Panel Management - Tobacco Cessation

Cassandra M Song, PharmD
Pharmacy Residency Program Director
CoEPCE Pharmacy Associate Director

Goal and Objectives

- Goal - Provide tools to develop and implement Tobacco Cessation Counseling and Therapy.

- Objectives:

  By the end of the program, the participant will be able to:

  1. Recall the main US Public Health Services Clinical Practice Guideline for Tobacco Dependence (2008) recommendations
  2. Describe Tobacco Dependence as a Chronic Disease
  3. Implement the “5 A’s” in Tobacco Cessation counseling
  4. Explain the place in therapy of different smoking cessation products

USPHS Key Guidelines

1) Tobacco dependence is a chronic disease

2) *Consistently* identify and document tobacco use status and treat tobacco user

3) Should encourage every patient willing to quit to use counseling and medication treatments outlined in guideline

4) Brief tobacco dependence tx is effective

USPHS Key Guidelines

5) Individual, group, and telephone counseling are effective and their effectiveness increases with treatment intensity. These two components especially effective
   - Practical counseling
   - Social support
6) Clinicians should encourage tobacco cessation medications for all attempting quitters (unless contraindicated)

USPHS Key Guidelines

7) The combination of counseling and medication are ***more*** effective than either alone (though each individually effective alone as well)

8) Ensure access to quitlines and promote its use

9) If patient unwilling to make quit attempt, use motivation treatments shown in this guideline (increases likelihood of future quit attempts)

10) Tobacco dependence treatments are highly cost effective

Tobacco Dependence, a Chronic Disease?

VA DoD guidelines emphasize that Tobacco dependence is not a habit, it is a chronic disease. What does this mean? What features of tobacco dependence make classify it as a “chronic disease”

Poll the Audience

What are the 5 A’s of tobacco cessation counseling?

The 5 A's of Tobacco Cessation

Ask about the tobacco use

- Identify and document tobacco use status of every patient at every visit

Advise to quit

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

Assess willing to quit at this time?

- Current user → willing to make an attempt
- Former user→ how recent did you quit and are there any challenges

Assist Offer support

- Willing to quit → offer medication, provider/refer for counseling
- Unwilling to quit → provide motivational interventions

Arrange for follow-up

Why ask EVERY time?

- A 3 minute intervention by a clinician can make a difference
- Intensity of intervention MATTERS
- Even when patients are not willing to make a quit attempt at this time, clinician-delivered brief interventions enhance motivation and increase likelihood of future quit attempts
- Tobacco users are influenced by a wide range of societal and environmental factors
- Smokers who receive clinician advice and assistance with quitting report greater satisfaction with their health care than those who do not
- Highly cost effective for health care
- Tobacco use has a high cases fatality rate

Who wants to quit?

Of the 45 million smokers in the US, what percent report that they want to quit?

a. ~25%
b. ~50%
c. ~70%
d. ~90%

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Who has tried to quit?

Of the 45 million smokers in the US, what percent report that they try to quit each year?

a. ~17%

b. ~44%

c. ~72%

d. ~96%

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Who is successful?

Of the 19 million adults who attempted to quit in 2005, how many were successful?

a. <1%
b. 2 - 4%
c. 4 - 7%
d. 10%

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How do we maximize success?

- Although effective treatments exist, about two thirds of quit attempts do not use any evidence-based treatment
- Less than 1/3 of people who quit use medication
- Less than 10% of people who quit use behavioral counseling
- Less than 6% of people use both medication and behavioral counseling during their quit attempt

How do we maximize success?

Recommendation: The combination of counseling and medication is more efficacious than either medication or counseling alone. Therefore, when feasible and not contraindicated, both counseling and medication should be provided to patients trying to quit smoking. Strength of Evidence=A

Tobacco Cessation Medications

Monotherapy

- Nicotine replacement therapy (NRT)
- Nicotine patch
- Nicotine gum
- Nicotine lozenge
- Nicotine inhaler (non-formulary)
- Nicotine nasal spray (non-formulary)

- Bupropion SR
- Varenicline (2nd line agent at VA Puget Sound)

