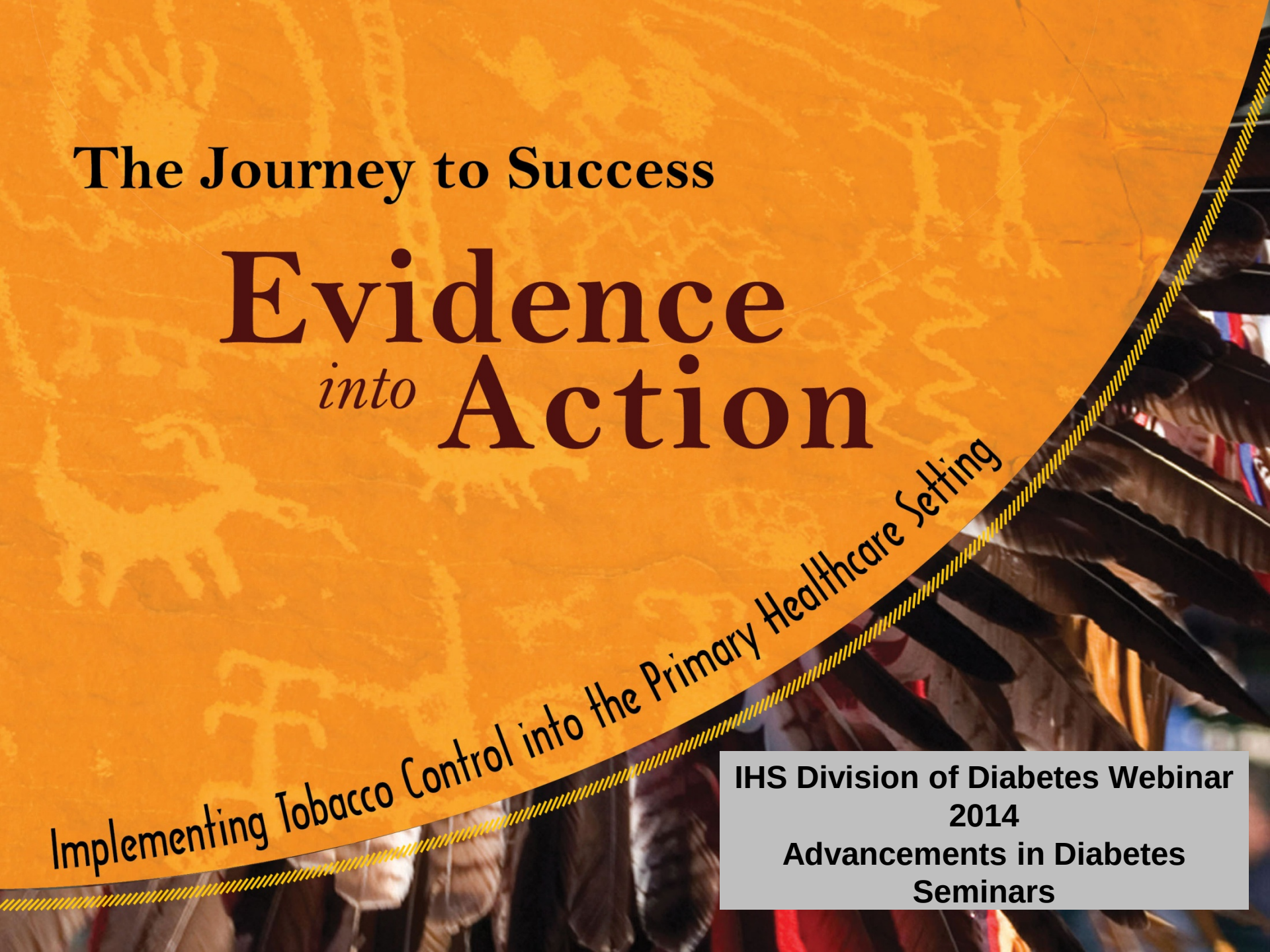
The Journey to Success

Evidence *into* Action

Implementing Tobacco Control into the Primary Healthcare Setting



IHS Division of Diabetes Webinar
2014
Advancements in Diabetes Seminars

Three Levels of Tobacco Interventions

- ***Minimal*** Intervention
- ***Brief*** Intervention
- ***Intensive*** Intervention

Brief Interventions

- 3 - 10 minutes
- Use ***5 A Model*** when counseling:
  - **A**sk **if they use tobacco**
  - **A**dvise **to quit**
  - **A**ssess **willingness to make quit attempt**
  - **A**ssist **in making quit attempt**
  - **A**rrange **for follow up contact**
- Pharmacotherapy

Intensive Interventions

- 4 or more visits with total contact time greater than (>) 40 minutes
- More effective than brief intervention
- Multiple providers
- Motivational Interviewing, problem solving, social support, coping skills
- Pharmacotherapy

Ask and Advise

ASK:

- Implement a system to identify all tobacco users in your healthcare setting.
- Ask **EVERY** patient at **EVERY** visit about tobacco use and exposure and document status.
- Keep it simple such as, “Have you ever used commercial tobacco?”

ADVISE:

- Your patient in a clear, strong, personalized manner to stop using commercial tobacco.

Assist and Arrange Follow Up

If your patient is **NOT READY** to quit now:

- conduct a *Brief **Motivational** Intervention*
- provide information for the patient
- repeat the message at each encounter

- If your patient is **READY to QUIT** now:
  - conduct a *Brief **Cessation** Intervention*
  - help the patient develop a Quit Plan
  - refer the patient for counseling and follow up

