

Workshop C07

A Practical Approach to Smoking Cessation: Effective Intervention in a Busy Schedule

Susan Urban, MD, Coordinator

Faculty

Sharon Parish, MD

Scott Sherman, MD, MPH

Ellie Grossman, MD, MPH

SMOKING CESSATION: PHARMACOTHERAPY

Most Smokers Have A Chronic Disease of Drug Dependence

- 1998 Surgeon General's Report recognized smoking as a disease of drug dependence.
- Nicotine is an addictive drug in tobacco that can create tolerance, physical dependence, and a withdrawal syndrome.

US Department of Health and Human Services,
Office of the Surgeon General 1988

Heavy Smoking Index for Nicotine Dependence

Abbreviated form of the Fagerstrom Test for Nicotine
Dependence (FTND)

How soon on awakening do you smoke your first cigarette?

- | | | | |
|------------------------|---|-----------------------|---|
| - Within 5 minutes | 3 | - Within 6-30 minutes | 2 |
| - Within 31-60 minutes | 1 | - After 60 minutes | 0 |

How many cigarettes a day on average do you smoke?

- | | | | |
|--------------|---|---------------|---|
| - 31 or more | 3 | - 21-30 | 2 |
| - 11-20 | 1 | - 10 or fewer | 0 |

Heatherton et al 1989; de Leon et al 2002; Chabrol et al 2005

Heavy Smoking Index: Sensitivity and Specificity

- Score of 4 or higher on the HSI has good sensitivity and specificity for dependence.
 - sensitivity of 79.5%
 - specificity of 96.5%

Dopamine Hypothesis of Drug Dependence

- Nicotine activates alpha 4 beta 2 nicotinic acetylcholine receptors on neurons in the ventral tegmental area of the brain.
- **Release of dopamine in nucleus accumbens reward center.**
- Modulation of release of dopamine by neurons projecting from prefrontal cortex and amygdala.
- Modulating pathways consist of glutamate and gamma-aminobutyric acid (GABA) neurons.

Withdrawal Syndrome

- Symptoms include restlessness, irritability, insomnia, difficulty concentrating, anxiety, depressed feelings, increased appetite.
- Symptoms begin within a few hours after the last cigarette, peak in 2-3 days, and then decrease over 3-4 weeks. Most resolve but cravings can last for years.

Pharmacotherapy: Indications

- Offer pharmacotherapy to all adult smokers with possible exceptions of pregnant or lactating women and those who smoke only an occasional cigarette.
- Most effective in motivated smokers.
- Most effective in dependent smokers (who are expected to have withdrawal symptoms).

First-Line Pharmacotherapies for Smoking Cessation as of 2/08

- Nicotine patch OTC
- Nicotine gum 2 and 4 mg OTC
- Nicotine lozenge 2 and 4 mg OTC
- Nicotine inhaler: prescription only
- Nicotine nasal spray: prescription only

- Bupropion SR (Wellbutrin, Zyban)
- Varenicline (Chantix)**

Nicotine Replacement Therapy: Increases Quit Rate by 1.5 to 2 fold

- Silagy 2007: odds ratio for abstinence with NRT compared with control 1.77 (CI = 1.66-1.88)
 - nasal spray 2.35
 - inhaler 2.14
 - lozenge 2.05
 - patches 1.81
 - gum 1.66

Nicotine Replacement Therapy

- Supplies lower dose nicotine which decreases withdrawal symptoms.
- Must stop smoking before starting NRT.
- “Contraindications” USPHS Guidelines 2000: MI within the past 2-4 weeks, unstable angina, life-threatening arrhythmias.
- Pregnancy category D

Nicotine Replacement Therapy: Which One?

- **Patient preference** and past experience.
- **Ease of use.** Patch easiest to use.
- **Cost** lowest with patch and the gum.
- **Contraindications:**
 - nasal spray and inhaler - reactive airways disease; nasal spray – chronic rhinitis
 - patch – extensive skin disease, allergy to adhesive. caution with humidity
- **Caution:**
 - gum – extensive dental work, no teeth, TMJ

Nicotine Replacement Therapy: Compliance Better with the Patch

- Patch 82%
- Gum 38%
- Spray 15%
- Inhaler 11%

Hajek et al. Arch Intern Med 1999

Individualizing Nicotine Replacement Therapy in the Future

- Smokers low to moderate dependence, not obese, and white - better abstinence rates with patch at 6 months.
- Smokers with high dependence, obese, or minority - better abstinence rates with nasal spray.

Nicotine Transdermal Patches

- Available by prescription since 1992.
- Nicoderm and Nicotrol OTC in 1996.
- Patches deliver nicotine transdermally providing steady levels.
- 3 patches: **Nicoderm CQ**, Habitrol, Nicotrol
- Typical Nicoderm CQ dosing
 - 21 mg/ 24 hrs for 4 weeks (4-6 weeks)
 - 14 mg / 24 hrs for 2 weeks (2 weeks)
 - 7 mg/24 hrs for 2 weeks (2 weeks) *

Nicotine Transdermal Patch: Instructions for Patients

- Stop smoking before applying the first patch. Do not smoke while using the patch.
- Apply one patch daily to different skin site between neck and waist. Apply to clean, dry, hairless skin.

