

Practical Issues in Applying the 5A's in Practice

5-5-10

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Goals

- Understand PHS Guidelines for Effective Tobacco Dependence Treatment
- Discuss evidence-based combination therapy of FDA medications for tobacco dependence
- Address practitioner needs regarding staying motivated to treat tobacco users



DISCLOSURE STATEMENT

- Dr. Williams has received speaker fees from Pfizer.
- No commercial support has been received for this program.
- Dr. Williams will be discussing combination medications as recommended in the Public Health Service Clinical Practice Guideline, "*Treating Tobacco Use and Dependence: 2008 Update.*" The FDA approved product labeling does not reflect recommendations in the Public Health Service Clinical Practice Guideline.



TAKE HOME POINT The "5 A's"

- ▶ **ASSESS** tobacco use and relevant risks
- ▶ **ADVISE** to quit
- ▶ **AGREE** collaboratively set goals
 - ▶ willingness to go for intensive treatment
- ▶ **ASSIST** in quit attempt
- ▶ **ARRANGE** for follow-up



Smoking in Perspective

- ▶ Kills more than 435,000 Amer. each year
- ▶ 21% of adult Americans smoke
- ▶ 4,000 12-17 y/o smoke first cig. every day
- ▶ 1,200 become daily cig smokers
- ▶ Causes cancer, CHD, stroke, pulmonary disease, and adverse preg. outcomes—shortens life expectancy 14 years
- ▶ Adds \$193 billion in costs per year
- ▶ One-third of all tobacco users in U.S. will die prematurely



Environmental Tobacco Smoke

- ▶ Kills 1 person, for every 8 killed by primary smoking
- ▶ 50,000 premature deaths each year
 - Conclusion of 3 independent scientific reports
 - 1 million ER visits for asthma each year
 - Platelet activation is predominate mechanism
 - ▶ Exp. to 1% of smoke has RR for CVD is 1.5
 - ▶ Exposure to smoking 20 cigs per day RR is 2.0
 - Banning ETS led to a 10-40% reduction in MI's
- ▶ Causes all diseases that primary smoke does
- ▶ The tobacco industry spends billions arguing the point



InterHeart Study

- ▶ Case Control Study of 27,000 for AMI
 - Tobacco use smoking OR = 2.95
 - Tobacco use chewing OR = 2.23
 - Tobacco use both OR = 4.09
 - Tobacco use former OR = 1.87 wi 3 yr

Tob use and MI Lancet
2006; 368:647-58

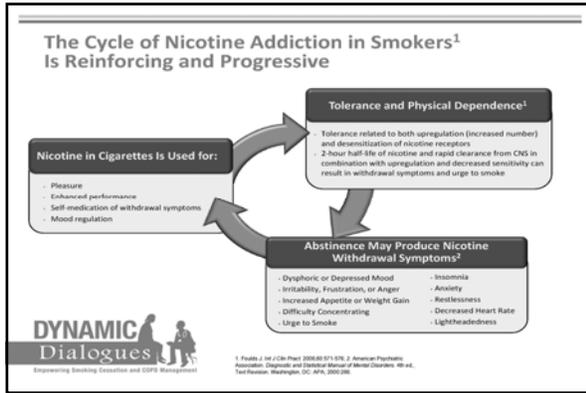


Health Benefits of Cessation

- ▶ **After 20 minutes**, your heart rate drops
- ▶ **After 12 hrs**, carbon monoxide level in your blood returns to normal
- ▶ **At 2 wks - 3 months**, your lung function begins to improve & your heart attack risks begin to drop
- ▶ **After 1 year**, CHD & stroke risk is half of a continued smoker's
- ▶ **After 5 years**, oral & esophageal cancer risks are halved
- ▶ **After 10 years**, lung cancer death rate is half of a smoker's