Nicotine replacement therapy

Medication	Dose	Duration	Side effects	Pearls
Nicotine gum	• 2 mg for < 25 cigarettes/d • 4 mg for > 25 cigarettes/d • Max 24 pieces/d	Up to 12 weeks	--	• Patients often don't use enough to get max benefit. • Chewing gum on fixed schedule for at least 1-3 mo may be more beneficial than PRN use
Nicotine patch	• 3 doses: 21 mg/day, 14 mg/day, 7 mg/day • Titrate down over time • Start w/lower dose patch in patients who smoke < 10 cigarettes/d	Evidence shows that 8 weeks or less found to be just as effective as longer duration	• 50% have local skin reaction, < 5% have to discontinue for this reason • Insomnia	• For skin reaction: topical hydrocortisone or triamcinolone, rotate sites • For insomnia: remove patch a few hours before bedtime

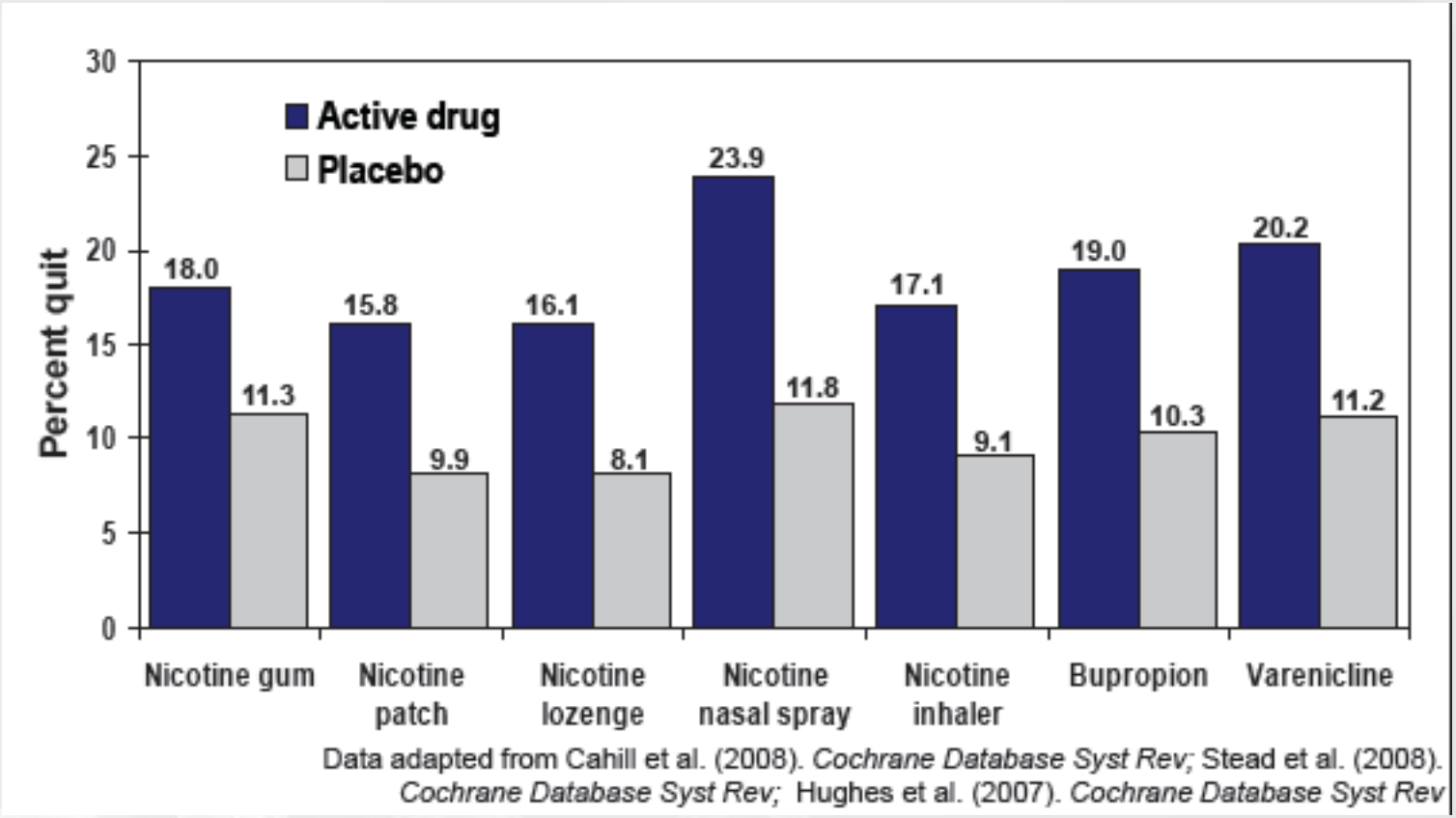
Nicotine Elimination

Medication	Dose	Duration	Side effects	Pearls
Bupropion SR	150 mg/d x 3 d → 150 mg/d q12h	• Start med prior to quit date • At least 7-12 weeks • If successful, consider ongoing maintenance	• Insomnia (35-40%) • Dry mouth (10%) • Contraindicated in seizure disorder, h/o eating disorder, or MAOI use in past 14 days	• If insomnia, take PM dose earlier in the day (at least 8h after prior dose) • Alcohol only in moderation
Varenicline	0.5 mg/d x 3 d → 0.5 mg BID x 4 d → 1 mg BID	• Start med 1 week before quit date, continue for 12 weeks • Another 12 week course can be useful for long-term cessation, but max 24 weeks	Most common: nausea, vomiting, sleep disturbances, constipation	• Dose reduce for severe renal impairment • No drug interactions • FDA black box warning added in 2008 for neuropsych symptoms (including suicidality) was removed in Dec 2016

Tobacco Dependence & Compliance with Medications

- Medications treat nicotine withdrawal rather than the disease itself.
- Failure to use a medication properly does not exacerbate the disease.
- Risk of overdose with NRT is small.
- Patients often use less medication than recommended (under dose).
- Patients often d/c medication too early.
- Cost of medication may compromise compliance.
- Improper technique with flexible dosing NRT can compromise efficacy.

Long-Term Quit Rates



Data adapted from Cahill et al. (2008). *Cochrane Database Syst Rev;* Stead et al. (2008). *Cochrane Database Syst Rev;* Hughes et al. (2007). *Cochrane Database Syst Rev*

Nicotine Withdrawal Disorder (DSM-IV)

- Reduction in amount used, followed within 24 hrs by ≥ 4 of:
  - Dysphoric or depressed mood
  - Insomnia
  - Irritability, frustration, or anger
  - Anxiety
  - Difficulty concentrating
  - Restlessness
  - Decreased heart rate
  - Increased appetite or weight gain

Withdrawal Experience

- Physical symptoms peak in 3-5 days.
- Normal physical withdrawal syndrome resolves significantly in 3-6 weeks.
- Cravings may persist, but become less frequent over time.
- Emotional ability common e.g. depressed affect, feeling out of control etc.
- Behavioral adjustments may last for months.

Additional slides

May include the following slides as time allows, but generally too detailed to be included in a brief clinical topic overview