Nicotine Transdermal Patch: Side Effects

- Skin Irritation in 35-54% of users
- Sleep disturbances (insomnia, vivid dreams) in up to 1/3 of users
- Other: headache, nausea, dyspepsia

Nicotine Polacrilex Gum (Nicorette)

- 2 mg formulation available in US in 1984
- 4-mg gum became available in 1992
- Both 2 mg and 4 mg became OTC 1995
- 2-mg gum: if smoke fewer than 15-25 cigarettes a day.
- 4-mg gum: if smoke 15-25 or more cigarettes a day.

Nicotine Gum: Efficacy

- Specialized cessation clinics: 27% vs 18% for nicotine gum vs placebo gum quit rates at 6 months
- General medical practices: no difference (12%)

Lam W, Lancet 1987

Nicotine Gum: Complex Instructions

- **Chew slowly** until feel tingling, spicy, or peppery taste.
- Then **park** between cheek and gum until the tingling goes away (usually about 1 minute).
- Then **chew slowly** again until the tingling spicy taste comes back.
- Then **park....**
- **Repeat chew/park steps** until the taste fades (usually about 30 minutes).
- **Rest** for the next 30 minutes.
- Then **restart the cycle.**

Nicotine Gum: Ad lib and Regular Use

IF USING FIXED DOSE SCHEDULE

- 1 piece every 1-2 hours for the first six weeks.
- 1 piece every 2-4 hours for weeks 7-9.
- 1 piece every 4-8 hours for weeks 10-12.
- Can use extra piece of gum during an hour if increased craving.

Nicotine Gum: Side Effects

Frequent but Minor

- Sore jaws, mouth irritation
- Dyspepsia, nausea, hiccups
- Excess salivation

CAUTION; dentures, extensive dental work, temporomandibular joint syndrome

Nicotine Polacrilex Lozenges: (Commit)

- Approved 2002 by FDA.
- 2 mg and 4 mg lozenges.
- Can be used prn cravings or on a regular basis.
- If used on a regular basis, can use similar schedule as for gum.
- Side effects: mouth irritation, nausea, heartburn, hiccups, headache.

Nicotine Lozenge: Efficacy

continuous abstinence rates

- Low dependence 2 mg
24.2 % vs 14.4% at 6 months (OR=1.96)
- High dependence 4 mg
23.6% vs 10.2% at 6 months (OR= 2.76)

Nicotine Vapor Inhaler: Nicotrol Inhaler

- Approved by FDA 1997; marketed in 1998.
- Consists of a mouthpiece and a plastic inhaler cartridge.
- Each cartridge contains 10 mg of nicotine, of which 4 mg is delivered and 2 mg is absorbed.
- Delivers nicotine buccally. Most is absorbed through mouth and throat.

Nicotine Vapor Inhaler: Continued

- Use about 80 deep inhalations over 20 minutes (equivalent to one cigarette).
- Use 6-16 cartridges per day for 12 weeks.
- Can then taper over 6-12 weeks.
- Can use up to 6 months.
- Side effects: mouth and throat irritation, cough, rhinitis, nausea, headache
- Contraindications: asthma, reactive airways disease

No Beverages/Food 15 Minutes Before or While Using Gum, Lozenge, or Inhaler

- Absorbed through buccal mucosa.
- Acidity can decrease absorption of nicotine.

Nicotine Nasal Spray: Nicotrol NS

- FDA approved 1996; first marketed 1997.
- Start with one dose every 30-60 minutes.
- Can use up to 5 doses per hour.
- Use at least 8 doses a day and maximum of 40 doses a day.
- Use 12 weeks. Can taper after 6 weeks.
- Not approved for more than 6 months.

Nicotine Nasal Spray

- Side effects:
 - nasal irritation: rhinorrhea, sneezing
 - Throat irritation, cough
 - Eye irritation: watery eyes
 - Nausea
- Contraindications
 - asthma, reactive airways disease
 - chronic nasal disorders

Bupropion Sustained - Release Doubles the Quit Rate

- Bupropion used alone: OR = 1.94 (C1.72-2.19)
- Insufficient evidence for increasing long-term abstinence by adding bupropion to nicotine replacement therapy.
- Lower odds of quitting with bupropion than with varenicline: OR = 0.60 (0.46-0.78).

Bupropion Sustained - Release (Zyban)

- Approved May 1997; available 1998.
- Atypical antidepressant which blocks the re-uptake of dopamine and norepinephrine
- Decreases withdrawal symptoms; may act as brain nicotinic receptor antagonist
- **Start 1 week before stopping smoking.**
- Dosage: 150 mg po daily for 3 days, then 150 mg po bid.
- Use for 12 weeks; can use 6 months and longer.

Bupropion SR: continued Side Effects

- insomnia 35-40%
- dry mouth 5-15%
- lowers seizure threshold (incidence of **seizures** is 0.1 %).
- nausea, anxiety, dizziness
- can increase blood pressure

Pregnancy category C

Bupropion SR: continued Contraindications

- Eating disorders: anorexia, bulimia.
- Use of monoamine oxidase inhibitor within the prior 2 weeks.
- History of seizure disorder
- Anything that increases risk of seizures: brain tumor; head trauma; cva; excessive ETOH; and some medications such as benzodiazepines; opiate/cocaine/ stimulant abuse.