Assist and Arrange
If Patient is *Not Ready* to Quit

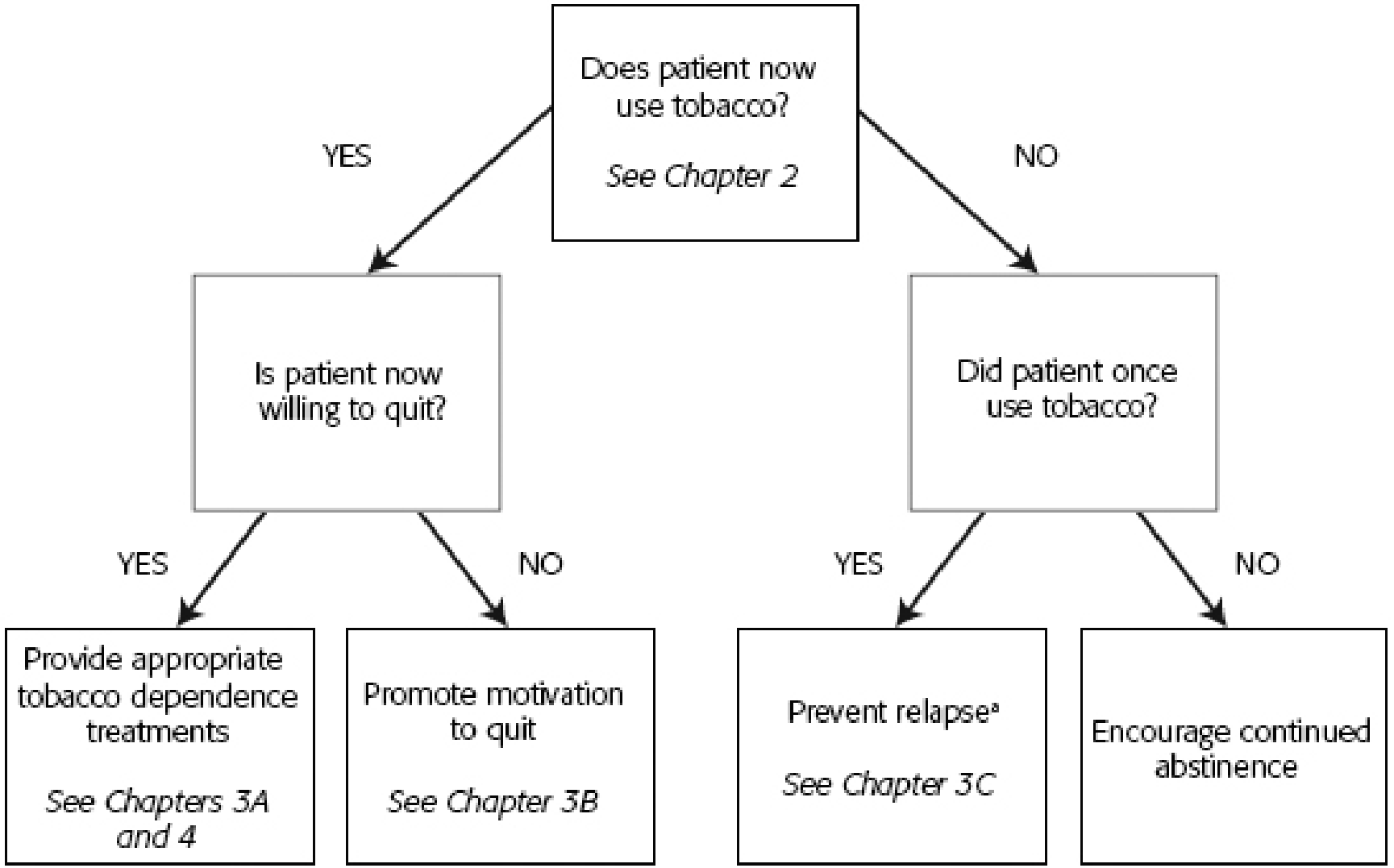
Provide *a brief Motivational Intervention utilizing* the “5 R’s”:

- **Relevant** Information
- **Risks** of Continued Tobacco Use
- **Rewards** of Cessation
- **Roadblocks** to Quitting
- **Repeat** the Message at Each Visit

Assist and Arrange
If Patient *Is* Ready to Quit

Develop a Quit Plan:

- Set a **Quit Date**
- Provide Intra-Treatment and help patient obtain Extra-Treatment **Social Support**
- Provide **Practical Counsel**ing (problem-solving and anticipate challenges)
- Recommend use of **Cessation Medication** if no contraindications
- Offer **Self-Help Materials**
- Refer to **Intensive Services**



[a]Relapse prevention interventions are not necessary in the case of the adult who has not used tobacco for many years.

Efficacy of Physician's Advice

Compared to no advice:

- Physician's advice to quit of three minutes or less increased quit rates 30%.

PHS 2008, pg 84

Healthcare Professional Advice *Matters*

Patients report that physician advice is the single most important motivating factor.

PHS 2008, pg 87

Efficacy of Healthcare Professional (HCP) Interventions

Compared to no provider:

- Self Help increased quit rates 10%
- Other HCP (e.g., nurse, dentist, counselor, psychologist, pharmacist, health educator) increased quit rates 70%.
- Physician increased quit rates 120%.

PHS 2008, pg 88

Efficacy of Healthcare Professional (HCP) Interventions (cont.)

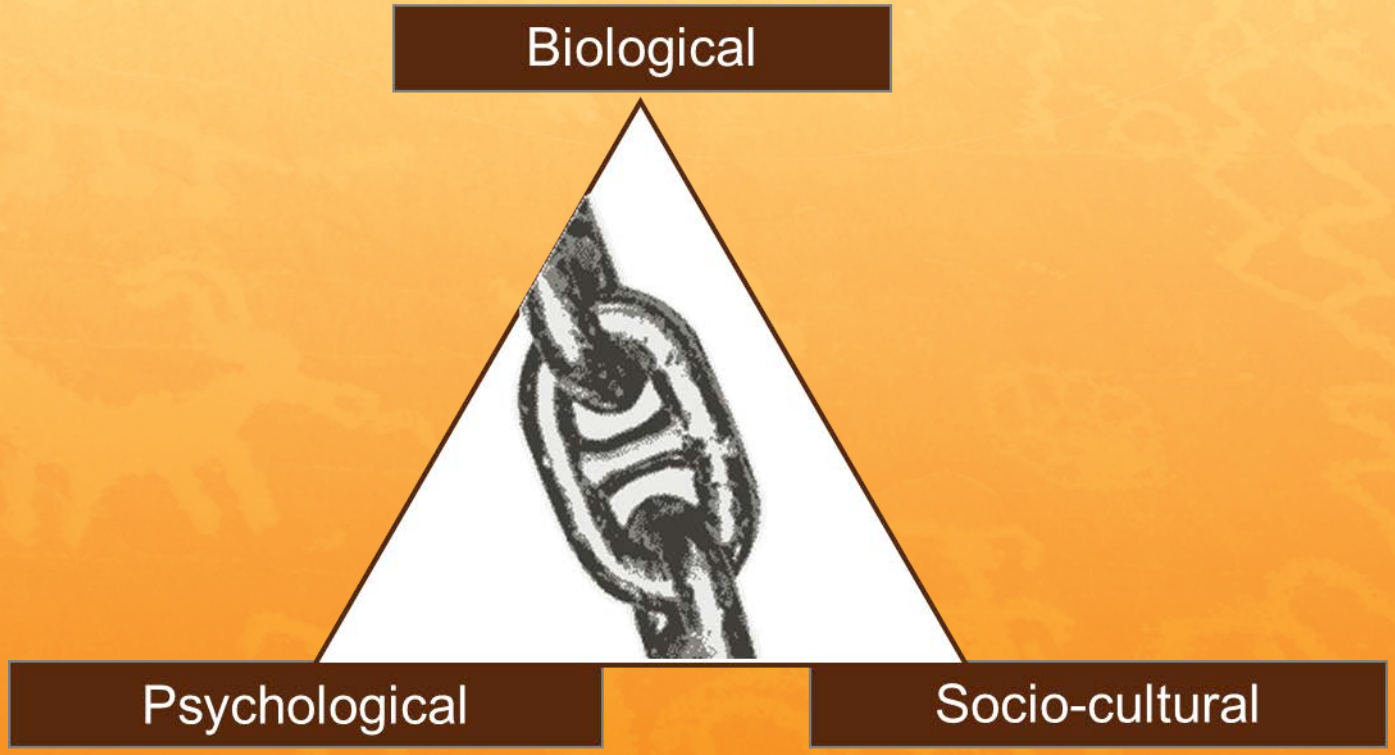
Cessation Rates by Number of Healthcare Providers

