



وزارة الصحة
Ministry of Health

Saudi Positional Statement on

Electronic Nicotine Delivery System Management (ENDS), 2023

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Introduction:

Electronic nicotine delivery systems (**ENDS**), denote varieties of names that includes, electronic cigarettes, e-cigarettes, vaping devices, or vape pens, are battery-powered devices used to smoke or “**vape**” a flavored solution. They are designed to deliver nicotine, flavorings, and other additives to the user via an inhaled aerosol (**Office of Surgen General, 2016**).

E-cigarettes are not safe for youth, young adults, and pregnant women, as well as adults who do not currently use tobacco products (**CDC, 2021**). CDC, the U.S. Food and Drug Administration (**FDA**), state and local health departments, and other clinical and public health partners are continuing to monitor e-cigarette, or vaping, product use-associated lung injury (**EVALI**) (**CDC, 2020**).

ENDS solution often contains nicotine, an addictive chemical, moreover, it contains a range of chemicals & flavors that make it a cause for direct harms to users by inhalation of a range of chemicals & flavors, which are significantly associated with self-reported COPD (**Hangchuan S., et al,2020**), cause cancer,& harm to unborn babies (**Bahl V et al, 2012**), a source of indoor air pollution, and increase the risk of uptake of smoking among young people (**Australian D. of H., 2019**). Some people use ENDS as a way to quit smoking cigarettes, but current evidence is insufficient to recommend ENDS for tobacco cessation in adults (**Siu AL.et al, 2015**).

In 2016, the Food and Drug Administration (**FDA**) expanded its regulatory authority to include the **manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of all tobacco products, including ENDS. Under this new law called the "Deeming Rule", the FDA :**

- Requires health warnings on ENDS and other tobacco products.
- Prohibits the sales of ENDS to youth under the age of 18.
- Bans free samples and prohibits the sale of ENDS in vending machines.
- Requires that ENDS manufacturers receive marketing authorization from the FDA.
- Requires vape shops that mix e-liquids to comply with legal requirements for tobacco manufacturers.

The American Academy of Family Physicians (**AAFP**), recognizes the alarmingly increased use of ENDS, especially among youth and young adults, as well as its use by those attempting to quit smoking tobacco. (**AAFP, 2017**)

The U.S. Preventive Services Task Force concludes that the current evidence is insufficient to recommend ENDS for smoking cessation.

Management of ENDS use:

A. General consideration:

1. ENDS emissions are not harmless water vapor, both the user and those around them are exposed to chemicals, some of which cause cancer.
2. There is insufficient evidence to suggest ENDS are less harmful to a fetus than traditional cigarettes, women who are pregnant or trying to become pregnant should be informed about the risks that ENDS pose for both maternal and neonatal health.
3. Ask the right questions: “Do you vape or use electronic cigarettes?” rather than “Do you smoke?” which is a less effective way to explore the current precise status of tobacco smoking.
4. E-cigarettes should be treated in a similar way to tobacco products and advise should be made not to be used indoors, in enclosed places, or near children, this exposes other contacts to the negative effects of poorer air quality, particularly when groups of smokers are using e-cigarettes in the same place at the same time.
5. Pregnant women need to seek advice and support from a health professional to reduce fetal exposure to nicotine to the lowest possible level. Behavioral support to stop smoking is recommended first line, but there should be clear public health messaging that when behavioral support alone has failed, nicotine replacement therapy is the recommended next option. Use of e-cigarettes without support to minimize the use of nicotine is not a safe alternative to smoking in pregnancy.

B. Behavioral Interventions for ENDS users:

Behavioral intervention is a recommended practice in the treatment of nicotine dependence and has been associated with successful quit rate and sustained abstinence. However, combining behavioral intervention with pharmacological agents is the most effective approach (**tobacco use consider both Habit & Addict**).

Behavioral intervention may be provided via face-to-face, or web-based interventions. The most recommended behavioral intervention is motivational interviewing and cognitive-behavioral therapy.

Motivational interviewing is a recommended behavioral intervention to motivate ENDS users to quit and commit to therapy. Motivational interviewing is bidirectional conversation that support ENDS users through listening and counseling them to quit. Through motivational interviewing, a health care provider should use non-judgmental language and express empathy to gain ENDS user’s trust. The conversation with ENDS users should address the barriers and benefits of quitting ENDS and setting goals for quitting ENDS. On the other hand, cognitive-behavioral therapy is another behavioral intervention to support ENDS users to quit and help them in overcoming quitting challenges. Cognitive-behavioral therapy includes intensive behavioral training that are focused on identifying personal, cognitive, and environmental issues that trigger ENDS use. Cognitive-behavioral therapy empowers ENDS users with behavioral tools that enable them to overcome quitting challenges and making commitment to change their behavior.