Varenicline (Chantix)

- Approved by the FDA May 2005
- Mechanism: partial nicotine agonist of the alpha4beta2 nicotinic acetylcholine receptor.
- Dosing: 0.5 mg daily x3 days, then 0.5 mg bid for 4 days, then 1 mg po bid.
- Side effects: nausea (about 30%), vomiting, insomnia, abnormal dreams.
- Caution: creatinine clearance less than 30 mL per minute – take half the usual dose.

Varenicline: Increases Quit Rate More than 3 -fold

- Varenicline vs placebo:
pooled odds ratio for continuous abstinence
at 12 months = 3.22 (CI 2.43-4.27).
- Varenicline vs bupropion:
pooled odds ratio = 1.66 (CI 1.28-2.16).

Varenicline **WARNING:** **Neuro-psychiatric Effects**

- Noted by FDA 11/20/07.
- Recent alert 2/1/08.
- Depressed mood, suicidal ideation, attempted and completed suicide.
- Usually develops during treatment but sometimes after stopping varenicline.
- Can occur in patients **without** pre-existing psychiatric illness; can worsen in those with pre-existing psychiatric illness.

Combination Pharmacotherapy: Possibly Higher Quit Rates

- Some evidence that combination therapy increases quit rates.
 - combined nicotine replacement therapies (patch plus gum, spray, or inhaler) can result in higher quit rates¹.
 - one study²: bupropion plus nicotine patch more effective than patch alone.
 - another study³: bupropion plus nicotine inhaler more effective than either alone.

¹.Silagy et al. Cochrane Database, 2007 ².Jorenby et al. N Engl J Med 1999.

³. Croghan et al. Mayo Clin Proc., 2007.

Other Pharmacotherapies

- Nortriptyline¹ (OR=2.14), clonidine² (OR=1.89); second-line agents; major side effects; not FDA approved.
- Naltrexone^{3,4}: may decrease weight gain.
- Mecamylamine⁵
- Lobeline⁶
- Rimonabant⁷
- Cytisine⁸

¹ Hughes et al, Cochrane 2007. ² Gourtay et al. Cochrane 2007. ³ David et al, Cochrane 2007. ⁴ O'Malley et al. 2006. ⁵ Lancaster and Stead, Cochrane 2007. ⁶ Stead and Hughes, Cochrane 2007. ⁷ Cahill and Ussher, Cochrane 2007. ⁸ Etter 2006.

Which Pharmacotherapy?

- Patient preference
- Patient's past experience
- Level of dependence
- Contraindications
- Patient's co-morbidities
- Side effects
- Cost
- Ease of use

**SMOKING CESSATION:
MOTIVATION
AND
BEHAVIORAL CHANGE**

Effective Intervention Targets Motivation or Readiness To Quit

- **Assess** motivation or readiness for change.
- Ready to change – **assist** with change by prescribing medication and counseling.
- Not ready to change – perform a **motivational intervention**.

