Pharmacist-Led Tobacco Cessation Program

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Disclosures

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I have no actual or potential conflict of interest in relation to this program/presentation.

Maimonides Medical Center
Brooklyn, New York
Goals and Learning Objectives

• Review regulatory requirements and performance measures for tobacco cessation
• Identify key principles of an inpatient pharmacist led tobacco cessation program
• Illustrate the operational workflow and outcomes of an effective inpatient quit system
• Describe evidence-based pharmacotherapeutic approaches to tobacco cessation therapies

50 Years Since the First Surgeon General's Report on Smoking

"I still smoke, but I'm careful to buy cigarettes that are gluten-free with no stains on them."
Hookah
Water Pipe Smoking

E-Cigarette

- Battery-powered device
- Not approved by FDA as a cessation method
- Unregulated, aggressively marketed
- No validation of purity and safety
- High rates of dual use, e-cigarettes and cigarettes
- Mayor Bloomberg prohibits “Vaping” in NYC

Cigarette substitute and/or tobacco cessation aid?
Background

• Smoking is the #1 cause of preventable death
• Cigarette smoke contains over 4,800 chemicals, 69 of which are known to cause cancer
• Approximately 20% of American men and women continue to smoke
• 90% of smokers begin as teenagers
• About half of Americans who smoke try to quit each year

Mortality Secondary to Smoking

New York City (15.5% of adults smoke)
• Smoking kills more than 7,000 New Yorkers annually

Nationwide (prevalence by state 12% to 29%)
• 45 million adult Americans use tobacco
• Smoking-attributed health care expenditures $193 billion/year
Affordable Care Act (ACA) and Smoking Cessation

- Places focus more on prevention in healthcare
- New private plans required to cover tobacco cessation
- Medicaid programs required to cover tobacco cessation for pregnant women
- Medicare enrollees eligible for wellness visit can also receive tobacco cessation treatment
- Tobacco cessation medications can no longer be excluded from state Medicaid coverage

The Joint Commission

- New performance measures address tobacco cessation for hospitalized smokers

Meaningful Use Stage 1 and 2

- Recording smoking status and delivery of tobacco cessation is an inpatient core objective

<table>
<thead>
<tr>
<th>Measure ID#</th>
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<td>TOB-1</td>
<td># of patients who were screened for tobacco use status</td>
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<td># of patients who received or refused practical counseling to quit and received or refused smoking cessation medication</td>
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<td>TOB-2a</td>
<td># of patients who received or refused practical counseling to quit and received smoking cessation medications</td>
</tr>
<tr>
<td>TOB-3</td>
<td># of patients who were referred or refused evidence-based outpatient-based counseling and received or refused a prescription for smoking cessation medication at discharge</td>
</tr>
<tr>
<td>TOB-3a</td>
<td># of patients who were referred to evidence-based outpatient counseling and received a prescription for smoking cessation medication at discharge</td>
</tr>
<tr>
<td>TOB-4</td>
<td># of patients contacted within 30 days after discharge and follow-up information regarding tobacco use is collected</td>
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</table>
Which best describes how your facility manages inpatient tobacco cessation?

A. There is no inpatient tobacco cessation program in place
B. Patients are only screened to determine their current smoking status
C. Pharmacists are excluded from your inpatient tobacco cessation program
D. There is a multidisciplinary tobacco cessation program in place that includes pharmacists

Why is Tobacco Cessation important in the inpatient setting?

• Tobacco dependence is a chronic disease that often requires repeated intervention
• Clinicians and healthcare delivery systems should consistently identify tobacco use status and treat every tobacco user
• Brief tobacco dependence treatment is effective
• The combination of counseling and medication is more effective than either alone.

Nicotine Withdrawal Symptoms

• Depressed mood
• Insomnia
• Irritability
• Increased appetite/Weight gain
• Difficulty concentrating
• Restlessness
• Decreased heart rate
• Anxiety
Nicotine Replacement Therapy (NRT)

- Permits patient to feel more comfortable
- 30 years of data to support its safe use
- No significant potential for abuse
- FDA revised labeling regarding warnings and limitations
  - Safe to use multiple OTC NRT products, including a cigarette
  - Begin therapy on quit day
  - Continued use is safe, in most cases

FDA -Approved Medications for Treating Tobacco Dependence

Nicotine Replacement Therapy (NRT)
- Transdermal nicotine patch (OTC)
- Nicotine lozenge (OTC)
- Nicotine gum (OTC)
- Nicotine nasal spray (Rx)
- Nicotine inhaler (Rx)

