


# Youth Tobacco Cessation: Science and Treatment Strategies


Experience with Cessation Therapies in Adolescents  
 Food and Drug Administration Public Meeting  
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 American Academy of Pediatrics Tobacco Consortium  
 May 15, 2019



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## PREVENTION IS PARAMOUNT


- While it is important to discuss drug therapies to support adolescents who are addicted to e-cigarettes, our primary goal must be preventing youth nicotine addiction at the outset.
- Strong FDA regulation aimed at eliminating youth access to e-cigarettes with enticing flavors and high nicotine content is critical to prevention, and may be a critical step toward adolescent cessation.
- We must prevent youth nicotine addiction before it starts, while also supporting the youth who have already fallen victim to this lifelong addiction.



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## CURRENT STATE OF THE EVIDENCE ON YOUTH CESSATION

- As noted, there is no conclusive evidence about effective adolescent e-cigarette cessation
- The body of evidence for adolescent cessation of combustible cigarettes is limited, and has been covered well by colleagues here today
- More work being conducted assessing phone-based applications for cessation
- Unpublished work within the pediatric office setting:




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## Preliminary Results: AAP Adolescent Smoking Cessation in Pediatric Primary Care






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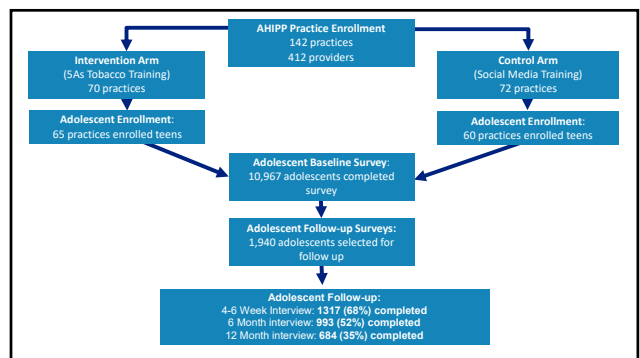
## METHODS



- Adolescent Health in Pediatric Practice (AHIPP)
- National RCT to assess the impact of primary care provider counseling interventions on adolescent smoking cessation
- AAP Pediatric Research in Office Settings (PROS) practice-based research network
- National Cancer Institute (R01 CA140576)
- PI: Jonathan Klein MD MPH FAAP



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### METHODS

- Pediatricians trained with a self-paced training binder that covered intervention and study protocol.
  - Trained to screen all patients (age 14+) during well-visits or non-urgent sick visits.
  - Trained counsel all tobacco users.
- Recruited 100 teens/practice.
  - Teens were age 14-23 (mean 16y)
  - Recruited during clinical visits (January 2012 - December 2014)
- Follow-up surveys assessed:
  - Provider delivery of tobacco screening and brief counseling intervention
  - Subsequent quit attempts, relapse
- Chi-square and regression analyses assessed:
  - Delivery of intervention, relationship with quit attempts and 12-month quit status

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### OVERVIEW: TEEN 5AS INTERVENTION

- **Ask** - All patients, at every visit if patient smokes and/or uses other tobacco
  - **Advise** - Every patient to quit
  - **Assess** - Readiness to quit
  - **Assist** - In quitting and finding resources
  - **Arrange** - For cessation services and follow up
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- **Adapted to appeal to youth:**
    - Linked advice about quitting to youth's athletic/artistic performance
    - Focus on short-term benefits of quitting
    - Schedule quit dates to avoid stressful times
  - Paired with provider screening tool, adjunct cessation materials, referral to quit resources



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### ASK

- **ASK** every adolescent, each time you see them: "Do you currently use tobacco?"

Ask	If yes, what kind?	If no
<input type="checkbox"/> "Do you currently use tobacco?"	<input type="checkbox"/> Cigarettes <input type="checkbox"/> Cigars <input type="checkbox"/> Chewing tobacco <input type="checkbox"/> Other (electronic cigarettes, hookah, etc.)	<input type="checkbox"/> Ex-tobacco user <input type="checkbox"/> Never used tobacco  <b>Reinforce</b> <input type="checkbox"/> "That's great!" <input type="checkbox"/> Continue to track

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### ADVISE/ASSESS

- Advice should be **STRONG, PERSONALIZED, EMPOWERING**

#### Advise

- "As your clinician, I strongly advise you to stop."
- Personalize the risk of not quitting and the benefits of quitting.
- "I believe you can do it, but that's got to be your choice and you have to be ready to try."