Assess Motivation as Stage of Change

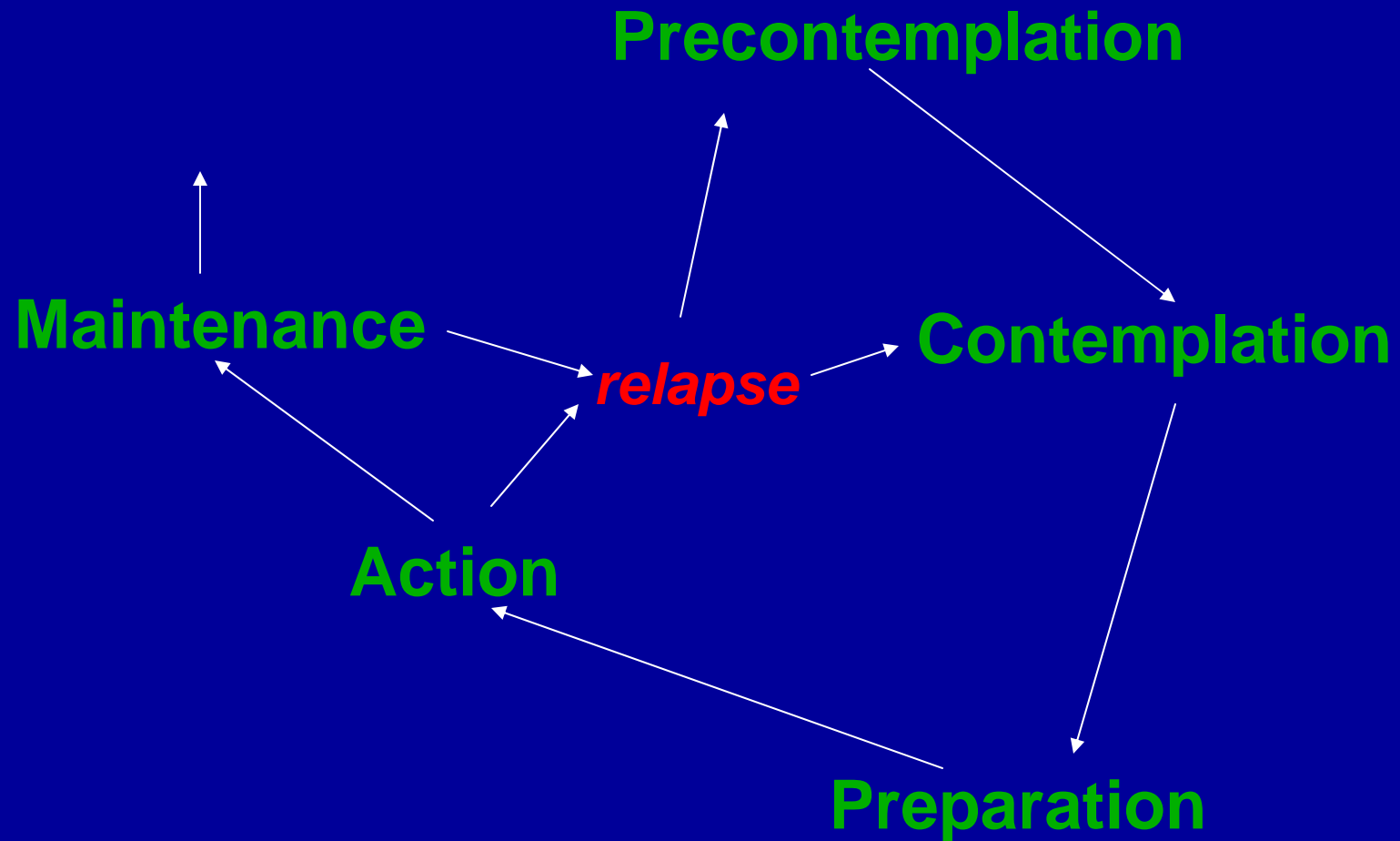
- Prochaska-DiClemente transtheoretical model of change describes 5 stages of change (in addition to relapse).
- Individuals cycle through stages.
- Different clinician responses are required depending on the stage of change.

Levinson W, Cohen MS, Brady D, Duffy F. Ann Intern Med 2001
Prochaska JO, DiClemente CC, Norcross JC. Am Psychol 1992;47:1102-4.

Prochaska-DiClemente Transtheoretical Model

- **Precontemplation** = resistance = the patient not currently interested in making a change
- **Contemplation** = ambivalence = the patient considering change but is not ready in the next month
- **Preparation/determination** = the patient is ready to change within the next month
- **Action** = the patient is in the first 6 months of the behavioral change
- **Maintenance** = the patient has changed more than 6 months ago.

Transtheoretical Model of Change: Stages of Change



Goal: Moving From One Stage To The Next

- Clinician facilitates movement of patient from one stage to the next.
 - precontemplation to contemplation
 - contemplation to preparation
 - preparation to action
- Brief interventions are effective.

Miller - Rollnick Motivational Interviewing (MI) Model

- Concepts: “Collaborative”, “evocative”, “patient autonomy”.
- Principles: “RULE” (resist, understand, listen, empower).
- Communication skills: Ask, Listen, Inform

Rollnick S, Miller WR, Butler CC. Motivational Interviewing in Health Care: Helping Patients Change Behavior. 2008.

Rollnick S, Heather N, Bell A. Journal of Mental Health 1992.

Motivational Interviewing Approach

- “Collaborative”: clinician and patient work together.
- “Evocative”: elicit patient’s point of view.
- “Patient autonomy”: the patient decides.

Motivational Interviewing: Principles “RULE”

- Resist the “righting reflex”: resist telling patient what to do.
- Understand patient’s motivations, concerns, and values.
- Listen to patient, specifically for patient’s perspective and for “change talk”.
- Empower the patient. Accept patient will decide whether to change.

