

Tobacco Dependence Treatment Guidelines



National Tobacco Control Programme
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India



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सत्यमेव जयते

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FOREWORD

Tobacco use is a major public health challenge globally. As per Global Adult Tobacco Survey 2010 (GATS) India, more than one third (35%) of the adults (15 years and older) are using tobacco in the country. The prevalence of smokeless tobacco use is 26% while 14% adults are smokers.

WHO Framework Convention on Tobacco Control (FCTC) recommends many strategies to reduce the demand and supply of tobacco. India has ratified this treaty and is committed to implement guidelines prescribed for tobacco control under it. The Government of India also enacted a comprehensive legislation, the Cigarettes and Other Tobacco Products (prohibition of advertisement and regulation of trade and commerce, production, supply and distribution Act), COTPA, 2003. To fulfill the commitments under the law and WHO FCTC, National Tobacco Control Programme (NTCP) was launched in the 11th Five Year Plan.

Providing assistance to tobacco users for quitting tobacco use is an established policy under "WHO MPOWER", to reduce the demand of tobacco. The Government of India was amongst the first few countries in the world to set up a chain of tobacco cessation clinics in collaboration with WHO in 2001-02. Under the National Tobacco Control Programme, cessation facilities are being provided at the district level. Efforts have also been made to expand the existing cessation facilities by building capacity of the health care delivery system, including training of doctors and health workers in tobacco cessation. Tobacco cessation clinics are also being set up in some primary, secondary and tertiary care settings.

Tobacco Dependence Treatment Guidelines have been developed with an objective to sensitize, train and equip health care providers with the knowledge and skills of providing treatment for tobacco dependence.

I hope that these guidelines would prove useful to strengthen and expand the tobacco cessation services in the country so as to meet the needs of tobacco users for quitting tobacco use.


(K. Chandramouli)

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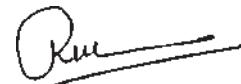


National Rural Health Mission

PREFACE

Tobacco epidemic has led to about 100 million deaths all over the world in the 20th century. Tobacco use is a risk factor for six of the eight leading causes of death. In India, 8-9 lakh persons die every year due to tobacco related diseases. At present, India is in the second stage of tobacco epidemic. There is an urgent need to reverse this entirely preventable epidemic. India faces huge challenge of tobacco control in view of high prevalence of tobacco use, as revealed by Global Adult Tobacco Survey (GATS) India 2010. With more than one third of adult population using large number of tobacco products, it becomes imperative to implement effective tobacco control strategies. The GATS India 2010 also revealed that there is demand for assistance to quit tobacco use in the community. It is a well established fact that in view of highly addictive nature of nicotine contained in tobacco, the tobacco users need assistance and treatment. The treatment for tobacco dependence may be in the form of behavioral counseling or pharmacotherapy.

The benefits of treatment for tobacco dependence have also been well documented. World Health Organization (WHO) has recommended “Brief Intervention” for tobacco cessation, which can be provided in different health care delivery settings. Studies have shown that people who quit tobacco live longer than people who continue to use tobacco. From the moment someone quit smoking, it only takes 20 minutes for the body to start undergoing beneficial changes. Thus cessation of tobacco use has extensive benefits and there is a need to make cessation facilities widely available. The “Tobacco Dependence Treatment Guidelines” have been developed recognizing the need for professional help to tobacco users to quit. It is imperative that these guidelines are widely distributed to reach all relevant stakeholders to ensure maximum output in terms of reduction of tobacco use. The document has been divided in to four sections to make it user friendly.



Dr R. K. Srivastava

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INTRODUCTION

Tobacco use is a leading cause of preventable deaths all over the world.^[1] Tobacco is also one of the major causes of deaths and diseases in India, accounting for almost a million deaths every year.^[2]

Global Adult Tobacco Survey (GATS) India (2010) data revealed that more than one out of three adults in India (35%) used tobacco in some form or the other. Among them, 21 % of adults used only smokeless tobacco, 9% only smoked and 5 % smoked as well as used smokeless tobacco. Overall tobacco use is much higher among Indian males at 48 percent but is also a serious concern among females among whom prevalence is 20 per cent.^[3]

In India, *khaini* or tobacco-lime mixture (12%) is the most commonly used smokeless tobacco product, followed by gutkha (a mixture of tobacco, lime and areca nut) (8%), betel quid with tobacco (6%) and tobacco dentifrice (5%).^[3] Bidi (9%) is most commonly used smoking product, followed by cigarette (6%) and hukkah (1%).^[3]

As per the Global Health Professions Student Survey (GHPSS), India, 2009, 6.5% third year dental students smoked cigarettes and 8.6% used other tobacco products.^[4] Among medical students, 13.4% third year medical students smoked cigarettes and 11.6% used other tobacco products.^[4] Global Youth Tobacco Survey(GYTS) India, 2009 revealed that 14.6% of 13-15 years school going children in India used tobacco products out of which 4.4% smoked cigarettes and 12.5% used other forms of tobacco.^[5] These figures are alarming because these professional students will themselves lead the war against tobacco, and because earlier initiation increases chances of long term dependence.

Article 14 of WHO FCTC (Framework Convention on Tobacco Control) prescribes demand reduction measures concerning tobacco dependence and cessation. It states that “each party (country) shall develop and disseminate appropriate, comprehensive and integrated guidelines based on scientific evidence and best practices, taking in to account national circumstances and priorities, and shall take effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence”.

To help countries fulfill the obligations under FCTC, WHO has established MPOWER, the policies of which are proven to reduce tobacco use

M – Monitor tobacco use and prevention policies.

P – Protect people from tobacco smoke.

O – Offer help to quit tobacco use.

W – Warn about the dangers of tobacco.

E – Enforce bans on tobacco advertising, promotion and sponsorship.

R – Raise taxes on tobacco.

India is a signatory to the FCTC. The Government of India passed the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act in 2003. Under National Tobacco Control Programme, being implemented in the XI Five Year Plan, cessation facilities are being made available at the district hospital level.

