

Philippine Clinical Practice Guidelines

Diagnosis and Treatment of Tobacco Use And Dependence 2014



Philippine College of Chest Physicians
Council on Tobacco or Health and Air Pollution

(Task Force)

FCAP

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Physicians

Philippine College of Physicians

Phil. Academy of Family
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Rationale of this Clinical Practice Guidelines

developed as a resource and guide for all health professionals to:

- *screen tobacco users*
- *identify those with tobacco dependence*
(ICD10 F17.2)
- *deliver evidenced-based tobacco-smoking cessation treatments for patients and specific population groups who use tobacco*

Intended for all health professionals:

physicians

dentists

nurses

pharmacists

dieticians

social workers

occupational therapists

physiotherapists

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:

Specific Populations

- Hospitalized and pre-operative patients
- Adolescents
- Pregnant women
- Patients with mental health disorder
- Substance and alcoholic abuse disorder
- Socially and geographically disadvantaged group* (to delete; based on concensus)

The guidelines are based on
comprehensive literature reviews on
recent evidence on tobacco use and
dependence treatments

Explanation of levels of evidence:

Level I Evidence obtained from systematic review of relevant randomized controlled trials

Level II Evidence obtained from one or more well designed, randomized controlled trials

Level III Evidence obtained from well designed, non-randomized controlled trials, or from well designed cohort or case control studies

Level IV Evidence obtained from case series, either post-test or pre-test and post-test

Level V Opinions of respected authorities based on clinical experience, descriptive studies, reports of expert committees

No evidence No evidence was found relevant to general practice on the issue being considered.

Strength of recommendation:

- A There is good evidence to support the recommendation
- B There is fair evidence to support the recommendation
- C There is poor evidence regarding the inclusion, or exclusion of the recommendation, but recommendations may be made on other grounds

Chapter 1

Emerging Trends of Tobacco Use

- Global Trends
- Smoking Prevalence in the Philippines
- E-Cigarette

Chapter 2

III Effects of Tobacco Smoking:

I. Toxicology of Tobacco

II. Addiction to Tobacco and Nicotine Dependence

III. Smoking and Related Diseases:

A. Cancer

B. Pulmonary Disease

C. Cardiovascular Disease

D. Stroke

E. Infection

F. Wound Healing

Chapter 2

III Effects of Tobacco Smoking:

IV. Harmful Effects of Second-Hand Tobacco Smoke

V. Third Hand Tobacco Smoke

VI. Smokeless Tobacco and Alternative Nicotine
Sources

Chapter 3

Benefits of Quitting

Chapter 4 : Diagnosis of Tobacco Dependence

How can tobacco use and dependence be documented or diagnosed ?

Screening is a cornerstone

Every healthcare provider should document cigarette smoking during history taking in all patient encounters Level I, Grade A

The patient should be asked directly regarding cigarette smoking regardless of the reason for consult

Level I, Grade A

Diagnosis is an essential part and the initial step in the tobacco use and dependence treatment interventions

Chapter 4: Diagnosis

Both for Level 1: ABC and Level 2: The 5 As Approach : first A (ask)

Ask every patient about tobacco use and document tobacco use status for all

For patients who smoke or have recently stopped using tobacco, the tobacco use status should be checked and updated on a regular basis

Patients who have never used tobacco or have not used for many years need not be asked repeatedly

Chapter 4: Diagnosis

Tobacco Consumption may be defined as :

a. number of cigarettes smoked per day

b. number of cigarette pack/years

(number of packs smoked/ day= no. of cigarette sticks smoked /20 per day) multiplied by the number of years smoking)