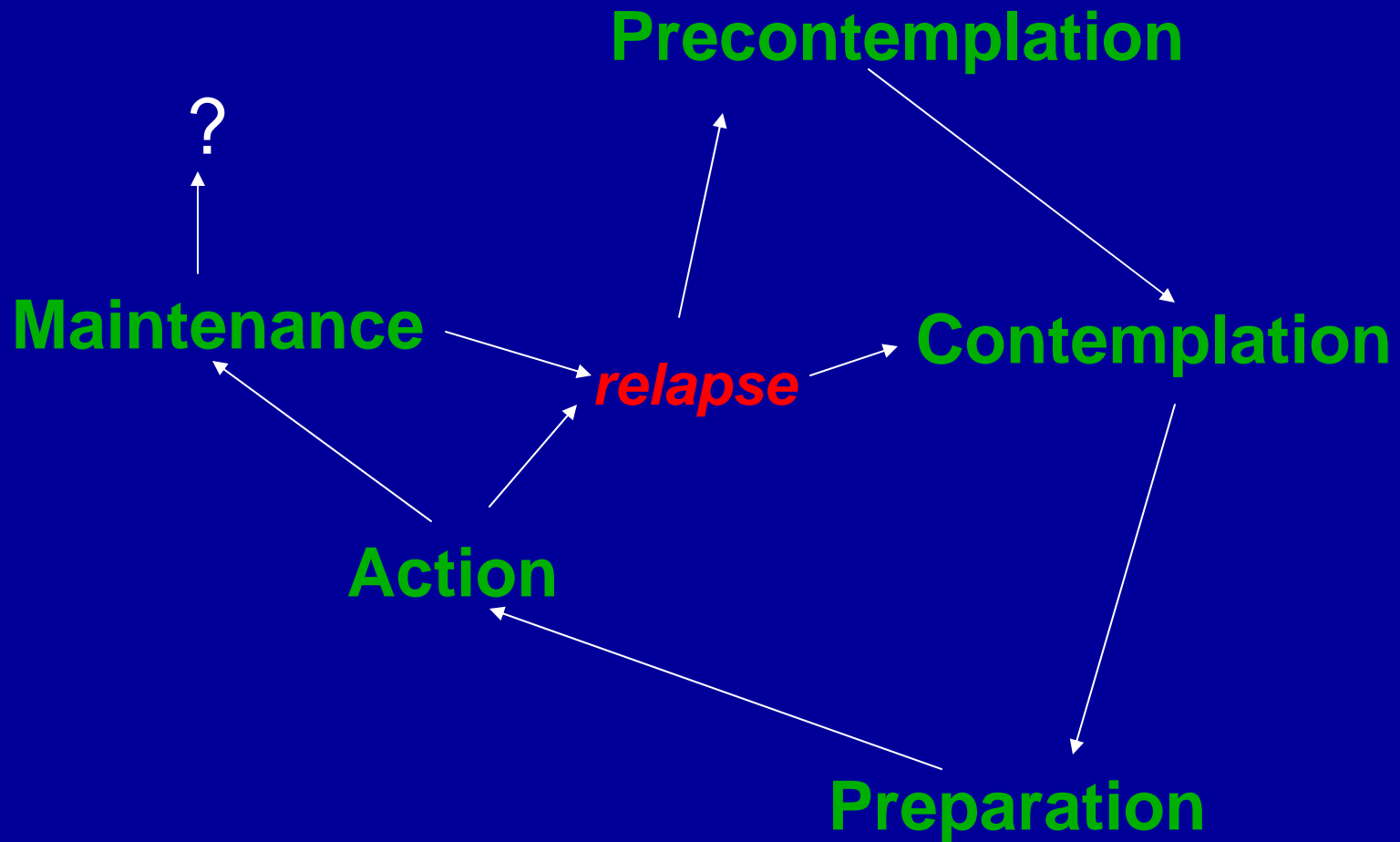
Motivational Interviewing Skills

- Asking **open ended questions** for patient's perspective.
 “Tell me about your smoking..”
 DARN questions: desire, ability, reasons, need (importance of change)
- Listening: **reflect** (resistance and change talk).
- Informing: **ask-tell-ask** paradigm, options.

Putting It All Together

- Patient who is smoking can be thought of as in the pre-contemplative, contemplative, or preparation stage.
- Typical patient responses for each stage.
- Motivational interviewing communication skills can be used.
- Goal: move from one stage to the next.

Stages of Change Model



Precontemplation Stage: Typical Patient Reactions

- Unaware or Denial: *“it is not a problem”*.
- Minimization: *“I don’t smoke that much”*.
- Changing the subject: *“I came here for my blood pressure”*.
- Annoyance/Hostility: *“I don’t like what you are saying”*.

Precontemplation Stage: Clinician Responses

- Ask permission to discuss smoking.
- Provide feedback, using the “Ask Tell Ask” paradigm.
 - *“Have you thought about how your smoking may be related to your cough?”...*
 - *“Your cough is related to your smoking.”...*
 - *“What do you think about that?”*
- Provide advice about quitting.

Use of Reflection

- Simple: restatement

“ I like smoking.” “You enjoy smoking.”

- Amplified: amplified restatement

“ I like smoking.” “You like smoking more than anything else.”

- Double sided: statements of both sides of a situation

“I like smoking. ...I like having my grandchildren visit.” “On the one hand you enjoy smoking, but on the other hand you love your grandchildren and don't want to expose them to secondhand smoke...”

