Nicotine Replacement Therapy and Adolescent Patients: Information for Pediatricians

Nicotine Replacement Therapy (NRT) can be an important tool for treating nicotine dependence in youth. Many pediatricians are uncertain about how to use this medication with adolescents, especially those who are under 18 years old. This document is intended to help pediatricians make informed decisions about using NRT with patients who wish to quit smoking or vaping.

What is Nicotine Replacement Therapy (NRT)?

- NRT is a medication that addresses nicotine withdrawal symptoms by providing a controlled amount of nicotine, thus helping reduce the urge to smoke or vape.\(^1\)
- NRT is safe and effective in helping adults quit tobacco use.\(^1\)
- NRT works best when paired with behavioral counseling interventions.\(^2\)
- NRT comes in five forms, including gum, patch, lozenge, nasal spray, and inhaler.
- Three forms of NRT (gum, patch, lozenge) are available over-the-counter for adults 18+.

Can Adolescents Use NRT?

- At present, the US Food and Drug Administration (FDA) has not approved NRT for youth under 18 years old.
- Research on the effectiveness of NRT for helping youth quit successfully is limited due to a lack of adequately-powered studies. Overall efficacy findings have been mixed, with generally more modest outcomes than in comparable adult trials. There is no evidence of serious harm from using NRT in adolescents under 18 years old.\(^3,4\)
- Given the effectiveness of NRT for adults and the severe harms of tobacco dependence, AAP policy recommends that pediatricians consider off-label NRT for youth who are moderately or severely addicted to nicotine and motivated to quit.\(^5\)
- Youth under 18 years old need a prescription from a healthcare provider to access all forms of NRT.
- Non-adherence and relapse after cessation of therapy is common, and close follow-up is recommended.

Is NRT safe?

- NRT is safer than cigarettes, e-cigarettes, and other tobacco products because it delivers nicotine without the toxic chemicals and carcinogens in tobacco and e-cigarette products.
- NRT has low potential for misuse because the nicotine is absorbed slowly.

What are the contraindications to NRT use?

- The only contraindication to NRT use is hypersensitivity to nicotine or any component of the medication. In addition, patients who are allergic to soya should not use the nicotine lozenge.\(^6\)
- Pediatricians should be aware of disease-related cautions when prescribing NRT, including cardiovascular disease, diabetes, and hyperthyroidism. However, it is important to note that these cautions are relative, not absolute: NRT is safer than continued tobacco use.
- Pediatricians should review full clinical drug information in a professional prescribing reference to address individual concerns about prescribing. The decision to prescribe a drug is the responsibility of the medical provider, who must weigh the risks and benefits of using the drug for a specific situation.

What does an NRT treatment plan look like?

- Pediatricians and other health care providers should inform patients of the benefits and drawbacks of the five NRT medications, screen for relative contraindications, and instruct patients in how to use the product appropriately.
- The choice of NRT medication for an individual patient should be based on preference, availability, and the patient’s experience of potential side effects.\(^1\)
- For best results, patients should be advised to pair a long-acting form of NRT (eg, nicotine patch) with a shorter-acting form (eg, gum, lozenge, spray, or inhaler). This combination therapy allows the patient to keep a steady level of nicotine in their bloodstream throughout the day, while also responding to cravings. In addition, patients should be advised that NRT works best when paired with behavioral counseling interventions.\(^2\)
- The table below provides treatment information for nicotine gum, patch, and lozenge. All three products are available over-the-counter for adults and by prescription for youth under 18 years old. There is also a nicotine nasal spray and a nicotine inhaler, which are available by prescription only within the adult population and are used far less frequently.
### Types of NRT:

#### Nicotine Transdermal Patch

*(OTC for 18+ Rx for <18)*

**Cost:**
Over-the-counter retail cost ranges from $25-$70 for 28 patches.

Out-of-pocket prescription costs will vary by insurance plan.

**Dosage:**
- 21mg, 14mg, 7mg

**Use Instructions:**
- Apply patch to clean skin, change patch every 24 hours
- 8-10 week treatment regimen:
  - Use first dose for 6 weeks, then "step down" to lower dose
  - Use lower dose for 2 weeks, then "step down" to lowest dose for 2 more weeks
- See package for full details

**Side Effects:**
- Skin Irritation, sleep disturbance

**Advantages:**
- Sustained blood levels of nicotine, compliance is relatively easy

#### Nicotine Gum

*(OTC for 18+ Rx for <18)*

**Cost:**
Over-the-counter retail cost ranges from $17-$50 for 100 pieces of gum.

Out-of-pocket prescription costs will vary by insurance plan.