Non Nicotine Replacement Agents (Rx)
- Bupropion SR
- Varenicline

Nicotine patch (OTC): 21 mg, 14 mg, 7 mg

Dose Regimen:
- Dependent on current tobacco intake (> or < 10 cigarettes/day)
- 16 or 24 hour coverage

Pros:
- Long-acting nicotine replacement
- Easy to use, once daily administration
- Provides continued nicotine all day

Cons:
- Local skin reactions and insomnia
- Vivid dreams
- Passive (nothing to do when craving)

Comments:
- Insomnia reduced if patched removed before bedtime
Nicotine Gum (OTC): 2 mg, 4 mg<sup>8,9</sup>

**Dose Regimen:**
- Heavy smokers (>25 cigs/day), Light smokers (<25 cigs/day)
- Prn or fixed scheduled, every 1-2 hours, maximum 24 pieces a day

**Pros:**
- Short-acting nicotine replacement

**Cons:**
- Jaw fatigue, hiccups, belching and nausea
  - Hard to use with denture

**Comments:**
- Chew and park (oral absorption)
  - Avoid acidic beverages
  - No food or drink for 30 minutes

Nicotine Lozenge (OTC): 2 mg, 4 mg<sup>8,9</sup>

**Dose Regimen:**
- Based upon time to first cigarette upon waking
- Within 30 minutes = 4 mg
- After 30 minutes = 2 mg
- Every 1-2 hours, maximum 20 lozenges/day

**Pros:**
- Delivers 25% more nicotine than gum
  - Dissolves easily

**Cons:**
- Heartburn, hiccups, flatulence

**Comments:**
- Dissolve in mouth, don’t chew
  - No food or drink for 30 minutes

Nicotine Nasal Spray (Rx)<sup>8,9</sup>

**Dose Regimen:**
- 1 spray into each nostril (1 mg = 1 dose), 1-2 doses per hour
- PRN or fixed schedule
  - Maximum daily dose is 40 mg

**Pros:**
- Fastest onset and rapid withdrawal relief

**Cons:**
- Nasal irritation, rhinorrhea, sneeze, and cough
  - May change taste or smell

**Comments:**
- Don’t sniff/inhale
Nicotine Inhaler (Rx):

10 mg/cartridge

Dose Regimen:
- Continuous inhalation over 20 min; 6 to 16 cartridges/day
- 1 cartridge lasts 3-4 uses, which is a 20 minute puffing session

Pros:
- Oral/hand behavior
- Prn use

Cons:
- Throat irritation/cough
- Visible

Comments:
- Must puff more frequently than cigarettes

Dosing for Nicotine Replacement

Dosing is dependent on current cigarette use:

Initial Dose
- Estimate of nicotine intake (2 mg/cigarette)
- Patch (21 mg delivered/24 hours)
- Gum/Lozenge (4 mg = 1-2 mg delivered)
- Inhaler (2 mg delivered per use: up to 16 cartridges/day)
- Spray (1 mg per dose: up to 40 doses/day)

Dose Adjustment
- Increasing dose
- Add agent

Bupropion SR (Rx)

Category:
- Dopamine Reuptake Inhibitor/Smoking Cessation Aid

Dosing:
- Begin 1 week before the patient stops smoking
- 150 mg ORALLY in the morning for 3 days
- Increase to 150 mg ORALLY 2 times a day (MAX dose 300 mg/day)

Duration:
- 3-6 months

Contraindications/Precautions:
- Seizure disorders, history of bulimia or anorexia,
- MAO inhibitors
**Bupropion SR (Rx)**

**Pros:**
- Helps prevent relapse and weight gain
- May be used with patch (with MD approval)

**Cons:**
- Insomnia, dry mouth
- Seizure risk

**Black Box:**
Use in Smoking Cessation — Serious neuropsychiatric events, including depression, suicidal thoughts, and suicide have been reported.

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**Varenicline (Rx)**

**Category:**
- Partial Nicotine Agonist, produces agonist activity at a sub-type of the nicotinic receptor while also preventing nicotine binding to alpha-4-beta-2 receptors

**Dosing:**
- Initial, 0.5 mg once daily for days 1 through 3
- Then 0.5 mg twice daily for days 4 through 7
- Then 1 mg twice daily

**Duration:**
- 3-6 months

**Contraindications/Precautions:**
- Neuropsychiatric symptoms
- Cardiovascular events
- Renal impairment

**Adverse Drug Events:**
- Intolerable nausea
- Insomnia
- Unusual dreams

**Black Box:**
Use in Smoking Cessation — Adverse psychiatric events, agitation, depressed mood, suicidal ideations

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**Varenicline (Rx)**
Meta Analysis Findings Regarding Treating Tobacco Use and Dependence

- Combination nicotine replacement therapy (NRT) resulted in highest abstinence rates (36.5%)
- Varenicline (Chantix®) resulted in highest abstinence rates among monotherapies (33.2%)
- Selective serotonin reuptake inhibitors (SSRIs) and naltrexone were not shown to be effective

Is some provider advice on smoking cessation better than no advice?¹⁰

Objective: Estimate the effect of provider advice on patient smoking cessation outcome.

