

Closing the Gap: Treatment of Tobacco Dependence



Disclosure of Relevant Financial Relationships

With any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

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1 = No relationship 2 = Relationship disclosed below

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Closing the Gap: Treatment of Tobacco Dependence

Objectives

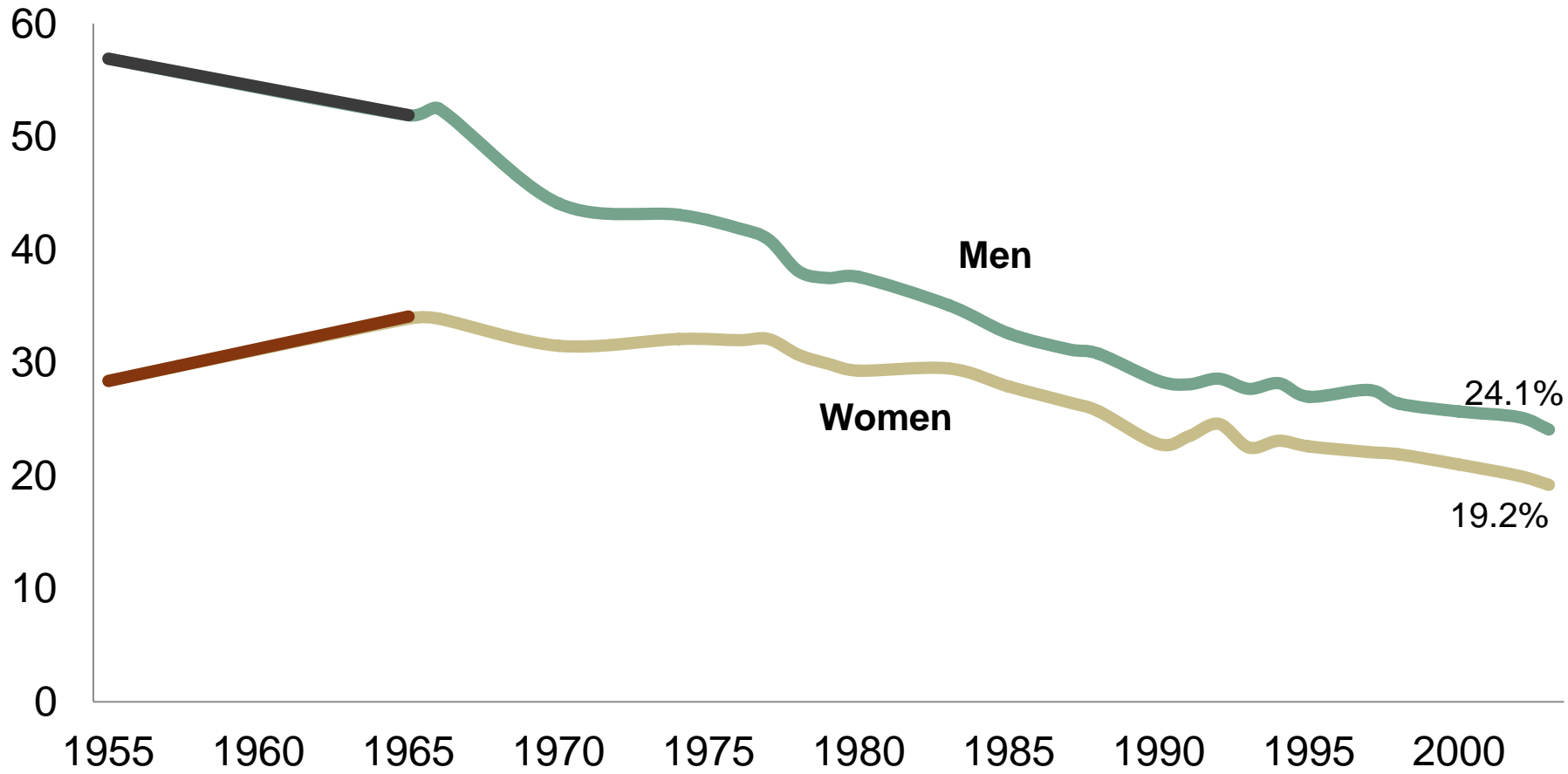
At the conclusion of this talk audience members should be able to:

1. Treat tobacco users using the 5 A's model of tobacco dependence treatment
2. Identify effective approaches to counseling and recognize components of a non-judgmental counseling method called motivational interviewing
3. Be able to confidently prescribe and list major side effects of the FDA approved smoking cessation medications
4. Answer your patients' questions about electronic cigarettes

Global Tobacco Epidemic

- Nearly 6 million deaths a year globally (WHO, CDC)
- By 2030 over 8 million deaths a year
- The leading cause of preventable disease, disability and deaths in the world
- USA 480,000 deaths per year including 42,000 from second hand smoke exposure
- One in five deaths
- Reduces life by 10-14 years
- Half of lifelong cigarette users die from smoking
- US 42.1 million people smoke

Trends in cigarette smoking* among adults aged ≥ 18 years, by sex - United States, 1955-2003



*Before 1992, current smokers were defined as persons who reported having smoked ≥ 100 cigarettes and who currently smoked. Since 1992, current smokers were defined as persons who reported having smoked ≥ 100 cigarettes during their lifetime and who reported now smoking every day or some days. 2003 estimate is for January-September.