**Dosage:**
- 4mg, 2mg

**Use Instructions:**
- "Chew and park" method:
  - Place the gum in your mouth and chew until you feel a tingling sensation
  - Stop chewing and "park" the gum between cheek and gums
  - After about a minute, start chewing again, until you feel a tingling sensation
  - Stop chewing and "park" the gum again
  - Repeating for about 30 minutes
- 12-week treatment regimen:
  - Chew 1 piece every 1-2 hours for first 6 weeks
  - Chew 1 piece every 2-4 hours for 3 additional weeks
  - Chew 1 piece every 4-8 hours for 3 additional weeks
- See package for full details

**Side Effects:**
- Jaw soreness, mouth irritation, indigestion, nausea, hiccups

**Advantages:**
- Flexible dosing, rapid delivery of nicotine into bloodstream

#### Nicotine Lozenge

*(OTC for 18+ Rx for <18)*

**Cost:**
Over-the-counter retail cost ranges from $15-$50 for 100 lozenges.

Out-of-pocket prescription costs will vary by insurance plan.

**Dosage:**
- 4mg, 2mg

**Use Instructions:**
- Dissolving method:
  - Place lozenge in your mouth, occasionally moving from side-to-side
  - Allow lozenge to slowly dissolve, do not chew or swallow the lozenge
  - Do not use more than 1 lozenge at a time
- 12-week treatment regimen:
  - Use 1 lozenge every 1-2 hours for first 6 weeks
  - Use 1 lozenge every 2-4 hours for 3 additional weeks
  - Use 1 lozenge every 4-8 hours for 3 additional weeks
- See package for full details

**Side Effects:**
- Oral irritation, nausea, hiccups

**Advantages:**
- Flexible dosing, rapid delivery of nicotine into bloodstream, no chewing (discrete)
Dosing Guidelines:

Patients who are motivated to quit should use as much safe, FDA-approved NRT as needed to avoid smoking or vaping.

When assessing a patient's current level of nicotine use, it may be helpful to understand that using one JUUL pod per day is equivalent to one pack of cigarettes per day. However, there is variation in nicotine content across e-cigarette products, and variation in use-patterns across individuals. For example, there is a marked difference in nicotine delivery among e-cigarette products that use salt-based nicotine solutions (eg, JUUL) and other brands that use freebase nicotine. Salt-based nicotine solutions deliver dramatically higher levels of nicotine without creating harsh, unpalatable effects.7

Pediatricians and other healthcare providers should work with each patient to determine a starting dosage of NRT that is most likely to help them quit successfully. Dosing is based on the patient's level of nicotine dependence, which can be measured using a screening tool. Some options are the Hooked On Nicotine Checklist (tailored for cigarettes or vaping), the E-Cigarette Dependence Scale, or the Modified Fagerstrom Tolerance Questionnaire (see Appendix for full measures). If a lower dose is prescribed but doesn't seem to be working, pediatricians should assess adherence and move the patient to a higher dose or consider a longer schedule for use and weaning/stepping down.

Pediatrician and patients should work together to wean NRT over time, when the patient feels that s/he is no longer at risk of returning to tobacco or nicotine use.

<table>
<thead>
<tr>
<th>Form of NRT</th>
<th>Level of Dependence</th>
<th>Link to full drug information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Moderately Addicted</td>
<td>Severely Addicted</td>
</tr>
<tr>
<td>Nicotine Gum</td>
<td>2mg</td>
<td>4mg</td>
</tr>
<tr>
<td></td>
<td><a href="https://medlineplus.gov/druginfo/meds/a684056.html">https://medlineplus.gov/druginfo/meds/a684056.html</a></td>
<td></td>
</tr>
<tr>
<td>Nicotine Patch</td>
<td>Start with 14mg patch, then step down</td>
<td>Start with 21mg patch, then step down</td>
</tr>
<tr>
<td></td>
<td><a href="https://medlineplus.gov/druginfo/meds/a601084.html">https://medlineplus.gov/druginfo/meds/a601084.html</a></td>
<td></td>
</tr>
<tr>
<td>Nicotine Lozenge</td>
<td>2mg</td>
<td>4mg</td>
</tr>
<tr>
<td></td>
<td><a href="https://medlineplus.gov/druginfo/meds/a606019.html">https://medlineplus.gov/druginfo/meds/a606019.html</a></td>
<td></td>
</tr>
</tbody>
</table>

References:
The Hooked on Nicotine Checklist (HONC)

The Hooked On Nicotine Checklist is scored by tallying the number of yes responses, from 0-10. Any score greater than zero indicates that the youth has lost some autonomy over their smoking/vaping. This indicates that nicotine addiction has begun.