Methods:
- Included adult patients who were current smokers or quit during the last 12 months
- Some contact with the health care providers or facilities

Principal Findings:
- Provider advice doubles the chances of success
- Probability of quitting in 12 months increased from 6.9 to 14.7%
- Both statistical (p< 0.001) and clinical significance

Conclusions:
- Provider advice delivered in routine practice settings has a substantial effect on the success rate of smoking cessation among smoking patients.
Which statement is correct?

A. Varenicline has the highest cessation success rate among monotherapies
B. Combination nicotine replacement therapy (NRT) is more effective than single agent (NRT)
C. Bupropion SR is contraindicated in patients with seizure disorders
D. All of the above

Pharmacist Led Inpatient Quit Tobacco System
Why Maimonides Became Involved

- Tobacco cessation is a key component in delivery of quality healthcare
- Recognized that patients, employees and community need assistance with tobacco cessation
- Evidence based programs produce results
- Cessation medication doubles the success rate
- Tobacco use may have caused or exacerbated hospitalization admissions
- Hospitalization presents tobacco-free environment

Key Components of an Effective Inpatient Quit Assessment

- EMR used for tobacco use information
- Tobacco use a mandatory assessment
- Determine patients readiness to quit
- Determine patients addiction level
- Educate patients on health hazards of smoking and the benefits of quitting

Key Components of an Effective Inpatient Quit Assessment

- Prescribe Nicotine Replacement Therapy (NRT)
- Identify the primary counselor
- Develop multidisciplinary approach
- Refer patients to multiple counsel resources
- 30- day post discharge follow-up
Leadership Support

- **Administrative / Senior Staff**
  - CEO, Human Resources, Facilities and Support Services
- **Clinical Staff**
  - Clinical Chairs
- **Performance Improvement**
  - Created performance improvement objective regarding tobacco use
- **P & T Committee**
  - Supported CDTM protocol

New Tobacco-Free Policy
Maimonides Medical Center

- Clinical Pharmacists: Trained in tobacco cessation
- **Medical Staff**: Cardiology, Stroke, Oncology, Psychiatry
- **Medical and Pharmacy Residents**
- **Nurse Practitioners**
- **Physician Assistants**
- **Respiratory Therapists**
- **Performance Improvement Specialists**: Hospital-wide PI Initiative
- **Information Systems**: Facilitated development of reports, Order sets and CDTM protocol
Training Pharmacists as Tobacco Cessation Specialists

- Several Pharmacists are Certified Tobacco Treatment Specialists (by UMDNJ-Tobacco Dependence Program)
- Clinical pharmacists were certified by the Tobacco Treatment Training Core Program http://www.farasig.com/TTTcoreprogram
- Pharmacists provided in-services to clinicians on evidence based smoking cessation strategies
- PGY-1 Pharmacy Resident Research project was to facilitate the implementation, and evaluation of our Pharmacist-Led Inpatient Tobacco Cessation Program

Education and Training Program for Clinicians

Goal: Effectively screen, counsel & initiate tobacco cessation

- Health hazards associated with tobacco use
- Evidence based treatment guidelines
  - Using 5 A's (Assist, Ask, Advise, Assess, & Arrange)
- Assessment of the patient's addiction level
  - Fagerstrom Test for nicotine dependence
- Pharmacotherapy treatment options
  - During hospitalization and at discharge
- Motivational interviewing for primary care
- Referral options available for quit counseling
  - Quit line, tobacco cessation programs

In-depth Tobacco Cessation Consultation

- Asking patient if they have used tobacco within the last 30 days
- Advising the patient to quit
- Assessing the patient’s willingness to quit
- Assisting the patient in a quit attempt by offering medications and providing counseling
- Arranging for follow-up contact
Collaborated with our IS Department to:

- Modify EMR - created mandatory assessment of tobacco users
- Created daily list of newly admitted current tobacco users - work lists for our clinical pharmacists
- Developed CDTM protocol order
- Developed (NRT) order sets - based upon patient’s current tobacco usage
- Developed flow sheet in the EMR

Initiate a Tobacco Cessation CDTM

Purpose:
- Provide effective and consistent tobacco cessation counseling
- Promote tobacco cessation during hospitalization
- Guidelines for nicotine replacement therapy (Nicotine Patch and Gum)
- Address TJC performance measure set

