The Doctor’s Dilemma:
Providing Guidance on E-cigarettes to Adult Smokers amid Controversy

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The doctor’s dilemma

- Patients are asking their doctors about e-cigarettes.
- Physicians are unfamiliar with these new consumer products and seek guidance.
- Little evidence is available to answer key questions about efficacy for cessation and long-term safety.
- New journal articles abound, often reporting harms.
Who can sort this out?

- Professional organizations and government-sponsored panels translate evidence into guidance
  - Synthesize evidence → meta-analyses
  - When evidence is lacking → seek consensus of experts

- Challenge: finding consensus amid uncertainty, controversy
  - “First do no harm” (*precautionary principle*) vs.
  - Take action when many are already being harmed

- When consensus is lacking → Shared decision making
### Who makes guidelines for treating adults?

<table>
<thead>
<tr>
<th>Audience</th>
<th>Public + Clinicians</th>
<th>Primarily Clinicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>U.S. Preventive Services Task Force (USPTF)*</td>
<td></td>
</tr>
<tr>
<td>Cardiology</td>
<td>American Heart Association (AHA)*</td>
<td>American College of Cardiology (ACC)*</td>
</tr>
<tr>
<td>Oncology</td>
<td>American Cancer Society (ACS)*</td>
<td>National Comprehensive Cancer Network (NCCN)*</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>American Lung Association (ALA)</td>
<td>American Thoracic Society (ATS)</td>
</tr>
</tbody>
</table>
US Preventive Services Task Force
*Tobacco Smoking Cessation in Adults*, 2015 – being updated

- “Current evidence is insufficient to recommend electronic nicotine delivery systems for tobacco cessation in adults.”
- “USPSTF recommends that clinicians direct patients who smoke tobacco to other cessation interventions with established effectiveness and safety.”
- Recommendation for practice (Category I): Clinicians should help patients understand the uncertainty about the balance of benefits and harms.

*Implicit recommendation*: Shared decision making
American Heart Association


- “If a patient has failed initial treatment, been intolerant to or refuses to use conventional cessation medication and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt.”

- Tell patients that “although e-cigarette aerosol is likely to be much less toxic than cigarette smoking, the products are unregulated, may contain low levels of toxic chemicals, and have not been proven to be effective as cessation devices.”
“In the absence of long-term safety studies of e-cigarette use, it may be appropriate to advise the patient to consider setting a quit date for their e-cigarette use and not to plan to use it indefinitely (unless needed to prevent relapse to cigarettes).”
Emphasize the goal of complete cessation of all combustible tobacco products. Even a single cigarette per day increases cardiovascular risk.

Recommend evidence-based, FDA-approved smoking cessation aids, which are known to be safe and effective.

Be prepared to discuss the evidence about e-cigarettes’ risks and benefits with patients who ask.
Added “Points to Cover in a Discussion with Patient who Asks”

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

- Switch completely → Avoid dual use
- Eventual goal is to stop e-cigs too (health effects of long term use)
- Heed safety instructions
- Avoid e-cigarette use around children
American Cancer Society

Position Statement on Electronic Cigarettes – Feb. 2018

- Advise patients to use FDA-approved cessation aids.
- Support patients to quit combustibles (and eventually e-cigs)
- If a patient is not willing to quit “despite firm clinical advice,” encourage switch to “least harmful form of tobacco product,” including exclusive use of e-cigs.
- Strongly discourage dual use of e-cigs and combustible tobacco products
“There is currently insufficient evidence to support the use of e-cigarettes in smoking cessation.”

“Insufficient evidence regarding the safety and efficacy of e-cigarette use in patients with cancer.”