Compared to No Provider:

- 1 HCP=increased 80%
- 2 HCP=increased 150%
- Three or more=increased 140%

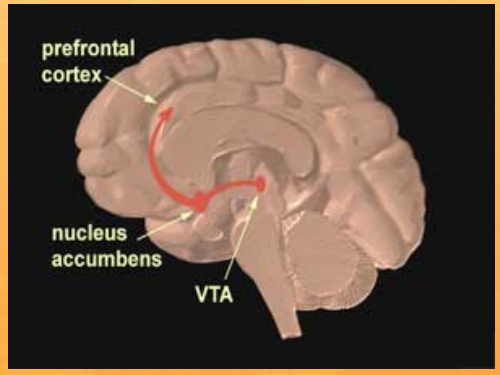
PHS 2008. pg 88

“Three Link Chain” of Nicotine Dependence



Nicotine Dependence

- Nicotine was classified as an addictive drug by the FDA in 1994.
- Most regular tobacco users are addicted to nicotine.
- The dependence-producing properties of nicotine are believed to be mediated by nicotinic acetylcholine receptor located in the ventral tegmental area (VTA) of the brain.



Nicotine Receptors, Tolerance, Withdrawal, and Craving

- Tolerance typically develops after longer-term nicotine use.
- A drop in nicotine level, in combination with up-regulation and decreased sensitivity of nicotinic receptors, can result in **withdrawal symptoms** and **cravings**.
- **Nicotine withdrawal symptoms** include depressed mood, insomnia, irritability, frustration, anger, anxiety, difficulty concentrating, restlessness, decreased heart rate, increased appetite and weight gain.

Socio-Cultural Factors

- Traditional tobacco plays an important role in Native American society.
- When discussing commercial tobacco use with patients, be aware of educational differences, family relations, learning styles, age, language, religious beliefs, and cultural norms.

Psychological Factors

- Reinforced conditioned drug-taking behavior, not only physical dependence, is central to the concept of addiction.
- As nicotine dependence develops, tobacco use is perpetuated by a corresponding set of emotions and behaviors.
- *People use nicotine for mood regulation, stress management, weight control, and improved concentration.*

Types of Counseling and Behavioral Therapy

- Practical Counseling
  (problem solving skills/skills training/stress management)
- Intra-treatment support
  (support from the clinician)
- Extra-treatment support
  (support from the smoker's environment)
- Aversive smoking procedures
  (rapid smoking, rapid puffing, other exposure)

PHS 2008 pg 96

Types of Counseling and Behavioral Therapies

Compared to no treatment:

- Social support during direct contact with a clinician increased quit rates 30%.
- Social support outside of treatment increased quit rates 50%
- Problem solving/skills training increased quit rates 50%.
- Aversive Smoking increased quit rates 70%.
- Rapid Smoking increased quit rates 100%

PHS 2008, pg 97

Types of Counseling and Behavioral Therapies (cont.)

Compared to no treatment:

- Negative affect increased quit rates 20%
- Cigarette fading increased quit rates 10%
- Relaxation/breathing increased quit rates 0%
- Contingency contracting increased quit rates 0%
- Weight/diet increased quit rates 0%

PHS 2008. pg 97

Intensity of Treatment by Healthcare Professionals

Compared to no contact:

- Minimal contact (less than (<) 3 minutes) increased quit rates 30%.
- Low Intensity counseling (3-10 minutes) increased quit rates 60%.
- Higher Intensity counseling (greater than (>) 10 minutes) increased quit rates 130%.

PHS 2008, pg 84

Duration of Treatment

Total contact time and increased quit rates

- 1 - 3 minutes 40%
- 4 - 30 minutes 90%.
- 31 - 90 minutes 200%
- 91 - 300 minutes 220%
- Greater than (>) 300 minutes 180%

PHS 2008, pg 85

Number of Treatment Sessions

Compared to one or fewer sessions:

- 2 - 3 sessions increased quit rates 40%.
- 4 - 8 sessions increased quit rates 90%.
- More than 8 sessions only increased quit rates 130%.

PHS 2008, pg 86

Formats for Behavioral Treatment with Documented Success*

- Self-help
- Telephone and other distance counseling
- Individual counseling
- Group counseling

*Outcomes are related to intensity, frequency and duration of treatment.

Cessation Rates Associated with Formats of Behavioral Therapy

- No intervention 10.8%
- Self-help 12.3%
- Proactive telephone counseling 13.1%
- Individual counseling 16.8%
- Group counseling 13.9%

PHS 2008, pg 90

Medication and Counseling

- Compared to Medication alone (21.7%)
  - Medication plus counseling = 27.6% (40% increase)

- Compared to Counseling alone (14.6%)
  - Medication plus counseling = 22.1% (70% increase)

PHS 2008, pg 102-103

Relapse Prevention

Quitting is a process.

Whether this is your first time to quit or fifth,

give yourself the permission to go back to your doctor, pharmacist, or counselor

if you need to try and quit again.

Motivational Strategies

- The Five R's to enhance motivation – for patients unwilling to quit at this time:
  - Relevance: Tailor advice and discussion to each patient. (e.g. cough, asthma, child's ear infections)
  - Risks: Outline risks of continued smoking.
  - Rewards: Outline benefits of quitting.
  - Roadblocks: Draw on previous quit attempts.
  - Repetition: Reinforce motivational message at every visit.

Relevance

- Make the information relevant to the patient's situation.
- A client who complains of chronic cough should be told that it may be related to smoking and may resolve if he or she quits.
- A smoker who complains that her children have frequent ear infections should be told that her smoking may be contributing to her children's illness.

Risks

- Ask the patient to identify potential negative consequences of using tobacco.
- Suggest and highlight those risks that seem most relevant to the patient.

Risks (cont.)

Short-Term Risks:

- Stained teeth, halitosis, exacerbation of asthma, impotence, infertility

Long-Term Risks:

- Heart attacks and strokes, lung and other cancers
- Chronic bronchitis and emphysema

Risks (cont.)

Environmental Risks:

- Increased risk of lung cancer in spouse and children
- Increased risk for children
  - Asthma and respiratory infection
  - Otitis media
  - Higher rates of tobacco use in children of smokers as compared to children of non-smokers

Rewards

- Ask the patient to identify potential benefits of quitting tobacco.
- Suggest and highlight those benefits that seem most relevant to the patient.

Rewards (cont.)

