Smoking Cessation in Primary Care: New Options for an Old Problem?

Matthew Carpenter, PhD

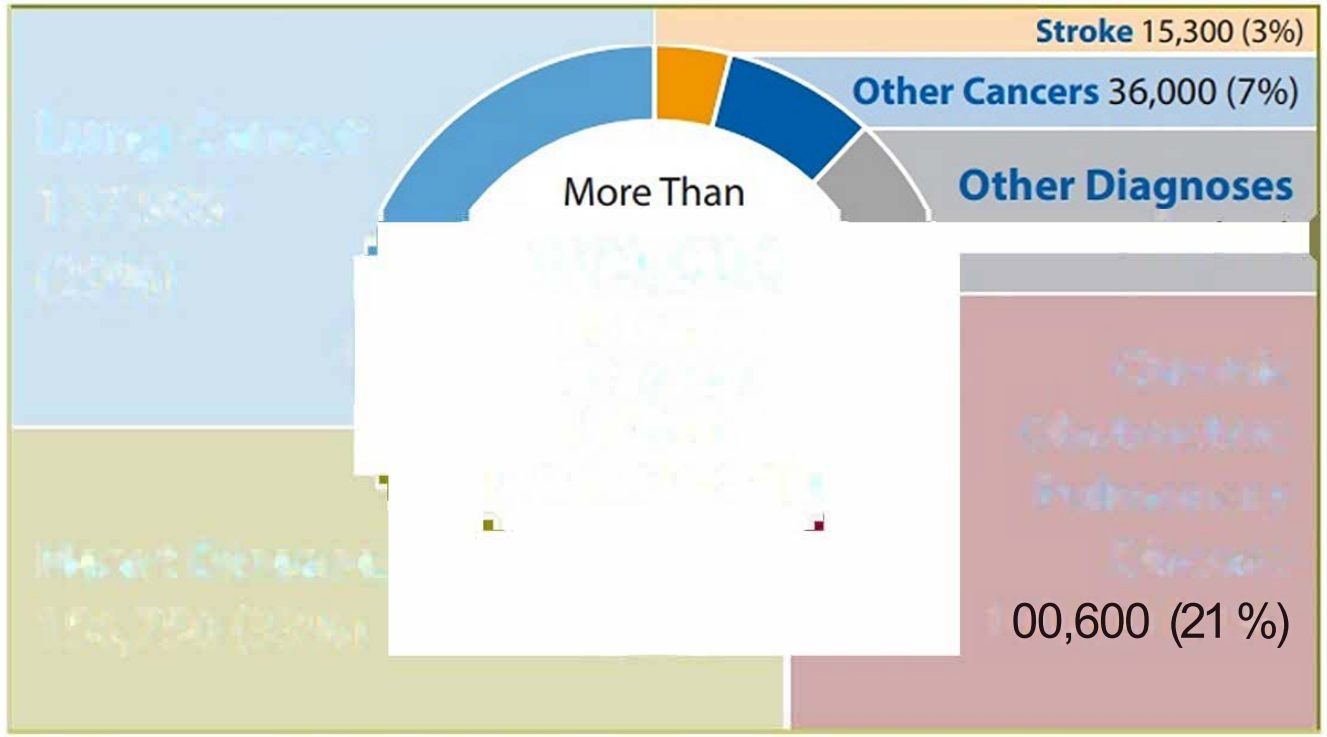
3rd Annual APRN Conference Behavioral Health Integration in Primary Care / August 2019

Disclosure: Consulting honoraria from Pfizer (2018)

MUSC
Medical University of South Carolina

Changing What's Possible | MUSC.edu

Why should I treat tobacco dependence?



70% of smokers visit a primary care provider each year

Source: AlHarthi, Al-Motlag, & Wati, 2017

Cigarette Smoking as a Learned Behavior

Cigarette Smoking as a Learned Behavior

Learned Associations

↓

Automatic Behaviors

↓

Psychological/Behavioral Dependence

The Cigarette: A Drug Delivery System

Drug delivery system:

- Gratification – Nicotine → Reinforcing Effect
  - Instant gratification (within seconds)
  - Consistent gratification (every puff)
  - Repeated gratification (hundreds of puffs/day)

The perfect drug delivery system

↓

Physical Dependence

Smoking Cessation

A Two-Pronged Approach to Treating Dependence:

1) Medication to address physical dependence
2) Lifestyle change to address psychological/behavioral dependence

Normalizing the Quit Process:

1) There is no magic bullet
2) Cessation is not a single event, but rather an ongoing process. It does not begin or end with the quit date. It's a marathon, not a sprint.
3) Challenge defeatist thinking
4) Enlist the support of others

Provider Advice Leads to Treatment Use . . .

	Counseling		Medication		Counseling + Medication	
	%	OR* (95% CI)	%	OR* (95% CI)	%	OR* (95% CI)
5 A's (Ask, Advise, Assess, Assist, Arrange)						
Received all 5	**31.7**	**11.2 (7.1-17.5)**	**46.8**	**6.2 (4.3-9.0)**	**29.0**	**14.6 (9.3-23.0)**
Received any 4	9.7	2.4 (1.6-3.5)	25.3	2.2 (1.7-2.8)	8.2	2.9 (2.0-4.4)
Received any 3	7.2	1.8 (1.2-2.9)	20.8	1.8 (1.3-2.5)	5.5	2.0 (1.3-3.3)
Received any 2	4.6	1.2 (0.7-1.9)	14.3	1.1 (0.8-1.5)	3.1	1.2 (0.7-2.0)
Received any 1 or 0	3.8	Ref	12.4	Ref	2.6	Ref

* Adjusted odds ratios

Kruger, et al (2016). Receipt of evidence-based brief cessation interventions by health professionals and use of cessation assisted treatments among current adult cigarette-only smokers: National Adult Tobacco Survey, 2009–2010. *BMC Public Health, 16*(141).

. . . Which Leads to Cessation

	Risk Ratio	95% CI
Brief Advice (vs. control)	1.66	1.4 – 1.9
More Intensive Intervention	1.84	1.6 – 2.2
Overall	1.76	1.6 – 2.0

Conclusion: Simple advice has a small effect on cessation rates. Assuming an unassisted quit rate of 2 to 3%, a brief advice intervention can increase quitting by a further 1 to 3%.

My interpretation: 1) Don't be fooled by small #s: Wide reach = deep impact; 2) How can we improve?

In fact: Among all preventive health services, tobacco screening and brief interventions are considered in top three to be most impactful and cost effective (Maciosek 2006)

Source: Stead et al (2013). Physician advice for smoking cessation. Cochrane Review.

Barriers to Treating

“Not enough time”

Minimal interventions lasting less than 3 minutes increase overall tobacco abstinence rates.

“Patients don’t want to hear about it”

Cessation interventions during medical visits are associated with increased patient satisfaction.

“I can’t help patients stop”

Effective clinical interventions exist!

Healthcare Provider Advice to Quit: USPHS Guidelines (The 5As)

Ask every patient if they use tobacco.

Advise the patient to quit.

Assess the patient's willingness to make a quit attempt.

Assist in making a quit attempt by providing or referring the patient to counseling and offering medication.

Arrange for follow-up contact with the patient.

Medical Interview: Things to Assess

- Age of smoking onset
- Years of smoking
- Amount currently smoking (cigs per day)
- Pack Years = amount x duration
  - Pack a day for 10 years = 10 pack years
  - Half a pack for 15 years = 7.5 pack years
- Motivation to quit / willingness to set a quit date
- Prior hx of cessation medication
- Length of time since most recent quit attempt
- Longest duration of abstinence
- Barriers to quitting (weight gain? Low confidence? Minimization of health risks?)

ASK

Implement an officewide system that ensures that, for ***every*** patient at ***every*** clinic visit, tobacco use status is queried and documented.

VITAL SIGNS

Blood Pressure:_____

Pulse:_____ Weight:_____

Temperature:_____

Respiratory Rate: _____

Tobacco Use (circle one): Current Former Never

Smoker in Home (circle one): Yes No

ADVISE

Advise all smokers to quit in a clear, strong and personalized manner

Clear - *"I think it is important for you to quit smoking now and I can help you." "Cutting down while you are ill is not enough."*

Strong - *"As your healthcare provider, I need you to know that quitting smoking is the most important thing you can do to protect your health now and in the future. The clinic staff and I will help you."*

Personalized - *"Continuing to smoke significantly increases your chances of getting heart disease, which is especially concerning given your family history. Quitting smoking will lower the risk of a heart attack."*

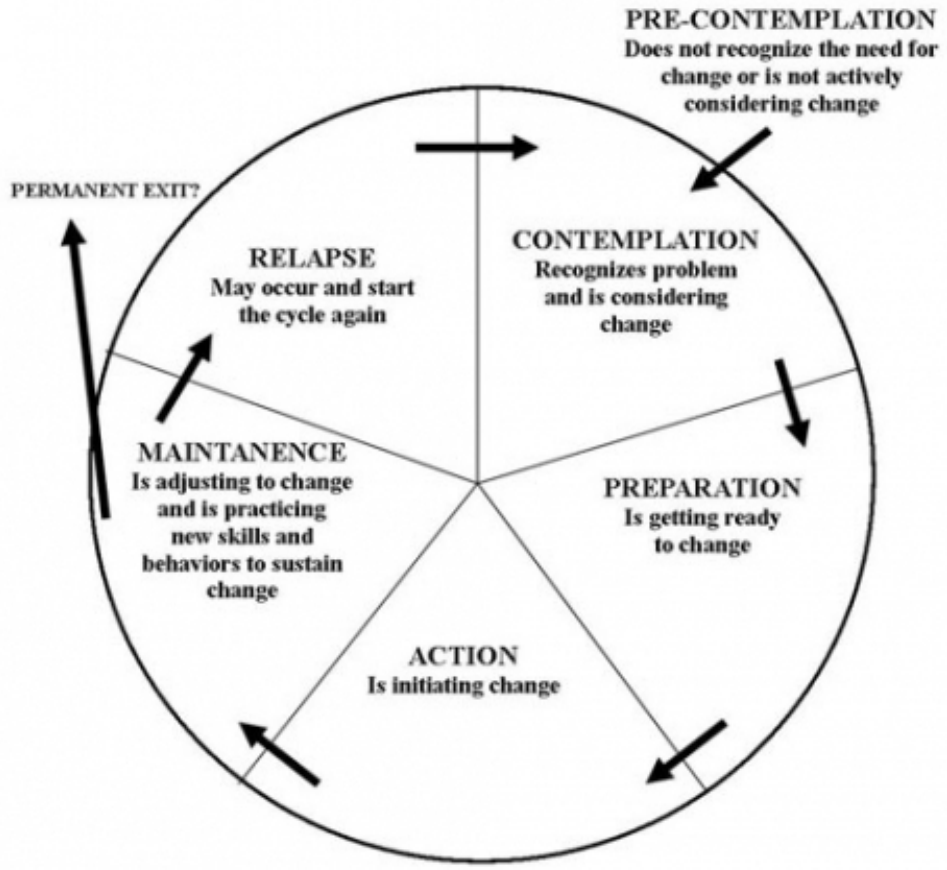
ASSESS

Assess every tobacco user's willingness to make a quit attempt at the time.

"Are you willing to give quitting a try?"

ASSESS

"Are you willing to give quitting a try?"



Transtheoretical Model
(Prochaska and DiClemente)

ASSESS

"Are you willing to give quitting a try?"