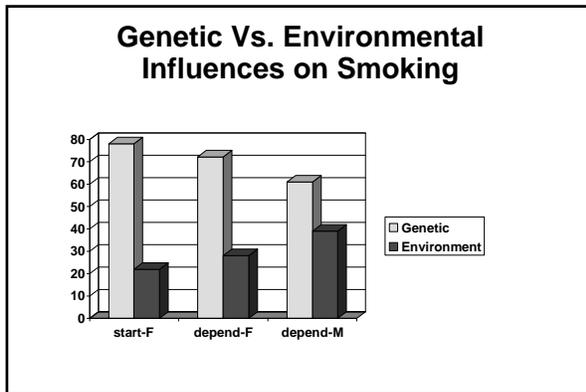
CDC, 2005





Genetic Vs. Environmental Influences on Smoking

- ▶ Increasing evidence that there are inherited vulnerabilities to nicotine addiction and differences in abilities to quit
- ▶ May allow tailored treatments
 - focusing on dopamine and noradrenergic systems in the brain
 - suggests long-term treatment may be needed

Tobacco use Presents a Rare Confluence of Circumstances

- ▶ A highly significant health threat
- ▶ A disinclination among clinicians to intervene consistently
- ▶ The presence of effective interventions



Translating Findings into Practice

Ten Key Guideline Recommendations

6. There are numerous effective medications for tobacco dependence and clinicians should encourage their use by all patients attempting to quit smoking, except when medically contraindicated or with specific populations for which there is insufficient evidence of effectiveness (i.e. pregnant women, smokeless tobacco users, light smokers and adolescents).
 - ▶ Seven first-line medications (5 nicotine and 2 non-nicotine) reliably increase long term smoking abstinence rates:
 - ▶ Bupropion SR
 - ▶ Nicotine gum
 - ▶ Nicotine inhaler
 - ▶ Nicotine Lozenge
 - ▶ Nicotine nasal spray
 - ▶ Nicotine patch
 - ▶ Varenicline
 - ▶ Clinicians should also consider the use of certain combinations of medications identified as effective in the Guideline.



Ten Key Guideline Recommendations

1. Tobacco dependence is a chronic disease that often requires repeated intervention and multiple attempts to quit. Effective treatments exist, however, that can significantly increase rates of long-term abstinence.
2. It is essential that clinicians and healthcare delivery systems consistently identify and document tobacco use status and treat every tobacco user seen in a healthcare setting.
3. Tobacco dependence treatments are effective across a broad range of populations. Clinicians should encourage every patient willing to make a quit attempt to use the recommended counseling treatments and medications in the Guideline.
4. Brief tobacco dependence treatment is effective. Clinicians should offer every patient who uses tobacco at least the brief treatments shown to be effective in the Guideline.
5. Individual, group and telephone counseling are effective and the effectiveness increases with treatment intensity. Two components of counseling are especially effective and clinicians should use these when counseling patients making a quit attempt:
 - Practical counseling (problem-solving/skills training)



Ten Key Guideline Recommendations

7. Counseling and medication are effective when used by themselves for treating tobacco dependence. However, the combination of counseling and medication is more effective than either alone. Thus, clinicians should encourage all individuals making a quit attempt to use both counseling and medication.
8. Telephone counseling is effective with diverse populations and has broad reach. Therefore, clinicians and healthcare delivery systems should both ensure patient access to quitlines and promote quitline use.
9. If a tobacco user is currently unwilling to make a quit attempt, clinicians should use the motivation treatments shown in the Guideline to be effective in increasing future quit attempts.
10. Tobacco dependence treatments are both clinically effective and highly cost-effective relative to interventions for other clinical disorders. Providing coverage for these treatments increases quit rates. Insurers and purchasers should ensure that all insurance plans include the counseling and medication identified as effective in the Guideline as covered benefits.



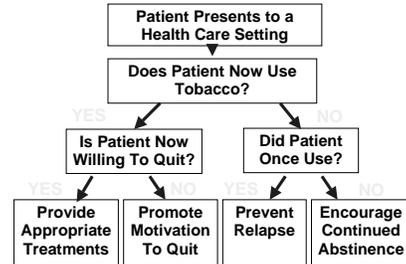
Ten Key Guideline Recommendations

- It is essential that clinicians and health care delivery systems consistently identify and document tobacco use status and treat every tobacco user seen in a health care setting.