TOBACCO DEPENDENCE

Tobacco dependence is defined as, “Cluster of behavioral, cognitive and physiological phenomena that develop after repeated tobacco use and that typically include a strong desire to use tobacco, difficulties in controlling its use, persistence in tobacco use despite harmful consequences, a higher priority given to tobacco use than other activities and obligations, increased tolerance and sometimes a physical withdrawal state”. (ICD – 10)

Both smoked and smokeless forms of tobacco contain nicotine, a highly addictive chemical, making it difficult for habituated tobacco users to quit.^{[6][7]} In fact, it is as addictive, or even more, than heroin or cocaine. Over time, users become dependent on nicotine and suddenly stopping produces both physical and psychological withdrawal symptoms.^{[8][9][10][11]}

Nicotine is readily absorbed from the respiratory tract, buccal mucosa and skin.^[12] There is minimal absorption through the gastrointestinal tract when administered orally. Cigarettes are highly effective mechanism for delivering nicotine. Inhaled nicotine takes about 10-19 seconds to reach the brain and its stimulation releases chemicals which ensure feeling of goodness, alertness and energy.^{[6][7][9]}

As the person stops tobacco use, these chemicals decrease in the body and withdrawal symptoms start. These can be very distressing for the unprepared tobacco user. Thus, the tobacco user is compelled to continue using tobacco, hence trapped in the vicious cycle.

Studies have shown that tobacco users must effectively deal with both the physical and psychological symptoms of withdrawal to quit and stay quit.^[15]

TOBACCO DEPENDENCE TREATMENT

Tobacco dependence is a chronic condition that often requires repeated interventions. Because effective tobacco dependence treatments are available, **every patient who uses tobacco should be offered at least one of these treatments.** Tobacco dependence treatments are both clinically effective and cost effective in relation to other medical and disease prevention interventions.

BEHAVIOUR INTERVENTIONS:

A variety of behavior therapies, ranging in complexity from simple advice offered by a physician or other health care providers or much more extensive therapy offered by counselors, have been shown to be efficacious for tobacco cessation.^[32]

Brief Advice – This consists of Advice to stop using tobacco, usually taking only a few minutes, given to all tobacco users, usually during the course of a routine consultation or interaction.^[33]

Behavioral support – This involves support, other than medications, aimed at helping people stop their tobacco use. It can include all cessation assistance that imparts knowledge about tobacco use and quitting, provides support and teaches skills and strategies for changing behavior.

Basic knowledge, certain competencies and skills are required to provide effective counseling for tobacco cessation.

STRATEGIES FOR TOBACCO CESSATION - THE 5 “A”S AND 5 “R”S

The Five A’s (Ask, Advise, Assess, Assist and Arrange) and Five R’s (Relevance, Risk, Rewards, Repetitions, Roadblocks) is a five to fifteen minute research based counseling approach that has proven global success.^[13]

STEP 1: ASK

Systematically identify all tobacco users at every visit. It should be an essential part of evaluation that for every tobacco user at every consultation, tobacco-use status be queried and documented. (Refer Annexure 1)

STEP 2: ADVISE “STRONGLY URGE ALL TOBACCO USERS TO QUIT”.

Advice should have:

- **Clear Message:** “I think it is important for you to quit tobacco now and I can help you.” “Cutting down while you are ill is not enough”.
- **Strong message:** “As your health carer, I need to advise you that quitting tobacco smoking/ chewing/sniffing is the most important thing you can do for your health and your family’s health.” . “I can surely help you in this matter.”
- **Personalized message:** Relate the tobacco use to current health/illness, and /or its social and economic cost, motivation level/readiness to quit, and /or the impact of tobacco use on children and others in the household.

All tobacco users should be firmly advised to quit in a way that is supportive and non-confrontational. Tell them about benefits of quitting.

BENEFITS OF QUITTING

It is important to tell the tobacco user about the benefits of quitting. Some hints are presented below. Individual users may have other motives to quit, which should be explored and documented for future use.

Begin thus - From the moment you quit smoking, it only takes 20 minutes for your body to start undergoing beneficial changes.

20 Minutes:

Blood pressure drops to normal; Pulse rate drops to normal; Temperature of hands and feet increases to normal.

Within 8 Hours:

Carbon-monoxide level in blood drops to normal; Oxygen level in blood becomes normal.

Within 24 Hours to 48 hours:

Chance of heart attack decreases.

Nerve endings start regenerating; Ability to smell and taste begins to improve.

Within 72 hours:

Bronchial tubes relax, making breathing easier.

Within 2 Weeks to 3 Months:

Circulation improves. Lung function increases up to 30%

Within 6 Months:

Coughing, sinus congestion, fatigue and shortness of breath decrease. The lungs function better, as congestion reduces, so does the chance of infection.

Within 1 Year:

Risk of coronary heart disease decreases to half that of a smoker.

Within 10 Years:

Risk of dying from lung cancer is reduced to half.

Within 15 Years:

Risk of dying from a heart attack is equal to a person who never smoked.

STEP 3: ASSESS

Assess: Determine willingness to make a quit attempt.

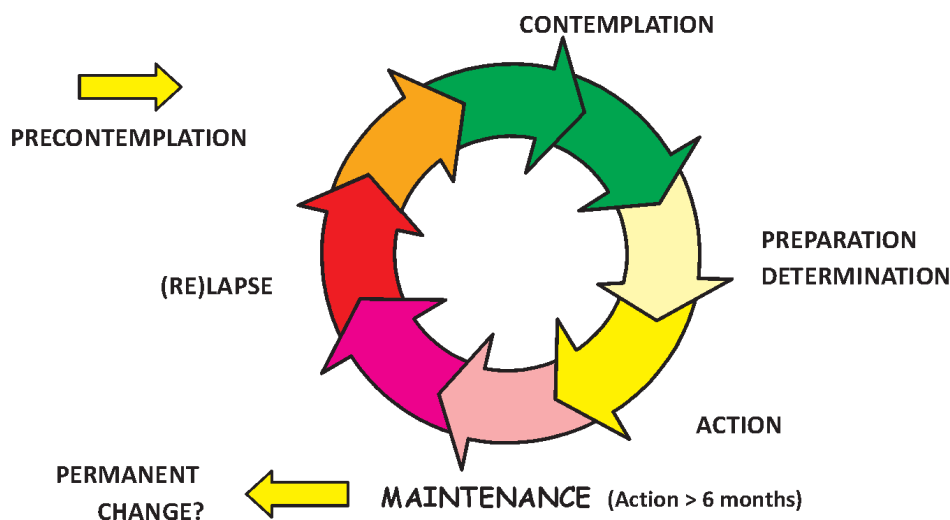
To be able to assist a tobacco user with tobacco cessation, assess his/ her willingness to commit to this change. Ask every tobacco user if he/she is willing to make a quit attempt at this time (e.g. within the next 30 days).