C. Eight steps approach management (NHS, Health Scotland, 2018):

In the absence of systematic review evidence, regarding effective reduction or cessation interventions for vaping, we recommend the following eight steps to take the individual through.

1. Assess the individual's current readiness and ability to cut down or quit vaping.

Explore the reasons why the individual wants to cut down or stop vaping completely.

2. Assess current vaping practice.

- a. Ask what strength or mg/ml of e-liquid the individual is using.
- b. How often does the individual feel they need to use an e-cigarette?
- c. Why does the individual feel they need to use it?
- d. At what times does the individual use it more often?

In that context & order to assess degree of dependence the Penn State Nicotine Dependence shown below, can be adopted *

3. Assess previous quit attempts.

- a. If NRT or prescribed medication (varenicline/bupropion) have been used before, what was the individual's experience of using them?
- b. Ask the individual if they have tried to quit vaping before and what helped with quitting.

4. Explain what is in e-cigarette liquid.

- a. E-cigarette liquids contain nicotine; flavoring, propylene glycol, and vegetable glycerine, there are many different types of e-cigarettes available which provide different levels of delivery and varying levels of nicotine content.

5. Explain nicotine dependence and inform the individual of withdrawal

- a. If the smoker experience withdrawal symptoms from e-cigarettes it is because they are still withdrawing from nicotine. However not everyone will experience withdrawal symptoms.
- b. Refer to the standard treatment guidance on withdrawal symptoms.

6. Discuss help available for support with cutting down or quitting.

7. Set a quit date or time period for cutting down and ensure commitment from the individual.

8. Provide a summary of the discussion, & arrange for follow up visit to assure quitting and prevent relapse: The individual should continue to attend sessions according to plan & appointments agreed on between the healthcare professionals & the client to help with quitting vaping.

*** The Penn State Nicotine Dependence Index:**

1. How many times per day do you usually use your electronic cigarette? (assume one “time” consists of around 15 puffs, or lasts around 10 minutes)

- 0-4 times/day = 0
- 5-9 = 1
- 10-14 = 2
- 15-19 = 3
- 20-29 = 4
- 30 or more = 5

2. On days that you can use your electronic cigarette freely, how soon after you wake up do you first use your electronic cigarette?

- Less than 5 minutes = 5
- 6-15 minutes = 4
- 16-30 minutes = 3
- 31-60 minutes = 2
- 61-120 minutes = 1
- More than 121 minutes = 0

3. Do you sometimes awaken at night to use your electronic cigarette?

- Yes = 1
- No = 0

4. If yes, how many nights per week do you typically awaken to do so?

- 0-1 nights = 0
- 2-3 nights = 1
- 4 or more nights = 2

5. Do you use an electronic cigarette now because it is really hard to quit (using e-cigs)?

- Yes = 1
- No = 0

6. Do you ever have strong cravings to use an electronic cigarette?

- Yes = 1
- No = 0

7. Over the past week, how strong have the urges to use an electronic cigarette been?

- None/Slight = 0
- Moderate/Strong= 1
- Very Strong/Extremely Strong = 2

8. Is it hard to keep from using an electronic cigarette in places where you are not supposed to?

- Yes = 1
- No = 0

9. (When you haven't used an electronic cigarette for a while or when you tried to stop using one:) Did you feel more irritable because you couldn't use an electronic cigarette?

- Yes = 1
- No = 0

10. Did you feel nervous, restless, or anxious because you couldn't use an electronic cigarette?

- Yes = 1
- No = 0

Results

- 0-3 = not dependent
- 4-8 = low dependence
- 9-12 = medium dependence
- 13 or more = high dependence

There are three options for support individuals to quit:

1. **Behavioral support only** (use the same protocol for cigarette smoking cessation) including cognitive-behavioral therapy which can effectively help smokers alleviate withdrawal symptoms. The following table may provide some suggested cognitive or behavioral interventions.