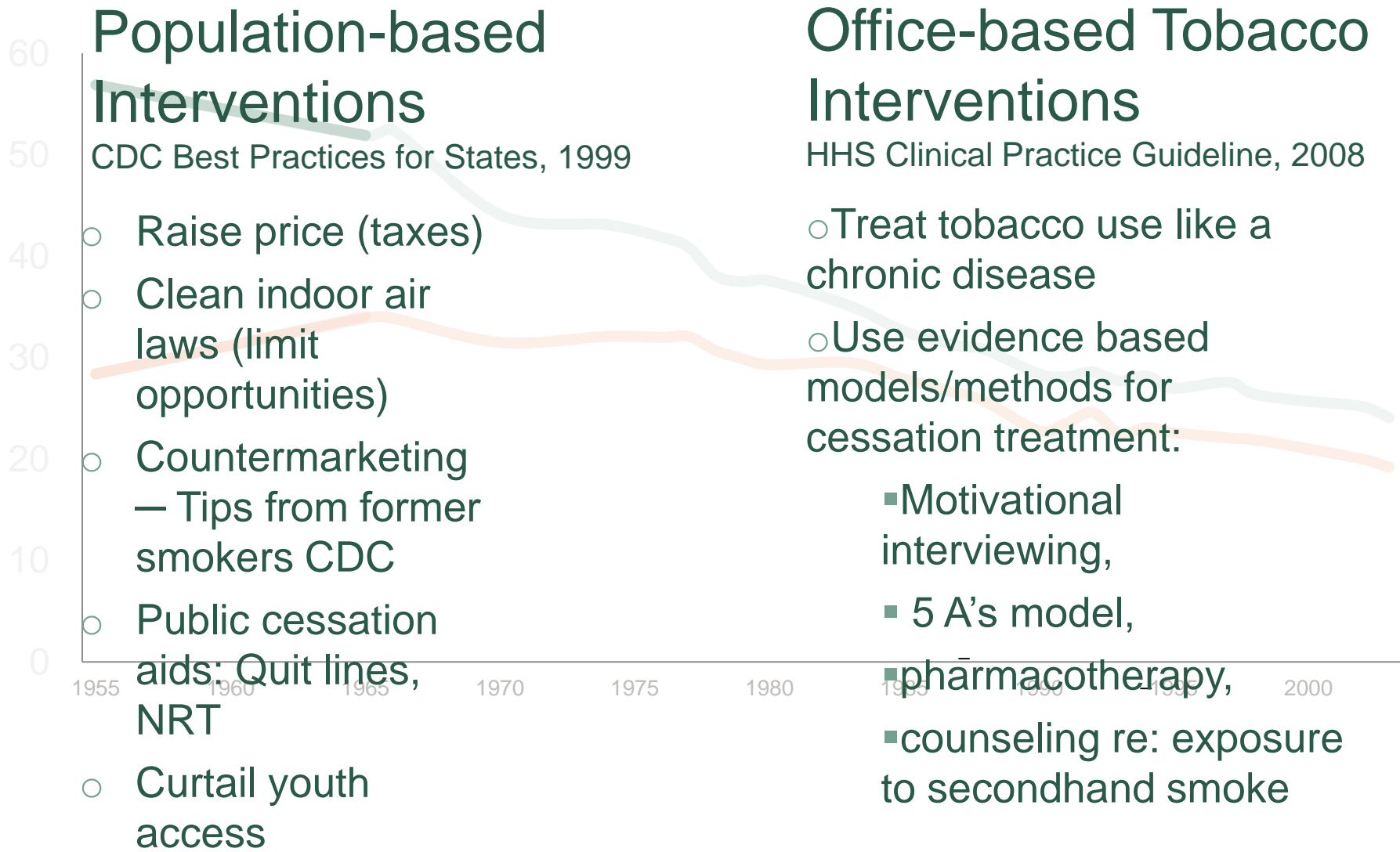


Adult Smoking Prevalence 2014

	TOTAL	MEN	WOMEN
USA	16.8%	18.8%	14.8%
NYS	14.5%	17%	12%
NYC	13.9%	18.1%	10%

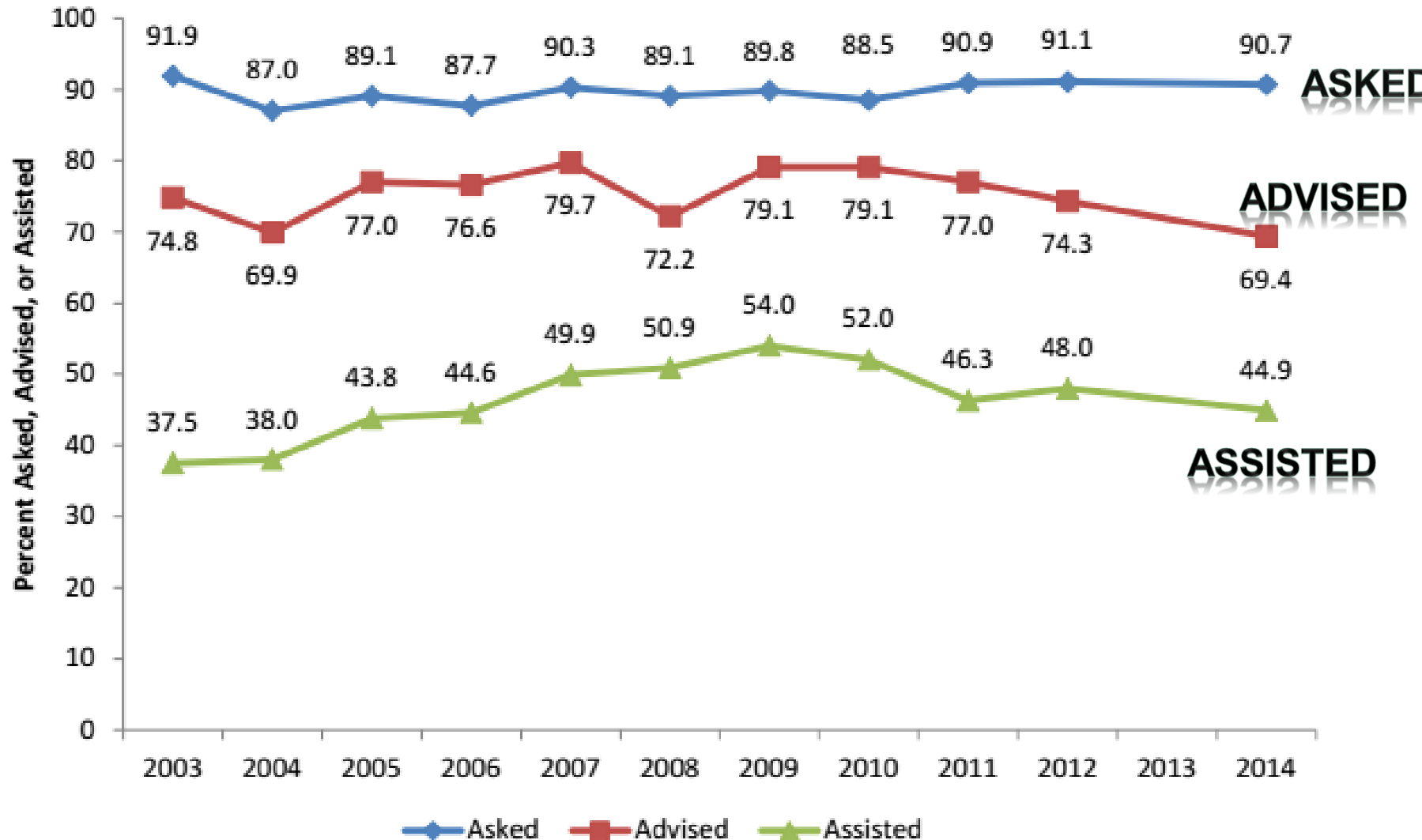
Source: CDC, New York City Department of Health