The stages of Readiness to change model is a valuable model for assessing a tobacco user's readiness to change the behaviour. Cessation is explained as a process, and tobacco users may go through the steps of being ready, quitting and relapsing, an average of three to four times, before achieving success. Tobacco users will be in different stages of readiness at different times, hence, readiness needs to be re-evaluated constantly. ^{[15][16][17]}

The stages may be,

- i) Not ready (Pre contemplation)
- ii) Unsure (Contemplation)
- iii) Ready (Preparation)
- iv) Action
- v) Maintenance.

MOTIVATIONAL INTERVIEWING TECHNIQUES – STAGES OF READINESS TO CHANGE MODEL



Not ready (Pre contemplation)

These tobacco users are not seriously considering quitting in the near future. They only see the positive aspects of tobacco and do not like to acknowledge the disadvantages.

- *Encourage such a person to think about his/her tobacco use and make an offer of help. Offer them written information on the harms of tobacco use and benefits of quitting.*

Unsure (Contemplation)

These tobacco users are seriously considering quitting in the near future. This group is particularly amenable to brief motivational interviewing. Talk to them about the relevant health effects of tobacco use and barriers to cessation.

- *Provide them the written information and inform them that quitting is possible with will power and support from the family, friends, peer group and health professionals.*

Ready (Preparation)

These tobacco users are planning and ready to quit and have usually made a 24-hour quit attempt in the past year. This group is motivated to quit soon and is the group most likely to attempt to quit in the near future.

- *This is the best opportunity, which may be available for only a short time, and is the group most likely to ask for help with quitting.*

Action

These are former tobacco users who have quit in the last 6 months. This is when the risk of relapse is highest with about 75% of relapses occurring in this stage, within the first week. This is a period where support and strategies to prevent relapse are important.

- If relapse occurs, it is important that this should not be seen as failure, but considered a learning experience and as part of quitting process.

Maintenance

These are tobacco users who quit for more than 6 months. The non-tobacco use behavior is established and the threat of tobacco use gradually diminishes. The chances of relapse diminish over time.

- Only about 4% of those who quit for more than two years ever go back to tobacco use.

Assessment of nicotine dependence— if the tobacco user is in the ready stage

Assess willingness to quit, and determine the level of Nicotine addiction. This can be measured by **Fagerstrom Scoring** (Annexure-2). The tool has six simple questions. Scoring is done as followed:

- A high level of addiction will rank between 7 and 10 points.
- A medium level of addiction will rank between 4 and 6 points.
- A low level of addiction will rank between 0 and 3 points.

STEP 4 - ASSIST

The following strategies are suggested to assist tobacco users in motivational stage:

Action	Strategies for implementation
Help in making a QUIT PLAN .	Preparations for quitting; Set a quit date; ideally, the quit date should be within 2 weeks. Tell family, friends, and co-workers about quitting, plan and seek their support. Anticipate challenges to planned quit attempt, particularly during the critical first few weeks. These include nicotine withdrawal symptoms. Remove tobacco products from surroundings. Avoid – <i>Avoid Smoking or Using tobacco in places where a lot of time is spent e.g. work place.</i> Avoid all forms of tobacco, do not substitute one tobacco product for another.

Action	Strategies for implementation
Provide practical counseling (Problem solving / skills training)	<p>Past quit experience-Identify what helped and what failed in previous quit attempts.</p> <p>Anticipate triggers or challenges in upcoming attempt – Discuss challenges and how user will successfully overcome them.</p> <p>Alcohol- The tobacco user should consider limiting/abstaining from alcohol while quitting.</p> <p>Other tobacco users in the household/ workplace - Quitting is more difficult when there is another smoker/ tobacco user in the household/ workplace. Other housemates/ coworkers/ peers should also be encouraged to quit.</p>
Provide intra-treatment social support.	Provide a supportive environment by encouraging tobacco users in their quit attempts.
Help in obtaining extra-treatment social support.	Provide help in developing social support for quit attempt in the environment outside of treatment. “Ask your spouse / partner, friends and coworkers to support you in your quit attempt.”
Recommend Pharmacotherapy.	Explain how the medications improve success rates and reduce withdrawal symptoms.

There is a strong dose response relation between the intensity of tobacco cessation counseling and its effectiveness.

PHARMACOTHERAPY

Medications available for tobacco cessation can broadly be divided into two groups:

1. Nicotine Replacement Therapy (NRT)
2. Non Nicotine Replacement Therapy

Nicotine replacement therapy: Nicotine Replacement Therapy (NRT) is a method of substituting the nicotine in tobacco products by an approved nicotine delivery product so that the tobacco user does not have uncomfortable withdrawal symptoms upon stopping the tobacco product. The dose of NRT is monitored and gradually reduced to make the process of cessation comfortable for the tobacco user. As compared to blood levels of nicotine following tobacco smoke inhalation, NRT blood levels increase relatively slowly. Nicotine through tobacco smoke reaches brain within few seconds compared to medicinal nicotine which take few minutes to hours. Hence motivation and patience are essential for the user. All types of NRTs viz. Nicotine patch, nicotine gum, nicotine inhaler, and nicotine nasal spray have been shown to have more or less similar success rates.^{[18][19][20]}

Nicotine Gum:

It acts as an oral substitute and provides a source of nicotine that reduces the withdrawal symptoms experienced when tobacco use is stopped. The gum is available in different strengths and can be used on either at regular intervals or on an as needed basis. Tapering can be considered after 8 to 12 weeks.