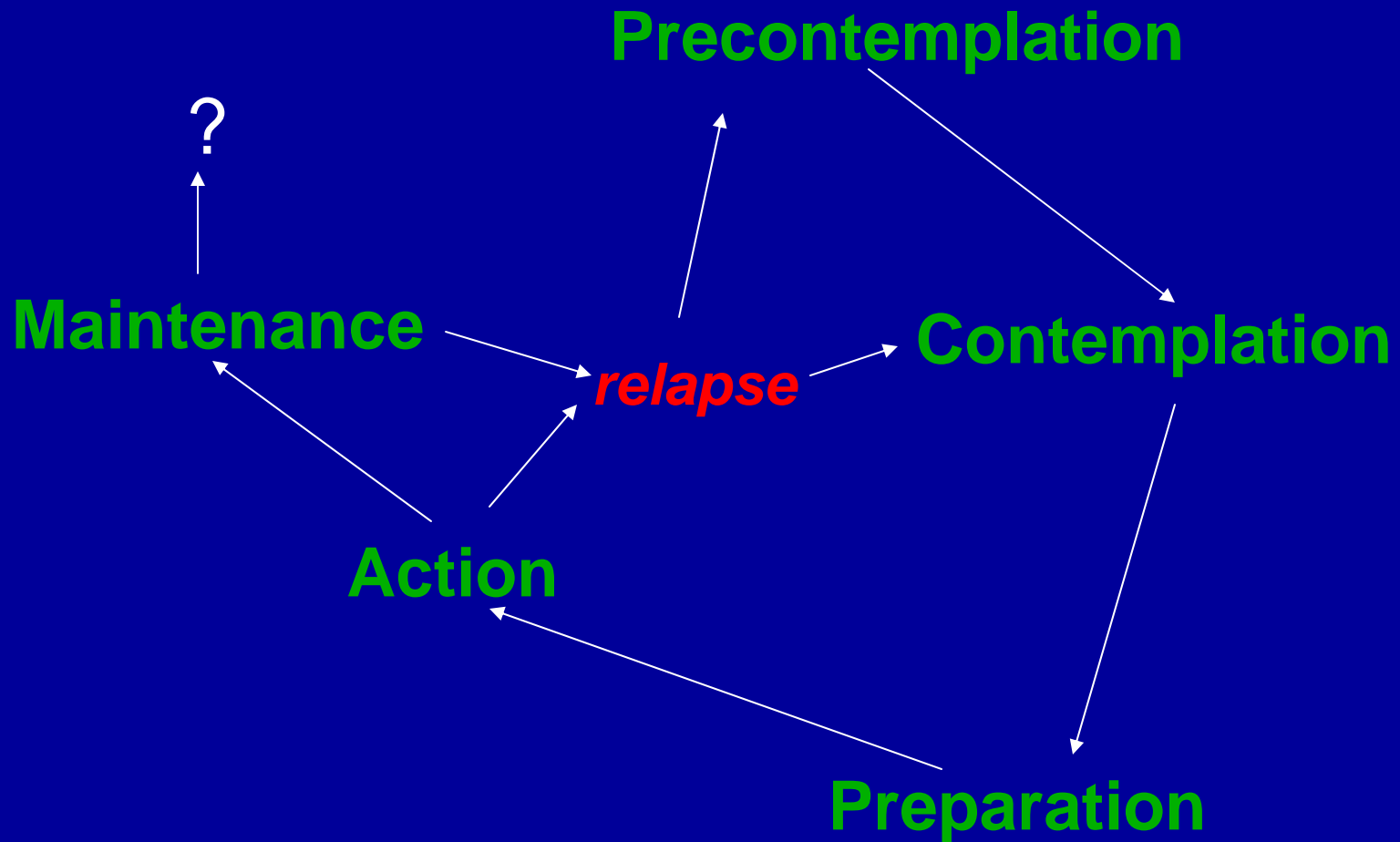
Using Reflection in Pre-contemplative Stage

- Can reflect thoughts, feelings, actions.
- Demonstrates active listening.
- Decreases “resistance” and increases collaboration.
- Reflecting negative statements helps elicit positive statements for change.
- Encourages dialogue.

Goal with Precontemplation Stage: Move to Contemplation Stage

- Increase awareness of behavior.
- Increase concern about behavior.
- Get the patient to begin to think about (contemplate) his behavior.

Stages of Change Model



Contemplation Stage: Typical Patient Responses

- Aware of the problem:
“I know that smoking affects my cough”.
- Would like to change but not ready yet:
“I would like to stop smoking but I am not ready yet”.
- Aware of pros and cons (ambivalence):
“I know that my smoking makes my lungs worse, but it is the only way I can get through my day”.

Contemplation Stage: Decisional Balance

- Facilitate patient discussion of pros and cons of smoking and of not smoking (ambivalence).

DECISIONAL BALANCE

smoking

quitting

pros decreases stress decreased lung disease

cons increased lung disease increased stress

- Facilitate weighing of pros of quitting.

Use of The “Ruler”

- “On a scale of 1-10, how **important** do you think it is to stop smoking?”
- “On a scale of 1-10, how **confident** are you that you can stop smoking?”
- “Why this number and not a lower number?” will **elicit “change talk”**.