Figure 1.2. Model for treatment of tobacco use and dependence

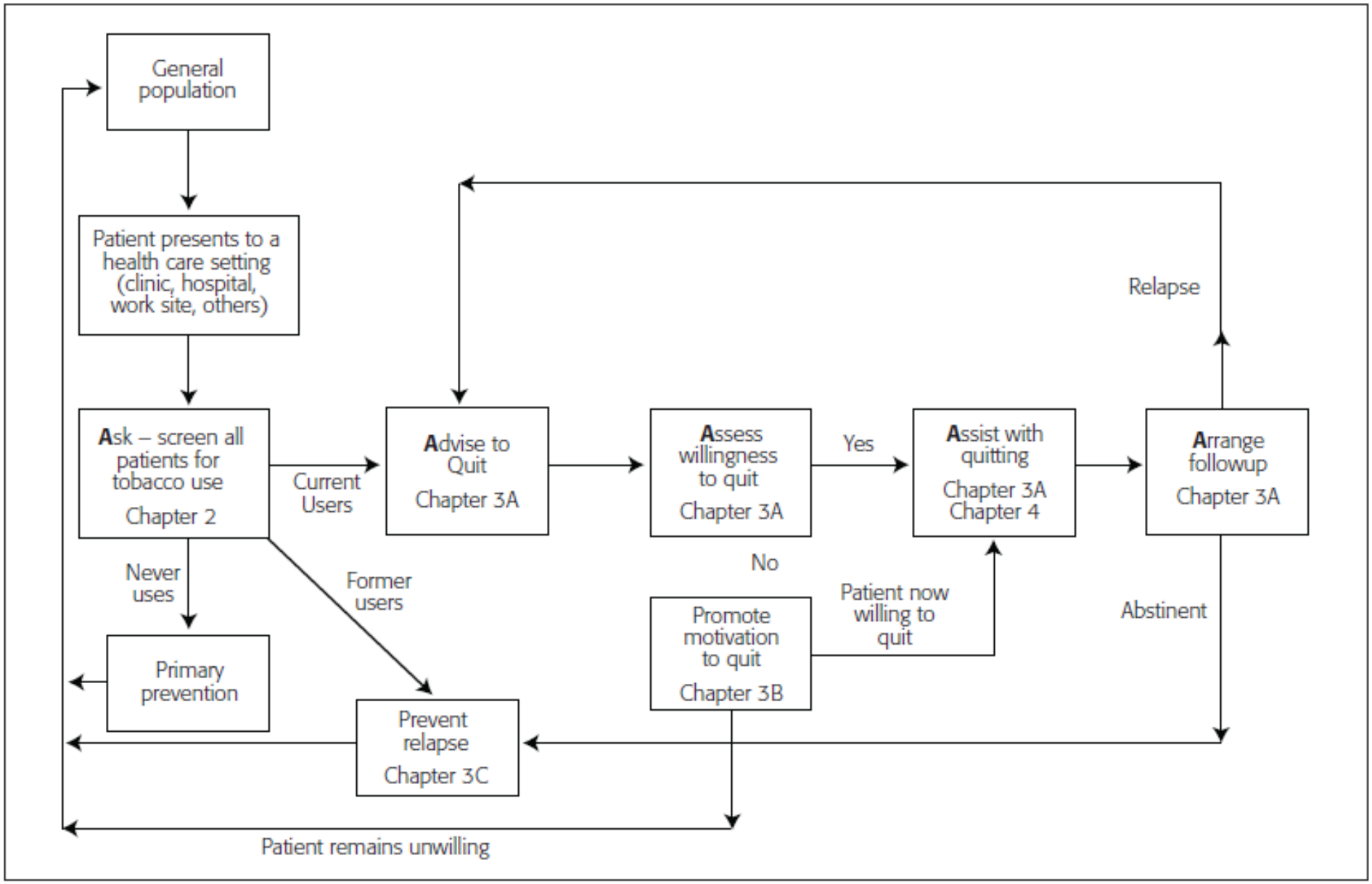
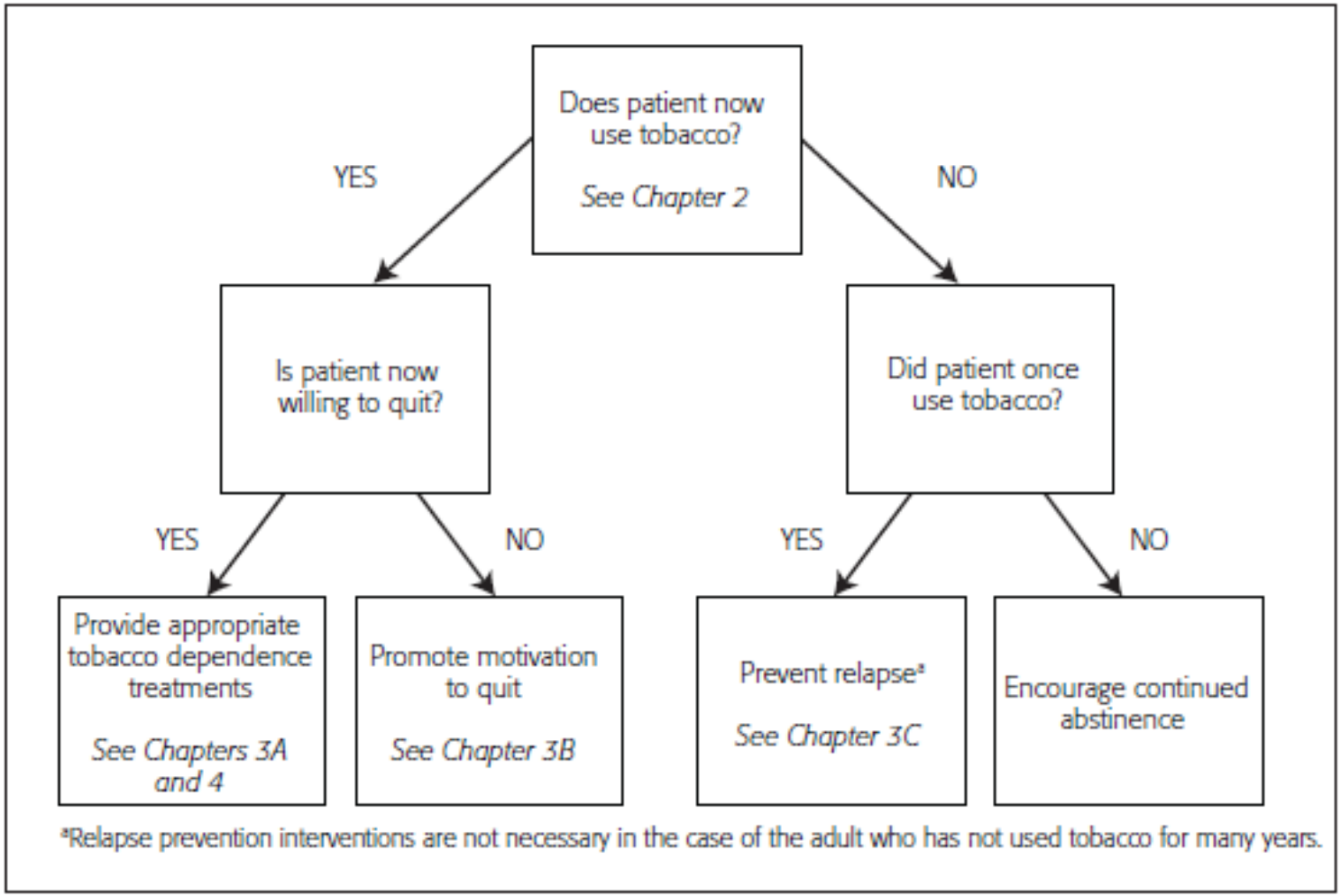
