proven to be efficacious which are recommended as first line agents for pharmacotherapy includes nicotine replacement therapies (NRT, e.g., gum, patch and inhaler) and sustained release (SR) bupropion(Fiore et al., 2000) (Level I).

Choice of a specific first-line pharmacotherapy must be guided by factors such as clinician's familiarity with the medications, contraindications for selected patients, patient preference, previous patient experience with a specific pharmacotherapy (positive or negative), and patient characteristics (e.g., history of depression, concerns about weight gain (Henningfield, 1995; Hughes & Goldstein, 1999). All allied-health care providers should be supervised by physician when pharmacotherapy is instituted in concordance with the existing law. Currently all the NRT's are listed under class "C" of the Poison Act 1952.

Special consideration should be given before using pharmacotherapy in selected populations:

- having medical contraindications (recent myocardial infarction, life-threatening arrhythmia, unstable or worsening angina, recent cerebrovascular accident or hypersensitivity to nicotine (Benowitz et al., 1997; Mahmarian et al., 1997)
- pregnant/breastfeeding women (Windsor et al.,1985: Walsh et al., 1997)
- adolescent smokers (Pierce et al., 1998)

Patients with hypertension, stable angina pectoris, cerebrovascular accident, occlusive peripheral arterial disease, heart failure, hyperthyroidism, diabetes mellitus, renal or hepatic impairment or peptic ulcer need closer monitoring (Hughes & Goldstein, 1999).

Table 2. 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) – *Appendix 3* 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 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. - *Appendix 4.* Absorption. Eating and drinking anything except water should be avoided for 15 minutes before and during chewing as acidic beverages (e.g., coffee, juices, 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. 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.

Adapted from Fiore et al., 2000.

Table 3. Clinical use of the 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 C) 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 8 weeks or less has been shown to be as efficacious as longer treatment periods. 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	Nicotinell TTS30,20,10 (21, 14 and 7 mg, respectively), Nicorette 15,10 and 5 mg		
Nicotinell TTS	≥ 20 cig/day TTS30 TTS20 TTS10	< 20 cig/day TTS20 TTS10 TTS10	Duration (weeks) 1-4 5-8 9-12
Nicorette	15 mg x 8 weeks, then 10 mg x 2 weeks and finally 5 mg x 2 weeks		
Prescribing instructions	Location. At the start of each day, the patient should place a new patch on a relatively hairless location, typically between the neck and waist. Activities. No restrictions while using the patch. Time. Patches should be applied as soon as the patient wakes on their quit day. In patients who experience sleep disruption, advise the patient to remove the 24-hour patch prior to bedtime or use the 16-hour patch.		

Adapted from Fiore et al., 2000.

Table 4. Clinical use of the 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 instructions	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, 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.

Adapted from Fiore et al., 2000.

Table 5. Clinical use of bupropion SR

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. 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 or who have used an MAO inhibitor in the past 14 days.
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.
Availability	Not yet available
Prescribing instructions	Cessation prior to quit date .Recognize that some patients will lose their desire to smoke prior to their quit date, or will spontaneously reduce the amount they smoke. Scheduling of dose .If insomnia is marked, taking the PM dose earlier (in the afternoon, at least 8 hours after the first dose) may provide some relief. Alcohol .Use alcohol only in moderation.

Adapted from Fiore et al., 2000.

Combination of agents

Strategies of combining agents available (e.g., two NRTs, a non-NRT, e.g. bupropion with a 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 (Silagy C et al., 2001, Covey LS et al., 2000, Hughes et al., 2001) (Level I).

4.2 Intensive Clinical Interventions

Evidence shows that intensive tobacco dependence treatment is more effective than brief treatment. This could be achieved by increasing the length of individual treatment sessions, the number of treatment sessions and specialized behavioural therapies. Intensive clinical interventions could be provided by any suitably trained doctors and other healthcare providers who have the resources available to give intensive interventions and are appropriate for any tobacco user willing to participate in them (Fiore et al., 2000) (Level I).

Components of an intensive intervention

- Assessments should ensure that tobacco users are willing to quit using an intensive treatment program. Other assessments can provide information useful in counselling (eg. stress, weight reduction and other medical conditions).
- Multidisciplinary team of clinicians and healthcare providers who deliver messages about health risks, benefits of pharmacotherapy and behavioural therapies.
- The intensity of the program should be longer than 10 minutes per session, minimum 4 sessions
- Either individual or group counselling may be used.
- Proactive telephone counselling as well as other methods of communications should be considered
- Use of adjuvant self-help material is optional.
- Follow-up assessment intervention procedures should be used

- Specialized counselling such as cognitive behavioural therapy
- Every smoker should be encouraged to use pharmacotherapies endorsed in this guideline.