Catastrophe Theory
(West)

- Most quit attempts occur spontaneously
- Many spontaneous/unplanned quit attempts are successful
- Stage-based interventions are not more successful than non-stage-based.
- Three T's:
  - Tension: Increase how much/often smokers feel like the want to or need to stop
  - Triggers: Things that happen that turn feelings into quit attempts
  - Treatment: Reduce impulse/want/need to smoke and/or increase want/need to refrain

Implications – capitalize on cues to quit; easy access to treatment; Treat all smokers actively regardless of motivation to quit

Source: West, et al. (2006) British Medical Journal; 332:458-460.

Time Invested Pays Dividends

Total Amount of Clinician Time	OR	95% CI	Estimated Abstinence
0 minutes	1.0	--	11%
1-3	1.4	1.1 - 1.8	14.4%
4-30	1.9	1.5 - 2.3	18.8%
31-90	3.0	2.3 - 3.8	26.5%
91-300	3.2	2.3 - 4.6	28.4%

Fiore M, et al. *Treating tobacco use and dependence: 2008 Update. Clinical Practice Guideline*. Rockville, MD: US Public Health Service, 2008.

The All Important Assist

You'll Hear Countless Stories of Cold Turkey. . . . It (usually) doesn't Work

Efficacy x Reach = Impact

Quit Method	Hypothetical Efficacy	Hypothetical Reach	Impact
	% Quit at 6 months	(# using)	(Total # Quitters)
Cold Turkey	5%	150,000	7,500
Treatment A	15%	30,000	4500
Treatment B	20%	20,000	4,000
Treatment A & B	30%	10,000	3,000

The only reason why there are so many cold turkey quitters is because so many have tried that method (reach), not because it works (efficacy)

We need to get smokers to use evidence-based methods to quit

Drug (Available Doses)	How Sold (U.S.)	Dosing Instructions†	Administration	Common Side Effects
Nicotine patch 21 mg 14 mg 7 mg	OTC or Rx	**Starting dose:** 21 mg for ≥10 cigarettes per day. 14 mg for <10 cigarettes per day. After 6 weeks, option to taper to lower doses for 2-6 weeks. Use ≥3 months. After 6 weeks, continue original dose or taper to lower doses (either option acceptable).	Apply a new patch each morning to dry skin. Rotate application site to avoid skin irritation. May start patch before or on quit date. Keep using even if a slip occurs. If insomnia or disturbing dreams, remove patch at bedtime.	Skin irritation Trouble sleeping Vivid dreams (patch can be removed at bedtime to manage insomnia or vivid dreams)
Nicotine lozenge 4 mg 2 mg	OTC or Rx	If 1st cigarette is ≤30 minutes of waking: 4 mg. If 1st cigarette is >30 minutes of waking: 2 mg. Use ≥3 months.	Place between gum and cheek, let it melt slowly. Use 1 piece every 1-2 hours (Max: 20/day).	Mouth irritation Hiccups Heartburn Nausea
Nicotine gum 4 mg 2 mg	OTC or Rx	If 1st cigarette is ≤30 minutes of waking: 4 mg. If 1st cigarette is >30 minutes of waking: 2 mg. Use ≥3 months.	Chew briefly until mouth tingles, then 'park' gum inside cheek until tingle fades. Repeat chew-and-park each time tingle fades. Discard gum after 30 minutes of use. Use ~ 1 piece per hour (Max: 24/day).	Mouth irritation Jaw soreness Heartburn Hiccups Nausea
Nicotine inhaler 10-mg cartridge	Rx only	10 mg/cartridge. Each cartridge has ~80 puffs. Use ≥3 months.	Puff into mouth/ throat until cravings subside. Do not inhale into lungs. Change cartridge when nicotine taste disappears. Use 1 cartridge every 1-2 hours (Max: 16/day).	Mouth and throat irritation Coughing if inhaled too deeply
Nicotine nasal spray 10 mg/ml (10 ml bottle)	Rx only	10 mg/ml. 0.5 mg per spray. Each bottle has ~200 sprays. Use ≥3 months.	Use 1 spray to each nostril. Use spray every 1-2 hours. (Max: 80/day).	Nasal and throat irritation Rhinitis Sneezing Coughing Tearing
Varenicline (tablet) 0.5 mg 1.0 mg	Rx only	Days 1-3: 0.5 mg/day. Days 4-7: 0.5 mg twice a day. Day 8+: 1 mg twice a day. Use 3-6 months.	Start 1-4 weeks before quit date. Take with food and a tall glass of water to minimize nausea.	Nausea Insomnia Vivid dreams Headache
Bupropion sustained release (SR) (tablet) 150 mg	Rx only	150 mg/day for 3 days, then 150 mg twice a day. Use 3-6 months.	Start 1-2 weeks before quit date.	Insomnia Agitation Dry mouth Headache

Source: 2018 American College of Cardiology Expert Consensus Decision Pathway on Tobacco Cessation Treatment

There are 7 FDA approved first line pharmacotherapies for smoking cessation.

Varenicline or Combo NRT are often consider the two best options

Why Pharmacotherapy?

Relief of withdrawal

Deconditioning of environmental cues

Summary of Medication Effectiveness

	# Arms	Estimated ORs	Estimated Abstinence Rate
Placebo	80	1.0	13.8
Monotherapies			
Nicotine patch (6-14 wks)	32	1.9	23.4
Long term patch (>14wks)	10	1.9	23.7
Nicotine Gum (6-14 wks)	32	1.9	23.4
Long term Gum (>14 wks)	6	2.2	26.1
High dose patch (>25mg)	4	2.3	26.5
Nicotine Inhaler	6	2.1	24.8
Nicotine Nasal Spray	4	2.3	26.7
Varenicline 2mg	5	3.1	33.2
Varenicline 1mg	3	2.1	25.4
Bupropion	26	2.0	24.2

Fiore M, et al. *Treating tobacco use and dependence: 2008 Update. Clinical Practice Guideline*. Rockville, MD: US Public Health Service, 2008.

Summary of Medication Effectiveness

	# Arms	Estimated ORs	Estimated Abstinence Rate
Placebo	80	1.0	13.8
Combination Therapies			
Long term patch + ad lib NRT (gum or spray)	3	3.6	36.5
Patch + Bupropion	3	2.5	28.9
Patch + Inhaler	2	2.2	25.8

Fiore M, et al. *Treating tobacco use and dependence: 2008 Update. Clinical Practice Guideline*. Rockville, MD: US Public Health Service, 2008.

Medication Effectiveness: Head to Head Comparison

	# Arms	Estimated ORs	95% CIs of OR
Nicotine Patch	32	1.0	--
Monotherapies			
Long term patch (>14wks)	10	1.0	0.9-1.2
Nicotine Inhaler	6	1.1	0.8-1.5
Nicotine Nasal Spray	4	1.2	0.9-1.6
Varenicline 2mg	5	1.6	1.3-2.0*
Varenicline 1mg	3	1.1	0.8-1.6
Bupropion	26	1.0	0.9-1.2
Combination Therapies			
Long term patch + ad lib NRT (gum or spray)	3	1.9	1.3-2.7*
Patch + Bupropion	3	1.3	1.0-1.8*

Fiore M, et al. *Treating tobacco use and dependence: 2008 Update. Clinical Practice Guideline*. Rockville, MD: US Public Health Service, 2008.

Medication Advantages & Disadvantages (OTC NRT)

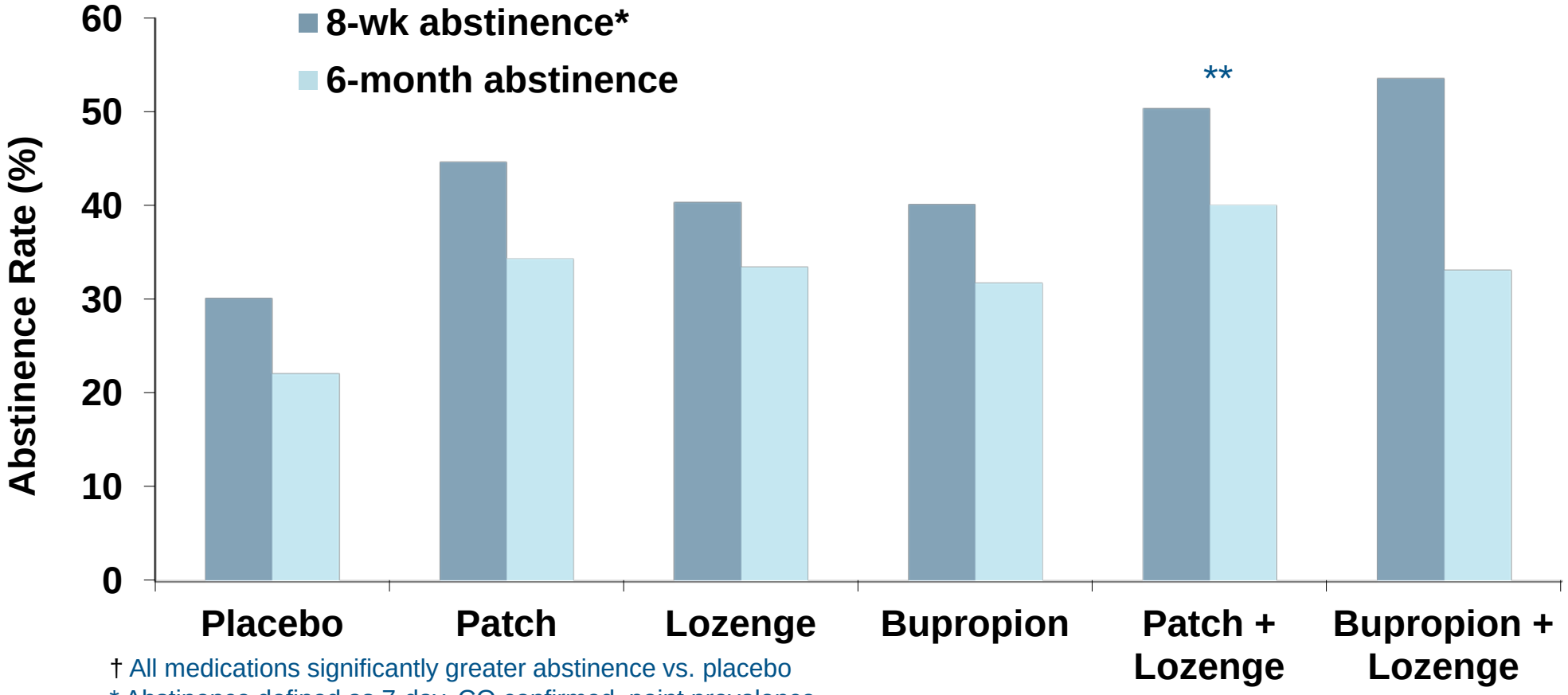
	Advantages	Disadvantages
Patch	Easiest nicotine product to use; Provides a steady nicotine level	Patient cannot alter dose if cravings occur throughout the day
Gum	Patient controls nicotine dose; Oral substitute for cigarettes	Not chewed in the same way as regular gum and requires careful instruction; Can damage dental work and be difficult to use with dentures; No food or drink 15 minutes prior to use and during use
Lozenge	Patient controls nicotine dose; Oral substitute for cigarettes; Easier to use than gum for those with dental work or dentures	No food or drink 15 minutes prior to use and during use
Combination (patch plus acute NRT)	Better for heavier smokers; Provides nicotine throughout day while giving you flexibility when you are really craving; Least likely to be in withdrawal	Risk of nicotine overdose (headache, dizziness, nausea)

Medication Advantages & Disadvantages (Prescription)

	Advantages	Disadvantages
NRT Inhaler	User controls nicotine dose; Mimics hand-to-mouth ritual of smoking cigarettes	Frequent puffing required
NRT Nasal Spray	User controls nicotine dose; Most rapid delivery of all nicotine among all NRT products	Has the most side effects of all NRT products; Some patients cannot tolerate local irritation to nasal mucosa
Bupropion	May lessen post-cessation weight gain while drug is being taken; Oral agent (pill)	Increases seizure risk: not for use if seizure disorder or binge drinking
Varenicline	Quit date can be flexible from 1 week to 3 months after starting drug; Dual action: relieves nicotine withdrawal and blocks reward of smoking; Oral agent (pill)	Because of previous FDA boxed warning (now removed) patients may fear psychiatric adverse events, even though they are no more common than with other cessation medications

Multiple Medications?