How we got as far as we did...



Source: 1955 Current Population Survey; 1965-2003 National Health Interview Surveys

Percentage of Smokers in New York who were Asked, Advised, or Assisted



Source: New York Adult Tobacco Survey, 2003-2014. accessed online at http://www.health.ny.gov/prevention/tobacco_control/reports/statshots/

Barriers in Treating Tobacco Dependence

- Lack of Time
- Insurance variability
- Office work flow
- Records and reminders inadequate
- Documentation for reimbursement not optimal for either a fee for service or value-based payment system
- Electronic health record not meeting needs
- Knowledge gap in counseling and pharmacotherapy

Tobacco Dependence : A Chronic Disease

- A long-term disorder with two components
 - Psychological, behavioral
 - Physiological addiction, withdrawal symptoms
- Remission and relapse
- High failure rate on a single attempt to quit: 60-90%
- Requires ongoing rather than acute care
- May take multiple attempts before quitting success

The 5 A's

A national clinical guideline –
Agency for Healthcare Research and Quality

- **Ask**
- **Advise**
- **Assess**
- **Assist**
- **Arrange**

Treating Tobacco Use and Dependence
2008 Update AHRQ

Assess Readiness for Change

Stages of change

(Prochaska & DiClemente 1983)

- Pre-contemplation- Not thinking about or ready for change
- Contemplation- Thinking about Change (Ambivalent)
- Preparation- Ready for Change
- Action- Making change
- Maintenance – Maintaining change

Counseling: Ready to Quit

Address Behavioral Change

- Quit date, environmental preparation
- Identify outside support: family, friends, co-workers
- Solve problems unique to patient
 - Family smokers, work,
- Discuss cravings and triggers
 - Intense craving only last 3-5 minutes
- Select medication
- Seek support
 - NYS Quitline www.nysmokefree.com
 - **1-866-NY-Quits** nysmokefree.com
 - Community quit programs



Counseling: Not Ready to Quit (Precontemplation/Contemplation)

- Consider Following Spirit and Using Principles of Motivational Interviewing and/or Brief Action Planning
 - *USPSTF, Ann Intern Med. 2015; 163:622-34*
- “Motivational Interviewing is a collaborative conversation to strengthen a person’s own motivation for and commitment to change”
 - *Miller & Rollnick, Motivational Interviewing, 3rd ed., 2013*
- “Brief Action Planning is a self-management support tool and technique based on the principles and practice of Motivational Interviewing”
 - *Gutnick et al, Journal of Clinic Outcomes Management, 2014*

Counseling: Motivational Interviewing (MI)

Spirit of MI

- A type of conversation about change
- Collaboration
Physicians and Patients are Equals
- Evocation
Ideas for Change come from Patient
- Acceptance
Respect Patients' Autonomy
Accept Patients' Decision to Change or Not
- Compassion
Physicians Keep Patient's Needs Primary, Never Their Own