**HONC—Smoking**

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Have you ever tried to quit, but couldn't?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) Do you smoke now because it is really hard to quit?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) Have you ever felt like you were addicted to tobacco?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4) Do you ever have strong cravings to smoke?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5) Have you ever felt like you really needed a cigarette?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6) Is it hard to keep from smoking in places where you are not supposed to, like school?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

When you tried to stop smoking... (or, when you haven't used tobacco for a while...)

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>7) did you find it hard to concentrate because you couldn't smoke?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8) did you feel more irritable because you couldn't smoke?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9) did you feel a strong need or urge to smoke?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10) did you feel nervous, restless or anxious because you couldn't smoke?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**HONC—Vaping**

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Have you ever tried to stop vaping, but couldn't?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) Do you vape now because it is really hard to quit?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) Have you ever felt like you were addicted to vaping?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4) Do you ever have strong cravings to vape?</td>
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<td></td>
</tr>
<tr>
<td>5) Have you ever felt like you really needed to vape?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6) Is it hard to keep from vaping in places where you are not supposed to, like school?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

When you tried to stop vaping...(or, when you haven't vaped for a while...)

<table>
<thead>
<tr>
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<th>YES</th>
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<td>7) did you find it hard to concentrate because you couldn't vape?</td>
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**The Four-Item E-cigarette Dependence Scale for Assessing Adolescent E-cigarette Nicotine Dependence**

To score the measure, take the mean of the item scores. Higher scores indicate higher levels of dependence.

**Instructions:** Please respond to each question marking one box per row.

<table>
<thead>
<tr>
<th></th>
<th>Never (0)</th>
<th>Rarely (1)</th>
<th>Sometimes (2)</th>
<th>Often (3)</th>
<th>Almost Always (4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I find myself reaching for my e-cigarette without thinking about it.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I drop everything to go out and get e-cigarettes or e-juice.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I vape more before going into a situation where vaping is not allowed.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>When I haven't been able to vape for a few hours, the craving gets intolerable.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Modified Version of the Fagerstrom Tolerance Questionnaire (mFTQ)

Scoring guidelines in parentheses; remove these from instrument prior to use. Total scores are obtained by summing the raw scores for each item. Scores indicate level of dependence:

- 0-2 = no dependence
- 3-5= moderate dependence
- 6-9 = substantial dependence

1. How many cigarettes a day do you smoke?
   a. Over 26 cigarettes a day (2)
   b. About 16-25 cigarettes a day (1)
   c. About 1-15 cigarettes a day (0)
   d. Less than 1 a day (0)

2. Do you inhale?
   a. Always (2)
   b. Quite often (1)
   c. Seldom (1)
   d. Never (0)

3. How soon after you wake up do you smoke your first cigarette?
   a. Within the first 30 minutes (1)
   b. More than 30 minutes after waking but before noon (0)
   c. In the afternoon (0)
   d. In the evening (0)

4. Which cigarette would you hate to give up?
   a. First cigarette in the morning (1)
   b. Any other cigarette before noon (0)
   c. Any other cigarette afternoon (0)
   d. Any other cigarette in the evening (0)

5. Do you find it difficult to refrain from smoking in places where it is forbidden (church, library, movies, etc.)?
   a. Yes, very difficult (1)
   b. Yes, somewhat difficult (1)
   c. No, not usually difficult (0)
   d. No, not at all difficult (0)

6. Do you smoke if you are so ill that you are in bed most of the day?
   a. Yes, always (1)
   b. Yes, quite often (1)
   c. No, not usually (0)
   d. No, never (0)

7. Do you smoke more during the first 2 hours than during the rest of the day?
   a. Yes (1)
   b. No (1)