Analysis of 1504 smokers randomized to single/joint medications†



† All medications significantly greater abstinence vs. placebo
* Abstinence defined as 7-day, CO confirmed, point prevalence
** Among 6-Month outcomes, only Combined Patch + Lozenge superior to placebo (adjusting for family-wise error)

Source: Piper et al. Arch. Gen Psych (2009);66:*1253-1262.*

Five Biggest Errors When Using Medications

1. Not using
2. Under-dosing
3. Not using long enough
4. Fear of using while tapering
5. Fear of using multiple medications

Don’t Forget Behavioral Approaches

Help the patient with a quit plan.

- ***S**et* a quit date. Ideally, the quit date should be within 2 weeks.
- ***T**ell* family, friends, and coworkers about quitting, and request understanding and support.
- ***A**nticipate* challenges to the upcoming quit attempt, particularly during the critical first few weeks. These include nicotine withdrawal symptoms.
- ***R**emove* tobacco products from your environment. Prior to quitting, avoid smoking in places where you spend a lot of time (e.g., work, home, car). Make your home smoke-free.

Provide practical counseling (problem solving/skills training).

- Strive for abstinence, but if you slip get back on track (don’t throw the baby out with the bath water).
- Identify what helped and what hurt in previous quit attempts. Build on past success.
- Anticipate triggers and problem solve in advance (Avoid, Alter, Substitute).
- Limit/abstain from alcohol and other substance use.
- Encourage other smokers in the household to quit as well.

Fiore M, et al. *Treating tobacco use and dependence: 2008 Update. Clinical Practice Guideline*. Rockville, MD: US Public Health Service, 2008.

Don’t Forget Behavioral Approaches

TABLE 5 Examples of Behavioral Interventions for Nicotine Dependence

Treatment	Examples
Cognitive behavioral skills training	Instructions, modeling, rehearsal, and feedback to teach smokers how to change their smoking behavior. Examples include: 1. Self-monitoring to identify triggers for smoking. Smokers are asked to keep a real-time record of the times, places, and situations in which smoking occurs. 2. Behavioral rehearsals, such as practice quit attempts and practicing how to respond to a lapse back to smoking. 3. Practicing self-control over smoking triggers. Avoiding triggers (e.g., putting away ashtrays, abstaining from alcohol), altering trigger situations (e.g., taking work breaks in a place in which you cannot smoke), using substitutes in place of smoking (e.g., gum, candy, a stress ball, exercise), and refocusing thoughts when cravings arise (e.g., statements of self-determination such as “I can do this”; delay statements such as “wait a minute or 2 and the urge will pass”). 4. Assertiveness training to help smokers better handle social situations likely to trigger cues to smoking. 5. Instruction and training (e.g., deep breathing, yoga, mindfulness training) for handling stress and negative emotions that are often linked to smoking urges. 6. Instructions on how to use medications properly to increase medication adherence and quit rates. 7. Biofeedback to smokers using a simple breath test measuring expired carbon monoxide to educate patients about immediate health risks from smoking and enhance motivation for cutting down and quitting. 8. Facilitated discussion with a group of smokers to share effective behavior change experiences and challenges.
Motivational interviewing	Motivational interviewing is a goal-oriented, client-centered counseling style that aims to elicit behavior change by helping smokers explore and resolve ambivalence about making changes in their behavior. The method relies on counselors eliciting from the clients their own motivations for change, rather than imposing a treatment plan on the smoker.
Incentives	Incentives, usually provided as cash or vouchers, can be used to motivate smokers to try to quit and to reward them for making changes in their smoking behaviors.

Source: 2018 American College of Cardiology Expert Consensus Decision Pathway on Tobacco Cessation Treatment

For Unmotivated Smokers: Enhancing Motivation (5Rs)

Relevance

How is smoking personally relevant for your health?

Risks

What potential negative consequences have you or will you experience from tobacco use?

Rewards

What are potential benefits from stopping tobacco use?

Roadblocks

What barriers might you encounter in trying to quit? How can I help you overcome those barriers?

Repetition

Let's revisit this during our next appointment. Most people make repeated attempts to quit before quitting for keeps.

Fiore M, et al. *Treating tobacco use and dependence: 2008 Update. Clinical Practice Guideline*. Rockville, MD: US Public Health Service, 2008.

New Options for an Old Problem?

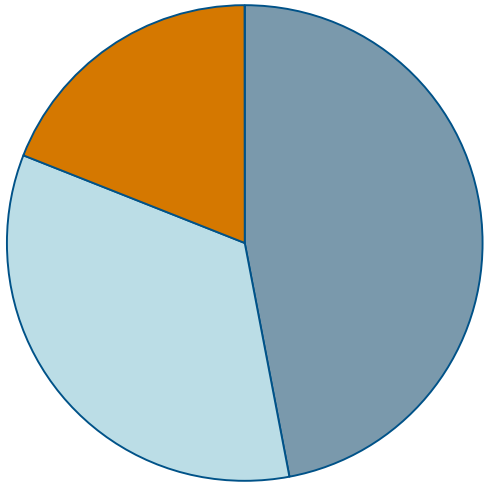
1. Medication Sampling
2. E-visits
3. Alternative Products (e-cigs)

New Options for an Old Problem?

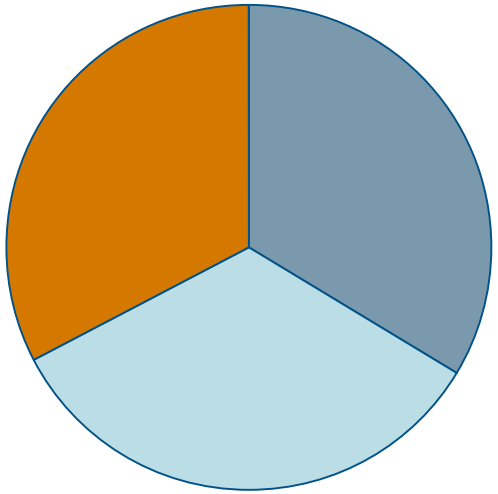
1. Medication Sampling

Effect of Nicotine Patch Question Presentation Order on Stage of Change

Asked Stages of Change



"Would you be interested in free NRT?" . . . Then asked stages of change



Precontemplation Contemplation Preparation

Source: Cunningham, et al. (2015). The Impact of Asking About Interest in Free Nicotine Patches on Smoker's Stated Intent to Change: Real Effect or Artefact of Question Ordering? *Nicotine & Tobacco Research* 18: 1215-217.

NRT Sampling

Cluster Randomized Controlled Trial

- Standard Care (SC): naturalistic, unscripted physician advice per routine
- SC + NRT: 2 week supply of both nicotine patch & lozenge (uniform dosing)

22 primary care clinics across South Carolina

- 12 SC clinics (2 poor performing clinics replaced)
- 10 NRT clinics
- All study procedures (screening, consenting, baseline assessment, treatment delivery) done by clinic staff; No research staff present
- All clinics given 1x 60-90min overview of USPHS Guidelines upon study start
- All providers were encouraged to deliver cessation advice as done typically
  - "baggies" given to all smokers in all clinics with cessation materials; +/- NRT

Final N = 1245 adult smokers, seen during routine clinic visit

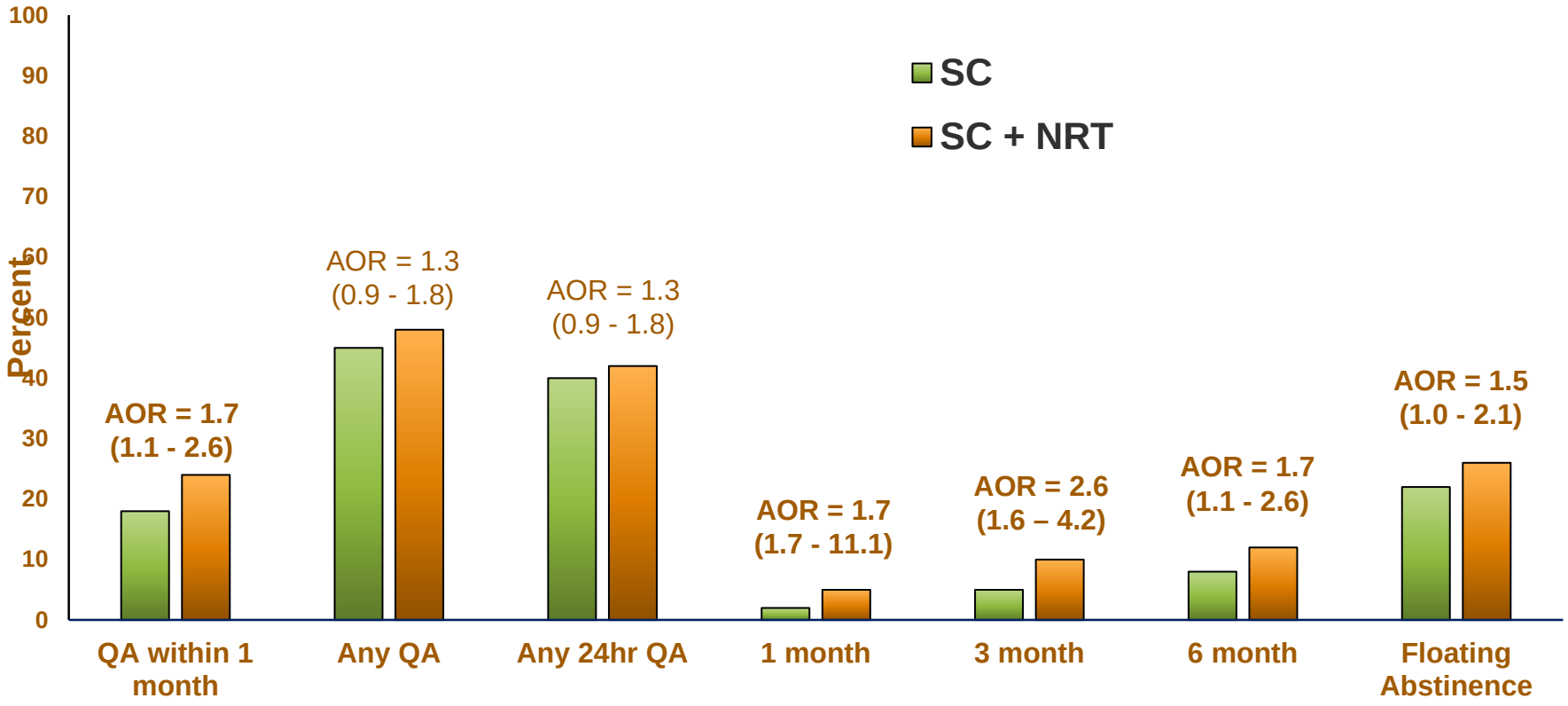
- Broad inclusion criteria
- MTQ not required, nor willingness to sample cessation medication

Follow-up thru 6 months, managed centrally by research staff via phone

Methods: Dahne et al. 2018. Contemporary Clinical Trials; 72:1-7.

