Evidence Based Approaches for Treating the Unmotivated Smoker

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Talk Overview – Helping Those Not Yet Ready to Quit

- Epidemiology
- Evidence
- Clinical Approaches
Almost 500,000 annual deaths attributable to cigarette smoking – United States

What can we do to help prevent more of these deaths?
Smoking Prevalence Among Adults 18 and Older, United States, 1965-2015

Source: NHIS/CDC

2015 = 15.2%
U.S. Smoking Prevalence: Projections Based on Recent Trends

Source: NHIS/CDC

2015 = 15.2%
U.S. Smoking Prevalence: What will it take to accelerate progress?
Smoking Population

30% Ready to Quit

70% Not Ready to Quit
The Treatment Reach Problem

- Too few smokers are being treated with evidence-based treatments
- Little to offer the 70% of smokers who are not ready to quit at time of a clinic visit
- Need to expand our reach to treat smokers who are not yet ready to quit
Talk Overview –
Helping Those Not Yet Ready to Quit

- Epidemiology
- Evidence
- Clinical Approaches
The Guideline

- PHS Guideline evidence-based treatments
  - Counseling
  - Medications
  - Health System Changes

- 2008 - Updated Guideline published

- Literature from 1975 – 2007

- Approximately 8,700 total articles
The "5 A's" Algorithm

**ASK**
Do you currently use tobacco?

**YES**

**ADVISE**
to quit

**ASSESS**
Are you open to making a quit attempt?

**YES**

**ASSIST**
Counseling and medication

**NO**

**ASSIST**
Motivation interventions

**ARRANGE**
Follow-up

---

**5 A's**

1. **ASK**: Do you currently use tobacco?
2. **ADVISE**: to quit
3. **ASSESS**: Are you open to making a quit attempt?
4. **ASSIST**
   - Counseling and medication (if YES)
   - Motivation interventions (if NO)
5. **ARRANGE**: Follow-up
The "5 A's" Algorithm

ASK
Do you currently use tobacco?

YES

ADVISE
to quit

ASSESS
Are you open to making a quit attempt?

YES

ASSIST
Counseling and medication

NO

ASSIST
Motivation interventions

ARRANGE
Follow-up
PHS Meta-analysis (2008): Effectiveness of NRT for smokers not willing to quit (but willing to change their smoking patterns or reduce their smoking) (n = 5 studies)\(^a\)

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Number of arms</th>
<th>Estimated odds ratio (95% C.I.)</th>
<th>Estimated abstinence rate (95% C.I.)</th>
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<tr>
<td>Nicotine replacement (gum, inhaler, or patch)</td>
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<td>2.5 (1.7–3.7)</td>
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</tbody>
</table>

\(^a\) Go to [www.surgeongeneral.gov/tobacco/gdlnrefs.htm](http://www.surgeongeneral.gov/tobacco/gdlnrefs.htm) for the articles used in this meta-analysis.
Newer Findings
Enhancing Smoking Treatment Effectiveness: 4 Key Components of Research Approach

1. **Recruitment** via Electronic Health Record (EHR) enhancements

2. **Translation** via treatments that are designed for, and evaluated in, real-world healthcare clinics

3. **Chronic Care** via effective interventions for every phase of treatment

4. **Treatments that Work Well Together** identified via powerful factorial designs that screen multiple intervention components to discover those with additive and synergistic effects
Guiding Model: Longitudinal Phase-Based Model of Cessation

- An approach based on tobacco dependence and smoking cessation research and theory.
- Suggests that the process of cessation can be divided into phases, with each phase presenting a different set of challenges and opportunities for intervention.
- Provides the foundation for building a better cessation intervention package.
Phase-Based Model of Smoking Cessation

Motivation | Preparation | Cessation | Maintenance | Relapse Recovery

Comparative effectiveness of motivation phase intervention components for use with smokers unwilling to quit: a factorial screening experiment

Jessica W. Cook¹,²,³, Linda M. Collins⁶, Michael C. Fiore¹,², Stevens S. Smith¹,², David Fraser¹,², Daniel M. Bolt⁴, Timothy B. Baker¹,², Megan E. Piper¹,², Tanya R. Schlam¹,², Douglas Jorenby¹,², Wei-Yin Loh⁵ & Robin Mermelstein⁷

(Article first published online: November 19, 2015.)
Goal

Identify intervention components that motivate smokers who are not ready to quit to make quit attempts sooner and increase success of those attempts*