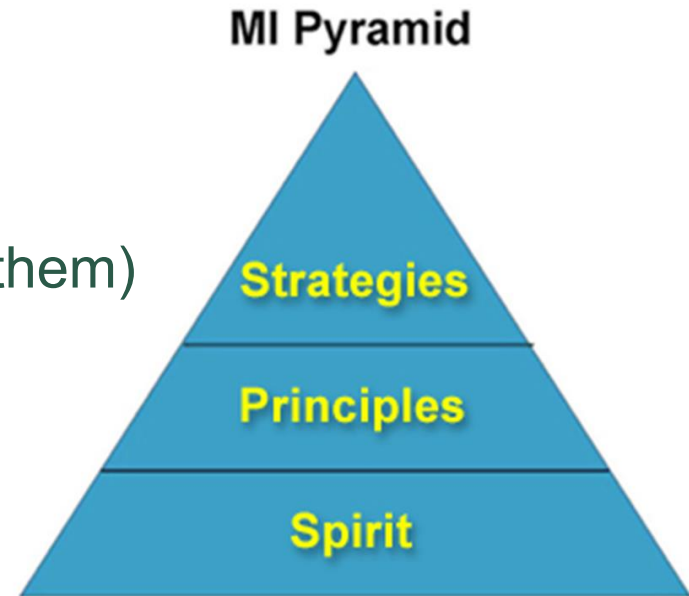


Counseling: Motivational Interviewing

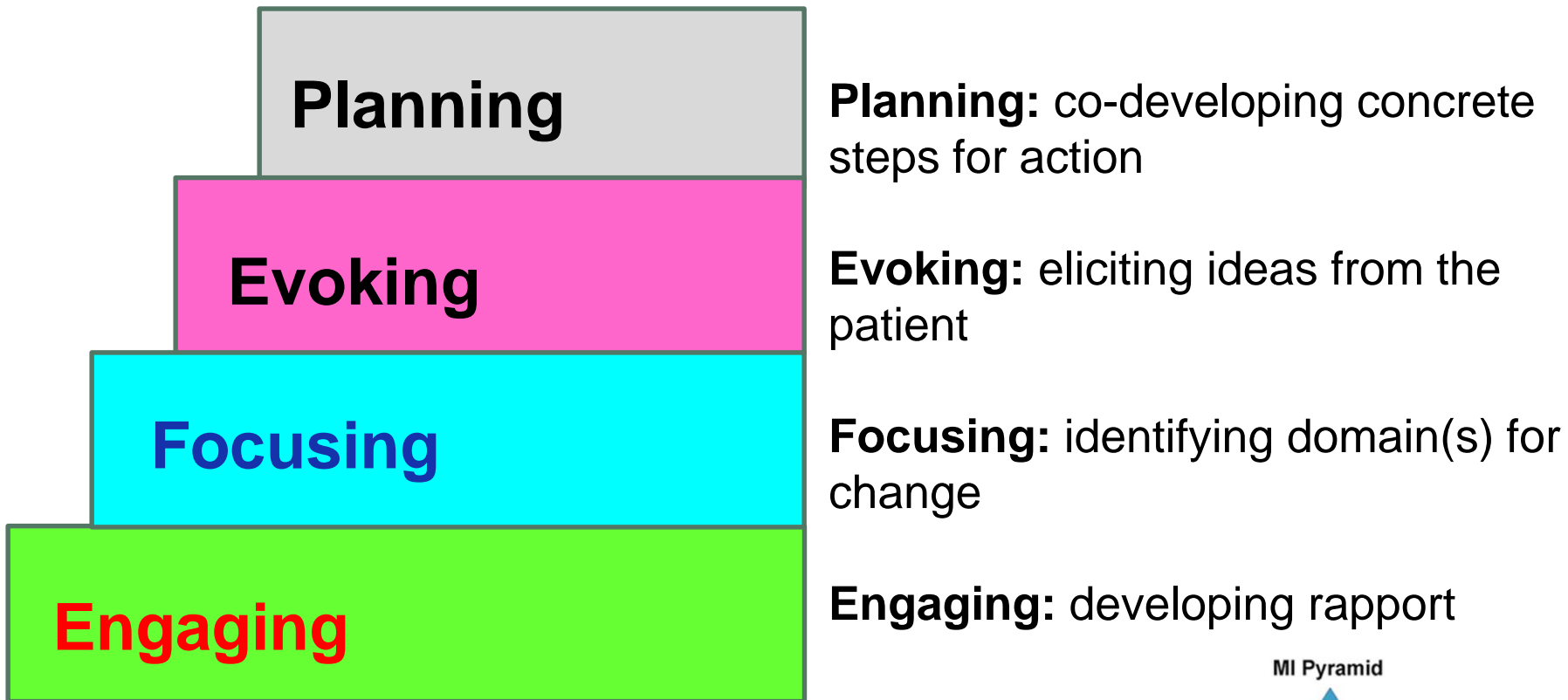
Principles of MI

RULE

- Avoid the righting reflex
(Do not tell patients what is “right” for them)
- Understand
(Express empathy)
- Listen
- Empower



Counseling: Four Core Processes of MI



Each process utilizes all of the concepts of the MI pyramid



Counseling: Motivational Interviewing

Strategies of MI: Difficult to Master

- Elicit Ambivalence & Help Resolve (ambivalence is normal)
- Elicit and Increase Change Talk (e.g. desire, ability, reasons, or need to change)
- Plan Change Collaboratively

Youtube video: *Mr Smith's Smoking Evolution* (Damara Gutnick MD)

- ACP Motivational interviewing workshop



Counseling: Brief Action Planning (BAP)

For Patients Contemplating Change

Adhere to Spirit of MI throughout, achieve engagement, then ask
Question One of BAP (which focuses and evokes change talk)

“Is there anything you’d like to do for your health (smoking) in the next week or two?”

If ‘yes’ then ask: *“What, when, how....”*

Help patient make an action plan that is “SMART”

(specific, measurable, achievable, realistic, time-based)