NRT Sampling: TIP TOP

Quit Attempts and Cessation

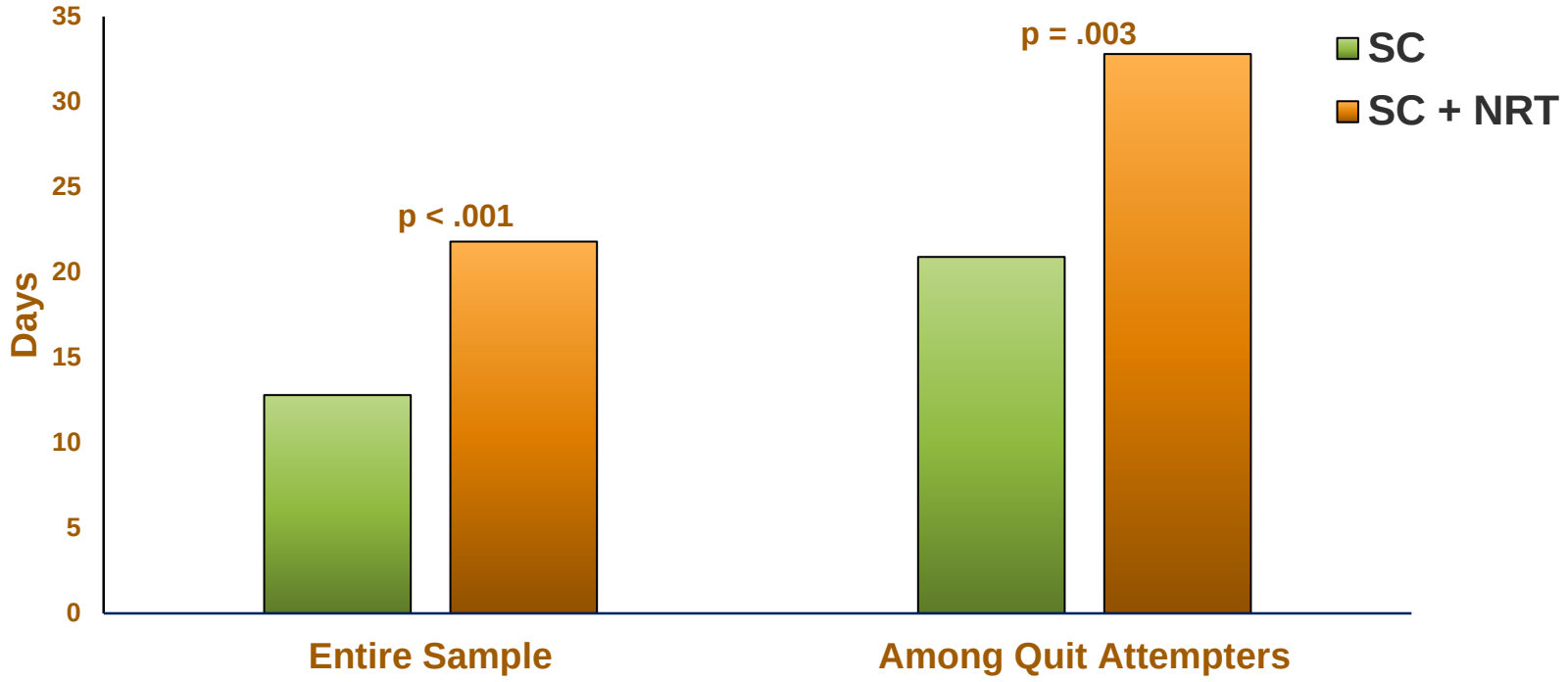


AOR adjusting for: a) site, b) nicotine dependence [Heaviness of Smoking Index], c) gender, and d) race. QA = Quit Attempt. Abstinence = 7-day self-reported not smoking, either Point Prevalence (1, 3, 6 months), or ever within follow-up period [floating].

(manuscript in review)

NRT Sampling: TIP TOP

Longest Quit Attempt



(manuscript in review)

Adjusting for: a) site, b) nicotine dependence [Heaviness of Smoking Index], c) gender, and d) race.

NRT Sampling: TIP TOP

Sensitivity Comparisons of Cessation-Related Outcomes by Baseline Motivation to Quit

	Low Motivation to Quit (n=573)					High Motivation to Quit (n=671)			
	SC (n=315)	SC + NRT (n=258)	AOR	p		SC (n=336)	SC + NRT (n=335)	AOR	p
Any QA	109 (35%)	94 (36%)	1.2	0.4		186 (55%)	193 (58%)	1.2	0.3
Any 24hr QA	92 (29%)	78 (30%)	1.2	0.4		166 (49%)	171 (51%)	1.2	0.3
Abstinence, 6 months	15 (5%)	20 (8%)	1.7	0.1		37 (11%)	50 (15%)	1.5	0.1
Floating Abstinence	44 (14%)	47 (18%)	1.6	.06		97 (29%)	105 (31%)	1.3	0.1

To Note:

1. All sub-group treatment comparisons non-significant (dimin. power)
2. Absolute QA & Abstinence rates: HMTQ > LMTQ
3. **All treatment effect sizes: LMTQ ≥ HMTQ**

(manuscript in review)

NRT Sampling – Big Picture

Two-Week NRT sampling:

- Resulted in fairly low cessation outcomes
- Will not be a panacea for smoking cessation
- Does not replace comprehensive/intensive tx fitting for chronic relapsing d/o
- Would be strengthened by biochemical verification (unnecessary for non-intensive interventions?)

But it also . . .

- Still outperformed standard care
- Offers strong potential for reach in busy clinical practices
  - few minutes to deliver
  - behavioral, concrete, and immediately actionable (vs. MI or brief advice- verbal)
  - minimal instructions or training needed, for both providers and patients
  - can be given to broad spectrum of smokers
- Cost effectiveness to be determined, but
  - nominally expensive treatment (~$60 for 2wks of combo NRT)
  - nominal adjunctive costs for the clinic
  - reasonable to believe that sampling could be cost effective

(manuscript in review)

New Options for an Old Problem?

2. E-visits

With acknowledgement to: Drs. Jen Dahne, Vanessa Diaz, Marty Player

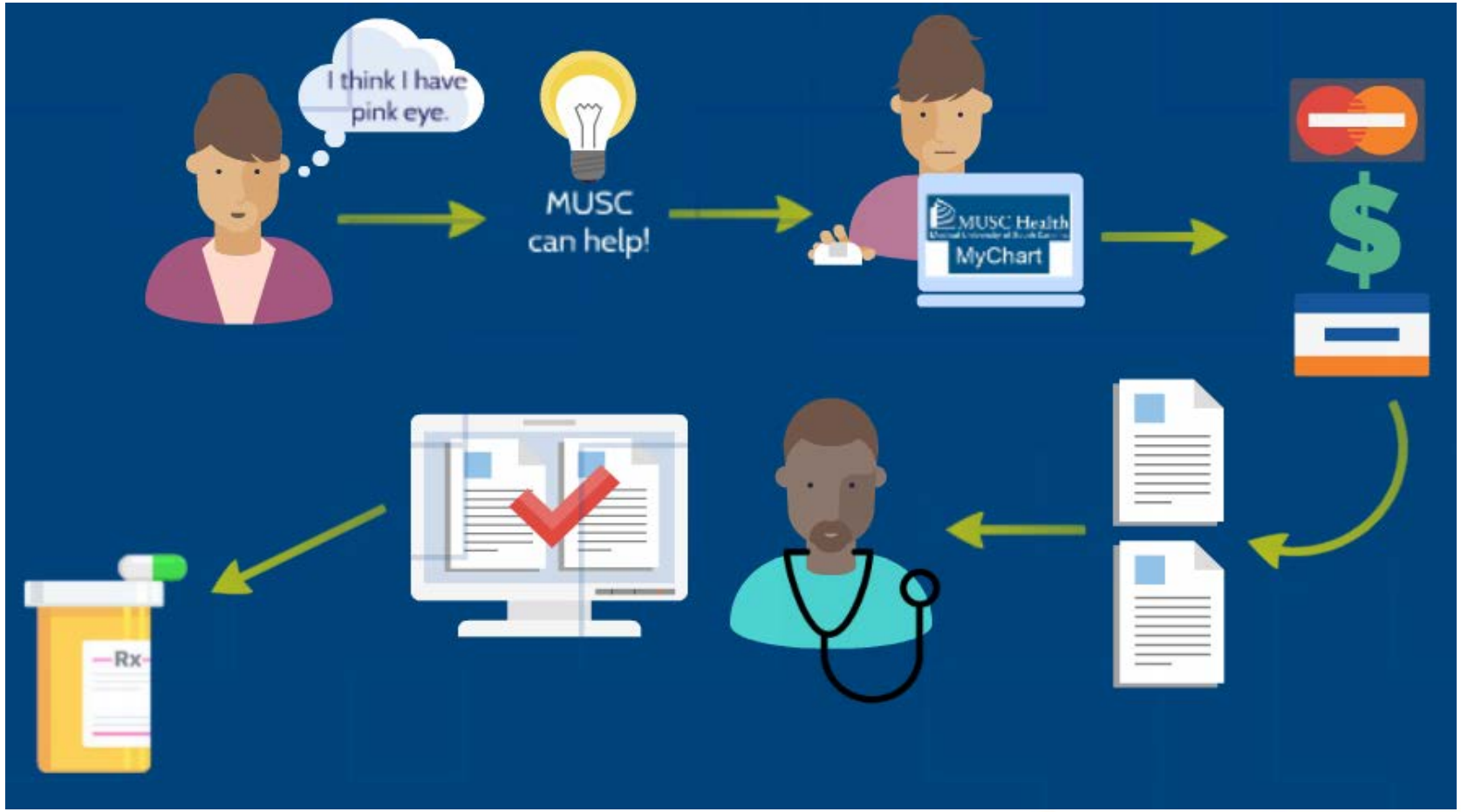
Telemedicine in Primary Care

- Use of telemedicine in primary care is increasing with benefits to patients and health systems
  - Convenience
  - Lower cost
  - Less travel
  - Less time spent waiting
  - Interaction with primary care provider or office
  - Billable?

With acknowledgement to: Drs. Jen Dahne, Vanessa Diaz, Marty Player

Electronic visits (E-visits)

- *Asynchronous* electronic interactions between patients and providers through patient portals.



With acknowledgement to: Drs. Jen Dahne, Vanessa Diaz, Marty Player

Patient Acceptability of E-Visits

Patient Satisfaction (n=665)

- How likely are you to use this service again?
  - Definitely/Probably Will- 93.2%

- The E-visit provider was able to address what was bothering me today.
  - Strongly Agree/Agree- 94.2%

- **If an e-visit were unavailable, where would you have gotten care otherwise?**
  Doctor's Office/PCP- 49%
  Urgent Care/Retail Clinic/ED- 42%
  Nowhere- 9%

Asynchronous e-visits appropriate for:

- Limited need of follow-up for the same complaint
- Low likelihood for change in initial diagnosis when follow-up occurred
- Utilized in place of office or urgent care/ED visits, supporting their use as an alternative form of care for specified common acute conditions.