*To be included as part of a comprehensive optimized cessation treatment.
The Multiphase Optimization Strategy (MOST): Engineering Interventions

- Developed by Linda Collins and colleagues at Penn State
- An engineering-inspired framework for development, optimization, and evaluation of interventions
Treatment Package Approach vs MOST approach

• Traditional Treatment Package Approach
  ▪ Multiple components brought together to form a treatment package that is then evaluated with RCT

• MOST
  ▪ Individual components evaluated first with empirically based optimization process (“screening”)
  ▪ Based on this evaluation, an optimized intervention assembled
  ▪ Optimized intervention then can be evaluated with RCT
Screening Study Design

• 4 factor fully crossed randomized design
  • \((2 \times 2 \times 2 \times 2) = 16\) conditions

• All factors have 2 levels: ON vs OFF
  • For each factor, 50% received the ON condition and 50% received the OFF condition
Intervention Factors

1. Nicotine patch
   - 6 weeks patch (ON) vs. none (OFF)
   - 14 mg

2. Nicotine gum
   - 6 weeks gum (ON) vs. none (OFF)
   - 2 mg
Intervention Factors

3. Behavioral Reduction Counseling
   - 1 in-person and 6 phone sessions (ON) vs. none (OFF)
   - Smoking reduction through delaying smoking, changing patterns, smoking substitutes

4. Motivational Interviewing Strategies
   - 1 in-person and 3 phone sessions (ON) vs. none (OFF)
   - Developing discrepancy between present smoking behavior and future goals, eliciting self-motivational statements
<table>
<thead>
<tr>
<th>Conditions</th>
<th>Nicotine Patch</th>
<th>Nicotine Gum</th>
<th>Behavioral Reduction Counseling</th>
<th>Motivational Interviewing Strategies</th>
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Intervention Approach - Motivation Study

- Six week intervention
- All interventions started with an in-person clinic visit
- All other intervention contacts by phone
- All participants received 6 weekly assessment calls regardless of intervention schedule
End of 6-week intervention period, participants had option to:

- Repeat 6-week Motivation intervention to which they were randomized
- Receive a cessation intervention
- No additional intervention

At any point during the intervention, participants could opt into cessation treatment

- 2 brief counseling sessions,
- 8 weeks nicotine patch + nicotine gum
Toward a Chronic Care Model for Treatment of Smokers

Move smokers who were not ready to quit through different phases of Cessation, from Motivation to Cessation
Our research program has two tracks – one for smokers who are ready to quit in the next month and one for smokers who want to cut down on their smoking; Which track would you be interested in?
Inclusion Criteria

- > 17 years old
- > 4 cigs/day for previous 6 months
- Not currently taking bupropion or varenicline
- Medically able to use NRT

- Not interested in quitting in next 30 days, but willing to reduce smoking
Sample

- 63% women
- 91% white and 5% African-American
- 1% Hispanic
- 15% college degree or higher
- 47.0 (SD = 15.0) years
- 17.4 (SD = 8.0) cigarettes per day
Key Outcomes

- Participation: will smokers not ready to quit engage in treatment and stay in treatment?

- Cigarettes per day
  - 12, 26 weeks

- One-week point prevalence abstinence
  - 12 & 26 weeks
  - Intent to treat
Participation

- Of 1699 participants enrolled in overall study, 517 (30%) were not interested in quitting but were willing to reduce their smoking.
- When you give primary care patients not seeking smoking treatment a choice, 30% chose the Motivation Phase.
Participation in Phone Calls

- Call 1: 85%
- Call 2: 81%
- Call 3: 75%
- Call 4: 72%
- Call 5: 70%
- Call 6: 76%

n=517
Enrolled in Additional Treatment

- Additional 6-weeks Motivation treatment: 21%

- Cessation treatment: 23%
Results: Cigarettes Per Day

- No main effects
- Significant 4-way interaction
Cigarettes Per Day: Significant 4-way Interaction

Nicotine Gum combined with BR, and, BR combined with MI resulted in the greatest smoking reductions.
Results: Point Prevalence Abstinence (N = 517)

Two main effects at 12 weeks post-treatment initiation:

- Patch was associated with decreased abstinence at 12 weeks ($p=.03$)
- BR counseling was associated with increased abstinence rates ($p=.04$)
Results: Point Prevalence Abstinence for those who Received Cessation Treatment (n = 100)

- No main effects
- 2, 2-way interactions
Gum X MI Interaction among Participants who Received Cessation Treatment (n=100)