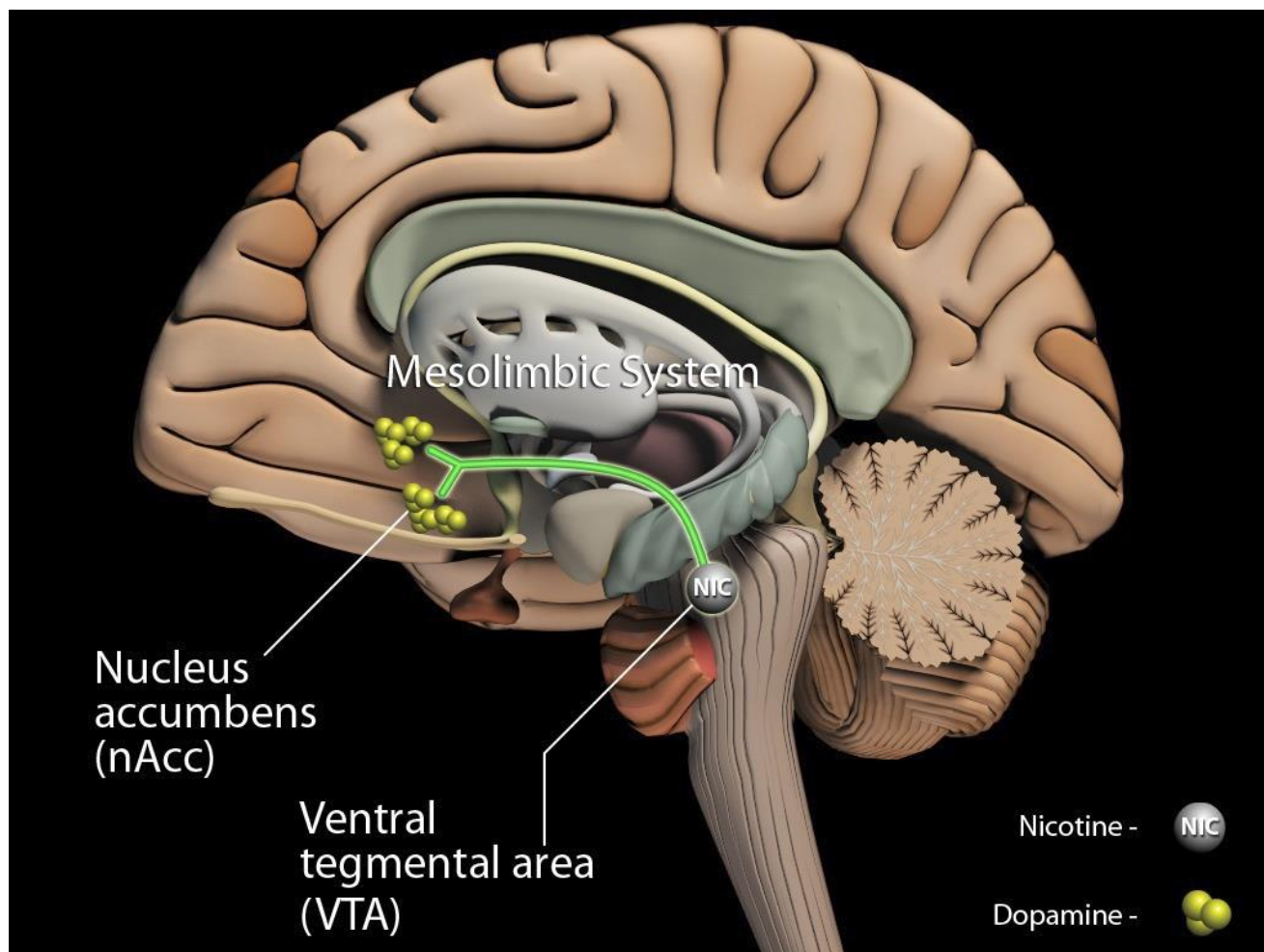
If a patient and physician develop a SMART action plan for health, consider using five other competencies of BAP (elicit commitment statement, scale for confidence, problem-solve for low confidence, offer accountability, follow-up)

BAP is more highly structured and not as difficult to master as MI

Pharmacotherapy:

Ready to Quit: Addressing Physiological Addiction

Goal: Ease the symptoms of withdrawal while learning to deal with stress, anger, hunger, dark moods, good times and other reasons people smoke—without smoking



Nicotine Withdrawal Symptoms

Symptoms	Duration	Prevalence
Urges to smoke	> 2 weeks	70%
Increase appetite	>10 weeks	70%
Poor concentration	< 2 weeks	60%
Depression	< 4 weeks	60%
Restlessness	< 4 weeks	60%
Irritability/aggression	< 4 weeks	50%
Mouth ulcers	> 4 weeks	40%
Night-time awakenings	< 1 week	25%
Constipation	> 4 weeks	17%
Light-headedness	< 48 hours	10%

First-Line Pharmacotherapies

FDA approved. safe and effective:

Nicotine Replacement Therapy (NRT):

Nicotine gum

Nicotine patch

Nicotine lozenge

Nicotine inhaler*

Nicotine nasal spray*

Bupropion SR*

Varenicline*

*prescription required

The Nicotine Patches

Delivery: Transdermal absorption

Screening: Screen for skin disorders

Dose: Fit with severity of addiction

>10 cig/day, start with 21mg dose; more if needed

Instructions: Place in AM on non-hairy area of skin above waist (upper arm or torso)

Use new spot every day

Side Effects: skin irritation, vivid dreams, insomnia

Additional Notes: Careful disposal



The Nicotine Gum

Delivery: Oral mucosal absorption

Screening: Screen for dentures, tooth loss, mouth ulcers; may have trouble with gum

Dose: 4mg, 2mg

Instructions: Chew on a schedule, 1-2 pieces per hour.
Or, dual therapy use for breakthrough urge
Review proper chewing technique with patients
Avoid beverages 15 minutes before and after use except water

Side Effects: mouth ulcers, jaw pain, “nicotine rush”: stomach pain, heartburn, hiccups, light headedness.

Additional Notes: Careful disposal



The Lozenges

Delivery: Oral mucosal absorption



Dose: 4mg, 2mg

Instructions: Slowly dissolve in mouth over 20-30 minutes moving to different cheek; do not chew or break. Every 1-2 hours.

Avoid acidic beverages 15 minutes before and after use

Side Effects: mouth irritation, ulcers, “nicotine rush”

The Nicotine Inhaler

Delivery: Oral mucosal absorption

Dose: 10mg

Instructions: A small cartridge containing 10 mg of nicotine is punctured and placed in a holder and nicotine is released in an aerosol into the mouth as the patient inhales.

The droplets do not descend into the lungs.