#### Assess

- "How convinced are you that you should quit smoking?"
- "How confident are you that you will be able to quit?"
- "Are you willing to try quitting smoking?"

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### ASSIST

- Strategies for success in helping teens quit depend on their readiness to quit using tobacco.

Ready to Quit	Considering Quitting	Not Ready to Quit
<input type="checkbox"/> "Great!" <input type="checkbox"/> Set a quit date. <input type="checkbox"/> Consider pharmacotherapy (if patient is 18 years old). <input type="checkbox"/> "I'd like to give you some materials." (give cessation brochure). <input type="checkbox"/> Refer to quitline or local quitting resources. <input type="checkbox"/> Discuss Web resources (www.smokefree.gov).	<input type="checkbox"/> Offer encouragement. <input type="checkbox"/> "Have are some things that can help you think about it." <input type="checkbox"/> Refer to quitting resources (give cessation brochure). <input type="checkbox"/> Discuss Web resources (including www.smokefree.gov).	<input type="checkbox"/> "Please think about what we discussed." <input type="checkbox"/> Offer AAP "Tobacco: Straight talk for teens" brochure. <input type="checkbox"/> Let me know when you are ready to quit - I have some things that can help."

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### ASSIST: QUIT RESOURCES



1-800-QUIT-NOW



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### ARRANGE FOLLOW-UP

- **Follow-up** (by phone or a visit) should be a few days or 1-2 weeks after their quit date

**Arrange Follow Up** *I'll check back with you (how? \_\_\_\_\_) by this date: \_\_\_\_\_*

For those ready to quit, follow-up focused on relapse prevention

For those considering quitting or not ready to quit, follow-up emphasized importance of quitting

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### FINDINGS...

Training in a tobacco screening/counseling intervention increases **physician counseling** of teen smokers

Factors Associated with Teens Being Screened for Tobacco			Factors Associated with Teen Smokers Being Counselled about Quitting		
Multivariable logistic regression* (n=1,317)	aOR	95% CI	Multivariable logistic regression* (n=602)	aOR	95% CI
Provider training in the 5As Intervention	2.20	1.71-2.83	Provider discussed confidentiality	4.50	2.03-9.97
Teen identifies as a smoker	1.89	1.46-2.45	Provider training in the 5As Intervention	2.08	1.47-2.95
Provider talked with teen privately	1.82	1.39-2.37	Provider talked with teen privately	1.72	1.15-2.60
Provider discussed confidentiality	1.76	1.13-2.74			

\*Models adjusted for youth demographics

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### FINDINGS...

Teen smokers who receive 5As counseling are **more likely to make quit attempts**, but still struggle

Receipt of 5As and quit attempts

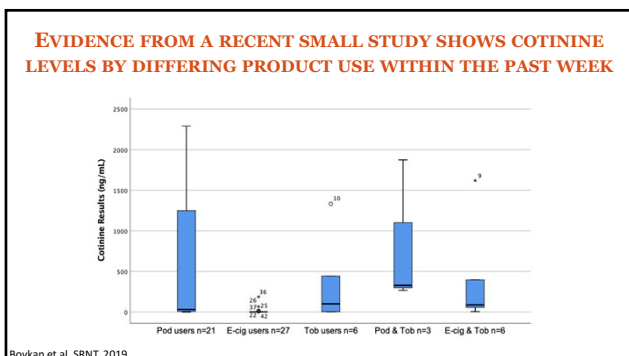
	Teens who received 5As	Teens who did not receive 5As	Sig.
Teen reports "trying to quit" at 4-6 week follow-up (n=602 smokers at baseline completing interview)	28%	17%	p=.012
Teen reports "trying to quit" at 6 month follow-up (n=414 completing follow-up interview)	52%	35%	p=.011
Teen reports a failed quit attempt at 6 month follow-up (n=414 completing follow-up interview)	64%	26%	p<.001