- Improved health
- Food will taste better
- Improved sense of smell
- Save money
- Feel better about yourself
- Home, car, and breath will smell better

Quit Smoking And...

20 Minutes Later:
Your pulse rate and blood pressure drop to the levels they were before you started smoking.

10 Hours Later:
The levels of oxygen and carbon dioxide in your blood return to normal.

3 Days Later:
Your lung capacity begins to increase.

4 Years Later:
You will reduce your risk of heart attack to that of a nonsmoker.

10 Years Later:
You will reduce your chances of dying of lung cancer to that of a nonsmoker.

"Give Yourself a Break"

Roadblocks

Identify and address barriers to cessation

- Withdrawal symptoms
- Fear of failure
- Weight gain
- Lack of support
- Depression
- Enjoyment of tobacco

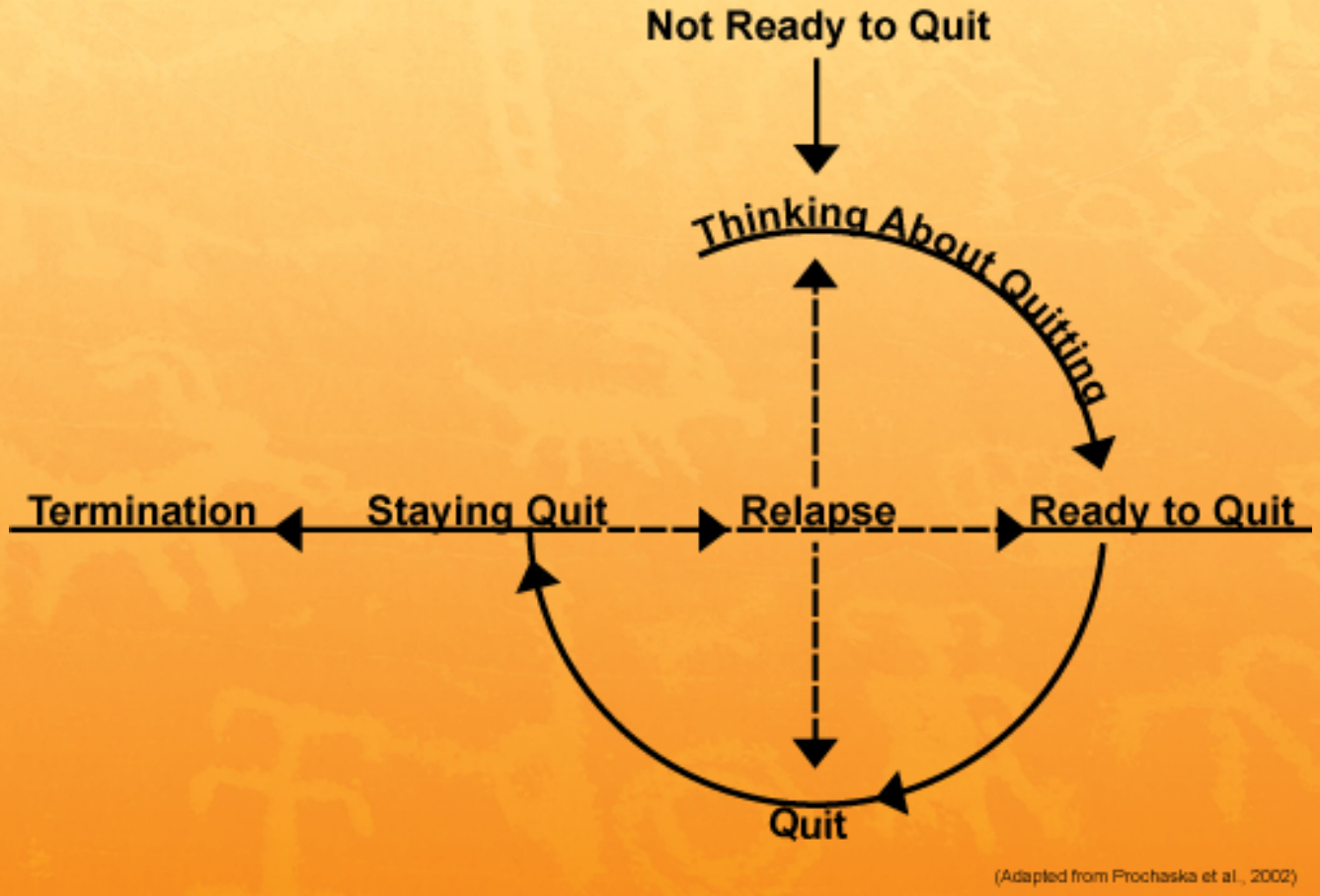
Repetition

- Repeat the motivational intervention every time the patient visits the clinical setting.

- Inform the patient that you will continue to ask about their tobacco use and advise them to quit at each healthcare visit.

Assess Readiness to Change

"Are you ready to set a Quit Date in the next 30 days?"



Preventing Relapse

- Provide positive reinforcement, encouragement
- Discuss process of relapse- difficult situations/events
- Assist patient develop strategies for handling—avoidance
- Provide self-help materials

Recommendation for Pharmacotherapy

- Use of pharmacotherapy for smoking cessation doubles long term quit rates compared to placebo use.
- All patients attempting to quit should be encouraged to use effective pharmacotherapy for smoking cessation except in the presence of special circumstances.

Medication for Treating Tobacco Dependence

- By using the pharmacotherapies found to be effective, clinicians can double or triple their patients' chances of abstinence.
- Pharmacotherapies are effective for a broad range of smokers, not just "hardcore" smokers.

PHS 2000

Medication for Treating Tobacco Dependence (cont.)

- Pharmacotherapies are effective at low as well as high levels of psychosocial treatment intensity.
- Therefore, clinicians should recommend effective psychosocial treatments such as counseling, in addition to pharmacotherapy, to all patients for whom it is appropriate.

FDA Approved Nicotine Replacement Medications for Tobacco Cessation

Nicotine Gum

- Efficacy 2mg: Odds ratio 1.5 (n=13 studies), Abstinence 23.7%
- Efficacy 4mg: Odds ratio 2.5 (n=4 studies), Abstinence 22.8%

Nicotine Patch

- Efficacy: Odds ratio 1.9 (n=27 studies), Abstinence 17.7%

Nicotine Inhaler

- Efficacy: Odds ratio 2.5 (n=4 studies), Abstinence 22.8%

Nicotine Nasal Spray

- Efficacy: Odds ratio 2.7 (n=3 studies), Abstinence 30.5%

Nicotine Lozenge

- Efficacy 2mg: Odds ratio 2.0 (n=1 study), Abstinence 24.2%
- Efficacy 4mg: Odds ratio 2.8 (n=1 study), Abstinence 23.6%

FDA Approved Non-Nicotine Replacement Medications for Tobacco Cessation

Zyban® (bupropion sustained release)

- Efficacy: Odds ratio 2.1 (n=2 studies), Abstinence 23.0%

Chantix ® (varenicline)