Three specific types of counselling and behavioural therapy categories yield statistically significant increases in abstinence rates relative to no-contact (e.g., untreated control conditions) (Davis et al., 1984; Platt et al., 1997). These categories are:

- providing practical counselling such as problem solving/skills training/ relapse prevention/stress management
- providing support during a smoker's direct contact with a clinician (intra-treatment social support
- intervening to increase social support in the smoker's environment (extra-treatment social support)

5. FOR THE PATIENT UNWILLING TO QUIT

Motivational interventions are most likely to be successful when the clinician is empathic, promotes patient autonomy (e.g., choice among options), avoids arguments, and supports the patient's self-efficacy (e.g., by identifying previous successes in behaviour change efforts) (Miller & Rolnick , 1991; Rundmo et al., 1997; Colby et al., 1998).

Patients unwilling to make a quit attempt during a visit may be due to:

- lack of information about the harmful effects of tobacco,
- may be demoralized because of previous relapse.
- lack the required financial resources
- may have fears or concerns about quitting

Such patients may respond to a motivational intervention built around the "5 R's": relevance, risks, rewards, roadblocks, and repetition.

Table 6. The 5 R's for enhancing motivation to quit tobacco

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 switching to low-tar/low-nicotine cigarettes or other forms of tobacco (e.g., smokeless tobacco, cigars, "rokok daun" and pipes) will still have similar risks. Examples of risks are: o Short-term risks: Shortness of breath, exacerbation of asthma, harm to pregnancy, impotence, infertility, increased serum carbon monoxide. o Long-term risks: Heart attacks and strokes, lung and other cancers (larynx, oral cavity, pharynx, oesophagus, pancreas, bladder, cervix), chronic obstructive pulmonary diseases (chronic bronchitis and emphysema), long-term disability and need for extended care. o Environmental risks: Increased risk of lung cancer and heart disease in spouses; higher rates of smoking by children of tobacco users; increased risk for low birth weight, 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: o Improved health. o Improved sense of smell. o Feel better about yourself. o Can stop worrying about quitting. o Food will taste better. o Save money. o Home, car, clothing, breath will smell better. o Set a good example for children. o Have healthier babies and children. o Not worry about exposing others to smoke. o Perform better in physical activities. o Reduced wrinkling/aging of skin.
Roadblocks • The clinician should ask the patient to identify barriers to quitting and note elements of treatment (problem solving, pharmacotherapy) that could address barriers. Typical barriers might include:

o Withdrawal symptoms. o Fear of failure. o Weight gain. o Lack of support. o Depression. o Enjoyment of tobacco. o Cost of treatment.
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., 2000.

6. PATIENT WHO HAS RECENTLY QUIT

Clinicians should provide brief effective relapse prevention interventions due to the chronic relapsing nature of tobacco dependence (Brandon et al., 1990; Zhu et al., 1996; Westman et al., 1997).

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

i. reinforce the patient's decision to quit
ii. review with patient the benefits of quitting
iii. assist the patient in resolving any residual problems arising from quitting.

Although most relapse occurs early (within first 3 months) in the quitting process, some relapse occurs months or even years after the quit date (Hatziandreu et al., 1990; Brandon et al., 1990). Therefore, clinicians should continuously engage in relapse prevention interventions.

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

Minimal practice relapse prevention

This is appropriate for most recent quitters and 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.

When encountering a recent quitter, use open-ended questions designed to initiate patient problem solving (e.g., How has stopping tobacco use helped you?).

The clinician should encourage the patients to actively discuss the topics below:

i. The benefits, including potential health benefits, the patient may derive from cessation.
ii. Any success the patient has had in quitting (duration of abstinence, reduction in withdrawal, etc.).
iii. The problems encountered or anticipated threats to maintaining abstinence (e.g., depression, weight gain, alcohol, other tobacco users in the household).

Every ex-tobacco user undergoing relapse prevention should be congratulated on any success and strongly encouraged to remain abstinent.

Intensive practice relapse prevention

Intensive relapse prevention components are individualized based on information obtained about problems the patient has encountered in maintaining abstinence. These interventions may be delivered during a dedicated follow-up contact (in-person or by telephone) or through a specialized clinic or program. Specific interventions recommended for problems related to maintaining smoking cessation are listed in Table 7. Long-term smoking cessation pharmacotherapy should be considered as a strategy to reduce the likelihood of relapse.