Steps to Implementing a Successful Inpatient Quit System

1. Leadership Support
2. Tobacco Status Required Field
3. Created Daily List
4. Developed NRT Order Sets
5. Trained Clinical Pharmacists & Clinicians
6. Developed CDTM Protocol
7. Interdisciplinary Flow Sheet
8. Inpatient Information Packet
9. Communication Tool
Maimonides Implementation Timeline
Inpatient Tobacco Cessation Program

2011 • Joined NYC Tobacco-Free Hospitals Campaign

2012 • Created Tobacco-Free campus policy
• Pharmacy initiated Employee Tobacco Cessation Program
• Training of clinicians on tobacco cessation counseling and nicotine addiction

2013 • Employee Cessation Program expanded to include family members
• P & T approves CDTM for pharmacists to manage tobacco cessation by protocol
• Inpatient Tobacco cessation program initiated
• Maimonides achieves “A” grade on Inpatient Quit System Tool

Mandatory Admission Assessment of Patient’s Current Tobacco Use

CDTM – Tobacco Cessation Medication Order Set
Cessation Services Provided to Inpatients

- Evidence based guidelines
- Pharmacotherapy treatment options
  - During hospitalization and at discharge
- Referral options available for counseling
  - NYS Smokers’ Quitline, hospital provided tobacco cessation programs, potential referral for CT lung scan
- Follow-up contact
  - 30 days post discharge smoking status; via telephone, email, or mail interview
  - Communication with patient’s primary care provider

Patient Selection

Inclusion Criteria
- Patients identified as tobacco users

Exclusion Criteria
- Nonsmokers
- Former smokers
- Patients with length of stay < 1 day
- Pediatric patients < 13 years old
- Maternity
- Intubated
- Lacking cognition
- Mental health disabilities
- Terminally ill

Impact on Tobacco Cessation Post-Discharge

- Based on patient’s response from February 2014,
  - 15% quit smoking or reduced the number of cigarettes smoked per day
March 2014 Demographics for Included Patients (n=35)

**Gender**
- Male: 74%
- Female: 26%

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March 2014 Demographics for Included Patients (n=35)

**Percentage (%) of Patients Based on Age (years)**

- 0-20: 10%
- 21-40: 20%
- 41-60: 30%
- 61-80: 20%

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Communication to Patient’s Primary Care Provider

- Communication to the patient’s primary care provider should be clear and concise.
- The patient should be informed of their medical condition and treatment options.
- Encourage open communication between the patient and their primary care provider.

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Maimonides Medical Center
Which is not key component of a effective tobacco cessation program?
A. Mandatory assessment of patients current tobacco status
B. Refer patients to counseling resources at discharge
C. Provide ample training for tobacco cessation counselors
D. Develop an interdisciplinary approach to cessation counseling
E. Availability of all FDA approved tobacco cessation therapies on the hospital formulary

NYC DOH Tobacco-Free Hospitals Campaign
- Helps hospitals achieve excellence related to inpatient assessment and treatment for tobacco use
- Inpatient Quit System (IQS) tool
- Review results and determine performance improvement priorities
Targeted Measures of Success

The impact will be measured using the TJC performance indicators which include:

- Tobacco use screening
  - Number of patients screened
- Tobacco Use Treatment Provided or Offered
  - Evidence-based counseling to quit
- Tobacco cessation medications provided during inpatient stay and at discharge
- Referral options offered upon discharge
- Patient’s smoking status 30 days after discharge

### March 2014 Outcomes of the Maimonides Medical Center Inpatient Tobacco Cessation Program

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<td># of patients who were screened for tobacco use status</td>
<td>35 patients were screened</td>
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<tr>
<td>TOB-2</td>
<td># of patients that received or refused practical counseling to quit and received or refused smoking cessation medication</td>
<td>13 patients</td>
</tr>
<tr>
<td>TOB-3</td>
<td># of patients who were referred or refused evidence-based outpatient-based counseling and received or refused a prescription for smoking cessation medication at discharge</td>
<td>10 patients</td>
</tr>
<tr>
<td>TOB-4</td>
<td># of patients contacted within 30 days after discharge and follow-up information regarding tobacco use is collected</td>
<td>35 patients</td>
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Lessons Learned & Next Steps for Maimonides

Lessons Learned
• Counseling for non-English speaking patients
• Provide printed information in multiple languages
• Modify exclusion criteria to optimize focus
• Motivational interviewing may require multiple encounters to engage the patient

Next Steps
• Expand discharge counseling program to include community clinics (HIV, Diabetes, CHF, etc.)
• Explore possible reimbursement options

Questions?

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References