- Efficacy: Odds ratio 2.4 (n = 2 studies), Abstinence 22.5%

Nicotine Replacement Therapy Dosing

CONTRAINDICATIONS: post MI, unstable angina, severe arrhythmias, category D in pregnancy

- **Nicotine Gum** 2, 4 mg OTC -- One piece every 1-2 hr for 6 weeks, then taper. Chew and moisten, then park
- **Nicotine Patch** 7, 14, 21 mg/24hr or 5, 10, 15 mg/16hr OTC. Highest dose for 4-6 weeks, then taper
- **Nicotine Inhaler** 4 mg per cartridge, Rx. 6-16 cartridges daily for 3-6 weeks, then taper. Puff frequently, 80 puffs over 20 minutes per cartridge
- **Nicotine Nasal Spray** 0.5 mg per spray, Rx. 1-2 sprays each nostril every hr for 4-8 weeks, then taper
- **Nicotine Lozenge** 2, 4 mg OTC. One piece every 1-2 hr for 6 weeks, then taper. Moisten, then park

Non-Nicotine Replacement Therapy Dosing

Bupropion SR: First non-nicotine replacement drug approved by FDA for tobacco cessation.

- ***CONTRAINDICATIONS***: Seizure disorder, anorexia/bulimia, MAO inhibitor
- **Dosage**: 150mg SR q am x 3 days, then twice daily
  - Discontinue tobacco use after 7-14 days, continue medication for 7-12 weeks

Varenicline: First non-nicotine replacement drug created specifically for tobacco cessation, approved FDA 2006.

- ***CONTRAINDICATIONS***: Not recommended if pregnant or nursing or are under age 18. Use with caution in patients with compromised renal function.
- **Dosage**: 0.5 mg daily x 3 days, 0.5 mg twice daily x 4 days, then 1 mg twice daily
  - Discontinue tobacco use after 7-14 days, continue medication for 12 weeks, if abstinent recommend additional 12 weeks

Nicotine Content of Common Tobacco Products

- 1 cigarette equals ~ 1 mg nicotine
- 1 dip chewing tobacco equals ~ 3 - 4 mg nicotine
- 1 cigar equals ~10 - 20 mg nicotine
- 1 bidi or kretek equals ~ 2 - 3 mg nicotine

Nicotine Gum

Nicotine Gum (*Nicotine Polacrilex*)	
Nicotine gum was first approved by the FDA in 1984 and became available without a prescription in 1996. A person will need to stop using tobacco completely before using the nicotine gum.	
Dosage	The gum is available in 2 mg and 4 mg (per piece) strengths. The recommended dosages are: » < 25 cigarettes/day: 2-mg » ≥ 25 cigarettes/day: 4-mg » Weeks 1-6: 1 piece every 1-2 hours » Weeks 7-9: 1 piece every 2-4 hours » Weeks 10-12: 1 piece every 4-8 hours » No more than 24 pieces/day
Duration	Nicotine gum should be used on a fixed schedule (at least one piece every 1 to 2 hours) for 6 to 12 weeks, then tapered off.
Efficacy	Use of nicotine gum increases the odds of quitting by 80% as compared to placebo (Fiore et al., 2008).
Precautions	» Tobacco users in any of the special circumstances groups should consult with a physician before using nicotine gum. » Extensive dental work/dentures » TMJ disease » Stop use if signs of nicotine toxicity develop. Symptoms of nicotine overdose include nausea, vomiting, dizziness, weakness, and rapid heartbeat.
Side Effects	» Mouth soreness » Jaw ache » Hiccups » Nausea/vomiting » Headache » Indigestion Side effects usually transient and mild, often relieved by correcting chewing technique. These effects are generally mild, subside over time, and often can be alleviated by correcting the chewing technique.
Instructions for Use	STOP ALL SMOKING » Chew until peppery or minty taste released, "park" between cheek and gum 1-5 minutes, then repeat » Park in different areas of the mouth » Use one piece no longer than 30 minutes » No eating or drinking 15 minutes before and during use (decreases nicotine absorption) » Fixed dosing for 1-3 months may be more useful than ad libitum

(Adapted from Fiore et al., 2008; Physicians' Desk Reference [PDR], 2005; PDR, 2007)

Nicotine Patch

Nicotine Patch
(Transdermal Nicotine System)

The nicotine patch was approved by the FDA in 1991 and became available without a prescription in 1996. A person will need to stop using tobacco completely before using the nicotine patch.

Dosage	The type and strength of the patch should be selected according to individual patient characteristics, such as previous experience with the nicotine patch, body weight, number of cigarettes smoked per day, and medical history.

16 hour	24 hour
» 15-mg x 6 wks, 10-mg x 2 wks, 5-mg x 2wks » Remove before sleeping » Only releases nicotine for 16 hours	» 21-mg x 6 wks, 14-mg x 2 wks, 7-mg x 2wks » 22-mg x 4 wks, 11-mg x 4 wks » May remove CQ patch after 16 hours

Duration	The nicotine patch may be used for 10 weeks. After approximately 6 weeks of treatment, the patient may begin using a lower strength patch and then taper off by reducing the dosage every 2 weeks until the patch is discontinued completely..
Efficacy	Use of nicotine patch doubles the odds of quitting as compared to placebo (Fiore et al., 2008). There is no difference in efficacy between 16-hour and 24-hour patches.
Precautions	» Tobacco users in any of the special circumstances groups should consult with a physician before using the nicotine patch. » Extensive skin disease » Hypersensitivity to patch adhesive » Stop use if signs of nicotine toxicity develop. Symptoms of nicotine overdose include nausea, vomiting, dizziness, weakness, and rapid heartbeat.
Side Effects	» Cutaneous hypersensitivity » Headache » Sleep disturbances/insomnia/abnormal dreams (w/24-hr use) » Approximately 50% of patients using the nicotine patch will experience local skin irritation. Rotate patch sites to reduce skin irritation. Less than 5% of patients using the nicotine patch must discontinue use as a result of skin irritation.
Instructions for Use	STOP ALL SMOKING » After waking up on quit day, apply patch to relatively hairless area between waist and neck. » Apply new patch at start of each day » Rotate patch site to minimize local skin irritation » If sleep disturbance occurs with 24-hour patch, remove patch at bedtime or try 16-hour patch.