Can we do this for smoking cessation?

With acknowledgement to: Drs. Jen Dahne, Vanessa Diaz, Marty Player

Epic

Cigarette smoker

Age 18+

Active MyChart account

Treated in Dept Family Medicine in the last 12 months

MUSC
Medical University of South Carolina

Department of Family Medicine
5 Charleston Center, Suite 263
MSC 192
Charleston, SC 29425
Tel 843-876-2912

Date

Dear PATIENT NAME,

Quitting smoking is one of the most important things you can do for your health. Even if you're not ready to quit, cutting down or reducing how much you smoke can also greatly improve your health.

We are writing to invite you to participate in a research study to help you change your smoking behavior. We have talked with Dr. PCP and your primary care team and they support this invitation. The purpose of the research study is to see if an electronic visit (e-visit) can help patients change their smoking behavior. You are being invited to join the study because you are listed as a current cigarette smoker in your electronic health record.

If you would like to know if you are eligible for this study, please click the link below to answer a few screening questions. This should take less than 3 minutes. If you are eligible based on this screening, a member of the research team will contact you to provide more information about the study so you can decide if you are interested. Compensation is available for those who are eligible and enroll in the study.

INSERT LINK HERE

If you have any questions about the study, please feel free to contact our research team:

Study Investigators

Vanessa Diaz, MD, MS
(843) 876-2923

Marty Player, MD, MS
(843) 876-2926

Jennifer Dahne, PhD
(843) 876-2280

Thank you for your time.
Best wishes,

Vanessa A Diaz, MD MSCR
Professor, Department of Family Medicine
Medical Director for Care Coordination, Primary Care ICCE

"An equal opportunity employer, promoting workplace diversity."

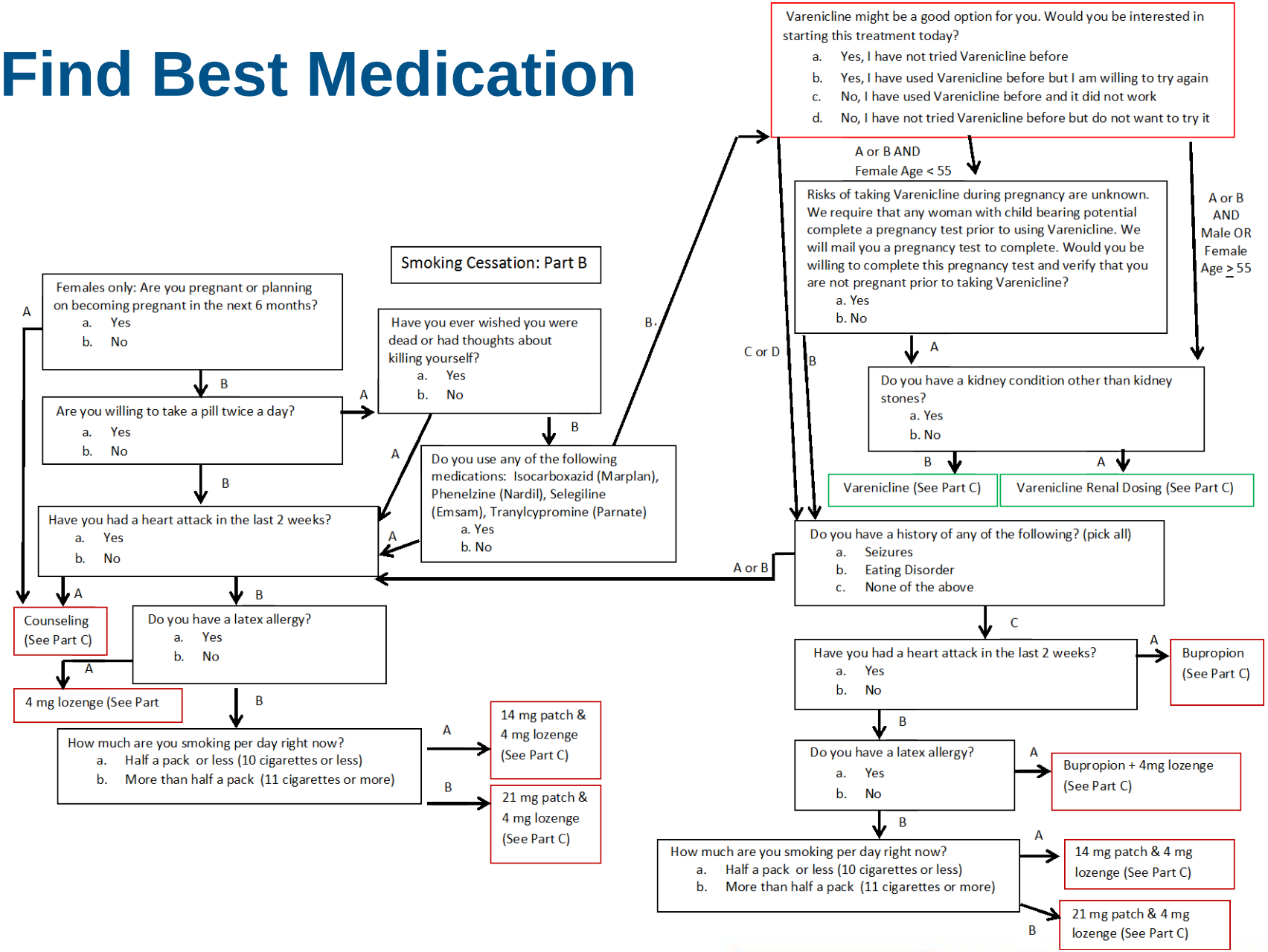
Musc Rsch Smoking Cessation Recruitment Screening Questionnaire

Question	[redacted]
How old are you?	18 years old or older
What is your gender (sex)?	Male
Do you have an email address that you check at leat once a day?	Yes
Are you currently smoking cigarettes daily?	Yes
About how many cigarettes per day do you smoke on a typical day?	5 or more cigarettes
During the past 30 days, on how many days did you smoke cigarettes?	20 days or more in the past 30 days
How long have you been smoking cigarettes regularly?	6 months or more
Are you fluent in English?	Yes

With acknowledgement to: Drs. Jen Dahne, Vanessa Diaz, Marty Player

Algorithm to Find Best Medication

(patient driven)



With acknowledgement to: Drs. Jen Dahne, Vanessa Diaz, Marty Player

Response from Provider to Patient
(via MyChart)

Vanessa A. Diaz, MD MSCR to [redacted]

Hi [redacted]

[redacted]

Hope you are doing well. Based on your responses, Chantix (varencicline) seems like the best choice to help you quit. You will wean up on it, so I sent in both a starter pack as well as a prescription for when you get to the regular dose. You can just get the 1 mg prescription (that's the regular dose) and cut those in half as you wean up if that is the cheapest option. The dosing is 0.5 mg once a day for three days, then 0.5 mg twice a day for four days. After the first 7 days, the dose is 1 mg twice per day, which is the regular maintenance dose.

I sent these to Harris Teeter, let me know if you need that sent somewhere else.

Let me know if you have any questions, or have any difficulties with the medicaiton.

This website provides info on the medication.

Best,

Vanessa Diaz, MD MS

[redacted]

With acknowledgement to: Drs. Jen Dahne, Vanessa Diaz, Marty Player

Automated Follow-up Assessment

(via MyChart)

Musc Rsch Smoking Cessation Follow Up Questionnaire

Question	1/8/2019 1:05 PM EST - Filed by Patient on 1/8/2019
Since your last e-visit, have you smoked any cigarettes at all, even a puff?	Yes
Since your last e-visit, have you made any attempts to stop smoking cigarettes for good?	Yes
Of the quit attempts you have made since your last e-visit, how long did your longest quit attempt last?	2 days
How many times have you tried to stop smoking for good since your last e-visit?	2
As a result of the last e-visit you completed for smoking cessation, were you prescribed a medication to help you quit smoking?	Yes
Did you receive the medication you were prescribed?	Yes
During the time since completing your initial e-visit, have you experienced any of the following symptoms more than normal? Rate Severity (Mild [0] - Severe [4])	
Nausea	3
Headache	0
Sleep disturbances	0
Skin irritation	0
Restlessness	0
Difficulty concentrating	0
Other	0
Since your last e-visit, have you or your family/friends noticed changes in your mood since quitting? Rate Severity (Mild [0] - Severe [4])	
Anger/hostility	0
Anxiety	0
Feeling depressed	0
Other issues	0
Since your last e-visit, have there been any situations that made you feel like you were at risk for going back to smoking (or that made you feel like you would be unable to quit smoking if you have not yet quit)?	No
Who is helping you with your smoking cessation efforts (check all that apply)?	Parent Spouse/significant other Friend
Are you interested in any of the following treatment options for smoking cessation? (check all that apply)	Chantix (Varenicline)

With acknowledgement to: Drs. Jen Dahne, Vanessa Diaz, Marty Player

Iterative Engagement between Provider : Patient
(via MyChart)

Vanessa A. Diaz, MD MSCR to [redacted]

Hi [redacted] [redacted]

I reviewed your e-visit for smoking cessation.

Sounds like you have been trying to quit, but we need to continue working on it.

This website gives you some different options on how to use the varenicline to quit.

https://www.chantix.com/getting-started-with-chantix/three-ways-to-quit#three-quit-approaches

I'll go ahead and send in 2 more months of varenicline in for you, so you can continue using it. Don't give up, it is hard to quit.

You can also consider trying to supplement the varenicline with nicotine replacement (either a patch, gum or lozenges). You can use these with the varenicline, and it can increase your chances of quitting. You might be eligible to get these for free through the SC quitline. (information below)

https://www.scdhec.gov/health/tobacco-cessation/tobacco-quitline

These are also available over the counter, but if you want me to send you in a prescription for them, I can also do that.

Keep working on cutting back your smoking, and let me know if there is anything else we can do to help.