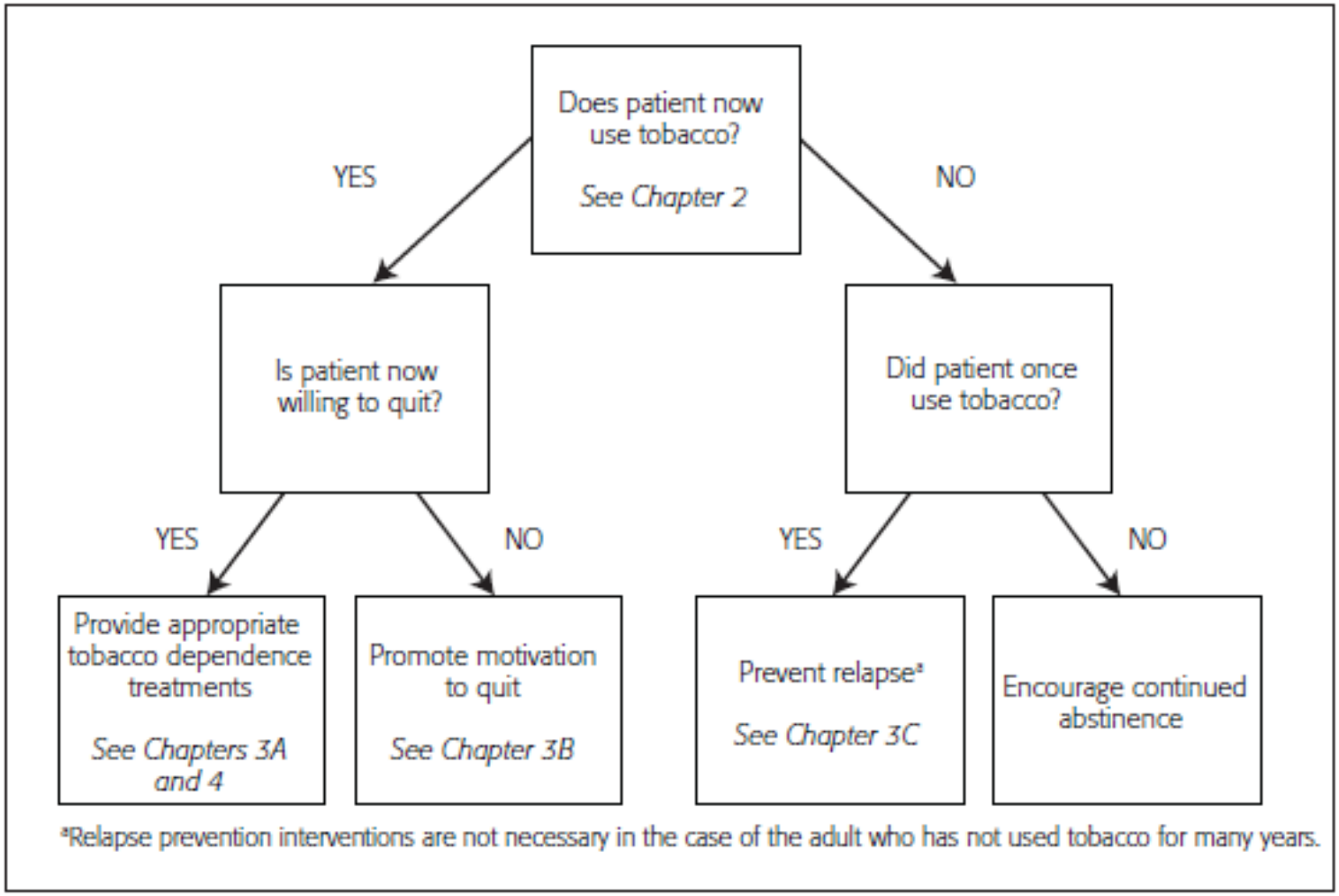