Chapter 4: Diagnosis

Tobacco dependence assessment :

presence of at least 3 out of the 7 definition criteria, if present at any moment during the past 12 months

strong desire to smoke

difficulty in controlling quantity

withdrawal symptoms when reducing or quitting tobacco

continued consumption despite obvious harmful effects

priority of smoking over other activities

high tolerance

physical tobacco withdrawal symptoms

Chapter 4: Diagnosis

Nicotine/cigarette dependence (ICD 10: F17.2)
*is mainly assessed using the **Fagerstrom***
***nicotine dependence test** that provide not only*
a yes/no answer but also a final score

IA

Karl Fagerstrom Nicotine Tolerance Questionnaire (6 questions)

	Points
1. How many cigarettes do you smoke per day? 10 or less, 11-20 21-30 31 or more	0 1 2 3
2. How soon after you wake up do you smoke your first cigarette? 0-5 min 30 min 31-60 after 60 min	3 2 1 0
3. Do you find it difficult to refrain from smoking in places where smoking is not allowed? Y/N	1/0
4. Do you smoke during the first hours after waking up than during the rest of the day Y/N	1/0
5. Which cigarette would you be most unwilling to give up? Morning/any other	1/0
6. Do you smoke even when you are ill? Y/N	1/0

Karl Fagerstrom Nicotine Tolerance Questionnaire (6 questions)

Total Score

0 -3 points

4 - 6 points

7 - 10 points

Level of Dependence

Low

Medium

High

The higher the score , the higher the nicotine dependence

A score of 4 or over indicates the need to administer pharmacologic treatment and predicts a more severe withdrawal syndrome

Short Version of the Fagerstrom Nicotine Tolerance Questionnaire

Key questions are questions :

1. the number of cigarettes smoked daily
2. the time of first cigarette after waking up in the morning

Recommendation

The original Fagerstrom (6 questions) and the short version (2 questions) may be used in the diagnosis of level of tobacco dependence based on the health professional's preference or available time of encounter with the patient

II B

Laboratory diagnosis of tobacco dependence

Smoking status as defined based on clinical criteria is also evaluated by biochemical laboratory tests to assess biomarkers of tobacco smoke exposure

such as *carbon monoxide concentration* in exhaled air and

level of *cotinine* as a result of the nicotine metabolism process.

Question: Should CO and/or Cotinine level determination be used as diagnostic tool for tobacco dependence ?

Carbon monoxide (CO)

Carbon monoxide is the easiest biomarker to monitor in the absence of CO in the environment, it measures tobacco consumption.

CO concentration in a smoker's body can be determined by asking the smoker to exhale into a carbon monoxide analyzer.

CO is measured in ppm (parts per million), a measurement unit that can be converted as carboxyhemoglobin equivalent, with the equipment currently in use

Carbon monoxide (CO)

Normally, CO concentration in exhaled air of a non-smoker should not exceed 4 ppm.

On the contrary, CO in exhaled air of a smoker may achieve 10-20 ppm (i.e. 2-5% carboxyhemoglobin).

Most non-smokers have < 5 ppm of CO exp, most smokers have more than 10 ppm with a dose relation increase .

The best cut-off value to separate smoker and non-smoker is 7 ppm.

Cotinine

Cotinine is the major metabolism product of nicotine. By monitoring its concentration in the body, one can assess an individual's tobacco smoke exposure.

The half-life of nicotine is about two hours; however nicotine concentration can vary depending on the moment of the day when the last cigarette was smoked.

In turn, cotinine has a half-life of 15-20 hours. It can be measured in blood, hair, saliva and urine.

Cotinine

A plasmatic cotinine concentration < 15 ng/ml is considered as a proof of non-smoking status.

In smokers, plasma cotinine is about 200 ng/ml, but may reach up to 1000 ng/ml depending on the intensity of smoking.

CO and Cotinine Determination

Recommendation:

CO and Cotinine level determination is not routinely recommended for diagnosis of Nicotine Dependence

Level of Evidence III

Degree of recommendation B

Chapter 5: Treatment

Smoking Cessation Intervention

The potential health benefits for the general population from smoking cessation interventions is considerable and should be offered to all smokers

Level I grade A

Non- Pharmacologic Intervention

Tobacco use and dependence treatment interventions can be carried out at 3 levels.