How it is used-

- Should be used orally as a chewing gum and not swallowed.

- Treatment is usually started by using 2 mg gum.
- Heavy smokers/ tobacco users may start the treatment by using 4 mg gum.
- Nicotine gum may be used by chewing one piece of gum every 1-2 hours at first, or by chewing one piece of gum whenever there is an urge to use tobacco.
- The gum should be chewed slowly until the taste of nicotine or slight tingling is felt in the mouth.
 - Stop chewing and place (park) the gum between cheek and gum.
 - Parking the nicotine gum is essential for the absorption of nicotine through the buccal mucosa, not doing so will lead to more nicotine being swallowed which might result in side effects such as nausea and vomiting.
 - Once the tingling is almost gone (almost one minute), start chewing again.
 - Repeat this procedure for about 30 minutes.
- Precautions –
 - Don't chew nicotine gum too fast.
 - Don't chew more than one piece of gum at a time.
 - Don't chew one piece too soon after another.
 - Don't chew more than 30 pieces of 2mg gum in a day if under supervision.
 - Don't chew more than 24 pieces of 2 mg gum in a day if not under supervision.
- Avoid eating and drinking (especially acidic beverages such as coffee or soft drinks) for 15 minutes before and during chewing of nicotine gum to prevent reduced absorption of nicotine.
- Gradually reduce the amount of nicotine gum use after 2-3 months, which prevents nicotine withdrawal symptoms.

Weaning of Nicotine Gum (NRT)

- Start decreasing the total number of nicotine gum pieces being used per day by about one piece in every 4-7 days.
- Decrease the chewing time with each piece from the normal 30 minutes to 10-15 minutes for 4-7 days. Then gradually decrease the total number of pieces used per day.
- Increase the duration between use of nicotine gum pieces.
- Increase intake of drinking water.
- Start substituting one or more pieces of nicotine gum with sugarless gums and gradually increase it over a period of time.
- If using 4 mg gum, replace it with 2 mg gum and apply any of the aforesaid steps.
- Consider stopping the use of nicotine gum when the craving for nicotine is satisfied by chewing just one or two pieces of gum per day.
- Avoid using nicotine gum for durations longer than 3 months.

Availability of Nicotine gum in India

Composition: Nicotine Polacrilex

Dosages: 2 mg and 4 mg

Nicotine pastilles have also been introduced in India. Here, the procedure to use is to roll the pastille in the mouth rather than chew.

Nicotine patches, inhalers and sprays are not presently available in India.



Non Nicotine Replacement Therapy:

In this type of therapy, medications which act on the similar set of neurotransmitters that are affected by nicotine and provide effective and behavioural regulation are used. This tackles the need, or impulse to use nicotine and to minimize withdrawal effects. While with nicotine replacement therapy, the tobacco user immediately quits tobacco use upon starting NRT, in the case of non NRT medication, the user sets a quit date one to two weeks after initiation of the medicine.

First Line drugs

1. Bupropion : Bupropion is a non-nicotine drug for treating tobacco dependence.^[21] It is an atypical antidepressant that has both dopaminergic and adrenergic actions. A quit date is decided preferably within 7 to 14 days of starting treatment with bupropion. This is because the steady state plasma concentration of bupropion and its active metabolites are achieved in approximately 8 days after initiation of therapy.^[22]
2. Varenicline: This is a partial nicotine agonist that selectively binds to the alpha (4) and beta (2) nicotinic acetylcholine receptors in the brain. It lessens the physical pleasure from taking in nicotine and helps lessen the symptoms of nicotine craving.^[23] Tobacco use may be stopped one week after initiating treatment with Varenicline.

TABLE : PHARMACOTHERAPY FOR TOBACCO CESSATION

1. Nicotine Replacement Therapy (NRT)*			
	Dosage and duration	Side effects	Contraindications**
a. Nicotine gum	For 1-24 cigarettes/ bidis - 2mg gum (up to 24 pieces/day) for 12 weeks For ≥25 cigarettes/ bidis – 4mg gum (up to 24 pieces/day) for 12 weeks Chewers need about half or a quarter of the dose as prescribed for smokers.	Mouth soreness, burning in the mouth, throat irritation, dyspepsia, nausea, vomiting, hiccups and excess salivation	Gastric Ulcers, myocardial infarction or stroke in the past two weeks or poorly controlled cardiovascular disease.*** If a patient has any serious medical condition, refer to an appropriate specialist.

* Only Nicotine gum is available in India (in 2 mg and 4 mg strengths).

** For pregnant and lactating mothers, shorter-acting NRTs such as gums are recommended.

*** NRT can be prescribed to persons with underlying stable cardiovascular disease, including angina and previous myocardial infarction.

	Dosage and duration	Side effects	Contraindications**
b. Nicotine patch	21mg/24 hours for 4 weeks then 15mg/24 hours for 2 weeks then 7mg/24 hours for 2 weeks.	Local skin reaction, insomnia	Myocardial infarction or stroke in the past two weeks or poorly controlled cardiovascular disease.*** If a patient has any serious medical condition, refer to an appropriate specialist.
c. Nicotine inhaler	6-16 cartridges/day for 6 months	Local irritation of mouth and throat	- As above -
d. Nicotine nasal spray	1-2 doses/hour for 3 to 6 months	Nasal irritation, irritation of throat, coughing and watering of eyes.	- As above -
2. Non Nicotine Replacement Therapy (Non- NRT)			
	Dosage and duration	Side effects	Contraindications**
a. Bupropion	150mg OD for 3days followed by 150mg BD for 7 to 12 weeks.	Agitation, restlessness, insomnia, gastrointestinal upset, anorexia, weight loss, headache and lowering of seizure threshold (at doses above 600 mg/day). Rarely allergic reactions can occur, including skin rashes, fever, muscle and joint pain.	History of allergy, tumours of central nervous system, severe liver diseases, undergoing unsupervised withdrawal of alcohol or benzodiazepenes, uncontrolled seizures, pregnant and lactating women, those below 18 years, and persons on monoamine oxidase inhibitors.
b. Varenicline	Initially 0.5 mg once daily for the first three days, increased to 0.5 mg twice daily for the next four days, and then increased to 1mg twice daily for 12 weeks. The person can quit one week after initiating Varenicline	Agitation, depression, restlessness, insomnia, bad dreams, suicidal ideations, gastrointestinal upset and headaches. Allergic reactions may occur rarely.	Pregnant women, children or people with mental illness. Stop treatment if changes in mood & behavior, agitation and suicidal ideations occur.