Table 7. Problem-related interventions to maintain smoking cessation

Problems	Recommended interventions
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 cessation counselling or support.
Negative mood or Depression	If significant, provide counselling, prescribe appropriate medications, 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 pharmacotherapy or adding/combining pharmacological medications to reduce strong withdrawal symptoms.
Weight gain	• Recommend starting or increasing physical activity; discourage strict dieting. • Reassure the patient that some weight gain after quitting is common and appears to be self-limiting. Emphasize the importance of a healthy diet. • Maintain the patient on pharmacotherapy known to delay weight gain (e.g., bupropion SR, NRTs, particularly nicotine gum). • Refer the patient to a specialist or program.
Flagging motivation/ feeling deprived	• Reassure the patient that these feelings are common. • Recommend rewarding activities. • Probe to ensure that the patient is not engaged in periodic tobacco use. • Emphasize that beginning to smoke (even a puff) will increase urges and make quitting more difficult.

Adapted from Fiore et al., 2000.

7. SPECIAL POPULATIONS

7.1 Female smokers

Smoking cessation clinical trials reveal that the same treatments benefit both men and women (Bjornson et al., 1995; Gritz et al., 1998). However, research suggests that some treatments are less efficacious in women than in men (e.g., NRTs) (Perkins et al., 1996;

Wetter et al., 1999). 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 include greater likelihood of depression, greater weight control concerns, hormonal cycles, and others (Gritz et al., 1996). This suggests that women may benefit from tobacco dependence treatments that address these topics, although few studies have examined programs targeted to one gender. Women who are considering pregnancy may be especially receptive to tobacco cessation.

Pregnant Women

All pregnant women should be strongly advised to quit smoking due to the adverse effects of smoking to the pregnancy and the foetus. Smoking has been implicated in the etiology of abruptio placenta, placenta previa, spontaneous abortion, premature delivery, and stillbirth. Intrauterine growth retardation is the most strongly documented adverse effect of smoking during pregnancy. Prenatal smoking is thought to account for about 18% of cases of low birth weight (<2500 g), and also increases risk of premature delivery, respiratory distress syndrome, and sudden infant death syndrome (Sexton M and Hebel JR 1984, Ershoff DH, Quinn VP, Mullen PD, et al 1990). A reduction in tobacco use increases birth weight, decreases the incidence of low birth weight infants and is cost effective. Cognitive ability is decreased in children whose mothers have smoked during gestation (Levin & Slotkin, 1998). Exposure to second hand smoke (passive smoking) may also have an adverse effect on birth weight (Fortier, et al 1994).

All pregnant smokers should be offered intensive interventions (Fortier, et al 1994). Although abstinence early in pregnancy will produce the greatest benefits to the foetus and expectant mother, quitting at any point in pregnancy can yield benefits. Therefore, clinicians should offer effective smoking cessation interventions to pregnant smokers at the first prenatal visit as well as throughout the course of pregnancy (Baric L 1976, Burling et al T 1984, McArthur C 1987, Lilley J and Forster DP1986). Pharmacotherapy should be considered when a pregnant woman is otherwise unable to quit, and when the likelihood of quitting, with its potential benefits, outweighs the risks of the pharmacotherapy and potential continued smoking (Baric L 1976, Burling T et al., 1984, McArthur C 1987, Lilley J and Forster DP 1986). Consultation with medical specialist is recommended before initiating pharmacotherapy.

7.2. 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. (Lightwood, 1997) Lung, head, and neck cancer patients who are successfully treated, but who continue to smoke, are at higher risk for a second cancer.(Gritz et al., 1991; Browman et al., 1993; Richardson et al., 1993; Fujisawa et al., 1999; Kawahara et al., 1998). Additionally, smoking delays bone and wound healing(Jones, 1985; Grossi et al., 1995; Chang et al., 1996).

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 (Hurt et al., 1992; Stevens 1993). Secondly, all hospitals in Malaysia are designated smoke-free areas (CTPR 2003). 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 are as follows:

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

7.3 Psychiatric patients.

Smoking cessation treatments should be provided to all smokers with psychiatric morbidity because of beneficial effects of intervention (Addington et al,1998; Kelly & McCreadie,2000; McEvoy & Joseph,2000). Bupropion SR is a drug of choice for smokers with depression. Evidence indicates that smoking cessation interventions do not interfere with recovery from chemical dependency. Therefore, smokers receiving treatment for chemical dependency should be provided smoking cessation treatments shown to be effective in this guideline, including both counselling and pharmacotherapy (Evins & Tisdale, 1999; Kelly & Mc Creadie, 2001) (Level II-3).