Whether the health professional is able to carry out interventions at all the 3 levels would depend on the amount of time available and the competency level of the health professional

Level 1

The ABC Approach (Basic Level Intervention)

Level 2

The 5 As Approach (Intermediate Level Intervention)

Level 3

Intensive Behavioural Support (Advanced Level Intervention)

Level 1: The ABC Approach

The aim of the ABC approach is to incorporate tobacco use cessation advice as a routine opportunistic first-line intervention when providing consultation to patients.

The simple steps to the ABC approach are as follows:

- *Ask and document status of tobacco use for every patient*
- *Brief advice to stop tobacco use for every patient who uses tobacco regardless of intention to quit*
- *Cessation support for every patient who expresses the intention to quit*

Level 2: The 5 As Approach

The 5 A's approach is a brief, goal-directed way to more effectively address tobacco use with patients with the goal of meeting tobacco users' needs in terms of readiness to quit.

Altogether, the 5 A's may take 3 to 10 minutes, depending on a provider's clinical setting and roles.

The 5 A's do not need to be applied in a rigid manner, and an entire office/clinical staff may be involved to support tobacco users.

The 5 A's

- **Ask:** About tobacco use every time
- **Advise :** Urge tobacco users to quit
- **Assess:** Determine willingness to make a quit attempt
- **Assist:** Provide help to move the individual toward a successful quit attempt
- **Arrange:** Follow-up contact

Level 3: Intensive Behavioural Support (Advanced Level Intervention)

Pharmacologic Intervention

Pharmacologic Intervention

What is the efficacy of NRT in smoking cessation?

Recent Cochrane collaboration in 2013(Cahill, et. al., 2013) recently looked at 12 treatment-specific reviews. The analyses covered 267 studies, involving 101,804 participants⁴. NRT was superior to placebo with odds ratios (OR) of 1.84; 95% credible interval (CredI) of 1.71 to 1.99

Evidence

Nicotine replacement therapy (NRT) increases quit rates at 6 to 12 months compared to placebo. **Level I**

There are no significant differences in the various forms of NRT in the effectiveness to aid in smoking cessation. **Level I**

Recommendation

NRT should be recommended to smokers who want to quit smoking. The choice of what form of NRT to use depends on personal and practical considerations.

Strength A

What is the appropriate dose of nicotine transdermal patch or gum to be given?

Nicotine transdermal patch should be used for at least 16 hrs/day, on a daily basis, for a minimum of 8 weeks. **Level I**

Recommendation

Nicotine patch can be given as follows:

<u>No. of cigarettes/day</u>	<u>Initial Dose</u>	<u>Duration</u>
<i>>10 cigarettes/day with weight >45 kg</i>	<i>21 mg/24 hr patch or 15 mg/16 hr</i>	<i>At least 8 weeks</i>
<i><10 cigarettes/day with weight <45 kg or cardiovascular disease</i>	<i>14 mg/24 hr patch or 10 mg/16 hrs</i>	<i>At least 8 weeks</i>

Patients should be encouraged to use nicotine patch for a sufficient period (8 weeks)

Strength A

What is the appropriate dose of nicotine transdermal patch or gum to be given?

Nicotine Gum

Eight (8) to twelve (12) pieces of gum per day is recommended.

Evidence

In people smoking more than 20 cigarettes per day, 4 mg gum is more effective than the 2 mg gum. **Level II**

Recommendation

If nicotine gum is chosen as the form of pharmacotherapy for smoking cessation, the 4 mg gum is recommended to be used over the 2 mg gum for those smoking more than 20 cigarettes per day.

Strength A

How do NRT in single form compare with combinations?

Combination NRT, in the Cochrane review in 2013, outperformed single formulations³.

