Learning Objectives

• Discuss the current evidence for the safety of electronic nicotine delivery systems (ENDS) and FDA regulations
• Describe the evidence for/against the role of electronic nicotine delivery systems (ENDS) in smoking cessation
• Discuss considerations for implementation of a smoking cessation program in a community-based setting

BACKGROUND
Authority to Furnish NRTs

- Regulations effective January 25, 2016
  - Title 16, California Code of Regulations, Section 1746.2
  - Section 4052.9a of California Business and Professional code
- Authorizes a pharmacist to furnish nicotine replacement therapy (NRT) approved by FDA for use by prescription in accordance with the BOP protocol

Protocol can be found online at CA BOP website: http://www.pharmacy.ca.gov/licensees/nicotine_info.shtml

Products Covered

- Prescription nicotine replacement products approved by the federal Food and Drug Administration and provided by a pharmacist for smoking cessation are covered under this protocol

- Pharmacists may continue to provide over-the-counter smoking cessation products without use of this protocol

Products Covered

- Pharmacists may furnish the following NRT products:
  - Gum (OTC)
  - Lozenge (OTC/Rx)
  - Patch (OTC/Rx)
  - Nasal spray (Rx)
  - Inhaler (Rx)
- These can be used alone or in combination
- Generic equivalent products may be furnished
- Through this protocol, pharmacists cannot furnish other smoking cessation medications, such as:
  - Varenicline (Chantix)
  - Bupropion (Zyban)
  - A separate collaborative practice agreement would be needed
Training and CE

- Pharmacist requirements to furnish NRT:
  - Minimum of 2 hours of approved CE program specific to smoking cessation and NRT or
  - Equivalent curriculum based training program completed within last 2 years in an accredited pharmacy school

- The pharmacist completes 1 hour of continuing education focused on smoking cessation therapy once every two years

Payment for smoking cessation services

- AB 1114: Requires pharmacist services to be a benefit under Medi-Cal. Covered services include:
  - Furnishing Travel Medications
  - Furnishing Naloxone for opioid overdose
  - Furnishing Self-administered hormonal contraception
  - Initiating and administering immunizations
  - Providing tobacco cessation counseling and furnishing nicotine replacement therapy

https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201520160AB1114

Giving up smoking is the easiest thing in the world. I know because I’ve done it thousands of times. ~ Mark Twain ~
SMOKING CESSATION TREATMENT APPROACH

Available Products

- Polacrilex gum
  - Nicorette (OTC)
  - Generic nicotine gum (OTC)
- Lozenge
  - Nicorette Lozenge (OTC)
  - Nicorette Mini Lozenge (OTC)
  - Generic nicotine lozenge (OTC)
- Transdermal patch
  - NicoDerm CQ (OTC)
  - Generic nicotine patches (OTC, Rx)

- Nasal spray
  - Nicotrol NS (Rx)
- Inhaler
  - Nicotrol (Rx)
- Non-nicotine medications
  - Bupropion (Rx)
  - Varenicline (Rx)
- Electronic nicotine delivery systems (ENDS)

http://rxforchange.ucsf.edu/file_downloads/A9%20PRODUCTS.pdf
Updates in smoking cessation therapy

Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES): a double-blind, randomised, placebo-controlled clinical trial

Paul Robert Lichtenstein, MD, PhD; Neal K. Bloom, MD, PhD; Robert Bloom, MD; Lisa S. Rubin, PhD; Thomas Meehan, MD; Sarah Lawrence, PhD; John Barner, MD; Elizabeth R. Benson, MD; John A. Eissen, MD

• First clinical trial comparing neuropsychiatric safety and efficacy of varenicline and bupropion with NRT and placebo