Patients with psychiatric illness have a higher prevalence of smoking compare to general population e.g., 3 times higher in those with schizophrenia (Hughes et al,1986; Dalack et al, 1996). 68% of patients with schizophrenia who smoked were classified as heavy smokers compared with 11% of those in the general population (Kelly et al, 2000). Smoking had been shown to decrease plasma levels of neuroleptics by inducing hepatic microsomal enzymes (Solokangas et al,1997). Therefore, patients who smoke require larger doses of drugs than non-smokers (Lohr & Flynn, 1992). A substantial proportion of the income of smokers with schizophrenia is spent on cigarettes (Mc Creadie & Kelly, 2000). Smoking ban on in-patient psychiatric units has met with some success but the most severely addicted patients are extremely resourceful and continue to smoke(Lavin et al, 1996). The symptoms of nicotine withdrawal can confuse or exacerbate the symptoms of schizophrenia. The use of NRT can substantially reduce these symptoms (Dalack & Meadow-Woodruf, 1999). Buproprion SR, alone or combination with NRT is the choice pharmacotherapy for tobacco cessation in these patients (Joren et al,1999; Evins & Tisdale,1999).

About 30% of those seeking smoking cessation in general population have a history of depression (Covey et al, 1998, Breckenridge, 1990). Smoking cessation may elicit or exacerbate depression among patients with a prior history of affective disorder (Hall et al,1993, Glassman et al1993). Smokers with depression have a heightened risk of relapse of depression if they quit smoking. Buproprion SR, alone or combination with NRT is recommended. Smokers with psychiatric and other chemical or substance dependence (eg. alcohol, should be referred to relevant specialist.

7.4 Children and adolescents

Healthcare providers should screen paediatric and adolescent patients, and their parents, for tobacco use and exposure. Counselling and behavioural interventions that have been shown to be effective are recommended for children and adolescents (Fiore et al., 2000) (Level I). The contents of these interventions should be modified according to the age of the child (Lawendowski 1998). When treating adolescent smokers, clinicians may consider NRT or bupropion SR when there is evidence of nicotine dependence and desire to quit (Fiore et al., 2000) (Level III). However, because of the psychosocial behavioural aspects of smoking in adolescents, clinicians should be very sure of the patient's tobacco dependence and intention to quit before instituting pharmacotherapy. Special consideration should be given to the degree of dependence, number of cigarettes per day, and body weight.

Healthcare providers in a paediatric setting should offer smoking cessation advice and interventions to parents or guardians to limit children's exposure to second-hand smoke (Fiore et al., 2000) (Level I).

Youth smokers of today are likely to become regular smokers of tomorrow (NIDA,1993). It is estimated that 90% of smokers start smoking before the age of18. Hence it is important to reduce the amount of tobacco use among youth so as to decrease the rate of nicotine dependence and subsequent morbidity and mortality in future adults (Riley et al 1996).

Adolescents are likely to model parents' behaviour and adopt similar norms. Youth who have family members and close friends who smoke have a stronger predilection to regular smoking. The role of socio-economic and demographic factors in smoking initiation/experimentation is well documented. These factors include low socio-economic status, smoking among family and friends, low self esteem, poor academic performances and behavioural problems (Flay et al., 1994).

7.5 Elderly

Smoking cessation in older smokers can reduce the risk of myocardial infarction, death from coronary heart disease, and lung cancer. Moreover, abstinence can promote more

rapid recovery from illnesses that are exacerbated by smoking and can improve cerebral circulation (Hermanson et al., 1988; Rogers et al., 1985). In fact, age does not appear to diminish the benefits of quitting smoking (Hermanson et al 1988).

Counselling interventions, (Burton et al., 1995; Morgan et al., 1996; Wetter et al., 1990) physician advice, (Morgan et al., 1996) telephone counselling, (Rimer et al., 1994; Osip-Klein et al., 1997) and the nicotine patch (Orleans et al., 1994) have all been shown to be effective in treating tobacco use in adults ages 50 and older.