No acidic beverages 15 min before and after use

Additional Notes: Less likely to produce stomach symptoms or nicotine “rush”



The Nicotine Nasal Spray



Delivery: Nasal mucosal absorption

Dose: one spray each nostril, 1 mg nicotine; 8-40 doses/day

Instructions: Blow nose, tilt head back slightly, do not inhale the spray

Side Effects: Nasal irritation, sneezing, tearing, throat irritation (tachyphylaxis develops)

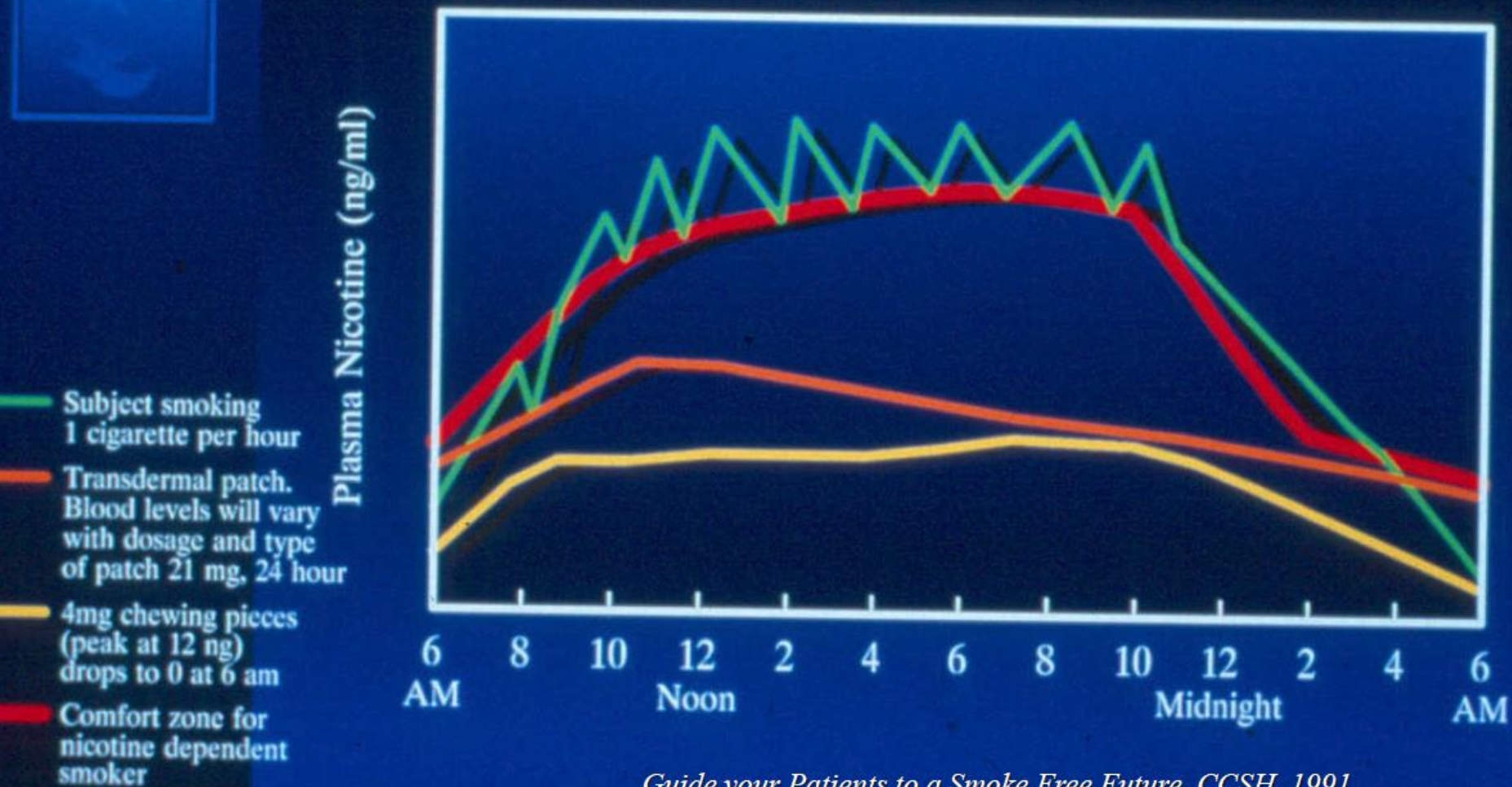
Additional Notes: Fastest delivery. Good for overwhelming urges. In Canada, there is an oral NRT spray with similar fast action

Special NRT Concerns

- Nicotine is a **POISON**, especially dangerous to children and small animals. Careful disposal of used gum, patches, cartridges, spray bottles is necessary
- **SYMPTOMS** of nicotine poisoning: GI irritation (nausea vomiting diarrhea), salivation, shakiness, weakness, dizziness, confusion.
- Tobacco smoke affects **DRUG-METABOLIZING ENZYMES**. Check drug interactions when prescribing.
- **CAFFEINE** levels can rise dramatically after smoking cessation. Stomach symptoms and “shakes” may be due to elevated caffeine, not nicotine overdose.

A
SMOKE
FREE
FUTURE

A Day in the Life of Blood Nicotine



Guide your Patients to a Smoke Free Future. CCSH. 1991

Combination Pharmacotherapy

- Nicotine patch plus gum, lozenge, or nasal spray
- Nicotine patch plus inhaler
- Nicotine patch plus bupropion or varenicline

These combinations all doubled or tripled the quit rate in research studies

Use NRT to "Reduce To Quit"

- In smokers "unwilling or unable" to make an abrupt quit attempt*
- Sustained abstinence (12m) 5.3% NRT v 2.6% placebo (RR=2.06)*
- No significant adverse events, cost effective*

Wang D et al. 'Cut down to quit' with nicotine replacement therapies in smoking cessation: a systematic review of effectiveness and economic analysis. Health Technol Assess 2008;12(2)

Bupropion SR (Zyban, Wellbutrin SR)

Delivery: 150mg slow release tablet, 8 hr time action

Screening: Screen for seizure risk (epilepsy, head injury, brain surgery), eating disorder, MAOI current or recent, heavy alcohol use, depression or other psychiatric illness

Mechanism: Blocks some nicotine receptors

Dose: Start taking before discontinuing smoking

150mg SR OD for 3 days then increased to BID

Some patients do not need two doses; in others, the second can be taken 8 hours after the first and be dissipated by bedtime

Side Effects: insomnia, dry mouth, Risk of seizures in susceptible individuals, headache, nausea, agitation, anxiety

Additional Notes: Antidepressant and anorexigenic actions that are useful in smoking cessation patients.