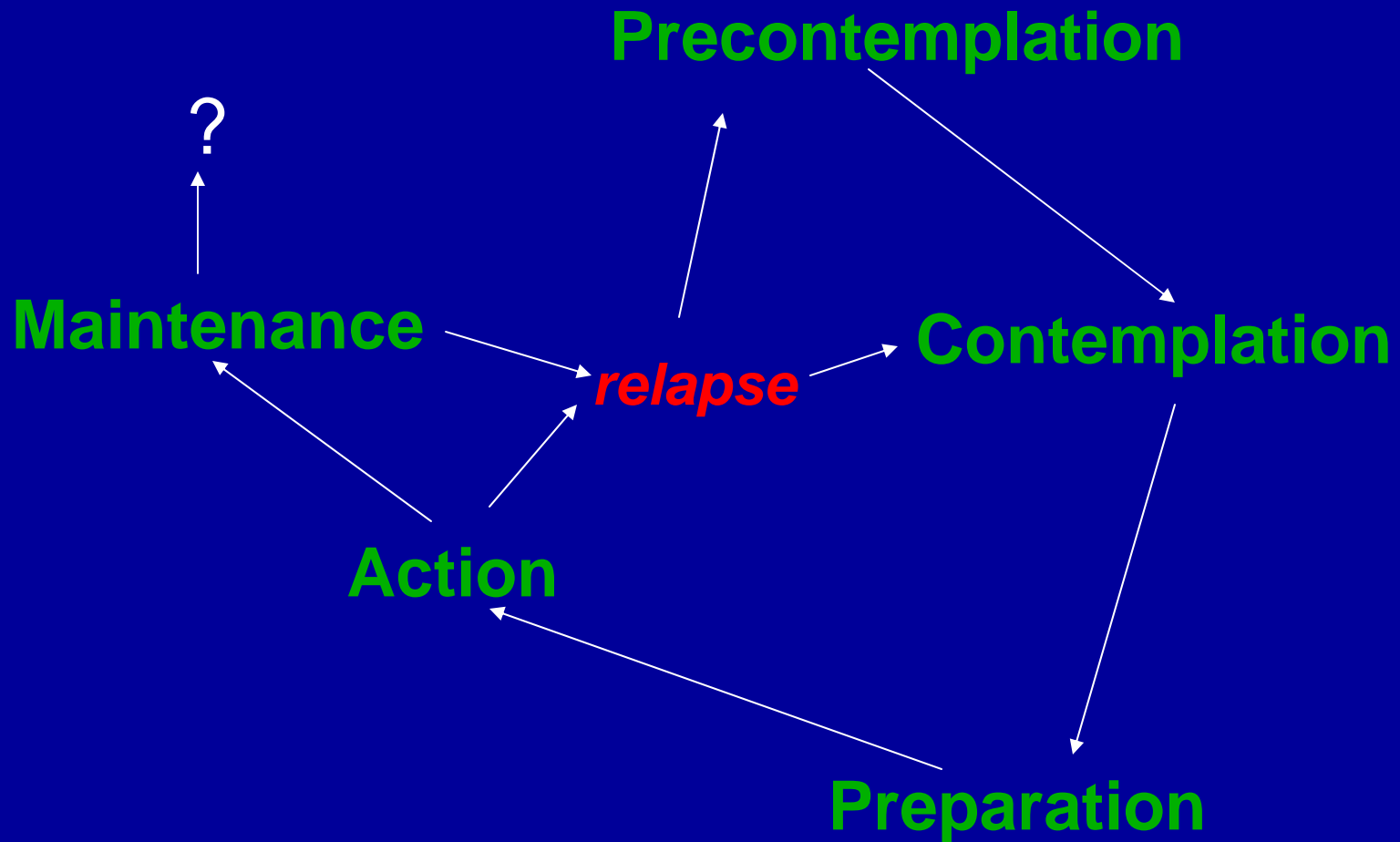
Contemplation Stage: Discussion of Barriers

- Elicit and discuss barriers to change.
- Elicit and Inform about possible solutions for perceived barriers (can use the Ask-Tell-Ask method).

Goal with Contemplation Stage: Move towards Preparation

- Increase patient motivation for change.
- Facilitate patient weighting of the pros of change (quitting).
- Get the patient to move towards commitment to change.

Stages of Change Model



Preparation Stage: Typical Patient Responses

- Commitment: “I have decided to stop smoking”.
- Time frame: planning to stop in the next four weeks.

Preparation Stage

Clinician Response: Assist with Quit Plan

- **STAR:** Set **quit date**, Tell friends and family, Anticipate (and discuss) challenges like withdrawal, Remove tobacco from home.
- Discuss pharmacotherapy options.
- Counsel about triggers and coping strategies.
- Offer your support (support self-efficacy).
- Encourage soliciting outside support.

Using Ask –Tell- Ask Skill in Preparation Stage

- Use ask-tell-ask paradigm when informing about withdrawal, pharmacotherapy.

“What do you know about.....:”

“I would like to share with you some information about...”

“What do you think about what we just discussed?”

Preparation Stage: Goal

- Increase motivation and commitment to make a change.
- Facilitate the patient setting a quit date and developing a plan.
- Get the patient to move from preparation to action (quitting).

Barriers to Cessation

- Dependence (withdrawal symptoms).
- Habit (coffee with cigarette).
- Coping mechanism (decreases stress).
- Social aspect (friends do it).
- Concern about weight gain.
- Concern about prior relapses.
- Depression, other psychiatric disorders.
- Alcohol and other substance use.

Barriers: Weight Gain

- 80% of smokers gain weight when quitting
- Women tend to gain more weight than men
- Heavier smokers (more than 25 cigs/day) gain more than lighter smokers
- Usually 5-10 lbs in the first one to two years
- Recommend exercise program, certain foods, and note that smoking cessation is more important than weight gain in the short-term

Barriers: Depression

- Depressed smokers less likely to quit and more likely to relapse than non-depressed smokers.
- Depression can increase when patient stops smoking.