Other organizations do not recommend e-cigarettes and recommend methods with established effectiveness…. (implies that NCCN will follow them)
“ENDS use have NOT been shown to be effective for stopping smoking. There are increasing concerns about the hazards to health of ENDS use, and of breathing in the emissions from ENDS devices.”
Areas of Agreement in U.S. Guidelines

- E-cigarettes are new products not yet approved by the FDA.
- E-cigarettes are less harmful than continuing to smoke cigarettes.
- Uncertainty exists about their efficacy as cessation aids and about the safety of long-term use.
  - Use FDA-approved treatments first.
  - Eventual goal is to stop using both e-cigarettes and cigarettes.
  - Avoid dual use → switch completely to e-cigarettes
Areas of Disagreement

- What to advise smokers who are unwilling or unsuccessful when using FDA-approved cessation aids?
  - Recommend e-cigs? (ACS)
  - Make no recommendation (USPTF, AHA, ACC, NCCN)
  - Support the attempt if patient makes the choice (AHA, ACC)
  - Discourage e-cigs? (ALA? ATS?)

- What to advise smokers who are not interested in quitting?
  - Harm reduction? (NCCN) E-cigs for harm reduction?
Areas of Uncertainty

- **What advice to give a smoker?** (if not discouraging e-cig use)
  - Which products to recommend?
    - Discourage some or all flavors?
  - How to use e-cigarettes?
    - Duration or frequency of use?
    - Use behavioral support?
    - Use with FDA approved cessation aids?
    - Safe use (child-proof containers, battery explosions)
  - Avoid vaping around children?
**American College of Cardiology**

**Expert Consensus Decision Pathway on Tobacco Cessation**

**JACC – 2018**

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### 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.
Another Article About E-Cigarettes: Why Should I Care?

K. Michael Cummings, PhD, MPH; Pamela B. Morris, MD, FACC, FAHA, FASPC, FNLA; Neal L. Benowitz, MD

**Table. Talking to Patients About E-Cigarettes**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Talking Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the best way to stop smoking?</td>
<td>• The most effective treatment for smoking addiction is behavioral counseling combined with FDA approved stop-smoking medications (i.e., nicotine replacement therapies, varenicline, bupropion).</td>
</tr>
<tr>
<td></td>
<td>• E-cigarettes have not been approved as a stop-smoking treatment by the FDA. However, smokers who are unable to stop smoking with approved FDA medications may benefit from use of e-cigarettes as a cessation aid, though evidence is limited.</td>
</tr>
<tr>
<td></td>
<td>• Because e-cigarettes deliver nicotine, they are likely to help reduce urges to smoke and ease withdrawal from cigarettes.</td>
</tr>
<tr>
<td>Are e-cigarettes safe?</td>
<td>• E-cigarettes are not risk free, but evidence suggests they expose users to much lower levels of toxins compared with use of combustible tobacco cigarettes.</td>
</tr>
<tr>
<td></td>
<td>• The most common side effects are irritation of the mouth and throat and dry cough.</td>
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<tr>
<td></td>
<td>• Long-term risks of e-cigarettes are unknown, and you should discontinue use after successful cessation of combustible tobacco cigarettes.</td>
</tr>
<tr>
<td></td>
<td>• Ingestion of nicotine liquids can be dangerous. Keep e-liquids in childproof containers and keep them out of the reach of children.</td>
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<tr>
<td></td>
<td>• Protect e-cigarette devices from extreme temperatures by not leaving it in direct sunlight or in a vehicle during freezing temperatures.</td>
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<tr>
<td></td>
<td>• Avoid vape battery explosions by:</td>
</tr>
<tr>
<td></td>
<td>a) Using devices with safety features such as button locks, vent holes, and protection against overcharging;</td>
</tr>
<tr>
<td></td>
<td>b) Keeping batteries in a case to prevent contact with metal objects (i.e., coins, keys);</td>
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<tr>
<td></td>
<td>c) Not charging the device with a phone or tablet charger;</td>
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<tr>
<td></td>
<td>d) Not charging the device unattended; and</td>
</tr>
<tr>
<td></td>
<td>e) Replacing batteries if they get damaged or wet.</td>
</tr>
</tbody>
</table>
RECOMMENDED ACTIONS FOR THE PEDIATRICIAN

I. Screen for e-cigarette use and exposure and provide prevention counseling in clinical practice.

II. Provide counseling that homes, cars, and places where children and adolescents live, learn, play, work, and visit should have comprehensive tobacco-free bans that include e-cigarettes as well as combustible tobacco products.