Best,

Vanessa Diaz, MD MS

[redacted]

With acknowledgement to: Drs. Jen Dahne, Vanessa Diaz, Marty Player

E-Visit for Smoking Cessation: Pilot Outcomes

- Cigarette Smoking (including quit attempts, abstinence)
- Medication usage
- Barriers to treatment (time lag to receiving medications)
- Patient and Provider satisfaction w e-visits

Next Steps

- Larger testing
- Smoking cessation e-visit specifically for high risk groups of socioeconomically disadvantaged smokers (e.g., Medicaid smokers, smokers experiencing homelessness)
- Adaptation of the smoking cessation e-visit platform to target other common comorbidities (e.g., depression, anxiety, other substance use)
- Deeper EPIC integration (e.g., provider dashboards)

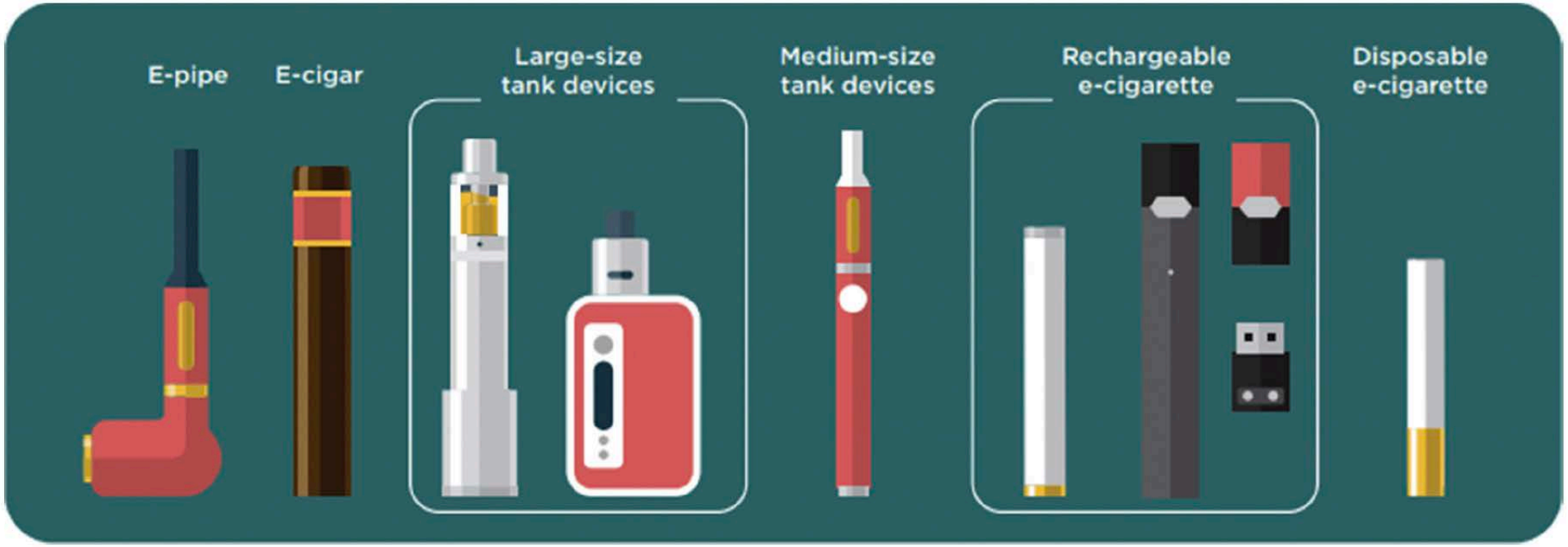
With acknowledgement to: Drs. Jen Dahne, Vanessa Diaz, Marty Player

New Options for an Old Problem?

3. Alternative Products (e-cigs)

What about e-cigarettes?

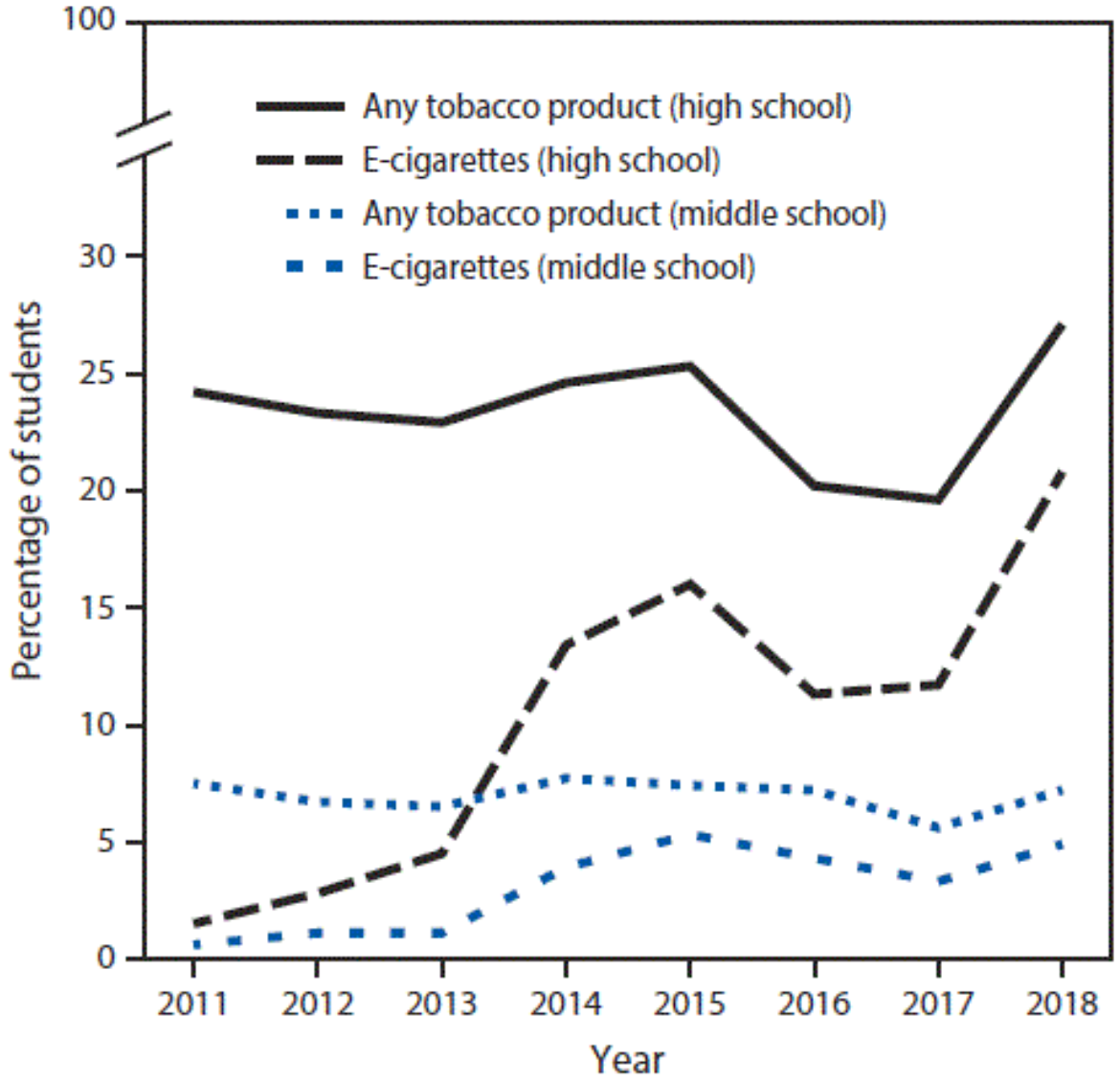
FIGURE 5 Electronic Nicotine Delivery Systems, Including Electronic Cigarettes



e-cigarette = electronic cigarette. Source: U.S. Department of Health and Human Services, 2016 (28).

Source: 2018 American College of Cardiology Expert Consensus Decision Pathway on Tobacco Cessation Treatment

Popularity of e-cigarettes among youth (NYTS 2011-2018)



CDC / MMWR (2018);67:1276–7.

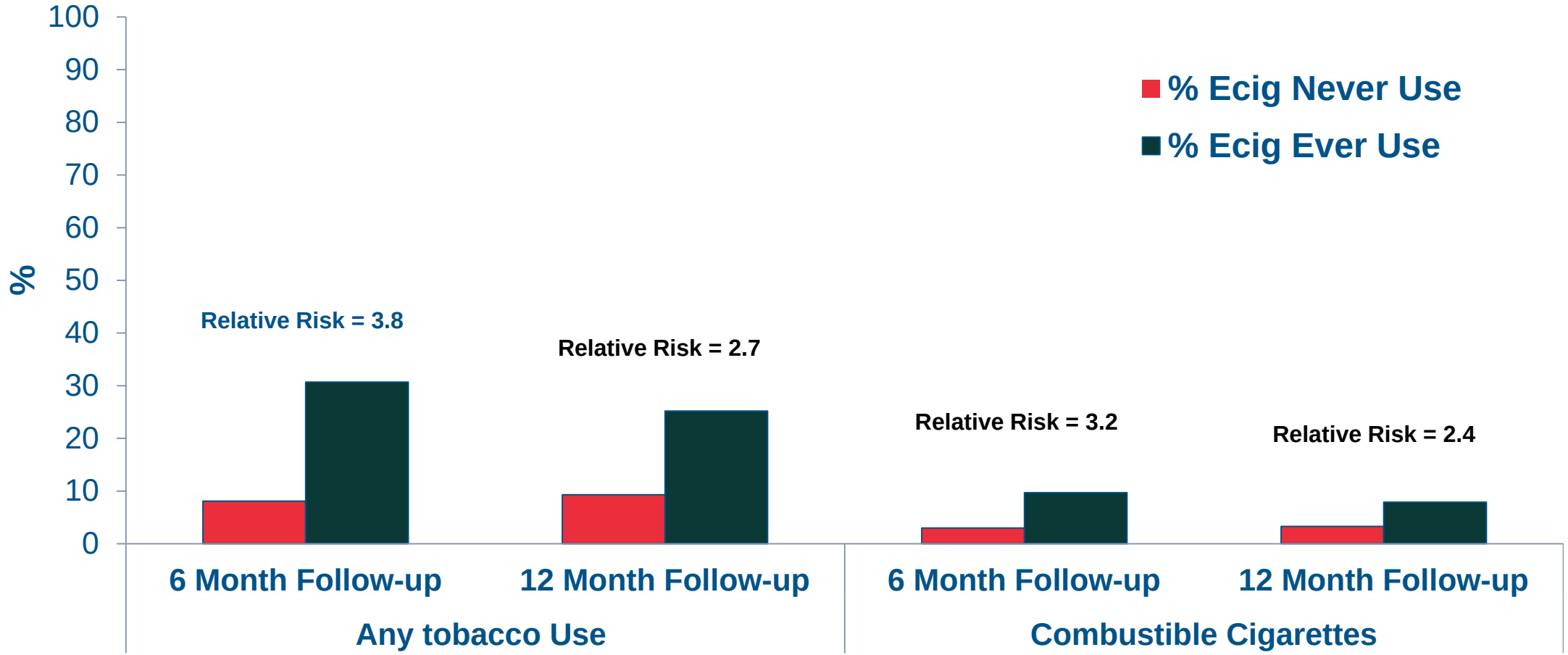
Juice, Candy, & E-Cigarettes: FDA Warnings 2018

One Mad Hit Juice Box

Candy King Batch/Candy King Sour Worms

Walley et al. (2019) Pediatrics;143: e20182741.

Other Tobacco Product Initiation among E-Cigarettes Users vs. Never Users



Leventhal et al. JAMA 2015

Replicated by a number of other studies!

(see Soneji et al JAMA 2017)

E-cigarettes: Safer vs. Safe?

Common Carcinogens	% reduction among smokers using ecigs for 5 days
Carbon Monoxide	⬇ 75%
Benzene	⬇ 90%
Acrolein	⬇ 71%
Ethylene oxide	⬇ 62%
NNK	⬇ 59%
Hydrogen cyanide	⬇ 39%
Pyrene	⬇ 64%
Many others	*Generally same pattern*
Round et al NTR 2018	

Comparison of toxicants levels between conventional and electronic cigarettes.

