

# Case Study: Use of Electronic Nicotine Delivery Systems (ENDS) By a Pregnant Woman

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**Introduction:** The use of electronic nicotine delivery systems (ENDS) such as electronic cigarettes, vapour cigarettes, and vapour/hookah pens is rapidly increasing. The effectiveness of ENDS for smoking cessation and their safety, particularly amongst pregnant women, is largely unknown. Some women who use tobacco products in pregnancy, such as the one described in this case study, switch to ENDS assuming they are a safer alternative to smoking traditional cigarettes. Many obstetric providers do not screen for ENDS use and may miss an opportunity to counsel their patients about ENDS usage, side effects, or alternatives.

**Case Description:** Motivated by concern for her baby's health, a 28-year-old patient reduced consumption of traditional cigarettes and began using ENDS shortly after learning she was pregnant. Her obstetric team did not screen for ENDS use and was unaware that she had started using ENDS. During the postpartum period, her providers ordered a tobacco cessation consult and the tobacco treatment specialist (TTS) discovered the patient's ENDS use as well as her desire to quit.

**Conclusions:** In the absence of consistent screening by providers and a lack of safety data regarding ENDS use during pregnancy, women are often given little guidance in deciphering the potential risks and benefits of ENDS use. In this case, the patient turned to ENDS because she thought it was safer than smoking tobacco cigarettes and was unaware that there is limited research on ENDS safety. This case highlights the importance of updating clinical screening tools to include ENDS and the need for further research investigating the safety of ENDS use during pregnancy.

## Background

Electronic nicotine delivery systems (ENDS) include many products, such as electronic cigarettes, vapour cigarettes, and vapour/hookah pens. ENDS use is rapidly growing worldwide. From 2010 to 2014, the percent of American adults who had ever used ENDS increased from 1.8% to 12.6% and current use increased from 0.3% to 3.7% (Schoenborn & Gindi, 2015). The rate of ENDS use amongst pregnant women is unknown, but most people believe that ENDS are less harmful than tobacco cigarettes in general and during pregnancy. For instance, almost all respondents to a survey examining perceptions of the safety of ENDS use during pregnancy indicated that tobacco cigarettes are definitely harmful, compared to 60% that indicated they believed ENDS to be harmful (Baeza-Loya et al., 2014). This belief may stem from the fact that ENDS companies advertise that their products con-

tain pure nicotine, similar to over-the-counter nicotine replacement products (NRT). Research indicates that this claim may not always be true (U.S. Food & Drug Administration, 2009).

This case describes a female patient who switched to ENDS during pregnancy because she thought it was safer than smoking conventional cigarettes. Her obstetric team was unaware of this switch, so they did not discuss potential risks, safety or benefits of ENDS use during pregnancy. Clinics providing care to pregnant women should adapt their policies to include screening and interventions around ENDS because the impact of ENDS use on the mother and foetus during pregnancy remains unknown. Even when obstetric providers are aware of a pregnant patient's ENDS use, it is still challenging to provide counselling on this topic due to the lack of data on safety and effectiveness of ENDS in pregnancy. Further research is needed in this area.

## Case Presentation

A 28-year-old patient presented for her first prenatal visit at 10-weeks gestational age. She had several complex medical problems, including asthma, chronic pain, bipolar disorder, anxiety, depression, prior sexually transmitted diseases, trauma, and substance abuse. She was smoking 1.5–2 packs per day at the outset of pregnancy. When her providers learned about her tobacco use, they counselled her to quit completely, and she stated that she was interested in quitting. She declined multiple offers for a prescription for bupropion to assist with cessation because of concerns about taking psychiatric medications during pregnancy. Her prenatal notes included no suggestions for obtaining behavioural cessation support and no discussion of her level of motivation to become completely tobacco free. Without use of additional approved tobacco cessation methods, she reported cutting down to 3–5 cigarettes per day in the first trimester, and she continued to smoke cigarettes at this level for the duration of her pregnancy.

She delivered a healthy baby boy at 39-weeks gestation, and while on the postpartum floor, her providers ordered a consult with the Nicotine Dependence Program because of her continued smoking. The tobacco treatment specialists (TTS's) assessment revealed that she had used ENDS throughout her pregnancy, and that she attributed its use to her success in reducing her daily cigarette consumption. Prenatal notes showed no mention of ENDS, and the patient confirmed that no obstetric providers inquired. During the consult, the patient indicated that she was open to using NRT, especially after learning about the lack of data on safety and potential health risks of ENDS combined with continued use of cigarettes. The TTS and the patient collaboratively developed a treatment plan, including NRT, behavioural cessation strategies, social support, and follow-up.