8. MANAGEMENT OF WEIGHT GAIN

For smokers who are greatly concerned about weight gain, it may be most appropriate to prescribe or recommend bupropion SR or NRT, in particular nicotine gum, which have been shown to delay weight gain after quitting (Fiore et al., 2000) (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 healthy diet to control weight
iii. recommend that patients 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. Most will gain less than 5 kilograms. It has been reported that about 10% of quitters gain up to 15 kilograms (Froom et al., 1998). However, weight gain that follows smoking cessation is a negligible health threat compared with the risks of continued smoking. Weight gain that follows smoking cessation is a negligible health threat compared with the risks of continued smoking (Williamson et al., 1981; Burnette et al., 1988). Post-cessation weight gain appears to be caused both by increased intake and by metabolic adjustments. The involvement of metabolic mechanisms suggest that even if smokers do not increase their caloric intake upon quitting, they will, on average, gain some weight (Gray et al., 1995; Hatsukami et al., 1993; Hofstette et al., 1986; Klesges et al., 1992; Moffatt et al., 1981).

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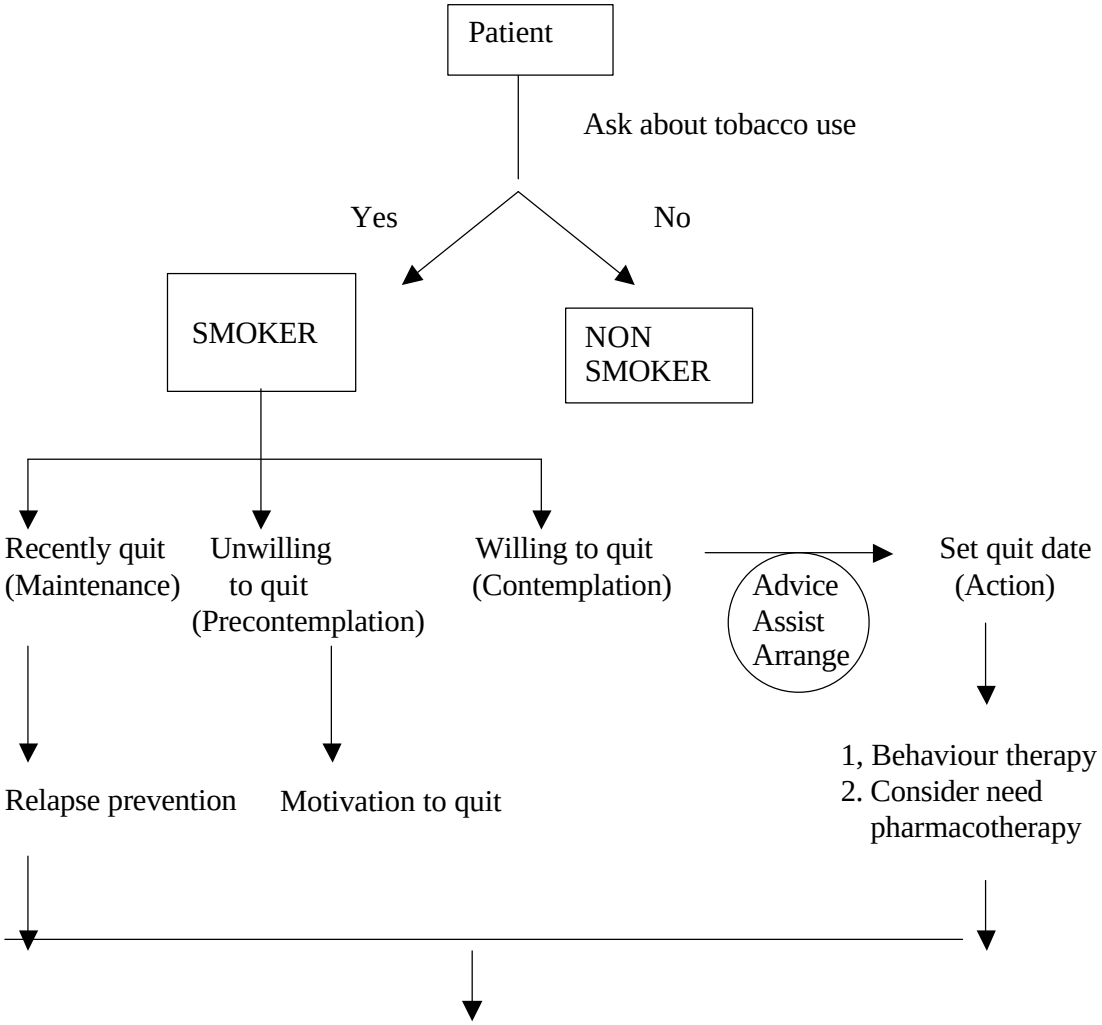
ALGORITHM FOR MANAGEMENT OF TOBACCO USE AND DEPENDENCE



GLOSSARY

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.