Toxic compound	Conventional cigarette (μg in mainstream smoke) [35]	Electronic cigarette (μg per 15 puffs)	Average ratio (conventional vs. electronic cigarette)
Formaldehyde	1.6-52	0.20-5.61	9
Acetaldehyde	52-140	0.11-1.36	450
Acrolein	2.4-62	0.07-4.19	15
Toluene	8.3-70	0.02-0.63	120
NNN	0.005-0.19	0.00008-0.00043	380
NNK	0.012-0.11	0.00011-0.00283	40

Goniewicz NTR 2014

BUT: Newer, stronger devices might have higher toxicants
We really don't know – don't have 20 years of vaping

E-Cigarettes & Smoking Cessation

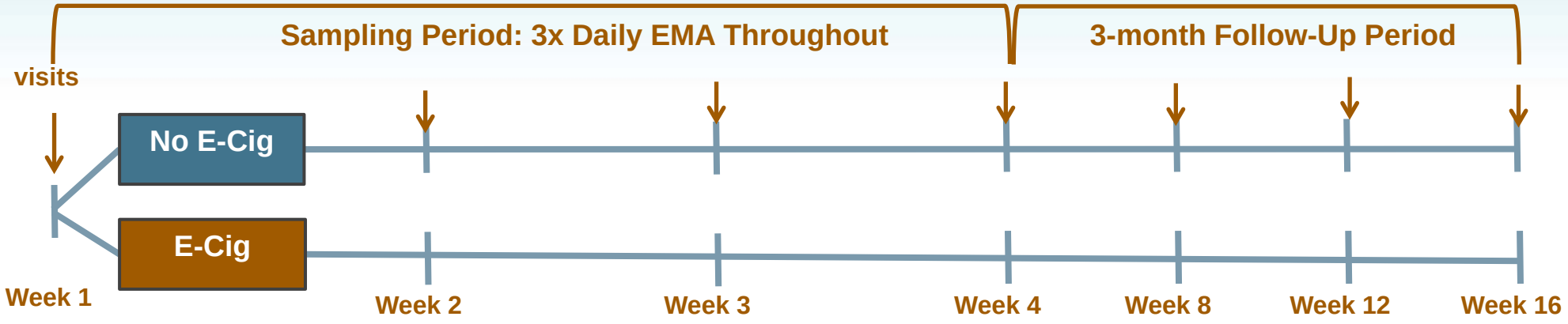
Lots of indirect evidence that links e-cigarette use to behavioral outcomes

- Some indirect evidence showing promotion of quitting.
  e.g., Hitchman 2015; Manzoli 2017
- Some indirect evidence to suggest just the opposite.
  e.g., Kalkhoran 2016; Vickerman 2013
- **But these studies are of self-selected users vs. non-users. Need RCTs.**

Best evidence to date comes from four RCTs (see Villanti 2018 Addiction review): E-cigarettes are effective in helping adult smokers to quit or to reduce their cigarette consumption, and that rates of smoking cessation with e-cigarettes are similar to or *better* (Hajek 2019 NEJM) compared to NRT.

- **But these studies are not naturalistic (purposeful reduction/cessation)**

Study Design

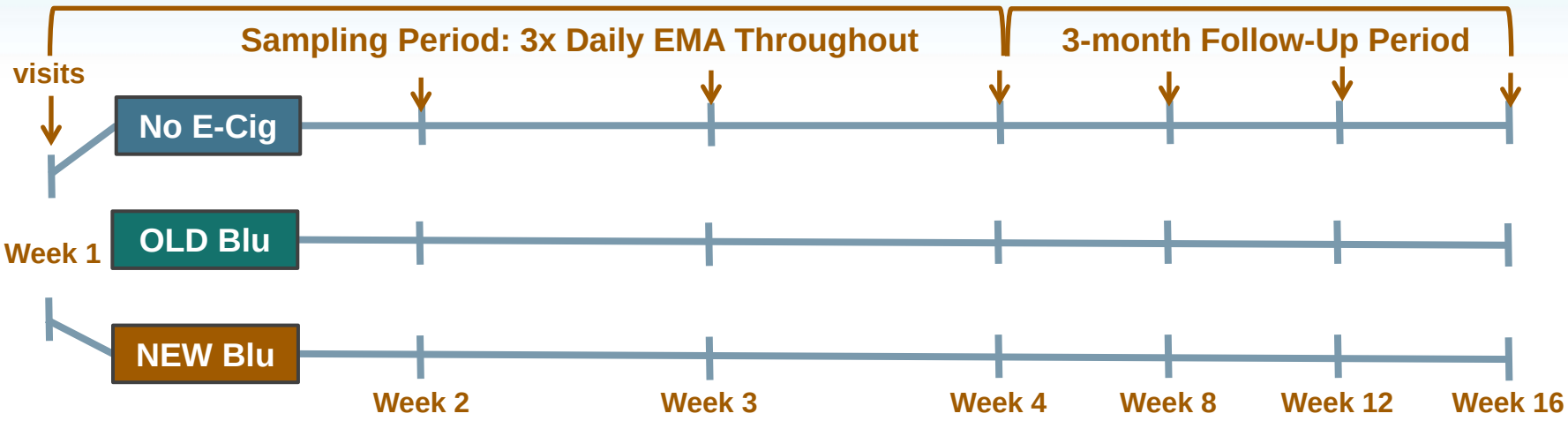


Study Sample:
Adult Daily Smokers, both motivated and unmotivated to quit (stratified randomization)
No use of E-cigarettes in past 6 months & Never purchase in lifetime
Final sample size for analyses: N=68 (46 E-Cig Sampling vs. 22 No Sampling)

E-Cigarette:
BluCig: Use as you wish; Allowed to keep any leftover at end of sampling period

Carpenter et al (2017). CEBP; 26: 1795-1803.

Study Design: Unanticipated but Opportunistic Changes

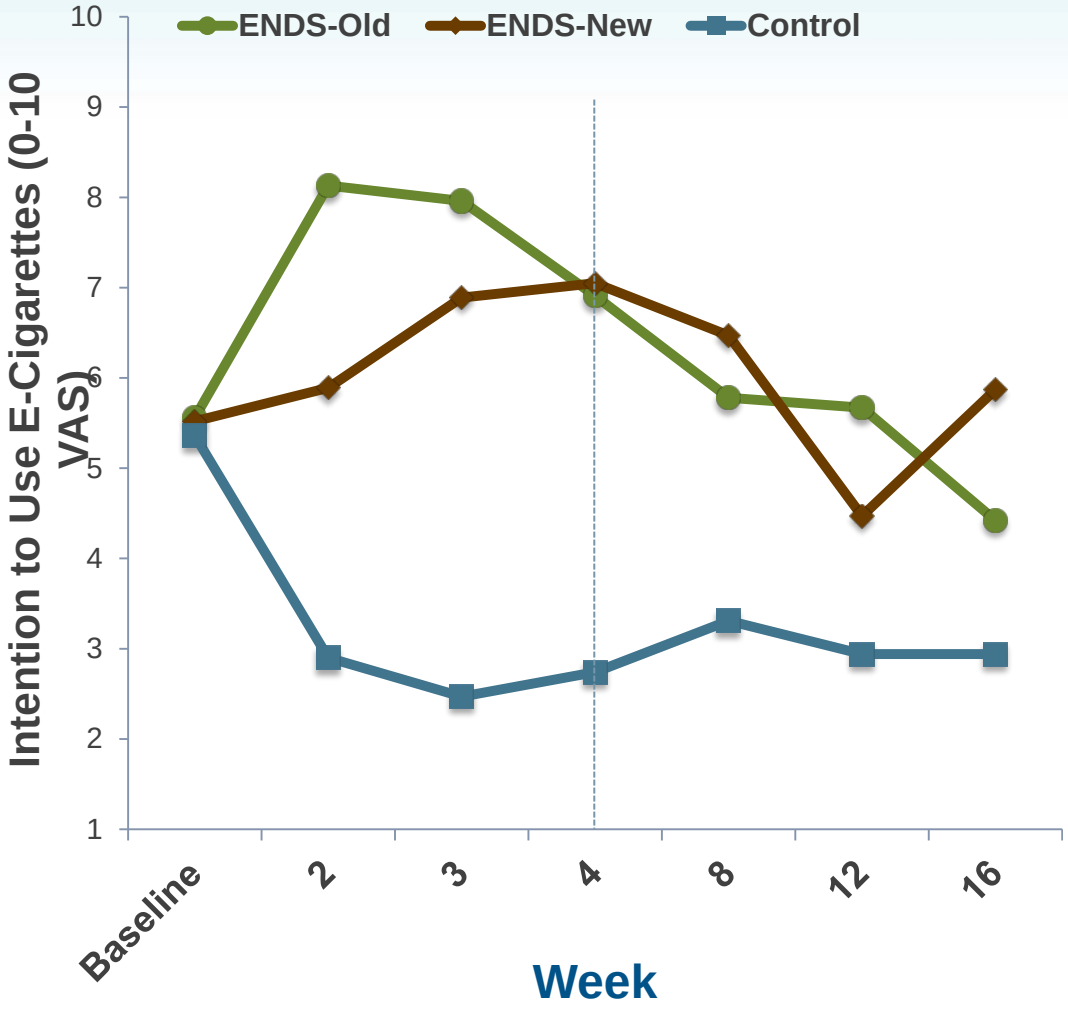


OLD BluCig: Blu Starter Pack → 1.6% nicotine
NEW BluCig: BluPlus+ → 2.4% nicotine, improved battery duration

- Only difference is strength of product.
- Everything else constant: manufacturer, style of device (ciga-like), packaging, participant instructions
- Both offered in either tobacco or menthol flavor.
- Up to 7 cartridges given out at Visits 1, 2, 3.

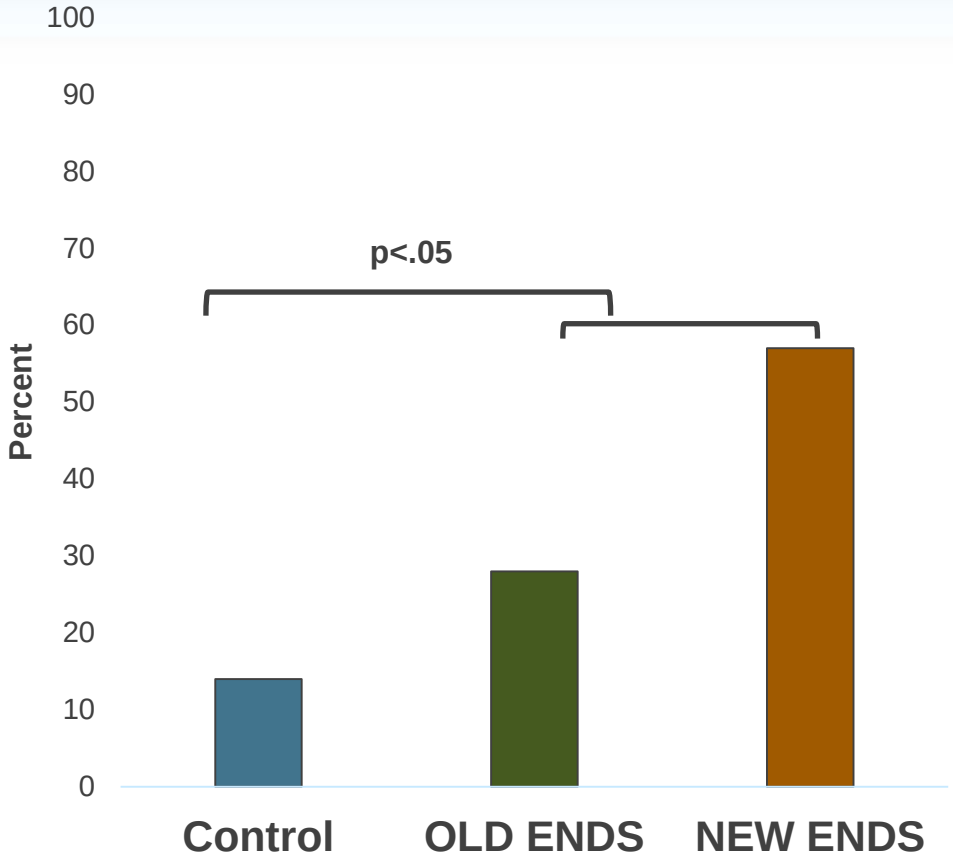
Carpenter et al (2017). CEBP; 26: 1795-1803.