Barriers: Substance abuse

- Association between substance abuse and smoking.
- Limit or stop alcohol.
- Stop illicit drug use.
- Avoid contact with others who use alcohol or drugs or who smoke.

Action Stage: Quit in Past Six months

- Goal: maintain abstinence and avoid relapse.
- Support action (quit effort); support self-efficacy.
- Review pharmacotherapy if still using and any withdrawal symptoms or cravings.
- Review slips and triggers and ways to avoid them.

Relapse

- Common: 70% - 80% at one year.
- Can be reframed as a learning opportunity.
Can review triggers leading to relapse.
- Increased relapse risk with current or past depression, risky alcohol use or history of alcohol dependence.
- Reassess patient motivation to quit again.
- Goal: move from relapse to preparation stage.

Summary: Role of Motivation in Behavioral Change

- Change in behavior depends on patient motivation.
- Behavioral change is a process and takes place over time.
- This process involves moving from not being interested in change to being ready to change and then changing.

Assess Readiness to Change or Stage of Change

- Prochaska-DiClemente transtheoretical model of change describes 5 stages of change.
- Stages: pre-contemplation, contemplation, preparation, action, maintenance.
- Can assess patient's readiness in terms of stage of change (if smoking will be pre-contemplation, contemplation, or preparation).

Use Communication Skills from Motivational Interviewing

- Approach: change comes from the patient and the role of clinician is to elicit, strengthen, and support motivation for change.
- “Spirit”: collaborative, evocative, patient autonomy.
- Skills: asking, listening, informing.
- **Specific skills: open-ended questions, reflection, ask-tell-ask method.**

Effective Intervention Targets Motivation or Readiness

- The clinician's intervention should be specific to the stage of change of the patient (motivational state).
- Goal is for the patient to move to the next stage.
 - precontemplation –contemplation
 - contemplation –preparation
 - preparation – action (quitting)

Guidelines

Susan Urban, MD

Scott Sherman, MD, MPH

Clinical Practice Guideline for Treating Tobacco Use and Dependence

The 5 A's for patients ready to quit:
ask, advise, assess, **assist**, **arrange**

The 5 R's for patients not ready to quit:
relevance, rewards, risks, roadblocks, repetition

US Public Health Service Report: A Clinical Practice Guideline
for Treating Tobacco Use and Dependence JAMA 2000

The 5 A's For The Patient Ready to Stop Smoking: Ask, Advise, Assess, Assist, Arrange

- Ask whether the patient smokes'
- Advise the patient to quit.
- Assess whether the patient wants to quit

Ask Whether the Patient Smokes

- Ask about smoking at every visit.

Suggestions:

-Ask permission to discuss smoking.

-Ask for patient's thoughts about smoking.

Advise To Quit Smoking

- Advice should be strong, clear, and personalized.

Suggestions:

- emphasize the positive and short-term.
- relate smoking to the patient's symptoms, disease, concerns, values.
 - ask what the patient thinks about what you have said.

Assess Whether Patient Wants to Quit

- Assess whether patient wants to quit.

Suggestions:

- assess level of motivation
- assess degree of dependence
- ask about prior quit attempts
- ask about patient's thoughts

If Ready to Stop Within 30 days: Assist with Quit Plan

- Help patient make a quit plan.
- Offer pharmacotherapy.
- Counsel about triggers, withdrawal symptoms, coping skills.
- Express support.
- Inform about websites, quit-lines, community groups.

Or can refer to cessation program *

And Arrange Followup

- After you have asked, advised, assessed, and assisted, then arrange followup.
 - contact patient on quit date
 - arrange for visit 1-2 weeks later
 - depending on that visit, arrange for visit 1 month later.

If Not Ready To Stop Within The Next 30 Days: Provide a Motivational Intervention

Discuss the 5 R's

- Relevance
- Risks
- Rewards
- Roadblocks
- Repetition

If Not Ready To Stop Within The Next 30 Days: Provide a Motivational Intervention

The 5 R's

- **Relevance:** how related to symptoms, disease status, family including spouse/partner, children
- **Risks:** acute (example SOB, cough) and long-term (example cardiovascular disease, cancers)
- **Rewards:** better health, food tastes better, feel better, more stamina, less wrinkling of skin
- **Roadblocks: identify barriers & solutions**
- **Repetition:** repeat this intervention every visit

GUIDELINES SUMMARY

- **Ask** all patients if they smoke.
- **Advise** all patients who smoke to quit.
- **Assess** motivation to quit.
- Tailor subsequent intervention according to the patient's motivation.

SUMMARY: CONTINUED

- If ready to quit, **assist** (help patient make quit plan; offer pharmacotherapy, counsel, support; and **arrange** follow up).
- If not ready to quit, provide a **motivational intervention** (discuss relevance, risks, rewards, roadblocks, and repeat at every visit).

Summary: Continued

- If patient **has quit recently**, provide relapse prevention.
 - ask about smoking status
 - ask about problems and counsel
- If patient quit more than 6 months ago, little need for specific intervention.

FYI

Updated Guidelines
Spring 2008