(Adapted from Fiore et al., 2008; Physicians' Desk Reference [PDR], 2005; PDR, 2007)

Nicotine Lozenge

Nicotine Lozenge *(Nicotine Polacrilex)*	
The nicotine lozenge was first approved by the FDA in 2002. A person will need to stop using tobacco completely before using the nicotine lozenge.	
Dosage	» If smoke>30 mins after waking: 2-mg » If smoke<30 mins after waking: 4-mg » Weeks 1-6: 1 lozenge every 1-2 hours » Weeks 7-9: 1 lozenge every 2-4 hours » Weeks 10-12: 1 lozenge every 4-8 hours » Do not use more than 5 lozenges in 6 hours. » Do not use more than 20 lozenges per day
Duration	The patient should follow a 12-week schedule (lozenges should not be used for more than 12 weeks).
Efficacy	Use of the nicotine lozenge doubles the odds of quitting as compared to placebo (Shiffman et al., 2002).
Precautions	» Tobacco users in any of the special circumstances groups should consult with a physician before using the nicotine lozenge. » Stop use if signs of nicotine toxicity develop. Symptoms of nicotine overdose include nausea, vomiting, dizziness, weakness, and rapid heartbeat. » Contains phenylalanine 3.4-mg per lozenge
Side Effects	» Insomnia » Nausea » Hiccups » Coughing » Headache » Heartburn These effects are generally mild and self-limiting. If side effects do not subside, or if they increase in severity, patients should discontinue use and consult a physician.
Instructions for Use	STOP ALL SMOKING » Suck lozenge until fully dissolved (20-30 minutes). There may be a warm tingling sensation. The lozenge should be occasionally moved from one side of the mouth to the other until dissolved completely. » Consume only one lozenge at a time » No eating or drinking 15 minutes before and during use (decreases nicotine absorption)

(Adapted from Fiore et al., 2008; Physicians' Desk Reference [PDR], 2005; PDR, 2007)

Nicotine Nasal Spray

Nicotine Nasal Spray	
The FDA approved the nicotine nasal spray in 1996 for prescription only. A person will need to stop using tobacco completely before using nicotine nasal spray.	
Dosage	A single dose of two sprays (one in each nostril) from the inhaler is equal to 1 mg of nicotine. » One dose = one 0.5-mg spray to each nostril (1-mg total) » Weeks 1-8: 1-2 doses/hour » Weeks 9-14: gradually reduce dosage and discontinue » Maximum: 40 doses/day (5 doses/hour)
Duration	Nicotine nasal spray may be used for 3–6 months.
Efficacy	Use of nicotine nasal spray nearly triples the odds of quitting as compared to placebo (Fiore et al., 2008).
Precautions	» Tobacco users in any of the special circumstances groups should consult with a physician before using nicotine nasal spray. » Severe reactive airways disease » People using nicotine nasal spray have the potential to become dependent; approximately 15–20% of patients report using nicotine nasal spray for longer periods than recommended. » Stop use if signs of nicotine toxicity develop. Symptoms of nicotine overdose include nausea, vomiting, dizziness, weakness, and rapid heartbeat.
Side Effects	» Moderate to severe nasal irritation in first few days of use (persistent sneezing, coughing, or runny nose and watery eyes) » Some irritation may persist for weeks » Nasal congestion » Throat irritation » Transient changes in taste and smell » People with a history of nasal irritation and sinus allergies should not use nicotine nasal spray. People who experience severe persistent sneezing, coughing, or runny nose and watery eyes after the first 2 days of using nicotine nasal spray should discontinue use and consult a physician.
Instructions for Use	STOP ALL SMOKING » The spray is best delivered with the head tilted slightly back » Avoid swallowing, sniffing, or inhaling during dosing to minimize side effects

(Adapted from Fiore et al., 2008; Physicians' Desk Reference [PDR], 2005; PDR, 2007)

Nicotine Inhaler

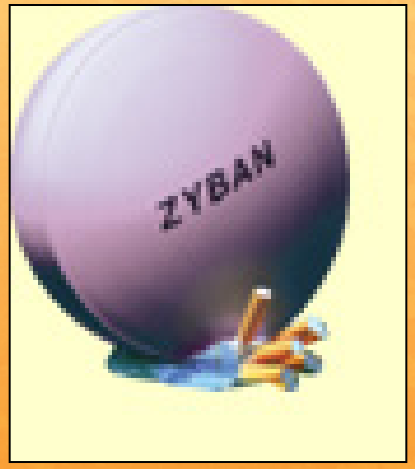
Nicotine Inhaler	
The FDA approved the nicotine inhaler in 1997 for prescription only. A person will need to stop using tobacco completely before using the nicotine inhaler.	
Dosage	» One dose = one puff or inhalation » One cartridge delivers 4-mg nicotine over approximately 80 inhalations (about 3-5 cigarettes) » Weeks 1 to 12: 6-16 cartridges/day
Duration	Treatment is recommended for up to 6 months. Use should be tapered off gradually during the final 3 months of the treatment.
Efficacy	Use of the nicotine inhaler increases the odds of quitting by 150% as compared to placebo (Fiore et al., 2008).
Precautions	» Tobacco users in any of the special circumstances groups should consult with a physician before using the nicotine inhaler. » Stop use if signs of nicotine toxicity develop. The symptoms of nicotine overdose include nausea, vomiting, dizziness, weakness, and rapid heartbeat.
Side Effects	» Around 40% of patients using the nicotine inhaler will present with local irritation (redness and/or swelling) of the mouth and throat. » Coughing (Approx. 32% of patients) » Rhinitis (Approx. 23% of patients) These symptoms are generally mild and decrease in severity over time. People who experience severe mouth or throat irritation while using the nicotine inhaler should discontinue use and consult a physician.
Instructions for Use	STOP ALL SMOKING People should use the nicotine inhaler any time that they begin to experience a craving for a cigarette or begin to feel other withdrawal symptoms. » *To use the inhaler*: The plastic mouthpiece should be separated into its two parts. One nicotine cartridge should be placed into the mouthpiece. The mouthpiece should be reassembled, pushing the two parts back together to break the seal on either end of the cartridge. The patient should place the end of the mouthpiece in his or her mouth and inhale. » Each cartridge provides 20 minutes of active puffing–approximately 80 draws or about 300 shallow inhalations. » Decreased nicotine delivery in low ambient temperatures (<40F): keep cartridges in pocket to keep warm » No eating or drinking 15 minutes before use and during use (decreases nicotine absorption) » Best effects with frequent puffing

(Adapted from Fiore et al., 2008; Physicians' Desk Reference [PDR], 2005; PDR, 2007)

Bupropion SR

Bupropion SR (Zyban®)	
Bupropion SR is the first non-nicotine replacement drug approved by the FDA for smoking cessation (1997). It is available by prescription only. Mechanism of action is presumed to be mediated through dopaminergic and/or noradrenergic mechanisms.	
Dosage	The recommended dose is 150 mg once daily for 3 days. Dosage then increases to 150 mg twice a day for 4 days (after which the patient should stop all tobacco use) and continue at this level for the remainder of the treatment.
Duration	Treatment with bupropion SR is recommended for 7 to 12 weeks.
Efficacy	Use of bupropion SR doubles the odds of quitting as compared to placebo (Fiore et al., 2008).
Precautions	» Tobacco users in any of the special circumstances groups should consult with a physician before using bupropion SR. » Contraindications: history of seizure disorder, eating disorder, serious head trauma, current alcoholism or alcohol abuse, concurrent use of another form of bupropion, use of MAO inhibitor in past 14 days. » Bupropion allergy » Seizure risk: 1 out of 1000 users » Bupropion SR is not currently recommended as a tobacco cessation treatment for pregnant women and adolescents.
Side Effects	» Insomnia » Dry mouth » Shakiness » Rash If insomnia is problematic, physicians should recommend taking the first dose earlier in the morning, so that the second dose (8 hours after the first dose) occurs earlier in the day.
Instructions for Use	» Start treatment with bupropion SR 1-2 weeks before quit date » Continue 150-mg b.i.d. for 7-12 weeks after quit date » If insomnia marked, take PM dose in afternoon » Use alcohol only in moderation