Combination Therapy:

Combined behavioral and pharmacological therapies appear to be the best approach for treating tobacco dependence. Because these therapies operate by different mechanisms, complementary and potentially additive effects may be expected. Nicotine Replacement Therapies (NRT) combined with supportive counseling are the most widely used and intensively reached treatment method. Although self help strategies alone marginally affect quit rates, individual and combined pharmacotherapies and counseling either alone or in combination can significantly increase cessation.^[25]

The tobacco cessation experience in India has shown that counseling with regular follow-up by health care provider also presents encouraging quit rates, more so among smokeless tobacco users.

** For pregnant and lactating mothers, shorter-acting NRTs such as gums are recommended.

*** NRT can be prescribed to persons with underlying stable cardiovascular disease, including angina and previous myocardial infarction.

WITHDRAWAL SYMPTOMS:

Commonly experienced withdrawal symptoms on stopping tobacco use include:^{[8][9][10][11]}

- Depressed mood
- Insomnia
- Irritability, frustration , anger
- Anxiety
- Craving and difficulty in concentration
- Restlessness
- Decreased heart rate
- Increased appetite or weight gain

Withdrawal symptoms of tobacco products should be discussed in advance with the tobacco user who is planning to quit. In addition, behavioral coping methods should be taught at the outset and it should be explained clearly that the worst of the physical symptoms are over within 2-3 days and most have passed after 10-14 days but in some, can last up to 4 weeks.

Some Common Withdrawal Symptoms and Coping Strategies are as follows:

Symptom	Coping Strategy
Irritability	Take walk, take bath, relax and talk to friends, listen to favourite music, do breathing exercises/ Yoga.
Fatigue	Relax, take naps, increase intake of fluids
Insomnia	Avoid tea, coffee, aerated drinks after 6pm; develop habit of reading books
Cough	Drink plenty of fluids, use lozenges, steam inhalation
Nasal Drip	Drink plenty of fluids
Dizziness	Change positions slowly, relax
Lack of Concentration	Plan workload, avoid stress, time management
Constipation	Add fiber to your diet through fresh fruits, vegetables etc; drink plenty of fluids
Headaches	Drink plenty of fluids, and practice relaxation, eat small snacks
Hunger	Increase intake of fruits/ vegetables/ fluids; avoid heavy meals, take smaller meals at shorter intervals
Craving for tobacco	Distract yourself – Drink water, read, exercise, talk to family members/friends. Remind yourself that the urge will die down in a few minutes

THE 5 “R”s APPROACH³⁵

For tobacco users who are not ready to make a quit attempt, provide a brief intervention designed to promote the motivation to quit and information about harmful effect of tobacco. The tobacco user may have fears and concerns about quitting, or may be demoralized because of previous unsuccessful attempts and relapse. This group may respond to a motivational intervention designed to educate, reassure and motivate and build around the 5 “R”s; i.e. Relevance, Risk, Rewards, Roadblocks and Repetition.

Relevance	Encourage the tobacco user to consider the personal relevance of cessation. Take into account the disease status (if any), family or social situation, health concerns, age and gender.
Risks	Discuss short term, long term and environmental risks of continued tobacco use, including effects of exposure to second hand smoke on the family members especially children. Relate with the symptoms.
Rewards	Encourage tobacco user to identify benefits of cessation. These may include withdrawal symptoms, fear and concern associated with quitting, depression, lack of social support, weight gain etc. Discuss strategies to address potential barriers.
Roadblocks	Barriers that the tobacco user may face in his/her quit attempt should be identified. Withdrawal symptoms, fear and concern associated with quitting, depression, lack of social support, enjoyment of tobacco are some of the barriers that the tobacco user may face in an attempt.
Repetition	This information should be reviewed regularly with tobacco users who are not yet ready to quit. It is also important for tobacco users who have not yet successfully quit to understand that most people attempting cessation quit several time before finally succeeding in quitting.

The health care provider should renew the strong message to quit and renew the offer of help