Results of EAGLES trial

• Randomized patients to treatment with nicotine patch, varenicline, bupropion or placebo in 1:1:1:1 ratio
• **Primary Endpoint**: Incidence of composite moderate and severe neuropsychiatric adverse events
• **Main efficacy endpoint**: biochemically confirmed abstinence for weeks 9-12
• Conclusions:
  – No significant increase in neuropsychiatric events attributed to varenicline or bupropion relative to nicotine patch or placebo
  – Varenicline more effective than nicotine patch, bupropion or placebo in achieving abstinence
  – Bupropion and nicotine patch more effective than placebo
Updates in FDA labeling

ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS)

Electronic Nicotine Delivery Systems (ENDS)

- ENDS include: electronic cigarettes, vaporizers, vape pens, e-pipes, hookah pens, and e-cigars
- Heat nicotine containing liquid (e-liquid) to create vapor for inhalation
  - E-liquids typically contain nicotine, flavorings, and humectants
  - Humectants: propylene glycol, glycerol
Use of ENDS in the United States

- On the market since 2006
- Most commonly used tobacco product among young people
- In ENDS users ≥45 years, most were current or former tobacco cigarette smokers, 1.3% had never smoked.¹
- In ENDS users aged 18–24 years, 40.0% had never been regular cigarette smokers.¹


ENDS: FDA Regulation

- In 2016, the FDA finalized rule extending authority to regulate ALL tobacco products including ENDS
- In 2018, all ENDS will contain this warning: “WARNING: This product contains nicotine. Nicotine is an addictive chemical.”

THE VAPE DEBATE: Should ENDS be recommended for smoking cessation?
The VAPE Debate:

“Guilty until proven innocent”
or
“Beneficial for adult smokers
seeking to quit”

What is the evidence?

The VAPE Debate

• Form small groups (3-5 people)
• Each group will be given a pro argument
  and a con argument for the use of ENDS
  for smoking cessation
• Assign roles:
  – Pro position
  – Con position
  – Observer(s)
• Make your case to the opposing position

Report from the National Academies of Sciences,
Engineering and Medicine (NASEM)

Public Health Consequences of E-Cigarettes
Safety of ENDS

- Contain potentially toxic substances
  - Variable depending on device, e-liquid, and user characteristics
  - Exposure to toxic substances substantially lower than in traditional tobacco cigarettes
  - ENDS aerosol contains metals
- Nicotine exposure is comparable
- Risk of burns and explosions

Health effects of ENDS

- Dependence on e-cigarettes (behavioral and nicotine-related)
- Cancer: limited evidence from animal studies
  - Chemicals present in e-cigarette aerosols capable of causing DNA damage
- Respiratory: moderate evidence of increased coughing and wheezing in adolescents with asthma
  - Possible reduction in symptoms with change from smoking to ENDS

Public health implications

- Users of ENDS more likely to use tobacco during lifetime
- Secondhand
  - Does increase particulate matter and nicotine in environment
  - Moderate evidence that exposure to nicotine is lower with ENDS compared to tobacco cigarettes
Substitution vs. Dual Use

- Completely substituting ENDS for tobacco cigarettes reduced exposure to toxicants and carcinogens
- Substituting reduced short-term adverse health outcomes
- Little to no evidence of benefit in dual users

ENDS for smoking cessation

<table>
<thead>
<tr>
<th>Quit Method Useda</th>
<th>Weighted %b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported using multiple quit methods</td>
<td>74.7</td>
</tr>
<tr>
<td>Gave up cigarettes all at once</td>
<td>65.3</td>
</tr>
<tr>
<td>Gradually cut back on cigarettes</td>
<td>62.0</td>
</tr>
<tr>
<td>Substituted some regular cigarettes with e-cigarettes</td>
<td>35.3</td>
</tr>
<tr>
<td>Used nicotine patch or nicotine gum</td>
<td>25.4</td>
</tr>
<tr>
<td>Switched completely to e-cigarettes</td>
<td>24.7</td>
</tr>
<tr>
<td>Got help from a doctor or other health professional</td>
<td>15.2</td>
</tr>
<tr>
<td>Used FDA-approved medications (Zyban or Chantix)</td>
<td>12.2</td>
</tr>
<tr>
<td>Got help from a website such as Smokefree.gov</td>
<td>7.1</td>
</tr>
<tr>
<td>Got help from a telephone quitline</td>
<td>5.4</td>
</tr>
</tbody>
</table>

