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)
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
<table>
<thead>
<tr>
<th></th>
<th>Counseling</th>
<th>Medication</th>
<th>Counseling + Medication</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>OR* (95% CI)</td>
<td>%</td>
</tr>
<tr>
<td>5 A’s (Ask, Advise, Assess, Assist, Arrange)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Received all 5</td>
<td>31.7</td>
<td>11.2 (7.1-17.5)</td>
<td>46.8</td>
</tr>
<tr>
<td>Received any 4</td>
<td>9.7</td>
<td>2.4 (1.6-3.5)</td>
<td>25.3</td>
</tr>
<tr>
<td>Received any 3</td>
<td>7.2</td>
<td>1.8 (1.2-2.9)</td>
<td>20.8</td>
</tr>
<tr>
<td>Received any 2</td>
<td>4.6</td>
<td>1.2 (0.7-1.9)</td>
<td>14.3</td>
</tr>
<tr>
<td>Received any 1 or 0</td>
<td>3.8</td>
<td>Ref</td>
<td>12.4</td>
</tr>
</tbody>
</table>

* Adjusted odds ratios

# Which Leads to Cessation

<table>
<thead>
<tr>
<th></th>
<th>Risk Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief Advice (vs. control)</td>
<td>1.66</td>
<td>1.4 – 1.9</td>
</tr>
<tr>
<td>More Intensive Intervention</td>
<td>1.84</td>
<td>1.6 – 2.2</td>
</tr>
<tr>
<td>Overall</td>
<td>1.76</td>
<td>1.6 – 2.0</td>
</tr>
</tbody>
</table>

**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)

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?)
VITAL SIGNS

Blood Pressure: ________________________________

Pulse: ____________________  Weight: ______________

Temperature: ________________________________

Respiratory Rate: ______________________________

Tobacco Use (circle one):     Current     Former     Never

Smoker in Home (circle one):      Yes        No
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 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 they 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

## Time Invested Pays Dividends

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

The All Important Assist
You’ll Hear Countless Stories of Cold Turkey. . . .
It (usually) doesn’t Work

Efficacy x Reach = Impact

<table>
<thead>
<tr>
<th>Quit Method</th>
<th>Hypothetical Efficacy</th>
<th>Hypothetical Reach</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% Quit at 6 months</td>
<td>(# using)</td>
<td>(Total # Quitters)</td>
</tr>
<tr>
<td>Cold Turkey</td>
<td>5%</td>
<td>150,000</td>
<td>7,500</td>
</tr>
<tr>
<td>Treatment A</td>
<td>15%</td>
<td>30,000</td>
<td>4500</td>
</tr>
<tr>
<td>Treatment B</td>
<td>20%</td>
<td>20,000</td>
<td>4,000</td>
</tr>
<tr>
<td>Treatment A &amp; B</td>
<td>30%</td>
<td>10,000</td>
<td>3,000</td>
</tr>
</tbody>
</table>

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

Varenicline or Combo NRT are often consider the two best options

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

Relief of withdrawal

Deconditioning of environmental cues
<table>
<thead>
<tr>
<th></th>
<th># Arms</th>
<th>Estimated ORs</th>
<th>Estimated Abstinence Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>80</td>
<td>1.0</td>
<td>13.8</td>
</tr>
<tr>
<td>Monotherapies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nicotine patch (6-14 wks)</td>
<td>32</td>
<td>1.9</td>
<td>23.4</td>
</tr>
<tr>
<td>Long term patch (&gt;14 wks)</td>
<td>10</td>
<td>1.9</td>
<td>23.7</td>
</tr>
<tr>
<td>Nicotine Gum (6-14 wks)</td>
<td>32</td>
<td>1.9</td>
<td>23.4</td>
</tr>
<tr>
<td>Long term Gum (&gt;14 wks)</td>
<td>6</td>
<td>2.2</td>
<td>26.1</td>
</tr>
<tr>
<td>High dose patch (&gt;25mg)</td>
<td>4</td>
<td>2.3</td>
<td>26.5</td>
</tr>
<tr>
<td>Nicotine Inhaler</td>
<td>6</td>
<td>2.1</td>
<td>24.8</td>
</tr>
<tr>
<td>Nicotine Nasal Spray</td>
<td>4</td>
<td>2.3</td>
<td>26.7</td>
</tr>
<tr>
<td>Varenicline 2mg</td>
<td>5</td>
<td>3.1</td>
<td>33.2</td>
</tr>
<tr>
<td>Varenicline 1mg</td>
<td>3</td>
<td>2.1</td>
<td>25.4</td>
</tr>
<tr>
<td>Bupropion</td>
<td>26</td>
<td>2.0</td>
<td>24.2</td>
</tr>
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## Summary of Medication Effectiveness