III. Do not recommend e-cigarettes as a tobacco-dependence treatment product.

Another Article About E-Cigarettes: Why Should I Care?

K. Michael Cummings, PhD, MPH; Pamela B. Morris, MD, FACC, FAHA, FASPC, FNLA; Neal L. Benowitz, MD

<table>
<thead>
<tr>
<th>What type of e-cigarette should I use?</th>
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<tbody>
<tr>
<td>• There are many different models of e-cigarettes with different levels of nicotine delivery and flavors.</td>
</tr>
<tr>
<td>• More advanced models that deliver nicotine more efficiently seem to work best for those trying to quit smoking tobacco cigarettes.</td>
</tr>
<tr>
<td>• Carefully read and understand the manufacturer’s recommendations for use and care of the e-cigarette. If the device did not come with instructions or you have further questions, contact the manufacturer.</td>
</tr>
<tr>
<td>• Go to the FDA’s website for updates on e-cigarettes and safety information <a href="https://www.fda.gov/TobaccoProducts/Labelling/ProductsIngredientsComponents/ucm456610.htm">https://www.fda.gov/TobaccoProducts/Labelling/ProductsIngredientsComponents/ucm456610.htm</a>.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How should I use the e-cigarette?</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Daily e-cigarette use is generally more effective for quitting smoking than intermittent use.</td>
</tr>
<tr>
<td>• It may take practice to learn to use the device to deliver the proper amount of nicotine to relieve the urge to smoke.</td>
</tr>
<tr>
<td>• Stop use of combustible tobacco cigarettes as soon as possible and discontinue e-cigarettes when you are comfortable that you have quit cigarette smoking for good.</td>
</tr>
<tr>
<td>• Avoid dual use of cigarettes and e-cigarettes if possible.</td>
</tr>
<tr>
<td>• E-cigarettes may be used along with an FDA approved stop-smoking medication such as a nicotine patch or varenicline.</td>
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</tbody>
</table>

<table>
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<tr>
<th>Where can I use an e-cigarette?</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Many public places do not allow smoking or use of e-cigarettes indoors.</td>
</tr>
<tr>
<td>• While the risks from secondhand vape are lower than that from smoking, it is best to vape outdoors and not around others.</td>
</tr>
</tbody>
</table>

JAHA, 2018
1.5 Advice on e-cigarettes

These recommendations are for health and social care workers in primary and community settings.

1.5.1 For people who smoke and who are using, or are interested in using, a nicotine-containing e-cigarette on general sale to quit smoking, explain that:

- although these products are not licensed medicines, they are regulated by the Tobacco and Related Products Regulations 2016
- many people have found them helpful to quit smoking cigarettes

- people using e-cigarettes should stop smoking tobacco completely, because any smoking is harmful
- the evidence[4] suggests that e-cigarettes are substantially less harmful to health than smoking but are not risk free
- the evidence in this area is still developing, including evidence on the long-term health impact. [2018]
I. Screen for e-cigarette use and exposure and provide prevention counseling in clinical practice.

II. Provide counseling that homes, cars, and places where children and adolescents live, learn, play, work, and visit should have comprehensive tobacco-free bans that include e-cigarettes as well as combustible tobacco products.

III. Do not recommend e-cigarettes as a tobacco-dependence treatment product.

Combining EC (the most popular source of support used by smokers in the general population), with stop smoking service support (the most effective type of support) should be a recommended option available to all smokers.
Final thoughts

- Agreement > disagreement
- Uncertainty > certainty
- Clinicians need practical guidance to convey what we know
- Will disagreements shrink as evidence accumulates?
- Will concerns about youth use of e-cigarettes overshadow the cessation potential of e-cigarettes?