(Adapted from Fiore et al., 2008; Physicians' Desk Reference [PDR], 2005; PDR, 2007)



Varenicline

Varenicline (Chantix™)	
Varenicline is a partial nicotinic acetylcholine receptor agonist. It was designed to bind to nicotine receptors in the brain and ease withdrawal symptoms in adult tobacco users. Varenicline blocks the effects of nicotine from cigarettes if the patient resumes smoking.	
Dosage	» Day 1 to Day 3: white tablet (0.5-mg), 1 tablet each day » Day 4 to Day 7: white tablet (0.5-mg), twice a day (1 in the morning and 1 in the evening) » Day 8 to end of treatment: blue tablet (1-mg), twice a day (1 in the morning and 1 in the evening) » Varenicline should be taken after eating with a full glass (8 ounces) of water.
Duration	Treatment with varenicline is recommended for 12 weeks. For patients who have quit smoking at 12 weeks, an additional 12 weeks of varenicline is recommended to further increase the likelihood of long-term abstinence (Tonstad et al., 2006).
Efficacy	Use of varenicline 3 times to nearly 4 times greater compared to placebo depending on which time point abstinence is assessed (Gonzales et al., 2006; Jorenby et al., 2006).
Precautions	» Tobacco users in any of the special circumstances groups should consult with a physician before using varenicline. » History of kidney problems or kidney failure » History of psychiatric illness » Advise patients and caregivers that the patient should stop taking varenicline and contact a healthcare provider immediately if agitation, depressed mood, or changes in behavior that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior. *Note:* Safety and efficacy not established in patients with serious psychiatric illness.
Side Effects	» Nausea » Changes in dreaming » Constipation, Gas » Vomiting *Note:* Nausea was reported by approximately 30% of patients treated with varenicline 1 mg twice a day, with approximately a 3% discontinuation rate during 12 weeks of treatment. Nausea was generally described as mild or moderate and often transient. Patients who cannot tolerate nausea may have the dose lowered temporarily or permanently.
Instructions for Use	» Start varenicline treatment one week before quit date » Varenicline should be taken after eating with a full glass (8 ouces) of water

(Adapted from Fiore et al., 2008; Physicians' Desk Reference [PDR], 2005; PDR, 2007)

Varenicline & Bupropion Boxed Warning

Neuropsychiatric Symptoms

- Changes in behavior
- Hostility
- Agitation
- Depressed mood or depression
- Suicidal thoughts or behavior
- Worsening of preexisting psychiatric illness

Review risks and benefits of smoking cessation and drug therapy

Source: U.S. Food and Drug Administration

Pharmacotherapy at 6 Months

Pharmacotherapy	Estimated Abstinence Rate (95% CI)	Estimated Odds Ratio (95% CI)
Placebo	**13.8**	**1.0**
Bupropion SR	**24.2 (22.2-26.4)**	**2.0 (1.8-2.2)**
Nicotine Gum (6-14 wks)	**19.0 (16.5-21.9)**	**1.5 (1.2-1.7)**
Nicotine Gum (>14 wks)	**26.1 (19.7-33.6)**	**2.2 (1.5-3.2)**
Nicotine Lozenge (2 mg)	**24.2[a]**	**2.0 (1.4-2.8)**
Nicotine Patch (6-14 wks)	**23.4 (21.3-25.8)**	**1.9 (1.7-2.2)**
Varenicline (1 mg)	**25.4 (19.6-33.6)**	**2.1 (1.5-3.0)**
Varenicline (2 mg)	**33.2 (28.9-37.8)**	**3.1 (2.5-3.8)**
Nicotine Patch (18-24 wks) + PRN NRT (gum, lozenge, spray x 26-52 wks)	**36.5 (28.6-45.3)**	**3.6 (2.5-5.2)**
Nicotine Patch + Bupropion SR	**28.9 (23.5-35.1)**	**2.5 (1.9-3.4)**
Nicotine Patch + Nortriptyline	**27.3 (17.2-40.4)**	**2.3 (1.3-4.2)**
Nicotine Patch + Nicotine Inhaler	**25.8 (17.4-36.5)**	**2.2 (1.3-3.6)**