- **Evidence**

Combination NRT is more effective than single NRT formulations as an aid to smokers who want to quit. **Level I**

Recommendation

Combination NRT should be considered over that of single NRT formulations especially in smokers who are heavily dependent on nicotine.

Strength A

Varenicline

Varenicline is a selective nicotinic-receptor agonist that was released in the Philippines in 2007. It is licensed as a prescription only medicine for smoking cessation. The standard regimen is as follows:

- 0.5 mg/ tablet, 1 tablet once a day for the first three (3) days then increased to 1 tablet twice a day from 4th-7th day. This titrated dose of varenicline is to reduce side effects and treatment should be started at least a week before the quit date.
- 1.0 mg/tablet, 1 tablet twice a day for 12 weeks.

Varenicline

In the 2013 Cochrane collaboration by Cahill et. al. that recently looked at 12 treatment-specific reviews, Varenicline increased the odds of quitting compared with placebo with OR of 2.88 (95% CredI 2.40 to 3.47)³.

Evidence

Varenicline is effective as an aid to smoking cessation. **Level I**

Recommendation

Varenicline should be recommended to smokers who want to quit smoking.

Strength A

Clonidine

Evidence

Clonidine appears to be effective as an aid to smokers who want to quit smoking. However, this is offset by the adverse events that occurred in a dose-dependent fashion in parallel with efficacy. **Level II**

Recommendation

With the dose-dependent adverse events noted with the use of Clonidine, it is reasonable to consider oral clonidine as a SECOND-LINE PHARMACOTHERAPY for smoking cessation. Close supervision is needed to titrate the dose appropriately and monitor for potentially severe adverse effects.

Strength A

How do NRT compare with Varenicline?

How do NRT in single form or in combination compare with Varenicline?

Evidence

Varenicline is more effective compared to any form of NRT as an aid to smokers who want to quit. **Level I**

Varenicline is equally effective as combination NRT in smoking cessation. **Level I**

Recommendation

Varenicline should be strongly considered as first-line pharmacotherapy in smoking cessation under acceptable clinical conditions. Appropriate assessment of the suitability of Varenicline to the clinical condition of the smoker must be done.

Strength A

Should pharmacologic therapy be offered to all smokers?

Evidence

Pharmacotherapy with Nicotine Replacement Therapy or Varenicline is an effective aid to assist motivated smokers to quit. **Level I**

The compliance with pharmacotherapy, especially duration of use, is an important determinant on the success rate of smoking cessation with economics of pharmacotherapy as the biggest determinant. **Level II**

Recommendation

In the absence of any contraindications, pharmacotherapy should be offered to ALL MOTIVATED smokers who have evidence of nicotine dependence. The choice of pharmacotherapy will depend on clinical suitability and choice of the patient.

Strength A

E-cigarettes

E-cigarettes are a form of Electronic Nicotine Delivery Device (ENDD). They are promoted as an alternative to tobacco products to deliver inhaled doses of nicotine (or non-nicotine) to the respiratory system from a vaporized solution without the need for combustion of tobacco.

E-cigarettes

Most e-cigarettes are designed to resemble tobacco cigarettes or other tobacco smoking products, and can give a physical sensation similar to that of inhaled tobacco smoke, as well as flavored vapor.

E-cigarettes

E-cigarettes may displace effective smoking cessation,⁵ and there is lack of evidence of the effectiveness of e-cigarettes as a tool or aid to smoking cessation.

Precisely because of this lack of evidence, the World Health Organization and the Department of Health, along with other organizations (most especially medical organizations), **do not** consider that currently there is sufficient evidence that e-cigarettes are suitable as a smoking cessation aid or agent.

E-cigarettes

Currently, there is no evidence to support the efficacy of electronic cigarettes as alternative form of NRT to achieve smoking cessation.