STEP 5: ARRANGE

Arrange - Schedule a follow-up contact

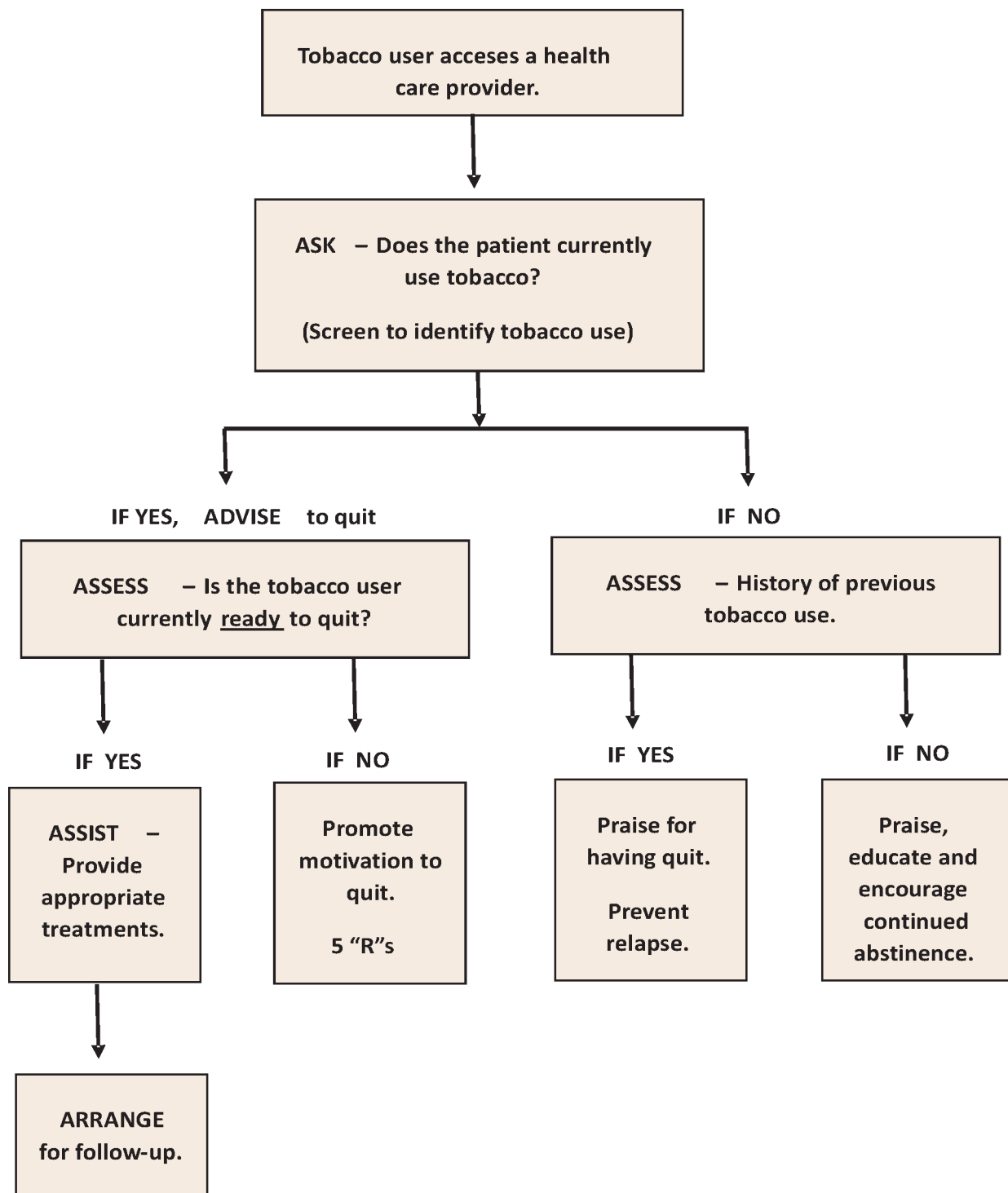
Time- Follow up contact should occur soon after the quit date, preferably during the first week. A second follow up contact is recommended within the first month. Schedule further follow up contact as indicated. Follow up visits after advice to quit have been shown to increase the likelihood to successful long term abstinence.

During the follow up, quitters have some common problems and a solution should be suggested accordingly. Some of these are described below:

Problems	Responses
Lack of support for cessation	<ul style="list-style-type: none"> • Schedule follow-ups or telephone calls with the tobacco user. • Help in identifying sources of support.
Negative mood or depression	<ul style="list-style-type: none"> • Provide counseling, prescribe appropriate medications, or refer to a specialist.
Strong or prolonged withdrawal symptoms	<ul style="list-style-type: none"> • Use an approved pharmacology or adding/combining pharmacologic medications to reduce strong withdrawal symptoms.
Weight gain	<ul style="list-style-type: none"> • Recommend starting or increasing physical activity. • Emphasize the importance of a healthy diet. • Reassure the tobacco user that weight gain is normal and will not increase beyond a point, and that there is just a need to watch it.
Flagging motivation/feeling deprived	<ul style="list-style-type: none"> • Reassure the tobacco user that these feelings are common. • Recommend rewarding activities. • Emphasize that (even a puff or chew) will increase urges.

Identify all tobacco users.
Document tobacco use and treatment offered.
Follow up.

Intervention Method Algorithm for Quitting Tobacco Use



TOBACCO CESSATION IN SPECIAL SITUATIONS

Pregnant and lactating females

Women who use tobacco during pregnancy and breast-feeding should strongly be advised against it. They should be asked to quit using the behavioral strategies that were mentioned earlier, to deal with withdrawal. However if they are unable to quit just by behavior counseling, then use of NRT may be considered. Pregnant and breast-feeding women who opt for NRT should be advised to use shorter acting products to minimize overnight foetal exposure to nicotine. (e.g. Nicotine gum)

Cardiovascular disease

In stable cardiovascular disease conditions, use of NRT is safe. Caution should be taken while considering NRT in patients of unstable angina, myocardial infarction, or stroke as nicotine is a vasoconstrictor. In these cases, rapidly reversible NRT like nicotine gum is preferable.

Patients with tobacco use related diseases

This is a group where tobacco cessation is an urgent clinical need, as continued tobacco use greatly increases the risk of further illness. There is evidence that pharmacotherapy with bupropion can increase cessation rates in chronic tobacco users with co-morbidity and those with mild to moderate Chronic Obstructive Pulmonary Disease. People with tobacco use related diseases may benefit from a multidisciplinary care plan.

Patients with mental illness

Patients with mental health problems have higher rates of smoking/tobacco use and are prone to serious health problems both on account of their mental illness and on account of tobacco use. The treatment of mental illness needs to be monitored carefully during tobacco cessation.

Persons with substance-use disorders

Smoking and tobacco use is common in persons with substance use disorders. Tobacco cessation must be offered to such persons in inpatient and outpatient settings.

Tobacco users with apprehension of weight gain

Some tobacco users are apprehensive of quitting tobacco use as it may lead to weight gain. Such persons should first be reassured that weight gain can be minimized by proper diet and exercise and the need to quit must be emphasized. Bupropion or nicotine gum has been shown to delay weight gain. Continuing reassurance and support are vital for successful quitting.