Intention to Use E-Cigarettes



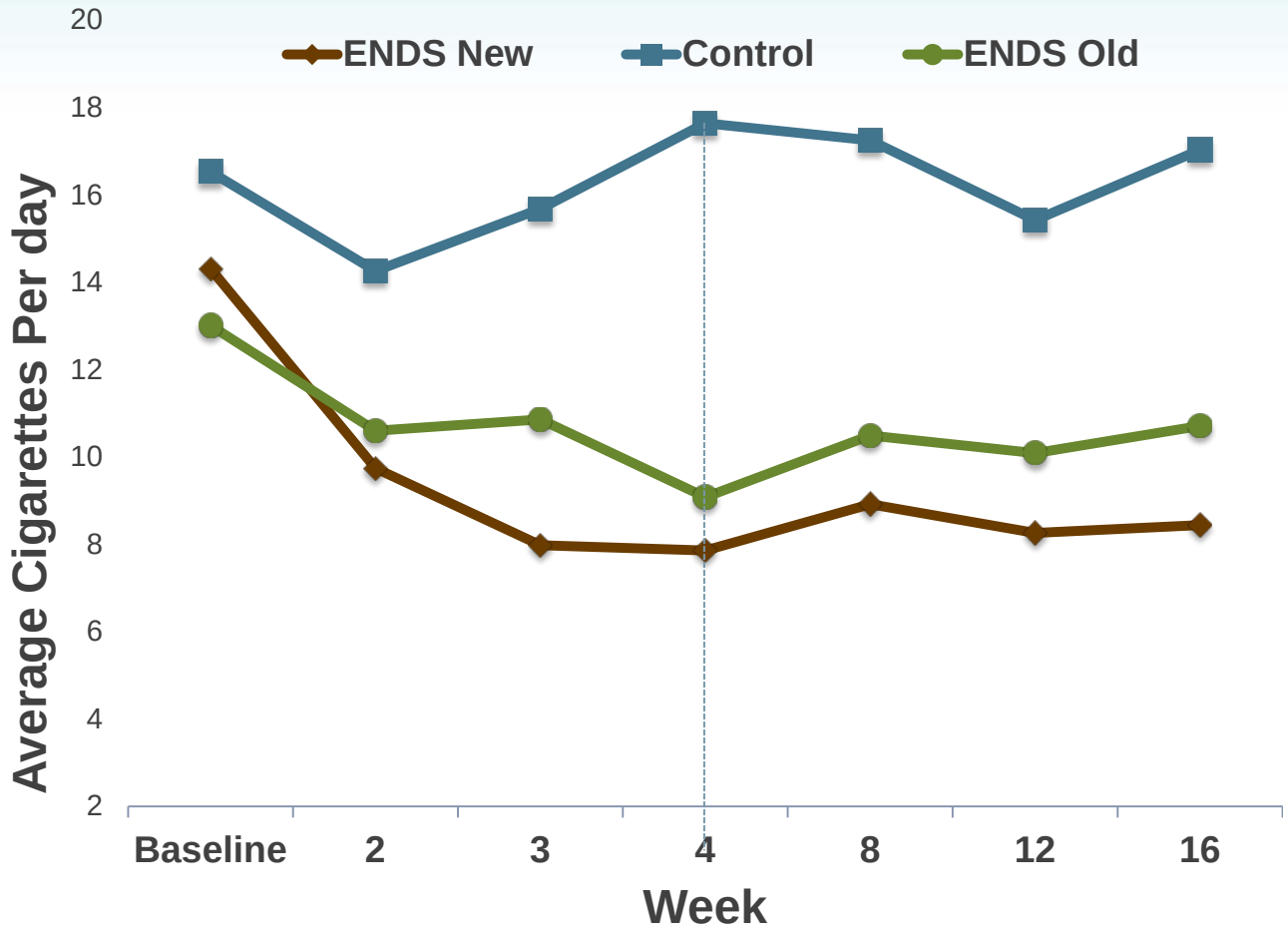
Time x group Interaction p < .0001

Independent Purchase of E-Cigs



Carpenter et al (2017). CEBP; 26: 1795-1803.

Changes in Cigarettes per Day*



50% Reduction from Baseline

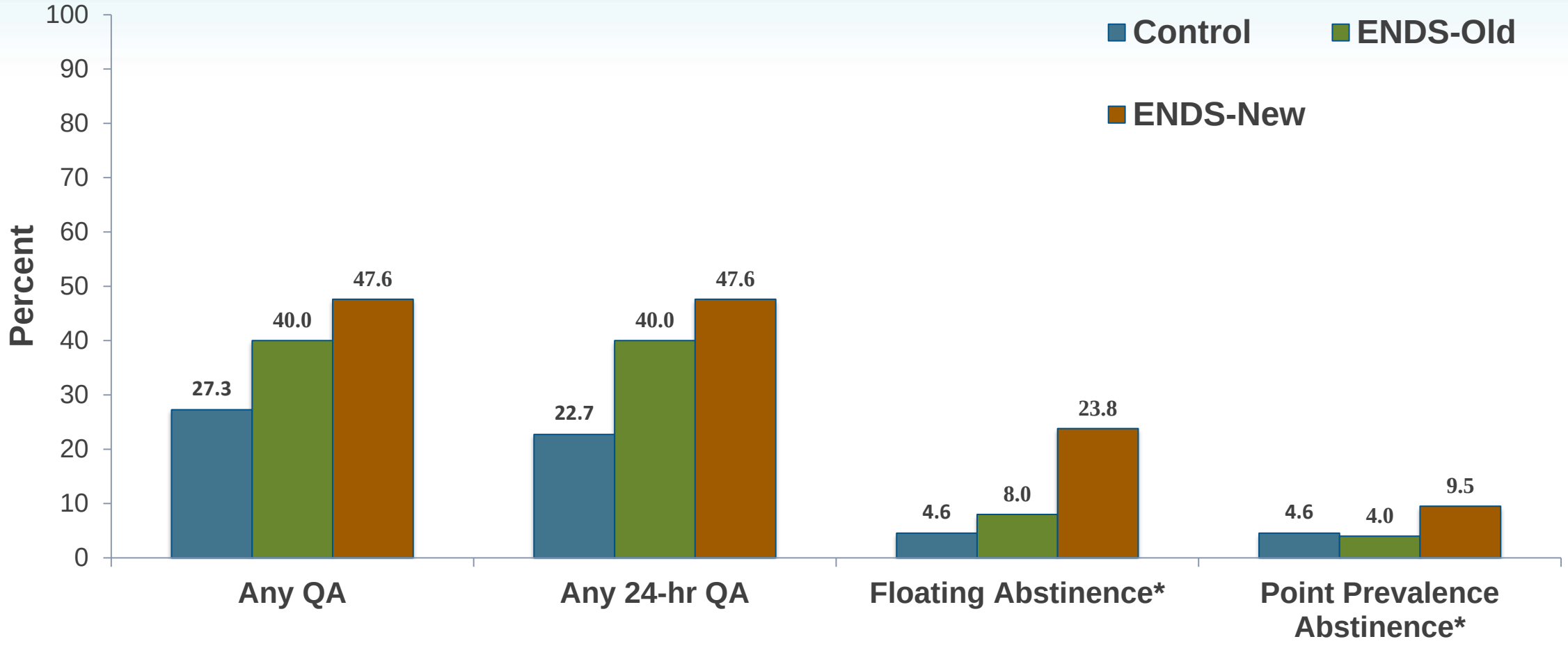
	End of . . . Sampling	Study
New	35%	47%
Old	30%	16%
Control	5%	19%

Time x group Interaction p = .03

* Average of 7 days preceding each visit

Carpenter et al (2017). CEBP; 26: 1795-1803.

Quit Attempts and Cessation



QA = Quit Attempt
*7-day, No Smoking, either floating (ever in study) or point prevalence at 4 months. Point prevalence abstinence at 4 month follow-up was CO verified; Floating abstinence is self-report.

Carpenter et al (2017). CEBP; 26: 1795-1803.

Study Conclusions

Despite use of a 1st generation product,

- naturalistic uptake of e-cigs is strong,
- palatable, with comparable perceptions vs. conventional cigs,
- resulting in partial substitution of smoking,
- and increased interest in future use/purchase,
- and trends towards increased cessation

- Cessation outcomes here are all non-significant. Don't over-interpret. But they are consistent with prior cessation-focused RCTs, showing positive cessation effects.
- These outcomes were stronger for smokers who received stronger ecig. We would expect similar or stronger outcomes with a 'better' ecig

Need for replication within larger trial ---> **CONNECT Trial (Carpenter R01)**

- Eventual N=660 (current N=235)
- NIDA SREC (tank system), w multiple flavors
- Naturalistic, Prospective, w subset collection of biomarkers

E-Cigarettes: What's a Clinician to Do?

TABLE 10 Guidance for Clinicians' Discussions of E-Cigarettes With Patients

Recommendations:

- Emphasize to smokers the importance of the goal of *complete* cessation of all combustible tobacco products. Even a single cigarette per day increases cardiovascular risk.
- Recommend that smokers use evidence-based, FDA-approved smoking cessation aids, which are known to be safe and effective.
- Clinicians should be prepared to discuss the evidence about e-cigarettes' risks and benefits with patients who ask about them.

Points to cover in a discussion with a patient who asks about e-cigarettes:

- E-cigarettes are devices that heat a nicotine-containing liquid, producing an aerosol that differs from the smoke produced by burning tobacco.
- E-cigarettes contain chemicals in addition to nicotine, including propylene glycol, glycerin, and flavoring chemicals that may pose a risk.
- Because they do not burn tobacco, e-cigarettes expose the user to fewer and lower levels of toxic compounds than smoking a cigarette does.
- Therefore, if used as a complete substitute for combustible tobacco products, e-cigarettes are expected to be less harmful than smoking combustible tobacco products in the short-term, but their long-term safety is uncertain.
- Because e-cigarettes are new products, scientific information about their health effects and effectiveness to help smokers quit is limited and rapidly evolving. They are not currently approved by the FDA as safe and effective cessation aids.
- E-cigarettes vary considerably in their design, in the contents of the e-liquids, and in nicotine and toxicant delivery to the user.

If smoker chooses to use e-cigarettes, provide evidence-based advice:

- Switch completely to e-cigarettes. Avoid dual use of both combustible tobacco products and e-cigarettes.
- The eventual goal is cessation of e-cigarettes as well as combustible cigarettes, because of uncertainty about e-cigarettes' long-term health risks. After stopping combustible tobacco, plan to taper off e-cigarettes.
- Heed safety instructions. Choose products with child-proof packaging to minimize the risk of nicotine poisoning of children. Follow instructions for device maintenance, battery recharging, and storage to minimize the risk of explosion.
- Avoid using e-cigarettes around children.

FDA = U.S. Food and Drug Administration.

Source: 2018 American College of Cardiology Expert Consensus Decision Pathway on Tobacco Cessation Treatment

We've come a long way . . .

Questions?
Matthew Carpenter, PhD
843.876.2436
carpente@musc.edu

. . . There's still time to save ourselves.

"This whole ordeal has really stressed me out. Johnson, swim back to the boat and get my Nicotine Patch."

© QuitSmoking.com www.quitsmoking.com