Treatment Delivery in the Real World: Expanded Reach Through Pragmatic Interventions

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MUSC Tobacco Retreat
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Our Best Interventions: Good but not Great

Cochrane Review: Pharmacological interventions for smoking cessation: An overview and network meta-analysis. 2013
Our Best Interventions: Real World Disconnect

Our Best Interventions: Consumer Barriers

<table>
<thead>
<tr>
<th></th>
<th>Patch</th>
<th>Gum</th>
<th>Lozenge</th>
<th>Bupropion</th>
<th>Varenicline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Too expensive</td>
<td>62%</td>
<td>67%</td>
<td>71%</td>
<td>60%</td>
<td>69%</td>
</tr>
<tr>
<td>Still craving during use</td>
<td>40%</td>
<td>37%</td>
<td>22%</td>
<td>31%</td>
<td>26%</td>
</tr>
<tr>
<td>Side effects too strong</td>
<td>14%</td>
<td>13%</td>
<td>9%</td>
<td>25%</td>
<td>37%</td>
</tr>
<tr>
<td>Overall, did it help you quit</td>
<td>49%</td>
<td>48%</td>
<td>54%</td>
<td>52%</td>
<td>74%</td>
</tr>
<tr>
<td>Excellent Medication</td>
<td>66%</td>
<td>46%</td>
<td>67%</td>
<td>63%</td>
<td>77%</td>
</tr>
</tbody>
</table>

Non-Pharmacologic Treatments

Motivational Interviewing works. . . .

Meta-Analysis vs. Brief Advice\(^1\) \hspace{1cm} OR = 1.27 \ [1.14 – 1.42]

. . . But is time and skill intensive: few opportunities for formal training, certifications not available, unlikely suited for busy clinical practice

Study of Doctor-Patient Conversations for Smoking Cessation\(^2\)
- Physicians offered MI adherent behaviors in 56% of discussions
- Physicians offered non-adherent behaviors in 57% of discussions

Most common MI non-adherent behaviors: Directing, Confronting, Warning the Patient

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Non-Pharmacologic Treatments

Other non-pharmacologic treatments that do not lend themselves to easy dissemination in medical practice:

• Contingency Management
• Behavioral skills training
  • Group Support
• Acceptance and Commitment Therapy

Common, Potentially Effective, But Inconsistently Applied:

• Fax to Quit (referrals to quitlines)
## Importance of Primary Care

<table>
<thead>
<tr>
<th></th>
<th># of Visits (in thousands)</th>
<th>Percent of Distribution</th>
<th># Visits per 100 persons per yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>All visits</td>
<td>1,008,802</td>
<td>100%</td>
<td>332.2</td>
</tr>
<tr>
<td>General &amp; Family Med</td>
<td>213,770</td>
<td>21.2%</td>
<td>70.4</td>
</tr>
<tr>
<td>Internal Medicine</td>
<td>139,843</td>
<td>13.9%</td>
<td>46.1</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>26,164</td>
<td>2.6%</td>
<td>8.6</td>
</tr>
<tr>
<td>Oncology</td>
<td>25,197</td>
<td>2.5%</td>
<td>8.3</td>
</tr>
<tr>
<td>Primary Care</td>
<td>560,295</td>
<td>55.5%</td>
<td>184.5</td>
</tr>
</tbody>
</table>

- 1 billion physician visits
- 332 visits per 100 people
- 56% of all visits made to primary care

National Ambulatory Medical Care Survey: 2010
U.S. Health Professionals’ Self-Report of 3 A’s

- Ask Smoking Status
- Advise Quitting
- Assess Motivation

Source: Tong et al. (2010). Nicotine & Tobacco Research;12: 724-733
U.S. Health Professionals’ Self-Report of Assist Efforts

- Sets quit date
- Refer to cessation program
- Provide quitline material
- Discuss medication*
- Arrange Follow-up

*Medication discussion not asked of nurses and dental hygienists

Source: Tong et al. (2010). Nicotine & Tobacco Research;12:724-733

Primary Care Physician (n=437)
Registered Nurse (n=388)
Dentist (n=391)
Dental Hygienist (n=377)
Provider-level obstacles:\(^1\)–\(^3\):
- insufficient time
- lack of familiarity with guidelines / inadequate knowledge or skills
- lack of confidence to counsel cessation
- belief that cessation counseling is ineffective

Primary care providers need more and better tools to treat smokers:
- Need for strategies that are brief, easy to implement, and noninvasive of either clinic procedures or doctor/patient dialogue

Most existing clinical strategies are verbally-based; i.e., based on persuasive messaging. **When words don’t work**, new strategies that do not rely on verbal counseling could provide an alternative to promote quitting

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Need for Pragmatic Studies

- Reliable
- Valid
- Sensitive to Change
- Feasible
- Important to Practitioners
- Public Health Relevance
- Actionable
- Broadly Applicable
- Low Cost
- Enhances Patient Engagement
- Do no Harm

Glasgow. What does it mean to be pragmatic? Pragmatic methods, measures, and models to facilitate research translation. Health Educ Behav. 2013.
What Does Pragmatic Mean to Me?