E- Cigarettes may promote nicotine addiction and unlikely to aid in smoking cessation particularly among the youth.¹²

THE USE OF E- CIGARETTES IS NOT RECOMMENDED AS AN ALTERNATIVE FORM OF NRT

LEVEL OF EVIDENCE : III

GRADE OF RECOMMENDATION : B

Chapter 5: Treatment and Management of Specific Populations

General Question: What smoking cessation intervention will be appropriate for each specific population?

I. HOSPITALISED & PRE-OPERATIVE PATIENTS

- Since all hospitals in the Philippines have smoke-free policies, a hospitalization episode represents an opportunity for patients who use tobacco to experience a period of abstinence.
- Hospitalized patients are bound not to smoke during confinement. Patients can be assessed appropriately as to what cessation intervention may be appropriate and will sustain smoke free status.

I. HOSPITALISED & PRE-OPERATIVE PATIENTS

Evidence :

Studies have shown the higher success rates of quitting for hospitalized patients compared to the general population with quit rate of 3-7% who remained abstinent one year after.(FCTC WHO GATS ,2009)

I. A. Hospitalized Patients

Hospitalized patients offered routine tobacco cessation behavioral support are more likely to quit tobacco use compared to those receiving brief advice.

In one meta-analysis of 33 studies, continuous 1-month behavioral support (telephone support) by a trained advisor increased the long-term quit rates by 65%.¹²⁸

Recommendation:

1. Where resources are available, behavioral support should be offered by a trained advisor for tobacco use and dependence to all hospitalized patients who are tobacco users.

Level of Evidence: I A

Recommendation:

2. NRT should be considered for hospitalized patients who are tobacco users and attempting to quit.

Level of Evidence: I A

I.B. PRE-OPERATIVE PATIENTS

Recommendation:

If resources are available, intensive behavioral support interventions for tobacco use and dependence, including the use of NRTs, should be offered to patients over a period of 4 to 8 weeks prior to surgery.

Grade A, Level 1+

Adolescents

Tobacco control measures for children and adolescents should be two pronged: primary prevention and smoking cessation programs.

Adolescents

Among the adolescent age group, what is/are the best method/s for smoking cessation? counseling/behavior modification or pharmacotherapy/ both?

Adolescents

Evidence:

1. The American Academy of Pediatrics Committee on Substance abuse recommends education, prevention, screening, and treatment, so more of behavioral interventions, but accedes to recommending that pediatricians familiarize themselves with NRT, bupropion, and varenicline.

Adolescents

Evidence :

2. The US Department of Health and Human Services /Veterans Affairs /Department of Defense recommend that all pediatric patients and their parents be, use the 5 As of 2008, DHHS does NOT recommend NRT for adolescents

Counseling and behavioral interventions are what they recommend.

II. PREGNANT AND BREASTFEEDING WOMEN

Recommended smoking cessation treatment during pregnancy

Pregnant women should be encourage to stop smoking completely

Summary statement 1: Smoking cessation should be encouraged for all pregnant, breastfeeding and postpartum women. (GRADE: 1A)

They should be offered intense support and proactive telephone counseling

Summary statement 2: During pregnancy and breastfeeding, Counseling is recommended as first line treatment for smoking cessation. (GRADE: 1A)

Self help material can supplement advice and support

II. PREGNANT AND BREASTFEEDING WOMEN

Summary statement 3: If counseling is found ineffective, Intermittent dosing nicotine replacement therapies (such as gum, lozenges) are preferred over continuous dosing of the patch after risk-benefit analysis. (GRADE: 1C)

If these conservative interventions are not successful, clinicians should consider NRT, after clear explanation of the risk involved.

Use of NRT should be considered when a pregnant woman is otherwise unable to quit. Intermittent NRT is preferred to patches (lower total daily nicotine dose)

II. PREGNANT AND BREASTFEEDING WOMEN

Summary statement 4: Partners, friends and family members should also be offered smoking cessation interventions. (GRADE: 2B)

Summary statement 5: Because of the uncertainty of the safety of NRT used during pregnancy, pregnant women wishing to quit using NRT should be monitored by a suitably qualified health professional

Summary Statement 6. Those who do quit should be supported to stay non-smokers long term.