Figure 2.1. Algorithm for treating tobacco use



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

Figure 2.1. Algorithm for treating tobacco use



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

The “5 R’s”

- Relevance
- Risks
- Rewards
- Roadblocks
- Repetition

Patients Not Ready To Make A Quit Attempt Now (The "5 R's"). U.S. Public Health Service. http://www.ahrq.gov/clinic/tobacco/5rs.htm

Using the 5 R's

- Relevance
  - Encourage the patient to indicate why quitting is personally relevant.
- Risks
  - Ask the patient to identify potential negative consequences of tobacco use.
- Rewards
  - Ask the patient to identify potential benefits of stopping tobacco use.
- Roadblocks
  - Ask the patient to identify barriers or impediments to quitting.
- Repetition
  - The motivational intervention should be repeated every time an unmotivated patient has an interaction with a clinician.

Nicotine - Precautions

Precautions

- Pregnancy
  - Pregnant smokers should be encouraged to quit first without pharmacologic treatment
  - Nicotine gum should be used during pregnancy only if the increased likelihood of smoking abstinence, with its potential benefits, outweighs the risk of nicotine replacement and potential concomitant smoking
  - Similar factors should be considered in lactating women (FDA Class D)

Nicotine - Precautions

Precautions (continued)

- Cardiovascular disease
  - Nicotine Replacement Therapy (NRT) is not an independent risk factor for acute myocardial events
  - NRT should be used with caution among particular cardiovascular patient groups
    - Those in the immediate (within 2 weeks) post-myocardial infarction period
    - Those with serious arrhythmias
    - Those with serious or worsening angina pectoris

Excessive Nicotine Dose

- Nausea & vomiting
- Diarrhea and perspiration
- Headache and dizziness
- Hearing and visual disturbances
- Mental confusion
- Weakness
- Nightmares & vivid dreams

Nicotine excess or nicotine withdrawal?

Bupropion SR (continued)

Precautions

- Pregnancy
  - Pregnant smokers should be encouraged to quit first without pharmacologic treatment
  - Bupropion SR should be used during pregnancy only if the increase likelihood of smoking abstinence, with its potential benefits, outweighs the risk of treatment and potential concomitant smoking. Similar factors should be considered in lactating women (FDA Class B)
- Seizure disorder or history of seizures
- Eating disorder
- Alcohol use disorder

Nicotine Mechanism of Action

Major mechanism:

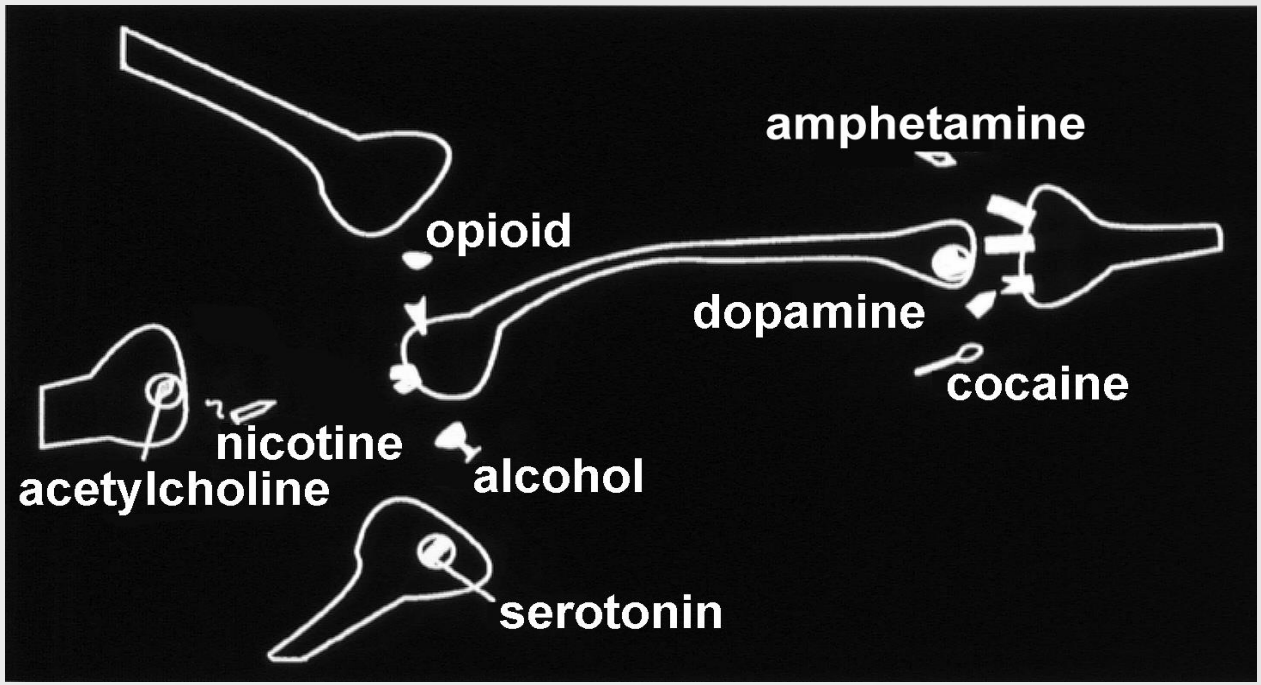
- Agonist at nicotinic acetylcholine receptors (nAChR) complexes
- nAChR complexes are found both in the peripheral and central nervous system
- Downstream effect is release of several neurotransimitters including, DOPAMINE!
  - Dopamine release signals a pleasurable experience, critical to reinforcing effects

  → addiction

Nicotine Effects

- Arousal, enhanced vigilance
- Improved performance of tasks
- Pleasure
- Relief of anxiety
- Reduced hunger
- Weight loss

Nicotine and Pleasure



Stahl SM. In: Essential Pharmacotherapy: Neuroscientific Basis and Clinical Applications. Cambridge, England: Cambridge University Press; 1996.

Nicotine Dependence

- “As an addictive substance, nicotine, on a milligram for milligram basis, is 10 times more potent than heroin…”

Sachs DPL. Advance in Smoking Cessation Treatment. In: Simmons, ed. Current Pulmonology. Chicago: Year Book Medical Publishers; 1981; 12:1139-1198.

Psychiatric Disorders Common Among Smokers

- Alcohol abuse 23%
- Drug abuse 8%
- Depression 21%
- Anxiety disorder 22%

1. Hughes J. What to do about smoking in those with psychiatric and alcohol/drug abuse disorders.
2. 2. Presented to the Pacific Center on Tobacco & Health Jan 2005.

Psychiatric Disorders Common Among Smokers

- Anxiety 87%
- Irritability 80%
- Difficulty concentrating 73%
- Restlessness 71%
- Tobacco cravings 62%
- Gastrointestinal problems 33%
- Headache 24%
- Drowsiness 22%

Nicotine Gum

Dosage

- Nicotine gum is available in 2 mg and 4 mg (per piece) doses
- The 2 mg gum is recommended for patients smoking less than 25 cigarettes per day, while the 4 mg gum is recommended for patients smoking 25 or more cigarettes per day
- Generally, the gum should be used for up to 12 weeks with no more than 24 pieces/day
- Clinicians should tailor the dosage and duration of therapy to fit the needs of each patient.

Nicotine Gum Pearls

Prescribing Pearls

- Scheduling of dose
  - Patients often do not use enough gum to get the maximum benefit: they chew too few pieces per day and they do not use the gum for a sufficient number of weeks
  - Instructions to chew the gum on a fixed schedule (at least one piece every 1-2 hours) for at least 1-3 months may be more beneficial than as needed use.