SETTING UP TOBACCO CESSATION SERVICES

While all health care providers must provide brief counseling for tobacco cessation as part of routine health care, dedicated tobacco cessation services can be set up in different health care settings at primary, secondary and tertiary care settings. Specialist care may be provided particularly to help people with more severe tobacco dependence.

Tobacco cessation services can be set up preferably in different departments of a hospital/ medical college e.g. dental, medicine, surgery, ENT, psychiatry, community medicine, TB & chest diseases, paediatrics, obstetrics & gynae etc.²⁹

A specialized setting can be run by a team consisting of a trained physician, counselor or social worker attendant. A trained nurse, pharmacist or health worker can also provide counseling services.

DISSEMINATION STRATEGIES FOR THE GUIDELINES

The Guidelines may be disseminated to following suggested stakeholders:

- Resource Centers for Tobacco Control (RCTCs) – Such centres have been set up under GOI-WHO collaboration programme.
- Professional Organisations –
 - Indian Medical Association (IMA)
 - Indian Dental Association (IDA)
 - Indian Pediatric Association
 - Indian Psychiatry Society
 - The Tuberculosis Association of India
 - Indian Chest Society
 - Indian Network of Chronic Respiratory Diseases
 - Indian Association for Chest Diseases
 - The Federation of Obstetrics and Gynaecological Societies of India
- Specialised Institutions – Regional Cancer Centres (RCCs), Public health institutions.
- Training Institutions
 - Medical/ Dental colleges
 - Nursing colleges
 - Pharmacy colleges

For more information access following websites :

<http://chooselifenottobacco.org/>

<http://www.mohfw.nic.in/National%20Programme%20for%20Tobacco%20Control.htm>

REFERENCES

1. WHO report on the global tobacco epidemic. Geneva, World Health Organization, 2008.
2. Jha P, Jacob B, Gajalakshmi V, Gupta PC, Dhingra N, Kumar R, et al. A nationally representative case-control study of smoking and death in India. *N Engl J Med* 2008, 358:1137-47.
3. F. Ram et al. Global Adult Tobacco Survey 2009-10 Document. New Delhi, India, National Tobacco Control Programme, Ministry of health and family welfare, Govt. of India, 2010
4. Global Health Professions Student Survey (GHPSS), India, 2009, (http://www.searo.who.int/LinkFiles/GHPS_India_2009_Dental.pdf and http://www.searo.who.int/LinkFiles/GHPS_India_2009_medical.pdf Accessed 13 January, 2011).
5. Global Youth Tobacco Survey (GYTS), 2009 (<http://www.who.int/tobacco/surveillance/gyts/en/> Accessed 13 January, 2011).
6. Davis, Ronald M. et al. (eds.) *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General, US, 1988* (<http://profiles.nlm.nih.gov/NN/B/B/Z/D/> Accessed 14 January, 2011).
7. Moxham J. Nicotine addiction. *BMJ* 2000; 320 : 391-2.
8. Hatsukami DK, Hughes JR, Pickens RW, Svikis D (1984) Tobacco withdrawal symptoms: an experimental analysis. *Psychopharmacology* 84:231–236.
9. Hatsukami DK, Gust SW, Keenan RM (1987) Physiologic and subjective changes from smokeless tobacco withdrawal. *Clin Pharmacol Ther* 41:103–107.
10. Hughes JR, Hatsukami D (1986) Signs and symptoms of tobacco withdrawal. *Arch Gen Psychiatry* 43:289–294.
11. Barker D (1994) Reasons for tobacco use and symptoms of nicotine withdrawal among adolescent and young adult tobacco users-United States, 1993. *MMWR Morb Mortal Wkly Rep* 43:745–750.
12. Hwa-Jeong Lee, Han-Young Guo, Sun-Kyung Lee et al. Effects of nicotine on proliferation, cell cycle, and differentiation in immortalized and malignant oral keratinocytes, *Journal of Oral Pathology & Medicine*, Volume 34, Issue 7, pages 436–443, August 2005.
13. VA/DoD Clinical Practice Guideline for the management of Tobacco Use: Update 2004. U.S. Army Medical Command, & The Veterans Health Administration.
14. Shiffman S (1991) Refining models of dependence: variations across persons and situations. *Br J Addiction* 86:611–615.
15. Miller and Rollnick. *Motivational Interviewing: Preparing People for Change*, 2nd ed. 2002.
16. Prochaska, J.O. & DiClementi, C.C. (1984). *The transtheoretical approach: Crossing the traditional boundaries of therapy*. Malabar, FL: Krieger.

17. Rollnick, Miller & Butler. Motivational Interviewing in Health care: Helping Patients Change Behaviour. 2008.
18. GH Thompson and DA Hunter, Nicotine replacement therapy, The Annals of Pharmacotherapy: Vol. 32, No. 10, pp. 1067-1075.
19. Belperio P, Chen T. (2009) Pharmacology for tobacco use cessation (TUC): 2008 Clinical Practice Guideline Update. Conference: 2/25/2009
20. Britton J. Nicotine replacement can be obtained on prescription. BMJ 2000; 321 : 379.
21. Holm KJ, Spencer CM (2000). Bupropion: A review of its use in the management of smoking cessation. Drugs, 59(4): 1007–1024.
22. Ferris RM, Cooper BR. Mechanism of antidepressant activity of bupropion. J Clin Psychiatry Monogr 1993;11:2-14
23. J. Taylor Hays MD. Jon O. Ebbert MD and Amit Sood MD. Efficacy and Safety of Varenicline for Smoking Cessation. The American Journal of Medicine Volume 121, Issue 4, Supplement 1, April 2008, Pages S32-S42
24. Sweeney C.T., Fant R.V., Fagerstrom K.O., McGovern J.F., Henningfield J.E; Combination Nicotine Replacement Therapy for Smoking Cessation: Rationale, Efficacy and Tolerability. CNS Drugs, Volume 15, Number 6, 2001 , pp. 453-467(15)
25. Zevin, S., & Benowitz, N.L. (1999). Drug interactions with tobacco smoking: An update. Clin Pharmacokinet. 36(6). 426-437.
26. World Health Organization, Regional Office for South-East Asia. Helping people quit tobacco. A manual for doctors and dentists. ISBN 978-92-9022-380-1
27. World Health Organization, Regional Office for South-East Asia. Tobacco cessation: A manual for nurses, health workers and other health professionals. ISBN978-92-9022-384-9.
28. Murthy P, Saddichcha S. (2010) Tobacco cessation services in India: Recent developments and the need for expansion. Ind J Cancer, 47; 5:69-74.
29. Tobacco Cessation Centre, NIMHANS. 2009. Starting tobacco cessation services. Available at:http://www.nimhans.kar.nic.in/deaddiction/1221/pub/Starting_TCC_Services-Nimhans_2009.pdf
30. Saddichcha S, Rekha DP, Patil B, Murthy P, Benegal V, Isaac MK. 2010. Knowledge, attitude and practices of Indian dental surgeons towards tobacco control: advances towards prevention.
31. Asian Pacific Journal of Cancer Prevention, vol 11:939-942
32. Policy recommendations for smoking cessation and treatment of tobacco dependence, WHO, 2003.
33. Guidelines for Article 14 of WHO, FCTC.
34. Byran J, Bailey, Jonas, T Johnson, Shawn D Newlands; Tobacco Cessation: How to guidance and resources for practitioners; in Head and Neck Surgery – otolaryngology.