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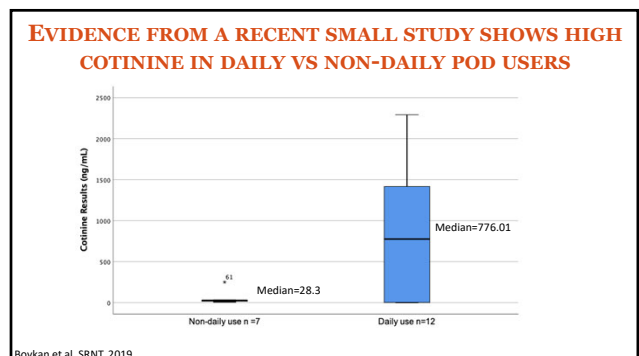
### 12-MONTH FOLLOW-UP, CESSATION RATES WERE LOW

- 12-month analyses are still underway
- Preliminary findings: **the only significant driver of cessation status at 12-month follow up is teen level of addiction at baseline (measured by HONC – data upcoming)**
- **More highly addicted teens are less likely to have quit at 12-month follow up**
- **Conclusion... we can increase screening and counseling, but we need a focus on strategies to support the most-addicted teens.**

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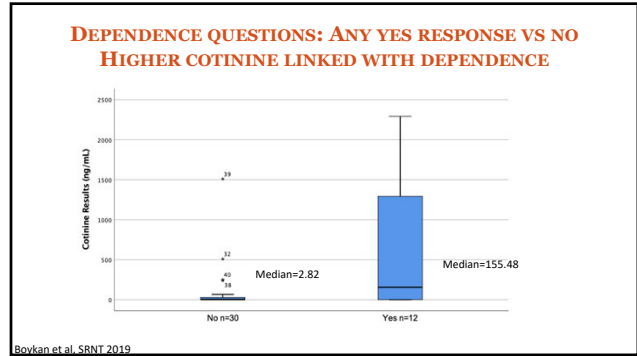
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**HONC/FAGERSTROM INDICATES HIGHER DEPENDENCE WITH POD-BASED E-CIGS**

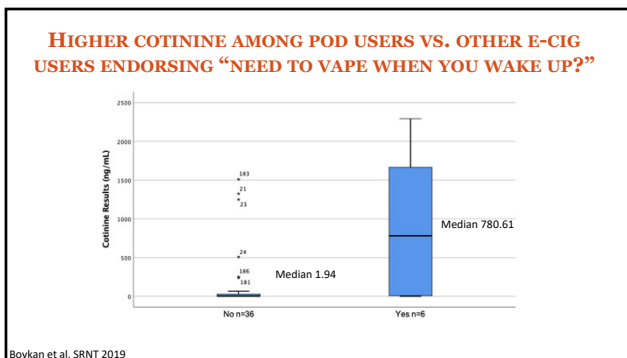
	Total (%)	Pod users (%)	E-cig users (%)	p
Desire interrupts thinking	3/42 (7)	3/20(15)	0/22 (0)	.06
Need to vape again	2/42 (5)	2/20 (10)	0/22 (0)	.13
Irritable without	5/42 (12)	4/20 (20)	1/22 (5)	.122
Stressed without	6/42 (14)	4/20 (20)	2/22 (9)	.32
Vape on awakening	6/42 (14)	6/20 (29)	0/22 (0)	.006

Boykan et al. SRNT 2019

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- YOUTH CESSATION: WHAT WE NEED TO KNOW**
- Effective interventions for adolescent e-cigarette users
    - Drug therapies, behavioral interventions, combination therapies
  - Trajectory of nicotine dependence among teens who use e-cigarettes as compared to those who use traditional combustible products
  - Level of dependence among adolescents using e-cigarettes to better target treatment paradigms based on the severity of dependence
  - Consideration of developmental stage of user – 14 yo very different than 18yo
  - Efficacy of currently approved NRT in treating adolescents dependent on e-cigarettes and potential modifications to NRT product characteristics to improve the performance of these products for adolescents

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- RECOMMENDED ACTION**
- We encourage FDA to use its authorities under law to increase the study of cessation drug therapies in adolescents, including under the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA)
  - We encourage FDA to urgently fund studies that evaluate behavioral, pharmacological and combination interventions for adolescent e-cigarette users, based on evidence from combustible cigarette cessation, that can be implemented and tested in real time
  - We encourage FDA to fund studies into outstanding questions around adolescent e-cigarette dependence, trajectories and nicotine dependence

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