Sources: USPHS Guideline 2008

Clonidine

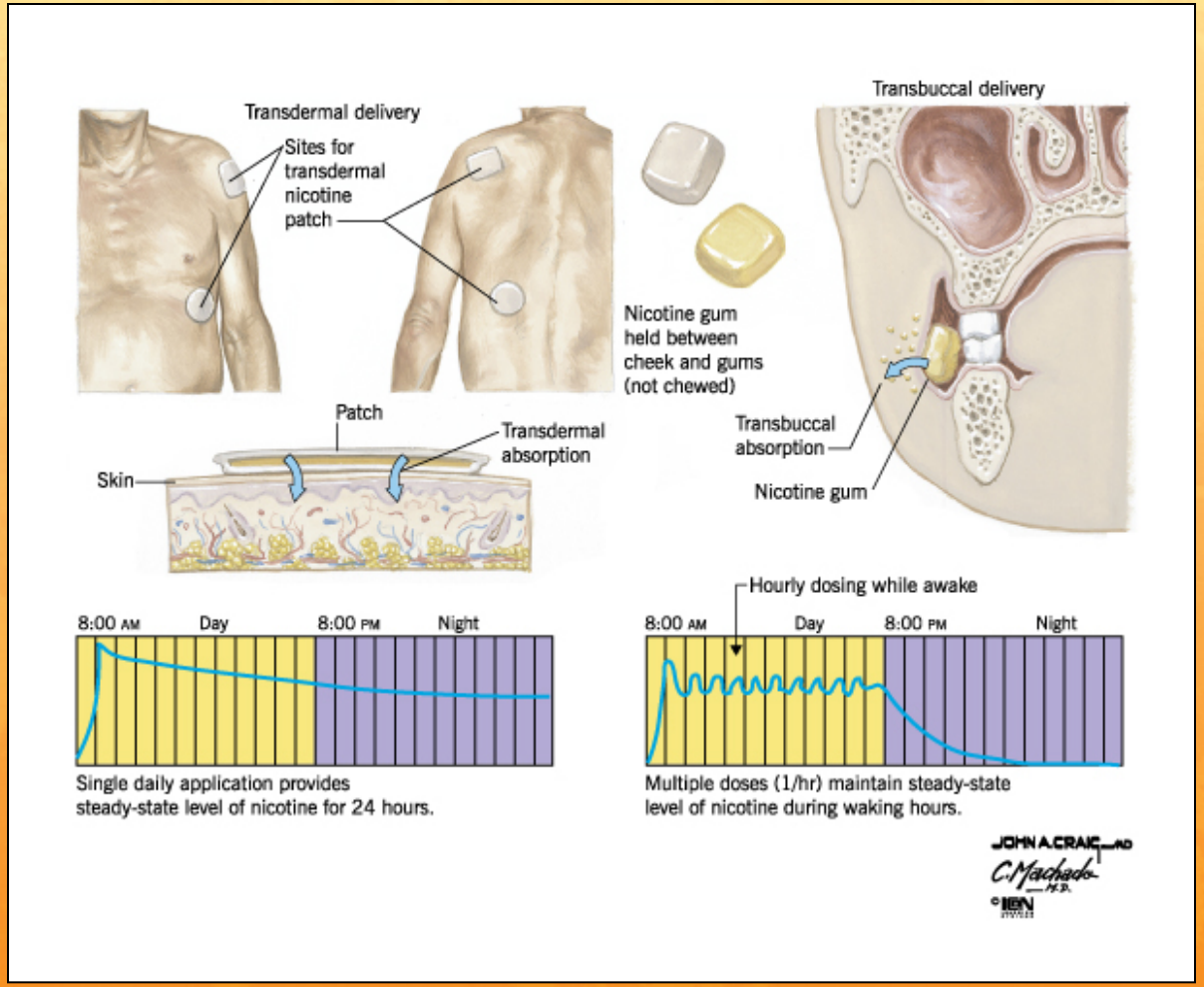
Clonidine	
Clonidine is appropriate as a second-line treatment for smoking cessation. Clonidine is not approved by the FDA for the treatment of tobacco dependence.	
Dosage	Doses used in various clinical trials have varied from 0.15–0.75 mg/day orally to 0.10–0.20 mg/day transdermal patch, without a clear dose-response relation to cessation.
Duration	Patients should begin taking clonidine shortly (3 days) prior to or on the quit date. Duration of treatment ranges from 3 to 10 weeks.
Efficacy	The use of clonidine doubles the odds of quitting as compared to placebo.
Precautions	» As an antihypertensive medication, clonidine can be expected to lower blood pressure in most patients. Monitoring blood pressure is therefore recommended during treatment. » Failure to gradually reduce dosage over 2–4 days before discontinuation may result in rebound hypertension.
Side Effects	The most commonly reported side effects of clonidine are dry mouth, drowsiness, dizziness, sedation, and constipation.
Instructions for Use	Initial dosing is typically 0.10 mg twice daily orally, or 0.10 mg/day transdermal patch. Increase by 0.10 mg/day per week as needed.

(Adapted from Fiore et al., 2008; Physicians' Desk Reference [PDR], 2005; PDR, 2007)

Nortriptyline

Nortriptyline	
Nortriptyline is appropriate as a second-line treatment for smoking cessation. Nortriptyline is not approved by the FDA for the treatment of tobacco dependence.	
Dosage	» Dosage begins 10–28 days before the quit date. » Initiate treatment at 25 mg/day, gradually increasing to 75–100 mg/day. Blood levels of nortriptyline may be monitored.
Duration	Duration of treatment in smoking cessation is approximately 12 weeks.
Efficacy	Use of nortriptyline triples the odds of quitting as compared to placebo.
Precautions	Use with extreme caution in patients with cardiovascular disease.
Side Effects	The most commonly reported side effects are sedation, urinary retention, light-headedness, dry mouth, blurred vision, and hand tremor.
Instructions for Use	Patients should begin taking nortriptyline 10–28 days before the quit date to allow the medication to reach a steady state in the blood.

(Adapted from Fiore et al, 2008; Physicians' Desk Reference [PDR], 2005; PDR, 2007)


Transdermal delivery
Sites for transdermal nicotine patch
Patch
Transdermal absorption
Skin
8:00 AM
Day
8:00 PM
Night
Single daily application provides steady-state level of nicotine for 24 hours.
Nicotine gum held between cheek and gums (not chewed)
Transbuccal delivery
Transbuccal absorption
Nicotine gum
Hourly dosing while awake
8:00 AM
Day
8:00 PM
Night
Multiple doses (1/hr) maintain steady-state level of nicotine during waking hours.
JOHN A. CRAIG, M.D.
C. Machado, M.D.

Special Circumstances to Consider with Medication

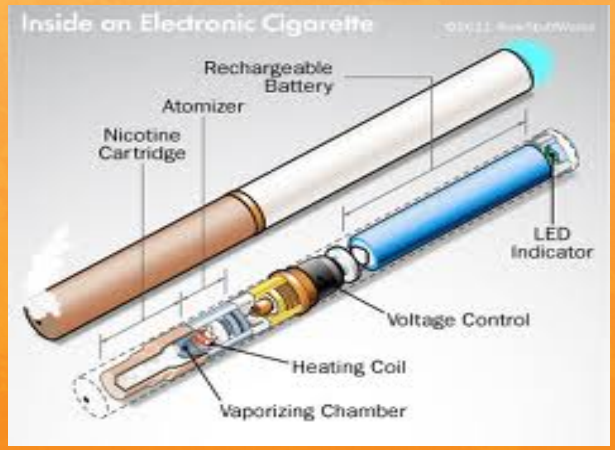
- The Guideline recommends that all tobacco users trying to quit should be encouraged to use effective medications for cessation except in specific populations where there is limited evidence of effectiveness:
  - Light Smokers - Patients who smoke less than 10 cigarettes a day
  - Adolescents
  - Pregnant women
  - Smokeless tobacco users

Medications **NOT** Recommended by Guideline Panel for Tobacco Cessation

- Antidepressants
  - Other than Bupropion SR and Nortriptyline
- Anxiolytics/Benzodiazepines/Beta-Blockers
- Opiod Antagonist/Naltrexone
- Silver Acetate
- Mecamylamine

Electronic Cigarettes

- FDA does not endorse any electronic cigarette due to safety concerns regarding:
  - Inconsistencies in nicotine delivery
  - Some contain small amounts of carcinogens (diethylene glycol and nitrosamines)
  - Additional studies are needed to establish the efficacy and safety of e-cigarettes for cessation



Conclusion

- Commercial tobacco is harmful, addictive, and every effort should be made to discourage its use.
- Knowing and using the 5A’s is an easy and professional way to discuss tobacco cessation and continued abstinence from the use of commercial tobacco.
- There is no such thing as a failed quit attempt; quitting is a process.
- Counseling and Cessation medications play a valuable role for patients that want the best chances of quitting.