II. PREGNANT AND BREASTFEEDING WOMEN

Evidence

There is currently lack of evidence on the safety of pharmacotherapy in pregnancy, but international guidelines recommend use of NRT in certain circumstances.

LEVEL V STRENGTH C

RECOMMENDATION

Behavioral intervention should be offered to all pregnant smokers A

***If pharmacologic intervention is warranted
(in case behavioral intervention will not suffice) C***

Smoking and Mental Health

SUMMARY OF EVIDENCE :

1. Rates of smoking are 2-4 times higher among people with mental disorder.^{1, 2, 144} (Level III, Grade C)
2. People with mental disorder are at least as motivated to quit as the general population (Level II, Grade B); 85% have tried to quit in the past (versus 78% without mental disorders); and more than half are contemplating quitting within six months.¹⁴⁵⁻¹⁴⁷
3. Smokers with mental disorders can quit successfully, but generally have lower quit rates (Level I, Grade A).¹⁴⁸⁻¹⁵⁰

Smoking and Mental Health

SUMMARY OF EVIDENCE

4. Smoking cessation does not exacerbate symptoms of mental disorders (Level I, Grade A), and improves symptoms in the longer term.^{130, 151-155}

5. Smokers with mental disorders are more likely to die from smoking-related disease than from mental disorder (Level I, Grade A).^{90-108, 156} Most of the excess mortality in smokers with mental disorder is caused by smoking.¹⁵⁷
relapse.^{4, 136-140}

IV. PATIENTS WITH CO-MORBID ALCOHOL ABUSE

Evidence

Research shows that smoking cessation does not disrupt alcohol abstinence and may actually enhance the likelihood of longer term sobriety.

In a 15-month follow-up study ² smoking cessation has been shown to improve drinking outcomes.

Individuals in treatment for alcohol use disorders who are motivated to stop smoking can safely be encouraged to do so without jeopardizing their sobriety ⁵

IV. PATIENTS WITH CO-MORBID ALCOHOL ABUSE

Evidence

two studies that included nicotine replacement in alcoholics in early alcohol treatment resulted in 14.1% cigarette abstinence at 6 months⁴ and 19% at 4 months.⁵

Study participation, increased awareness of cigarette smoking, and/or the nicotine patch may have all played a role in the 6-month outcomes.

IV. PATIENTS WITH CO-MORBID ALCOHOL ABUSE

Recommendation:

All alcohol dependent patients who are also tobacco users, including those undergoing alcohol addiction treatment programs, should be offered treatment for tobacco use and dependence.

Level II+, Grade B

Substance Abuse and Smoking Cessation

Treatment for nicotine dependence requires screening, assessing for readiness to change tobacco use behavior, and intervention.

A review of tobacco cessation studies among substance abuse users found that quit rates ranged from 7-60% directly after treatment and from 13-27% at 12 months, which are comparable to those in non-treatment populations.⁸

Majority of smoking cessation interventions used a combination of medication, educational and cognitive-behavioral approaches.

Substance Abuse and Smoking Cessation

Some studies found that concurrent treatment for smoking and other drugs is not associated with increased use of alcohol or other drugs.⁶

Incorporating smoking cessation interventions in substance abuse treatment is associated with a 25% increase in the likelihood of maintaining long-term alcohol and drug abstinence.⁹

Substance Abuse and Smoking Cessation

Recommendation:

Majority of smoking cessation interventions used a combination of medication, educational and cognitive-behavioral approaches. II B

Eliminating tobacco use is associated with decreased use of other abused substances. IIB

V. Low Socioeconomic group

What intervention will be effective for the financially and geographically disadvantaged groups?

Thank You