Nicotine Patches

Side effects

- Skin reactions
  - 50% of patients using the nicotine patch will have a local skin reactions. Skin reactions are usually mild and self-limiting, but may worsen over the course of therapy. Local treatment with hydrocortisone cream (1%) or triamcinolone cream (0.5%) and rotating patch sites may ameliorate such local reactions.
  - < 5% of patients, such reactions require the discontinuation of nicotine patch treatment
- Insomnia (can remove few hours prior to bedtime)

Nicotine Patches

Dosage

- Treatment of 8 weeks or less has been shown to be as efficacious as longer treatment periods
- Consider individualizing treatment based on specific patient characteristics such as precious experience with the patch, amount smoked, degree of addictiveness, etc.
- Consider starting treatment on a lower patch dose in patients smoking 10 or fewer cigarettes per day

Bupropion SR

- Antidepressant
  - Inhibits reuptake of dopamine, noradrenaline, and serotonin
  - Non competitive nicotine receptor antagonist

  Unclear which effect accounts for antismoking activity

- Equally effective in smokers with and without depression

  Antidepressant effect unrelated to anti-smoking effect

Bupropion SR (continued)

Side effects

- The most common side effects reported were insomnia (35-40%) and dry mouth (10%)

Contraindications

- Contraindicated in individuals with a history of seizure disorder, a history of an eating disorder, who are using another form of bupropion (Wellbutrin or Wellbutrin SR), or who have used an MAO inhibitor in the past 14 days.

Bupropion SR (continued)

Prescribing instructions

- Cessation prior to quit date
  - Recognize that some patients will lose their desire to smoke prior to their quit date, or will spontaneously reduce the amount they smoke
- Scheduling of dose
  - If insomnia is marked, taking the PM dose earlier (in the afternoon, at least 8 hours after the first dose) may provide some relief.
- Alcohol - Use alcohol only in moderation.

Bupropion SR (continued)

Dosage

- 150 mg daily for 3 days, then increase to 150mg every 12 hours
- Should continue for at least 7-12 weeks
- If patient is successfully abstinent after 7-12 weeks, consider ongoing maintenance therapy based on individual patient/risk benefit

Varenicline (Chantix®)

Features

- Selective partial α4β2 nicotinic Ach receptor agonist
- Causes milder stimulation of receptor than nicotine and blocks receptor from nicotine
- Reduces urge intensity, withdrawal symptoms
- Blocks dopaminergic stimulation responsible for reinforcement & reward associated with smoking
- No clinical drug interactions

Varenicline (Chantix®) (continued)

Dosing

- Escalate dose:
  - 0.5 mg daily days 1-3,
  - 0.5 mg twice daily days 4-7,
  - 1 mg twice daily days 8-end of treatment
- Begin therapy 1 week prior to quit date and continue for 12 weeks
- Dose reduce for severe renal impairment

Varenicline (Chantix®) (continued)

Side Effects

- Most common (>5%) are nausea, vomiting, sleep disturbances (insomnia, abnormal dreams), and constipation
- Hypersensitivity reactions
- Serious skin reactions (SJS, erythema multiforme)
- Accidental Injury (falls, collisions)

Varenicline (Chantix®) (continued)

Warnings

- FDA added warning in 2/2008 for neuropsychiatric symptoms because of post-marketing data
  - Psychosis/hallucinations/paranoia/delusions
  - Mood changes(depression, mania)
  - Homicidal ideation/hostility
  - Agitation/anxiety/panic
  - Suicide/suicidality

FDA removed this black box warning Dec 2016

Continue to use with caution in hx of mental health

Varenicline (Chantix®) (continued)

- Current data shows greater efficacy than placebo and bupropion
- Prescription only
- Effective both short and long term
- Multiple 12 weeks courses (up to 24 weeks) can be useful for long term cessation

Patient Case #1

- Veteran N.W. asks you about switching from the nicotine gum to Chantix (varenicline) because his jaw gets too tired chewing the gum all day. What do you tell him?

Patient Case #2

- K.R. is a 25 year-old male with Sulfa allergy. He used nicotine gum when he tried to quit about three years ago but was not successful. Then, about a year ago, he tried again with nicotine patch, but after two weeks he went back to smoking. He is interested in quitting starting about one week from today. What further information do you want? What pharmacotherapy would you recommend to him?