<table>
<thead>
<tr>
<th></th>
<th># Arms</th>
<th>Estimated ORs</th>
<th>Estimated Abstinence Rate</th>
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<tbody>
<tr>
<td>Placebo</td>
<td>80</td>
<td>1.0</td>
<td>13.8</td>
</tr>
<tr>
<td><strong>Combination Therapies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long term patch + ad lib NRT (gum or spray)</td>
<td>3</td>
<td>3.6</td>
<td>36.5</td>
</tr>
<tr>
<td>Patch + Bupropion</td>
<td>3</td>
<td>2.5</td>
<td>28.9</td>
</tr>
<tr>
<td>Patch + Inhaler</td>
<td>2</td>
<td>2.2</td>
<td>25.8</td>
</tr>
</tbody>
</table>

# Medication Effectiveness: Head to Head Comparison

<table>
<thead>
<tr>
<th>Treatment</th>
<th># Arms</th>
<th>Estimated ORs</th>
<th>95% CIs of OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine Patch</td>
<td>32</td>
<td>1.0</td>
<td>--</td>
</tr>
<tr>
<td><strong>Monotherapies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>Long term patch (&gt;14wks)</td>
<td>10</td>
<td>1.0</td>
<td>0.9-1.2</td>
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<td>3</td>
<td>1.3</td>
<td>1.0-1.8*</td>
</tr>
</tbody>
</table>

# Medication Advantages & Disadvantages (OTC NRT)

<table>
<thead>
<tr>
<th></th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patch</strong></td>
<td>Easiest nicotine product to use; Provides a steady nicotine level</td>
<td>Patient cannot alter dose if cravings occur throughout the day</td>
</tr>
<tr>
<td><strong>Gum</strong></td>
<td>Patient controls nicotine dose; Oral substitute for cigarettes</td>
<td>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</td>
</tr>
<tr>
<td><strong>Lozenge</strong></td>
<td>Patient controls nicotine dose; Oral substitute for cigarettes; Easier to use than gum for those with dental work or dentures</td>
<td>No food or drink 15 minutes prior to use and during use</td>
</tr>
<tr>
<td><strong>Combination</strong></td>
<td>Better for heavier smokers; Provides nicotine throughout day while giving you flexibility when you are really craving; Least likely to be in withdrawal</td>
<td>Risk of nicotine overdose (headache, dizziness, nausea)</td>
</tr>
</tbody>
</table>
# Medication Advantages & Disadvantages (Prescription)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRT Inhaler</td>
<td>User controls nicotine dose; Mimics hand-to-mouth ritual of smoking cigarettes</td>
<td>Frequent puffing required</td>
</tr>
<tr>
<td>NRT Nasal Spray</td>
<td>User controls nicotine dose; Most rapid delivery of all nicotine among all NRT products</td>
<td>Has the most side effects of all NRT products; Some patients cannot tolerate local irritation to nasal mucosa</td>
</tr>
<tr>
<td>Bupropion</td>
<td>May lessen post-cessation weight gain while drug is being taken; Oral agent (pill)</td>
<td>Increases seizure risk: not for use if seizure disorder or binge drinking</td>
</tr>
<tr>
<td>Varenicline</td>
<td>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)</td>
<td>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</td>
</tr>
</tbody>
</table>
Multiple Medications?

Analysis of 1504 smokers randomized to single/joint medications†

- **8-wk abstinence***
- **6-month abstinence**


† 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)
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.

• **Set** a quit date. Ideally, the quit date should be within 2 weeks.
• **Tell** family, friends, and coworkers about quitting, and request understanding and support.
• **Anticipate** challenges to the upcoming quit attempt, particularly during the critical first few weeks. These include nicotine withdrawal symptoms.
• **Remove** 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.

# Don’t Forget Behavioral Approaches

## TABLE 5 Examples of Behavioral Interventions for Nicotine Dependence

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Examples</th>
</tr>
</thead>
</table>
| 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.

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

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

Asked Stages of Change

- Precontemplation
- Contemplation
- Preparation

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

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

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

<table>
<thead>
<tr>
<th></th>
<th>Low Motivation to Quit (n=573)</th>
<th>High Motivation to Quit (n=671)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SC (n=315)</td>
<td>SC + NRT (n=258)</td>
</tr>
<tr>
<td>Any QA</td>
<td>109 (35%)</td>
<td>94 (36%)</td>
</tr>
<tr>
<td>Any 24hr QA</td>
<td>92 (29%)</td>
<td>78 (30%)</td>
</tr>
<tr>
<td>Abstinence, 6 months</td>
<td>15 (5%)</td>
<td>20 (8%)</td>
</tr>
<tr>
<td>Floating Abstinence</td>
<td>44 (14%)</td>
<td>47 (18%)</td>
</tr>
</tbody>
</table>

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?
Electronic visits (E-visits)

• **Asynchronous** electronic interactions between patients and providers through patient portals.
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
Cigarette smoker

Age 18+

Active MyChart account

Treated in Dept Family Medicine in the last 12 months

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
Vanessa A. Diaz, MD MSCR to [Redacted]

Hi [Redacted]

Hope you are doing well. Based on your responses, Chantix (varenicline) 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 medication.