- BRIEF
- Active treatment for ALL smokers, not just those wanting to quit
- No extensive training needed
- No complicated instructions
- Face valid to smoker and clinician

- Yes, intensive usually is better. But willing to sacrifice some efficacy if it means getting better reach

\[ \text{Impact} = \text{Efficacy} \times \text{Reach} \]
Real Life Quit Attempts

- Are often spontaneous and sometimes more successful vs. planned QAs\(^1\)
- Are often undisclosed to others\(^2\)
  - \(~45\%\) of smokers will not tell others of a quit attempt in advance
  - Might do better than those who disclose

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted</th>
<th>Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% achieving 30 days quit</td>
<td>OR</td>
</tr>
<tr>
<td>Told others in advance</td>
<td>58%</td>
<td>1.0</td>
</tr>
<tr>
<td>Did NOT tell others</td>
<td>67%</td>
<td>1.5</td>
</tr>
</tbody>
</table>

Thus, there is need to increase accessibility of treatments:
- Lower cost
- Less than full course treatment: once/day packaging, [free] sampling
  - Available on a whim
  - Removal of messaging of “need to quit for good”

NRT Sampling – Part I

Design: 6 weeks of sampling NRT, in the context of a practice quit attempt. Everyone followed for additional six months. N=849 smokers NOT motivated to quit, nationwide

Practice Quit Attempt
- short period (hours, days) of sampling abstinence
- remove stress of trying to quit for good
- learn coping behaviors
- what works, what doesn’t

PQA + NRT
- same as above
- sample NRT
- learn how it works, what it does, what it doesn’t do, etc
- NRT → nicotine lozenge: OTC, prn dosing, minimal side effects

NRT Sampling – Part I

* Abstinence: 7 day point prevalence (self report)

NRT Sampling – Part I

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>End of Treatment</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NRT Sampling</td>
<td>Control</td>
<td>NRT Sampling</td>
</tr>
<tr>
<td>MTQ (0-10)</td>
<td>2.4</td>
<td>2.6</td>
<td>ns</td>
</tr>
<tr>
<td>Abstinence Self-Efficacy (0-10)</td>
<td>4.0</td>
<td>3.9</td>
<td>ns</td>
</tr>
<tr>
<td>Knowledge of NRT (0-10)</td>
<td>4.7</td>
<td>4.9</td>
<td>ns</td>
</tr>
<tr>
<td>+ Attitudes toward NRT (1-4)</td>
<td>3.0</td>
<td>3.0</td>
<td>ns</td>
</tr>
<tr>
<td>- Attitudes toward NRT (1-4)</td>
<td>2.8</td>
<td>2.6</td>
<td>ns</td>
</tr>
</tbody>
</table>

What would happen if we gave the same sampling intervention, with no accompanying behavioral support, to all smokers? How important is motivation to quit? Will treatment be wasted? N=157 smokers statewide.

**MNQ:**
- Smokers Motivated to Quit
- Given 2 weeks supply of patch & lozenge
- Quitline referral

**UNQ:**
- Smokers Not Motivated to Quit
- Given 2 weeks supply of patch & lozenge
- Quitline referral

**UQ:**
- Smokers Not Motivated to Quit
- Quitline referral

**Shared Commonality:**
- Active Treatment
- Not Motivated to Quit

NRT Sampling – Part III
Get Real and Go Big

**Design**: Cluster-randomized controlled trial of 1160 smokers within SC primary care practices (n=20 clinics). Nurses/physicians do it all: a) screening, b) consenting, c) baseline assessment, d) intervention.

**Intervention**: Bag of smoking cessation support (+/- NRT patch & lozenge) for everyone, no matter if you [don’t] want to quit.

**Major Outcomes thru Six Months**:  
- **Individual Level**  
  - Cessation & Quit attempts  
  - Treatment utilization (medication, quitlines)  
  - Mediators (self efficacy, autonomy over quitting; knowledge of NRT; social support)  
  - Cost effectiveness  
- **Provider Level**  
  - Knowledge, Comfort, Satisfaction of cessation counseling  
- **Aggregate clinic behavior**  
  - Screening & treatment of ALL smokers

**Status**: 3 clinics down; 17 more to go. Current N~190. Stay tuned.
Conclusions

• As long as tobacco is available, there will never be a silver bullet to get smokers to quit. Even with best treatments, most will fail.

• Best way to ensure eventual success is to keep trying, increasing quit attempts and making smart quit attempts (EBT).

• Most treatments are kept under lock and key. Increasing uptake and accessibility is critical.

• Keep it Simple. Keep it Pragmatic. Increase smoker engagement in treatment. Increase provider engagement in the process.

Not all trials need to be pragmatic interventions. Still a clear need for novel treatment development, both pharmacologic and behavioral. But all interventions must have eventual downstream dissemination potential.
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Thank you.

Wild applause.