Varenicline (Chantix)

Delivery: Oral GI absorption

Screening: Screen for kidney disease and mental illness.

Mechanism: partial agonist of $4\beta 2$ nicotinic acetylcholine receptors. Reduces cravings and prevents nicotine reward

Dose: Begin 1 week before quit date

Taking: **Start pack** begins with 0.5mg OD days 1-3, 0.5mg BID days 4-7, then 1mg BID. **Continuation pack**

Take after eating with full glass of water.

Side Effects: nausea, vivid dreams, insomnia, immediate hypersensitivity, skin reactions, neuropsychiatric illness

BLACK BOX: Monitor for depression, suicidality, hostility, agitation, behavior changes, or worsening preexisting psychiatric disease.

FDA 2015 warning: increases intoxication with alcohol

Neuropsychiatric Symptoms and Smoking Cessation

Retrospective cohort study done in the UK 2015

- 164 766 patients given Rx (106 759 for nicotine replacement treatment; 6557 for bupropion; 51 450 for varenicline)
- No evidence of any increased risk of cardio-vascular or neuropsychiatric adverse events in smokers using varenicline or bupropion when compared with NRT users.
- Reduced depression and ischemic heart disease
- Effective in psychiatric patients

• D Kotz et al. Cardiovascular and neuropsychiatric risks of varenicline: a retrospective cohort study. *Lancet Respir Med* 2015;3:761

Combinations of Varenicline with NRT and Bupropion

Combination NRT and varenicline was more effective than varenicline alone at 12 weeks, main side effect, rash from patch

(Koegelenberg CF et al [JAMA](#). 2014 Jul;312(2):155-61)

Combination bupropion and varenicline was more effective than varenicline alone and was more effective in men and the highly nicotine dependent

(Combination bupropion SR and varenicline for smoking cessation: a systematic review [Am J Drug Alcohol Abuse](#). 2016 Mar;42(2):129-39.

[Am J Psychiatry](#). 2014 Nov 1;171(11):1199-205)

New Developments in Treatment Paradigm: FDA Proposed Label Changes

- NRT use permitted while still smoking. Use NRT to reduce
- Use of multiple NRT products allowable
- Safe to extend treatment beyond label recommendation

Food and Drug Administration (2013b). Nicotine replacement therapy labels may change. FDA Consumer Health Information. Silver Spring, MD: U. S. Department of Health and Human Services.

New Developments-2

Ottawa Conference on Smoking Cessation 2016:

“As much as it takes, for as long as needed”

- More than one patch: up to 4/day have been used safely.
- Combination of Varenicline and NRT
 - Unable to quit on Varenicline alone, add NRT
 - Use NRT to decrease # of daily cigarettes, then start Varenicline
 - When nausea is severe, use NRT with a lower dose of Varenicline

Electronic cigarettes

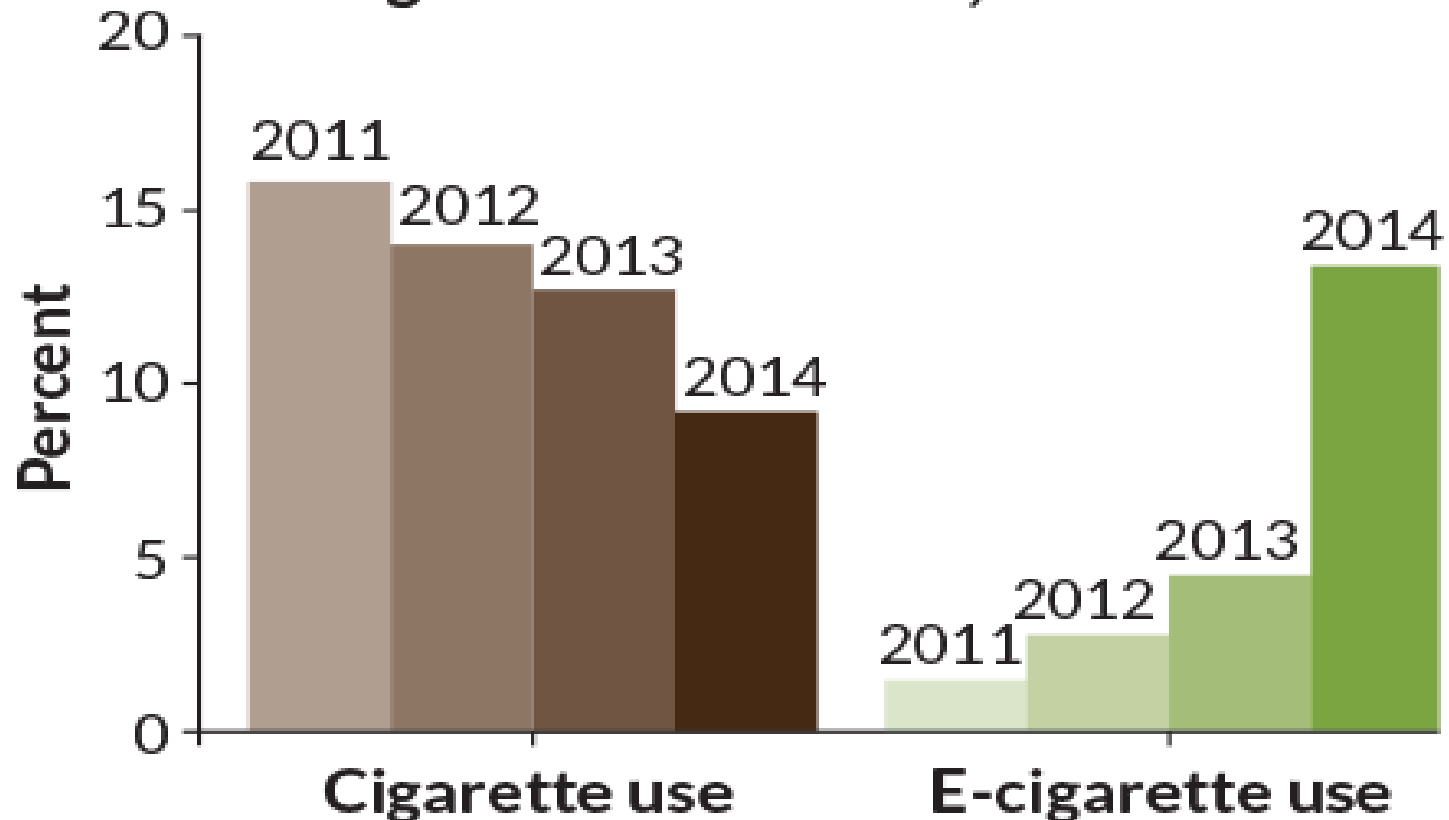
- No restrictions on advertising
- No quality control of ingredients or manufacture
- Vaporized carrier, additives and nicotine can all cause cellular damage and symptoms
- Toxins identified in inhaled as well as environmental vapor