*2008 Clinical Practice Guideline, Treating Tobacco Use and Dependence



Assessment of Tobacco Use



Vital Signs Stamp

VITAL SIGNS

Blood Pressure: _____

Pulse: _____ Weight: _____

Temperature: _____

Respiratory Rate: _____

Tobacco Use: Current FormerNever
(circle one)



The "5 A's" For Patients Willing to Quit

- ▶ **ASSESS** tobacco use and related risks
- ▶ **ADVISE** to quit
- ▶ **AGREE** collaboratively set goals
 - ▶ willingness to go for intensive treatment
- ▶ **ASSIST** in quit attempt
- ▶ **ARRANGE** for follow-up



Elements of a Counseling Intervention STAR

- ▶ **S**et a quit date- negotiate within 2 weeks ideally
- ▶ **T**ell others about your plan-family, friends, and ask for support
- ▶ **A**nticipate challenges, including withdrawal
- ▶ **R**emove all tobacco products. Before quitting, avoid smoking in places where you spend a lot of time (house, work, and car)



Ten Key Guideline Recommendations

7. Counseling and medication are effective when used by themselves for treating tobacco dependence. The combination of counseling and medication, however, is more effective than either alone. Thus, clinicians should encourage all individuals making a quit attempt to use both counseling and medication.

*2008 Clinical Practice Guideline, Treating Tobacco Use and Dependence



Counseling and Use of Medications

- ▶ 90% of smokers report being asked if they use tobacco, and >70% report receiving some counseling.
- ▶ Only 21% of smokers who tried to stop for 1 day used cessation medication.
- ▶ Smokers believe that nicotine is harmful.

PHS 2008



Meta-analysis (2008): Effectiveness of and estimated abstinence rates for the combination of counseling and medication vs. counseling alone (n= 9 studies). Table 6.24

Intervention	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
Counseling alone	11	1.0	14.6
Medication and counseling	13	1.7 (1.3-2.1)	22.1 (18.1-26.8)

From PHS 2008 guidelines pg 103



Meta-analysis (2008): Effectiveness of and estimated abstinence rates for the number of sessions of counseling in combination with medication vs. medication alone. (n= 18 studies) Table 6.22

Intervention	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
Medication alone	8	1.0	21.7
Medication and counseling	39	1.4 (1.2-1.6)	27.6 (25.0-30.3)

From PHS 2008 guidelines pg 102



Ten Key Guideline Recommendations

- Seven first-line medications (5 nicotine and 2 non-nicotine) reliably increase long-term smoking abstinence rates:
 - Bupropion SR
 - Nicotine gum
 - Nicotine inhaler
 - Nicotine lozenge
 - Nicotine nasal spray
 - Nicotine patch
 - Varenicline
- Clinicians also should consider the use of certain combinations of medications identified as effective in this Guideline.

*2008 Clinical Practice Guideline. Treating Tobacco Use and Dependence



Ten Key Guideline Recommendations

- Numerous effective medications are available for tobacco dependence, and clinicians should encourage their use by all patients attempting to quit smoking – except when medically contraindicated or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents).

*2008 Clinical Practice Guideline. Treating Tobacco Use and Dependence



Meta-analysis (2008): Effectiveness and abstinence rates for various medications and medication combinations compared to placebo at 6-months postquit (n= 83 studies) Table 6.26

Medication	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
Placebo	80	1.0	13.8
Monotherapies			
Varenicline (2 mg/day)	5	3.1 (2.5-3.8)	33.2 (28.9-37.8)
Nicotine Nasal Spray	4	2.3 (1.7-3.0)	26.7 (21.5-32.7)
High-Dose Nicotine Patch (>25 mg) (included both standard or long-term duration)	4	2.3 (1.7-3.0)	26.5 (21.3-32.5)
Long-Term Nicotine Gum (>14 weeks)	6	2.2 (1.5-3.2)	26.1 (19.7-33.6)
Varenicline (1 mg/day)	3	2.1 (1.5-3.0)	25.4 (19.6-32.2)
Nicotine Inhaler	6	2.1 (1.5-2.9)	24.8 (19.1-31.6)
Clonidine	3	2.1 (1.2-3.7)	25.0 (15.7-37.3)
Bupropion SR	26	2.0 (1.8-2.2)	24.2 (22.2-26.4)
Nicotine Patch (6-14 weeks)	32	1.9 (1.7-2.2)	23.4 (21.3-25.8)
Long-Term Nicotine Patch (>14 weeks)	10	1.9 (1.7-2.3)	23.7 (21.0-26.6)
Nortriptyline	5	1.8 (1.3-2.6)	22.5 (16.8-29.4)
Nicotine Gum (6-14 weeks)	15	1.5 (1.2-1.7)	19.0 (16.5-21.9)