ANNEXURE – 1

(SUGGESTED PROFORMA FOR PATIENT INPUTS)

TOBACCO CESSATION SERVICES - INTAKE AND FOLLOW-UP FORM

Note: This is the minimum required information for the database. Each health care facility is encouraged to maintain a detailed clinical record for each client.

Client No.

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Date

--	--	--	--	--	--	--	--

1. Name : _____

2. Age : _____

3. Gender : Male Female

4. Address : _____ Ph. No. _____

5. Education (Numbers of years of formal education) _____

6. Marital Status: Unmarried Married Widowed
 Separated or Divorced Not Applicable

8. Occupation: Professional and Semiprofessional
 Skilled, Semiskilled & Unskilled worker Retired
 Housewives Students Others/ Not Classified.
 Unemployed

9. Details of Tobacco use:

Type	Age at Starting Tobacco use	Smokeless tobacco/bidi/cigarette years (Numbers of cigs/ <i>bidis</i> /sachets of tobacco used per day X No. of years of regular tobacco use)	Average numbers of cigarette/sachets amount of tobacco chewed per day in the last one month
Smokeless 1. 2. 3.			
Smoking 1. 2. 3.			

11. Expense per month on tobacco (Average month last year) Rs. _____
12. Alcohol use in the last 1 year: Daily Drinking
 Regular Drinking (3 or more times a week)
 Social Drinking (<3 times/ week)
 None
13. Average units per drinking day (30 ml spirit/60ml wine/1/2 mug beer= 1 unit) _____ Units
14. Others Substance use: Yes No If Yes specify substance: _____
15. Number of previous attempts at quitting which lasted for at least one month _____.
16. Apply Fagerstrom Test (Annexure 2)
17. Tobacco use in first \-degree relatives: Smoking Smokeless Both None
18. History & Symptoms suggestive of: Hypertension (yes, No) Diabetes (Yes, No)
 Heart Attack (Yes, No) Stroke (Yes, No)
 Asthma/ Bronchitis (Yes, No)
 Oral/ Lung Cancer (Yes, No)

Physical Examination

19. Weight _____ Kgs. 20. Height _____ cms. 21. Pulse _____ 22. BP Systolic _____ Diastolic _____
- 23 Oral Cavity: Leukoplakia Yes, No Erythroplakia Yes, No
 Sub mucous fibrosis Yes, No Denta Caries Yes, No

24. Significant current co-morbid disorder:

- a) _____
 b) _____
 c) _____

25. Intervention: Behavioral Counselling Behavioral Counselling+ Medication
 Behavioral Counselling + NRT

26. Follow up

	Date	No Change (or<50% reduction from baseline*)	Reduced use (50% or greater reduction from baseline*)	Stopped Use	Lost to follow up	Cotinine test (+ve or -ve) or not done
2 weeks						
4 weeks						
6 weeks						
3 months						
6 months						

Any other remarks:

(FAGERSTROM TEST)**Screening for nicotine dependence**

The Fagerstrom test for nicotine dependence is widely used as a screening test for the physical aspects of nicotine dependence. There are scales for both smoking and smokeless tobacco. Based on the score, the level of addiction can be low (score less than 4), medium (score 4-6) or high (score more than 6).

Fagerstrom test for smoking	Modified Fagerstrom test for smokeless tobacco users
1. How soon after you wake up do you smoke your first cigarette/bidi? Within 5 minutes 3 6 to 30 minutes 2 31 to 60 minutes 1 More than 60 minutes 0	1. How soon after you wake up do you use your first dip/chew? Within 5 minutes 3 6 to 30 minutes 2 31 to 60 minutes 1 After 60 minutes 0
2. Do you find it difficult to refrain from smoking in places where it is forbidden? Yes 1 No 0	2. How often do you intentionally swallow tobacco juice? Always 2 Sometimes 1 Never 0
3. Which cigarette/bidi would you hate to give up most? The first one in the morning 1 All others 0	3. Which tobacco chew would you hate to give up most? The first one in the morning 1 All others 0
4. How many cigarettes/bidis do you smoke per day? 10 or less 0 11-20 1 21-30 2 31 or more 3	4. How many cans/pouches of tobacco do you use per week? More than 3 2 1-3 1 Less than 1 0
5. Do you smoke more frequently in the first hours after waking up than during the rest of the day? Yes 1 No 0	5. Do you chew tobacco more frequently in the first hours after waking up than during the rest of the day? Yes 1 No 0
6. Do you smoke when you are so ill that you are in bed most of the day? Yes 1 No 0	6. Do you chew tobacco when you are so ill that you are in bed most of the day? Yes 1 No 0
Total score:	Total score:
Level of dependence: ➤ 6: high ➤ 4-6: moderate ➤ Less than 6: low	