Comparison to other smoking cessation quit aids

- E-cig use negatively associated with quitting in patients accessing FDA-approved smoking cessation treatment1
- Meta analysis of 20 studies showed lower odds of quitting than either NRT or no cessation aids (odds ratio, 0.72; 95% confidence interval [CI], 0.57 to 0.91)2
- Large survey-based study in UK showed odds of abstinence greater in e-cig users compared to using no quit aid or OTC NRT3
- Cochrane review 2016 rated evidence for e-cig effectiveness in long-term smoking cessation as “Low”4

Efficacy for smoking cessation

• 3 randomized controlled trials
  – Limitations in design
  – 2 studies not assessing smokers who wanted to quit
  – Older ENDS models
• Mixed results in cohort studies
• Insufficient evidence about effectiveness compared to no treatment or FDA approved treatments
  – But more frequent ENDS use increased likelihood of cessation


ENDS Continuum

Advantages
• Deliver nicotine, reduce urges and decrease withdrawal symptoms
• May be safer than continuing to smoke
• Some evidence that e-cigs may work to help patients quit smoking

Disadvantages
• Trading one bad habit for another?
• Safety concerns: unknown chemicals and long-term effects
• May promote continued nicotine use in people who quit smoking
• May promote nicotine use in young people

PROGRAM IMPLEMENTATION

Program Details

- Any health care provider may refer patients to the smoking cessation clinic
- Patients may refer themselves to the smoking cessation clinic
- May initiate smoking cessation treatment and counseling when deemed necessary or beneficial
  - Furnish NRTs per BOP protocol
  - Furnish Varenicline or Bupropion per CPA
- Average length of program is about 12 weeks
  - Visits once weekly

Program Expectations

- To educate patients about the health benefits associated with smoking cessation
- To assess the need for and initiate appropriate smoking cessation related medications
- To help patients maintain abstinence and prevent relapse
- To serve as an information resource and referral center for patients
Initial Visit Procedures

- Review referral information
- Describe program and review goals
- Discuss health benefits and advantages of smoking cessation
- Review smoking history & assess nicotine dependence
- Identify reasons for quitting, barriers, and triggers
- Assess motivation, confidence, and commitment level towards quitting smoking
- Review medication list and allergies
- Perform vitals such as blood pressure, pulse, and weight measurements
- Develop an action plan
- Recommend medication
- Provide patient education materials such as but not limited to
  - You Can Quit Smoking Consumer Guide
  - Countdown to quit date, behavioral & withdrawal education
- Schedule a follow-up visit

Follow-Up Visit Procedures

- Monitor blood pressure, pulse, and weight measurement as clinically necessary
- Review progress including cravings, triggers, withdrawal symptoms, barriers, and slips
- Assess commitment and progression of therapy
- Identify problem list or medication changes
- Review behavioral modification recommendations and education
- Motivate to continue progress
- Schedule a follow-up visit

Carbon Monoxide Monitoring
Terms of Discharge

- Patient experiences intolerance to therapy
- Patient has completed the smoking cessation program successfully
- Non-compliance with visits (>2 consecutive appointments missed without reason)
- Patient voluntarily withdraws from program
- Patient does not respond to 2 consecutive phone call attempts by smoking cessation clinic after submission of a clinician referral

Payment

- Patient pays an enrollment fee for the program
- Patient responsible for co-pays of medications or NRTs
- Discount may be available for OTC NRTs

Implementation Considerations

- Assess patient’s motivation and readiness to quit
- Method of visits
  - In-person appointment
  - Telephone call
- Regular, consistent schedule (weekly appointments)
- Time spent per visit
  - 30 minutes for initial visit
  - 15 minutes for follow-up visit
Thank You!

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