From PHS 2008 guidelines pg 109

Factors to Consider When Prescribing a Pharmacotherapy

- ▶ Medications can double or triple quit rates
- ▶ Contraindications for selected patients
- ▶ Previous experience and preference with NRT
- ▶ Patient characteristics: weight, depression
- ▶ Cigarettes smoked per day (1 mg/cig)

Clinical Guidelines, 2000



Nicotine Replacement Therapy

- ▶ No evidence of increased cardiovascular risk with NRT except with acute disease
- ▶ Medical contraindications:
 - immediate myocardial infarction (< 2 weeks)
 - serious arrhythmia
 - serious or worsening angina pectoris
 - accelerated hypertension



Pharmacotherapeutic Interventions

- ▶ All patients attempting to quit smoking should be encouraged to use pharmacotherapy except under special circumstances such as:
 - Medical contraindications
 - Smoking fewer than 10 cigarettes/day
 - Pregnant/breastfeeding women
 - Adolescents



Combination Nicotine Replacement Therapy

- ▶ Combining the nicotine patch and a self-administered NRT (either nicotine gum or nicotine nasal spray) is more efficacious than a single form of NRT



Meta-analysis (2008): Effectiveness and abstinence rates of medications relative to the nicotine patch (n= 83 studies) (continued) Table 6.28

Medication	Number of arms	Estimated odds ratio (95% C.I.)
Nicotine Patch (reference group)	32	1.0
Combination therapies		
Patch (long-term; >14 weeks) + NRT gum or spray	3	1.9 (1.3-2.7)
Patch + Bupropion SR	3	1.3 (1.0-1.8)
Patch + Nortriptyline	2	0.9 (0.6-1.4)
Patch + Inhaler	2	1.1 (0.7-1.9)
Second-generation antidepressants & patch	3	1.0 (0.6-1.7)
Medications not shown to be effective		
Selective Serotonin Re-uptake Inhibitors (SSRIs)	3	0.5 (0.4-0.7)
Naltrexone	2	0.3 (0.1-0.6)

From PHS 2008 guidelines pg 122

Why do you counsel?

- ▶ Please consider why you feel it is important to do this counseling?



Practitioner Motivation

Practitioner Barriers to Providing Tx

- ▶ Lack knowledge
 - Identify tobacco users
 - Which treatments are successful
- ▶ Inadequate institutional support
- ▶ Time constraints
- ▶ Inadequate reimbursement
- ▶ Low success rates
- ▶ Limited training

PHS 2008, p 12



Tobacco Dependence as a Chronic Disease

- ▶ Tobacco dependence demonstrates features of a chronic disease:
 - Long-term disorder
 - Periods of relapse and remission
 - Requires ongoing rather than acute care



Opportunity for Intervention

- ▶ 70% of smokers have made at least one unsuccessful quit attempt
- ▶ 40% try to quit each year
- ▶ More than 70% of smokers visit a health care setting each year
- ▶ Effective treatments exist which produce long-term or permanent abstinence



Motivation to Treat Smokers

- ▶ More than half of all smokers have stopped since '64
- ▶ More cost effective than many standard medical interventions (HTN, Chol, CABG)
- ▶ All clinicians can be effective
- ▶ Patient satisfaction increases with counseling whether they want to stop or not
- ▶ When training is provided key motivations increase
- ▶ When systems support counseling and abstinence rates increase

PHS 2008



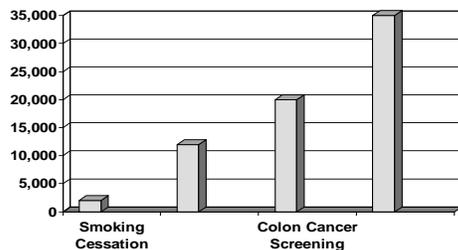
Efficacy of Interventions Delivered by Various Types of Clinicians (n = 29 studies)