## Discussion

This case raises several important findings and questions. First, this case demonstrates the need to screen all pregnant women for ENDS use. A recent survey found that 40% of obstetrician respondents do not screen for ENDS use (England et al., 2014). By not asking about ENDS, the patient's obstetric team in this case missed the opportunity to counsel her regarding the potential benefits and risks of using these products.

Second, this case shows the potential complexity involved in ENDS use during pregnancy, where ENDS was simultaneously used with daily tobacco cigarettes. Though ENDS may have initially helped her reduce the number of tobacco cigarettes she used during pregnancy, she remained at risk for adverse pregnancy outcomes, including birth defects and numerous complications, by not quitting entirely (Suter, Mastrobattista, Sachs, & Aagaard, 2015). Therefore, it remains unclear whether or not the patient's

or her baby's health benefited by the use of ENDS as a tool to reduce her cigarette smoking.

Third, this patient may have subjected herself and her baby to other adverse health risks because of ENDS use, including exposure to nicotine and other harmful constituents. A recent review of the impact of nicotine on the foetus concluded that there is no safe nicotine level in pregnancy (Suter, Mastrobattista, Sachs, & Aagaard, 2015). The level of nicotine reported on ENDS labels is often incorrect, so a pregnant woman who believes she is using ENDS with a low nicotine content may actually be exposing her foetus to high levels of nicotine (Hutzler et al., 2014). The US Food and Drug Administration analysed various types of ENDS cartridges and found that they contained tobacco-specific nitrosamines that may cause cancer (U.S. Food & Drug Administration, 2009). While no published studies have directly examined the safety of ENDS during pregnancy, adverse health effects on a woman and her unborn child from ENDS are a legitimate concern.

Fourth, the patient's providers, while offering assistance with bupropion as a pharmacologic aid for cessation, did not document assistance with evidenced-based behavioural therapies that could have helped her quit tobacco products entirely. For instance, psychosocial support is an effective evidenced-based treatment for pregnant women wishing to quit tobacco (Meernik & Goldstein, 2015). Other behavioural approaches could have included case management, practical skills management, peer support, or referral to a quitline. Such support can increase cessation rates by 35%–50% compared with less intensive behavioural interventions (Meernik & Goldstein, 2015).

Fifth, even if the patient's providers knew that she was using ENDS throughout pregnancy, it is unknown whether they would they have suggested that ENDS is acceptable or a better alternative to smoking. A survey of physicians found that two-thirds (67%) of the respondents, including obstetric providers, believed that ENDS may be helpful for smoking cessation, and 35% had recommended ENDS to their patients (Kandra, Ranney, Lee, & Goldstein, 2014). This survey did not specifically ask about recommendations to pregnant patients, which may be lower because of the added concerns about potential risk to the foetus; however, the responses of obstetricians/gynecologists did not differ from other specialties. An additional survey of obstetric providers found that 13.5% of respondents believed that there were no adverse health effects associated with ENDS, and 29% thought ENDS were safer than tobacco cigarettes (England et al., 2014). Given these findings, it is unclear whether the patient's providers would have encouraged her to continue using ENDS to assist with cessation or whether they would have advised her to quit ENDS because of unknown health consequences.

Finally, if the patient's providers had advised this patient to quit ENDS, would they have offered her NRT

to assist with cessation? It is unlikely that her providers would have prescribed NRT, as she was otherwise not offered NRT in pregnancy. This may relate to conflicting evidence on the safety and efficacy of NRT use in pregnant women. A systematic review concluded that there is insufficient evidence to determine whether NRT is safe or effective in pregnant women (Coleman, Chamberlain, Davey, Cooper, & Leonardi-Bee, 2012). A recent study reported that though single NRT was not effective, pregnant women were successful in quitting when using combination NRT (Brose, McEwen, & West, 2013). Though evidence on the safety and efficacy of NRT during pregnancy is unclear (Coleman, Chamberlain, Davey, Cooper, & Leonardi-Bee, 2012), levels of nicotine in NRT can be closely monitored by clinicians. However, estimations of potential nicotine and other chemical exposure from ENDS may be inaccurate due to lack of standardisation in manufacturing and labelling (Hutzler et al., 2014).

### Limitations

Several limitations of this case exist. Data sources for this case study were limited to patient self-report and prenatal notes written by her providers. As such, some questions were left unanswered. For example, it is unknown whether behavioural cessation interventions and/or NRT were offered after providers learned about her continued smoking. It is possible that these interventions were offered, but this effort was not documented. The patient was also lost to follow-up, so her tobacco use status post discharge is unknown. Another consideration involves this patient's multiple psychiatric comorbidities. It is well documented that patients with co-occurring substance use and/or mental health problems are offered subpar tobacco treatment (Thorndike, Stafford, & Rigotti, 2001). This may partially explain her obstetric team's failure to screen for ENDS use.