This website provides info on the medication.

Best,

Vanessa Diaz, MD MS

With acknowledgement to: Drs. Jen Dahne, Vanessa Diaz, Marty Player
Automated Follow-up Assessment
(via MyChart)

Musc Rsch Smoking Cessation Follow Up Questionnaire

<table>
<thead>
<tr>
<th>Question</th>
<th>1/8/2019 1:05 PM EST - Filed by Patient on 1/8/2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Since your last e-visit, have you smoked any cigarettes at all, even a puff?</td>
<td>Yes</td>
</tr>
<tr>
<td>Since your last e-visit, have you made any attempts to stop smoking cigarettes for good?</td>
<td>Yes</td>
</tr>
<tr>
<td>Of the quit attempts you have made since your last e-visit, how long did your longest quit attempt last?</td>
<td>2 days</td>
</tr>
<tr>
<td>How many times have you tried to stop smoking for good since your last e-visit?</td>
<td>2</td>
</tr>
<tr>
<td>As a result of the last e-visit you completed for smoking cessation, were you prescribed a medication to help you quit smoking?</td>
<td>Yes</td>
</tr>
<tr>
<td>Did you receive the medication you were prescribed?</td>
<td>Yes</td>
</tr>
<tr>
<td>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])</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>3</td>
</tr>
<tr>
<td>Headache</td>
<td>0</td>
</tr>
<tr>
<td>Sleep disturbances</td>
<td>0</td>
</tr>
<tr>
<td>Skin irritation</td>
<td>0</td>
</tr>
<tr>
<td>Restlessness</td>
<td>0</td>
</tr>
<tr>
<td>Difficulty concentrating</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
</tr>
<tr>
<td>Since your last e-visit, have you or your family/friends noticed changes in your mood since quitting? Rate Severity (Mild [0] - Severe [4])</td>
<td></td>
</tr>
<tr>
<td>Anger/hostility</td>
<td>0</td>
</tr>
<tr>
<td>Anxiety</td>
<td>0</td>
</tr>
<tr>
<td>Feeling depressed</td>
<td>0</td>
</tr>
<tr>
<td>Other issues</td>
<td>0</td>
</tr>
<tr>
<td>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)?</td>
<td>No</td>
</tr>
<tr>
<td>Who is helping you with your smoking cessation efforts (check all that apply)?</td>
<td>Parent, Spouse/significant other, Friend</td>
</tr>
<tr>
<td>Are you interested in any of the following treatment options for smoking cessation? (check all that apply)</td>
<td>Chantix (Varenicline)</td>
</tr>
</tbody>
</table>

With acknowledgement to: Drs. Jen Dahne, Vanessa Diaz, Marty Player
Iterative Engagement between Provider : Patient
(via MyChart)

Vanessa A. Diaz, MD MSCR

Hi [Name],

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.


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

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-pipe
- E-cigarette
- Large-size tank devices
- Medium-size tank devices
- Rechargeable e-cigarette
- Disposable e-cigarette

\[e-cigarette = \text{electronic cigarette. Source: U.S. Department of Health and Human Services, 2016 (28).}\]
Popularity of e-cigarettes among youth (NYTS 2011-2018)

CDC / MMWR (2018);67:1276–7.
Juice, Candy, & E-Cigarettes: FDA Warnings 2018

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

Replicated by a number of other studies!
(see Soneji et al JAMA 2017)
E-cigarettes: Safer vs. Safe?

E-Cigarettes are safer than combustible cigarettes. So if you're comparing to cigs, e-cigs are better.

E-Cigarettes are NOT safe. So if you're comparing to nothing, e-cigs are potentially harmful.

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

Comparison of toxicants levels between conventional and electronic cigarettes.

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

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

Goniewicz NTR 2014

Round et al NTR 2018
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

**Study Design: Unanticipated but Opportunistic Changes**

Visits:
- Week 1
- Week 2
- Week 3
- Week 4
- Week 8
- Week 12
- Week 16

**Sampling Period:** 3x Daily EMA Throughout 3-month Follow-Up Period

**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.

Intention to Use E-Cigarettes

- ENDS-Old
- ENDS-New
- Control

Time x group Interaction p < .0001

Changes in Cigarettes per Day*

Time x group Interaction p = .03

* Average of 7 days preceding each visit

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.

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 . . .

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

“\textit{This whole ordeal has really stressed me out. Johnson, swim back to the boat and get my Nicotine Patch.}”