Type of Clinician	Odds Ratio (95% CI)	Estimated Abstinence Rate
No clinician (reference group)	1.0	10.2%
Self-help	1.1 (0.9-1.3)	10.9%
Non-physician clinician	1.7 (1.3-2.1)	15.8%
Physician clinician	2.2 (1.5-3.2)	19.9%

MEDICINE OF THE HIGHEST ORDER



Cost Per Life Year Saved



Look for Short Successes

- ▶ Validated predictors of cessation (Farkas, 1996; Dale, 2001)
 - ▶ smoking >15 cigs/day and within 30 minutes of waking 10.8% vs 27.8% cessation 2 years later
 - ▶ smoking daily (14%) vs smoking some days (35%)
 - ▶ quit for 6 or more days in 12 mo. 26% vs 14%
 - ▶ quit for >1 year anytime 26% vs 13%



Medical Professionalism – A Physician Charter & Biomedical Ethics

- Primacy of patient welfare: a dedication to serving patients' interests
- Patient autonomy: to empower patients to make informed decisions
- Social justice: to eliminate discrimination

ABIM Foundation. *Ann Intern Med.* 2002;136:243-246
Beauchamp & Childress. *Biomedical Ethics* 2001.

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Psychological Needs: Supporting Optimal Motivation

- Autonomy
 - The need to feel choiceful and volitional in one's behavior
- Competence
 - The need to feel optimally challenged and capable of achieving outcomes
- Relatedness
 - The need to feel connected to and understood by important others

Deci & Ryan, 1991, 2000
Ryan & Deci, 2000

In Summary

- ▶ Brief tobacco dependence treatment is effective and every patient who uses tobacco should be identified, urged to quit, and offered at least one of these treatments:
 - Patients willing to quit should be provided treatments identified as effective
 - Patients unwilling to quit should be provided an intervention to increase their motivation to quit



Nicotine Gum

- ▶ **Advantages:**
 - Orally gratifying, useful to offset cravings
- ▶ **Disadvantages:**
 - Poor taste, mouth soreness, dyspepsia, hiccups
- ▶ **Dosage:** Maximum dose: 24 pieces/day
 - patient smokes < 25 cigs/day: 2mg
 - patient smokes > 25 cigs/day: 4mg

**must use correctly: chew & park*

Clinical Guidelines, 2008 & NYS Smokers' Quidsite



FDA Approved Medications

Nicotine Patch

- ▶ **Advantages:**
 - Easy to use, private, one per day, helps with early morning cravings
- ▶ **Disadvantages:**
 - Skin reactions, not orally gratifying, vivid dreams, insomnia
- ▶ **Dosage:** 4 weeks - 21mg/24hrs.
 - then 2 weeks - 14mg/24hrs.
 - then 2 weeks - 7mg/24 hrs.

Clinical Guidelines, 2008 & NYS Smokers' Quidsite



Nicotine Lozenge

- ▶ **Advantages:**
Keeps mouth busy, easy to use in social situations
- ▶ **Disadvantages:**
mouth/throat irritation, heartburn, indigestion, hiccups & nausea
- ▶ **Dosage:** minimum dose: 9 lozenges/day
 - ▶ 2mg: smokes 1st cigarette after 30 min. of waking
 - ▶ 4mg: smokes 1st cigarette within 30min.of waking

Shiffman, S. et al, 2002



Nicotine Nasal Spray

prescription

- ▶ **Advantages:**
Higher nicotine levels, fast relief for heavy smokers, rapid delivery of nicotine
- ▶ **Disadvantages:**
Nasal irritation, sneezing, coughing, runny nose
- ▶ **Dosage:** 1 – 2 doses/hour (in each nostril)
minimum dose: 8 doses/day
maximum dose: 40 doses/day

NYS Smokers' Quitline & Lerman, et al, 2004



Nicotine Inhaler

prescription

- ▶ **Advantages:**
Mimics smoking, keeps hands & mouth busy
- ▶ **Disadvantages:**
mouth & throat irritation, coughing, rhinitis, less effective below 40° F
- ▶ **Dosage:** 6 – 16 cartridges/day
one cartridge lasts 20 min. continuous puffing

Clinical Guidelines, 2008 & NYS Smokers' Qitsite



Bupropion SR

prescription

- ▶ **Advantages:**
Antidepressant, less weight gain, FDA approved for maintenance therapy (6mos)
- ▶ **Disadvantages:**
May disrupt sleep, possible headaches, & dry mouth, seizure risk
- ▶ **Dosage:** Begin 1-2 weeks prior to quit date
150mg q am for 3 days
Increase to 150mg b.i.d.