- Battery-powered devices that heat a solution of liquid nicotine and other chemicals creating an emission which is inhaled by the user
- Little is known about the contents of ENDS liquid.

2014 National Youth Tobacco Survey

Cigarette and e-cigarette use among U.S. high school students, 2011–2014



Arrazola et al. Tobacco use among middle and HS students 2011-2014. MMWR2015;65:381-5
CDC Press Release: <http://www.cdc.gov/media/releases/2015/p0416-e-cigarette-use.html>

New Challenges & Current Laws

ENDS (electronic nicotine delivery system)

Long-term effects unknown

“Nicotine exposure at a young age may cause lasting harm to brain development, promote addiction, and lead to sustained tobacco use.”

-Tom Frieden, M.D., M.P.H Director, Centers for Disease Control and Prevention (CDC)

- New York City**

 - No sale to persons under age 21**

 - No use in places where smoking tobacco products is prohibited**

- New York State**

 - No sale to persons under age 18**

Using the NYS Quitline: 1-866-NY-Quits nysmokefree.com

- Refer-to-Quit (online registration) or Fax-to-Quit
 - If patient agrees, send referral from office, and NYS Quit follows up
 - Progress report sent back later
 - Coach calls patient 5 times, sends letter if no contact
 - Two weeks of NRT if eligible
 - Patient can call Quitline as often as needed

The screenshot displays the website for the New York State Smokers' Quitline. At the top left, the logo features a map of New York with a blue circle containing a white telephone handset. The text reads: "New York State Smokers' Quitline", "1-866-NY-QUITS (1-866-697-8487)", and "The NY State Department of Health Tobacco Control Program". To the right is a search bar with a "Go!" button and social media icons for Facebook, LinkedIn, and Twitter. A navigation menu includes: Home, Quit Now, Stay Smoke-Free, Facts & Myths, Resources, Employers & Health Plans, and Healthcare Providers & Partners. Below the menu is a large banner with two images: a woman on a phone and a group of people. Text on the banner says: "CALL FOR QUIT COACHING SUPPORT, AND TO SEE IF YOU QUALIFY FOR NICOTINE PATCHES: 1-866-NY-QUITS (697-8487), OR REQUEST TO BE CALLED BY A QUIT COACH." and "ONLINE COMMUNITY". Below the banner is a "News Feed" section with a "New Voice Club" article and a "Tobacco Free Tips" section. A "Tweets by @nysmokefree" section shows a tweet about cataracts and a "THIS MONTH IS SAVE YOUR VISION" graphic. At the bottom right, there is an "Embed" button and a "View on Twitter" link.

Using the NYS Quitline: 1-866-NY-Quits nysmokefree.com

More resources from the NYS Quitline

- Medication Discount cards, NYC & NYS
- Savings calculator
- Insurance coverage look-up
- Statewide listing of local programs
- Materials for patients and providers
- Text messaging and social media programs to help with quitting

Insurance Variability

The ACA says “Do it,” but...

- Medicare
 - All drugs-- Part D plan?
 - Two 2 quits/year with 4 counseling sessions
- NYS Medicaid
 - Two quits/year with 4 counseling sessions
 - Gum and patch, rest variable
- Market Place and Employer Sponsored “Preventive”
 - 90 days of all FDA approved drugs
 - Two quits, with 4 counseling sessions
 - No prior authorization, no cost sharing
- Grandfathered Plans
 - Can if they want

Office

- Intake, “vital sign”
- Staff involvement
- Literature and resources for patients: NYQuitline info
- Document for an accurate bill
 - 99406: 3-10 minutes
 - 99407: >10 minutes
- Knowledge of insurance coverage
- Follow-up responsibilities: return visit or phone call

Summary

- Cost effectiveness: Smoking \geq HTN, $>$ hyperlipidemia
- Nicotine dependence is a chronic disease
- Identify smoking status of all patients
- Advise and assess readiness
- Motivational interviewing effective
- Use NRT – as much and as long; bupropion, varenicline and combinations,
- Electronic nicotine delivery devices unknown effects and efficacy
- **Questions?**
- Thank you.