Withdrawal symptoms	Cognitive-behavioral therapies
Headaches	If the smoker experiencing frequent headaches, make sure he/ she is getting enough sleep, eating regularly, and partaking in physical activity. These lifestyle changes should help keep headaches less in their severity.
Coughing	Staying hydrated is key to manage any coughing smoker may experience. A spoonful of honey, warm teas, juices, inhaling water vapors, and avoiding dairy are common “remedies” to deal with coughing.
Cravings	The 4Ds Strategy to Deal with Smoking Cravings 1) Delay: set a time limit before smoker gives in to smoking a cigarette. Delay as long as he/she can. If smoker feels that must give in to his/ her urge, move on to step 2. 2) Deep breathing: ask the smoker to take 10 deep breaths to relax. Trying to mediate with deep breathing to relax his/her self from within until the urge passes. If the urge does not subside, move on to next step. 3) Drink water: drinking water is a healthy alternative to sticking a cigarette in smoker mouth. Water also helps flush out toxins to refresh the smoker body. If he/she still crave for cigarettes, move on to next step. 4) Do Something else to distract his /her self: read, go for a walk, watch TV- engage in any hobby other than smoking!
Increased appetite or weight Gain	Weight gain is one of the most common roadblocks and side effects responsible for derailing smokers trying to quit. It is true that when the smoker quits, he / she are likely to have a larger appetite and be tempted to replace cigarettes with food. However, Smoker can avoid weight gain by making healthy eating choices (fruits, vegetables, and other healthy snacks) and drinking lots of water, which will also help to make an important step towards a healthier lifestyle as well!
Mood changes (sadness, irritability, frustration, or anger)	Try focusing on positive thoughts about quitting , smoker should remind him / her self of all the benefits of quitting smoking; think of how much better he/ she will physically feels.
Restlessness	The best way to deal with restlessness is to get up and move around! Engage in physical activity, go for a walk!
Difficulty concentrating	The best way to deal with difficulty in concentrating is through the smoker mind. Yoga, meditation, and mental imagery are great ways to focus on concentrating and regain the smoker abilities to function normally.
Flu-like symptoms	As is with any case of the flu, or common cold, the best “medicine” is rest and hydration. Smoker should keep drinking water and making sure his/her body is getting enough sleep.
Insomnia	Relaxation methods and regular exercise are good for overcoming the smoker sleeping problem.

2. Behavioral & Social Connections & Recommended interventions: (WHO, 2014)

Below are just a few suggestions on how to begin breaking the links of smoking and certain behaviors.

Action/behavior	Suggestion to break the link
Smoking associated with eating	Begin a new activity immediately after eating. Smoker should distract from the temptations and urges, exercise, read, or do other activities.
Smoking as a social activity (while with friends or coworkers)	Smoker should avoid these situations until he/ she have successfully quit smoking. He / she should not have to cease ties with your friends all together, just avoid going out, with them until he /she are strong in their commitment to abstain.
Smoking as a stress reliever	This is a common misconception believed by many smokers. Smoking has absolutely no connection to stress relief. However, there are many other ways to deal with stress. Drinking water or tea , carry around a stress ball to keep hands busy, practicing deep breathing or exercise to relieve stress, as well as discussing stress management strategies suitable to the smoker situation.
Smoking while on the phone	Smoker should engage in another activity while on the phone. Whether it's playing with a stress ball, or walking around, distract from the urge to smoke.

3. Pharmacotherapy for ENDS cessation:

a. Treatment with NRT and behavioral support

- NRT can be used for those who vape and want to cut down or stop vaping. NRT provides nicotine at levels which are not addictive, but some people will use NRT long term to avoid relapsing back to smoking (Le Houezec J, et al, 2003).
- NRT provides a non-addictive levels of nicotine, but some of the People use nicotine replacement therapy for a long term to avoid relapse and return to smoking
- The doctor needs to determine the degree of nicotine dependence using the Penn State nicotine dependence index.
- There is evidence that by using combination therapy (more than one NRT product at a time) a person will be more successful in a quit attempt (NCSCT,2019).
- The physician to remind the smokers that too much nicotine through continuing to vape along with NRT could result in side effects such a headaches and nausea

b. Treatment with varenicline and behavioral support

- The same guidance for prescribing varenicline for stopping smoking tobacco will apply for quitting vaping.
- Varenicline is not licensed for use in individuals under 18 years of age or those who are pregnant. (Saudi Guideline for Tobacco ,2018)

The expert committee agreed on the following recommendations:

- **Addiction of electronic nicotine delivery systems can be treated using the same protocol as smoking tobacco.**
- **Electronic nicotine delivery system products are not safe and considered hazardous to health.**
- **Electronic nicotine delivery systems are not recommended as a safe method or alternative tool for smoking cessation.**
- **Strengthening the World Health Organization (FCTC-MPOWER) strategy to control the Tobacco Epidemic, including use of electronic nicotine delivery systems.**
- **We invite scientific institutions and universities in the Kingdom of Saudi Arabia to conduct researches related to the use of electronic nicotine systems and the risks related to it.**

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