### Conclusion

In the absence of research illustrating the impact of ENDS use during pregnancy and appropriate screening mechanisms for ENDS, patients are often given no guidance on interpreting the risks and benefits of ENDS use. In this case, the patient turned to ENDS because she thought it was safer than smoking tobacco cigarettes, and she was unaware of any potential negative health consequences or lack of safety data regarding ENDS. The patient's undetected ENDS use masked her ongoing tobacco use and likely interfered with her receiving the highest quality treatment, including more intensive behavioural counselling. More research is needed to guide obstetric providers in their counselling of pregnant ENDS users, including an urgent need to identify the safest and most effective strategies that help pregnant women abstain from all tobacco products and ENDS.

### Learning Points

1. Medical settings must update their assessment procedures to include screening for ENDS use.
2. Tobacco use during pregnancy is known to cause multiple health problems. NRT should be offered to pregnant women only after behavioural support proves ineffective. NRT use should be closely monitored by a clinician and should be recommended before ENDS use given the lack of regulation of ENDS and lack of evidence regarding safety.
3. Data should be collected on the prevalence of ENDS use amongst pregnant women, and future studies should investigate further the safety and effectiveness of ENDS use during pregnancy.

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### Conflict of Interest

None.

### Ethical Standards

Not applicable.

### References

- Baeza-Loya, S., Viswanath, H., Carter, A., Molfese, D. L., Velasquez, K. M., Baldwin, P. R., et al. (2014). Perceptions about e-cigarette safety may lead to e-smoking during pregnancy. *Bull Menninger Clinic*, 78(3), 243–252. doi:10.1521/bumc.2014.78.3.243.
- Brose, L. S., McEwen, A., & West, R. (2013). Association between nicotine replacement therapy use in pregnancy and smoking cessation. *Drug Alcohol Dependence*, 132(3), 660–664.
- Coleman, T., Chamberlain, C., Davey, M.-A., Cooper, S. E., & Leonardi-Bee, J. (2012). Pharmacological interventions for promoting smoking cessation during pregnancy. *Cochrane Database System Reviews*, 9, CD010078. doi:10.1002/14651858.CD010078.
- England, L. J., Anderson, B. L., Tong, V. T. K., Mahoney, J., Coleman-Cowger, V. H., Melstrom, P., et al. (2014). Screening practices and attitudes of obstetricians-gynecologists toward new and emerging tobacco products. *American Journal of Obstetrics & Gynecology*, 211(6), 695.e1–e7. doi:10.1016/j.ajog.2014.05.041.
- Fiore, M. C., Jaen, C. R., Baker, T. B., Bailey, W. C., Bennett, G., Benowitz, N. L., . . . Dorfman, S. F. A. (2008). A clinical practice guideline for treating tobacco use and dependence: 2008 update. A US Public Health Service report. *Am J Prev Med*, 35(2), 158–76. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/18617085/>.

- Goedhart, G., van der Wal, M. F., Cuijpers, P., & Bonsel, G. J. (2009). Psychosocial problems and continued smoking during pregnancy. *Addictive Behaviors, 34*, 403–406.
- Hutzler, C., Paschke, M., Kruschinski, S., Henkler, F., Hahn, J., & Luch, A. (2014). Chemical hazards present in liquids and vapors of electronic cigarettes. *Archives of Toxicology, 88*(7), 1295–1308.
- Kandra, K. L., Ranney, L. M., Lee, J. G., & Goldstein, A. O. (2014). Physicians' attitudes and use of E-cigarettes as cessation devices, North Carolina, 2013. *PloS One, 9*(7), e103462.
- Meernik, C., & Goldstein, A. O. (2015). A critical review of smoking, cessation, relapse and emerging research in pregnancy and post-partum. *British Medical Bulletin, 114*, 135–146.
- Schoenborn, C. A., & Gindi, R. M. (2015). Electronic cigarette use among adults: United States 2014; US DHHS, CDCP, National Center for Health Statistics.
- Suter, M. A., Mastrobattista, J., Sachs, M., & Aagaard, K. (2015). Is there evidence for potential harm of electronic cigarette use in pregnancy? *Birth Defects Research A Clinical Molecular Teratology, 103*(3), 186–195.
- Thorndike, A. N., Stafford, R. S., & Rigotti, N. A. (2001). US physicians' treatment of smoking in outpatients with psychiatric diagnoses. *NTR, 3*(1), 85–91.
- US Food and Drug Administration. (2009). Evaluation of E-Cigarettes. FDA, Center for Drug Evaluation and Research Division of Pharmaceutical Analysis.