Higher intensity counselling. 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. (not found but should be kept?)

Minimal counselling. Minimal counselling 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. (not found either!)

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. Self-explanatory?

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 day. The day 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 programs; mass media community-level interventions; lists of community programs; reactive telephone hotlines/helplines; and computer programs/Internet.

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

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 Modified Fagerström Test for Nicotine Dependence

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)

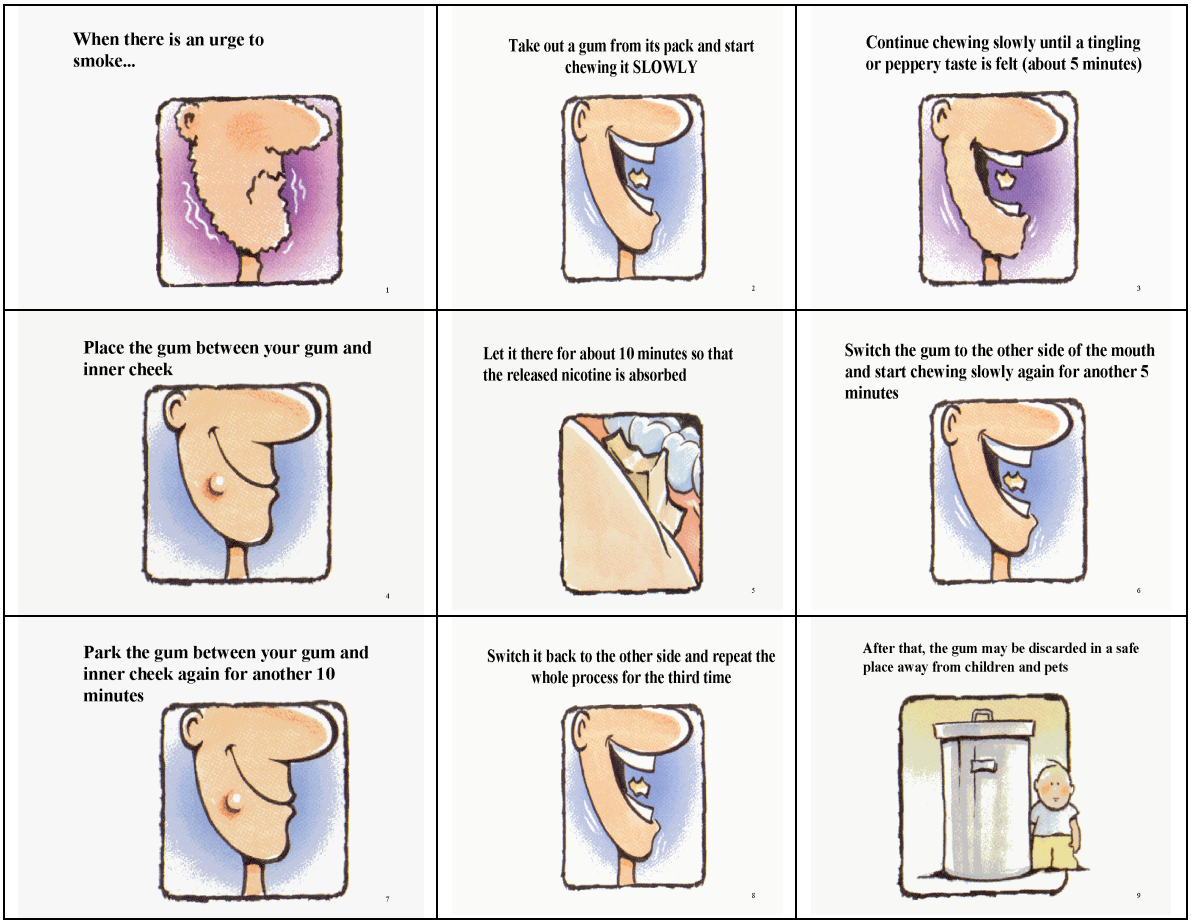
Scoring: 7 to 10 points = highly dependent; 4 to 6 points = moderately dependent; less than 4 points =minimally dependent.

Modified Fagerström test for evaluating intensity of physical dependence on nicotine.Adapted 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. (PERMISSION NOT YET GRANTED)

APPENDIX 2 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 fetal damage, or are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage, or there are evidence of an increased occurrence of fetal 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 fetal 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 3 Nicotine gum chewing technique



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