Clinical Guidelines, 2008 & NYS Smokers' Qitsite



Varenicline

prescription

- ▶ **Newest FDA approved medication for smoking cessation (May 2006). Partial agonist selective for the nicotine acetylcholine receptor**
- ▶ **Disadvantages:**
 - Nausea, insomnia, vivid dreams , headache
- ▶ **Dosage:** Begin 1 week prior to quit date
 - Days 1 – 3: 0.5 mg qd
 - Days 4 – 7: 0.5 mg bid
 - Days 8 – 28: 1 mg bid

An additional 12 wks recommended for those who quit
 *Should be taken after eating and with full glass of water
 Adjust dose for renal insufficiency 0.5 mg/d for GFR < 30



Meta-analysis (2008): Effectiveness and abstinence rates of medications relative to the nicotine patch (n= 83 studies) Table 6.28

Medication	Number of arms	Estimated odds ratio (95% C.I.)
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High-Dose Nicotine Patch (>25 mg; standard or long-term)	4	1.2 (0.9-1.6)
Long-Term Nicotine Gum (>14 weeks)	6	1.2 (0.8-1.7)
Varenicline (1 mg/day)	3	1.1 (0.8-1.6)
Nicotine Inhaler	6	1.1 (0.8-1.5)
Clonidine	3	1.1 (0.6-2.0)
Bupropion SR	26	1.0 (0.9-1.2)
Long-Term Nicotine Patch (>14 weeks)	10	1.0 (0.9-1.2)
Nortriptyline	5	0.9 (0.6-1.4)
Nicotine Gum	15	0.8 (0.6-1.0)

From PHS 2008 guidelines pg 121

Extended Use of Pharmacotherapy

- ▶ First-line tobacco dependence medications may be considered for extended use, especially in patients with persistent withdrawal symptoms
- ▶ Evidence demonstrates that a minority of patients continue ad libitum NRT agents
- ▶ Does not present known health risks
- ▶ US FDA has approved bupropion SR for a long-term maintenance indication



Ten Key Guideline Recommendations

10. Tobacco dependence treatments are both clinically effective and highly cost-effective relative to interventions for other clinical disorders. Providing coverage for these treatments increases quit rates. Insurers and purchasers should ensure that all insurance plans include the counseling and medication identified as effective in this Guideline as covered benefits.

*2008 Clinical Practice Guideline. Treating Tobacco Use and Dependence





Online Smokefree Community

- ▶ QUNITY: Web-based interactive community

Featuring **Breathe**

Two overlapping screenshots of the QUNITY website. The top screenshot shows the "Taking the First Steps" page, and the bottom screenshot shows the "Fitness & Exercise" page. Both pages feature a navigation menu on the left and a main content area with various links and resources.

Join Breathe! Your Personal Quit Plan
Click Here

Online Smokefree Community

A screenshot of the QUNITY website homepage. The page features a navigation bar with links for Home, Forum, Blog, and more. The main content area is divided into several sections: "Welcome to Qunity" with a list of recent posts, "My Qunity" with a profile for Anthony Brown, and "Where to start?" with a list of resources. A "Join Breathe! Your Personal Quit Plan" button is visible at the bottom.

Online Smokefree Community

Why Qunity/Breathe

- ▶ Provide alternative methods of cessation support
- ▶ Help more NY residents live smoke-free.
- ▶ Assist people who may not want to call for support.
- ▶ Cost savings
- ▶ Social Networks – tie in
- ▶ Create tailored Quit Plan

QUIT ONLINE! Click to join your QUNITY Smokefree Community

Join Here FREE

learn • chat • express yourself • get your personalized quit-coach • live

Join Breathe! Your Personal Quit Plan
Click Here