26-Week Point Prevalence Abstinence

<table>
<thead>
<tr>
<th>Treatment</th>
<th>% Abstinent</th>
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</thead>
<tbody>
<tr>
<td>Gum/MI</td>
<td>23.8</td>
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<tr>
<td>No Gum/MI</td>
<td>40</td>
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<tr>
<td>Gum/No MI</td>
<td>58.3</td>
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<tr>
<td>No Gum/No MI</td>
<td>30</td>
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</table>
Gum X BR Interaction among Participants who Received Cessation Treatment (n=100)

26-Week Point Prevalence Abstinence

<table>
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<th>Condition</th>
<th>% Abstinent</th>
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<tbody>
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<td>Gum/BR</td>
<td>46.2</td>
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<tr>
<td>No Gum/BR</td>
<td>23.8</td>
</tr>
<tr>
<td>Gum/No BR</td>
<td>34.5</td>
</tr>
<tr>
<td>No Gum/No BR</td>
<td>41.2</td>
</tr>
</tbody>
</table>
Conclusions

- Participation in the Motivation Study was excellent
  - Smokers who want to cut down but are not ready to quit will engage in treatment and stay in treatment
  - Nearly half requested more treatment

- Across the set of analyses, Nicotine Gum and BR appear to be the most promising Motivation phase components.

- Effectiveness of intervention components was often meaningfully affected by the components with which they were paired

- No combinations of three or more components were especially effective (cost to treatment complexity)
Project 1 – Helping Smokers Who Aren’t Ready to Quit (Cook, et al)

<table>
<thead>
<tr>
<th>Treatment Components Tested:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Nicotine gum</td>
</tr>
<tr>
<td>2. Nicotine patch</td>
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<tr>
<td>3. Behavioral reduction counseling</td>
</tr>
<tr>
<td>4. Motivational interviewing</td>
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</tbody>
</table>

**Rationale:**
Each component was designed for real-world use in health care settings. All participants were primary care patients visiting clinics in Wisconsin for routine healthcare.

<table>
<thead>
<tr>
<th>Promising Treatment Components Identified:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Nicotine gum</td>
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<tr>
<td>2. Behavioral reduction counseling</td>
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</table>

**Factorial Experiment (N=517)**

**Potential Clinical Application:**
Smokers not ready to quit can use nicotine gum and behavioral skills to reduce their smoking and increase their odds of later quitting.
Where Are We Now?

New screening study for smokers unwilling to quit:

- Nicotine mini-lozenge
- Behavioral Reduction Counseling
- Motivational 5Rs (Relevance, Risks, Rewards, Roadblocks)
- Behavioral Activation
Talk Overview –
Helping Those Not Yet Ready to Quit

- Epidemiology
- Evidence
- Clinical Approaches
Tobacco Dependence Treatment Guideline Recommendation: Motivational Interviewing techniques appear to be effective in increasing a smoker’s likelihood of making a future quit attempt. Therefore, clinicians should use motivational techniques to encourage smokers who are not currently willing to quit to consider making a quit attempt in the future.

(USHHS Clinical Practice Guidelines, 2008)
Treating Smokers in the Health Care Setting

Michael C. Fiore, M.D., M.P.H., M.B.A., and Timothy B. Baker, Ph.D.
For Smokers Who Are Unwilling to Quit Now

Use *Motivational Interviewing* techniques

- Express empathy
  - Respond so that the patient feels heard and understood and knows that you care about his or her views and wishes.
  - Use reflective listening to communicate understanding: “I hear that you are worried about weight gain and about not being successful in quitting.”
  - Normalize the patient’s feelings and concerns: “Most smokers, like you, have tried several times before they quit successfully.”
For Smokers Who Are Unwilling to Quit Now

Use *Motivational Interviewing* techniques

- Support patient’s autonomy
  - Acknowledge that patient has control “I hear that you are not ready to quit. Just let me know when you would like to try and I will help.”
For Smokers Who Are Unwilling to Quit Now

Use *Motivational Interviewing* techniques

- Help the patient recognize the discrepancy between his/her continued smoking and the importance of quitting.
  - Accept the patient’s ambivalence about quitting, but reinforce strongly held values and goals that are inconsistent with smoking.
  - Highlight how the patient’s current behavior is discrepant with important values and goals: “So, you are strongly committed to your kids, and you worry that your smoking is not the best thing for them.”
  - Strengthen the patient’s values that conflict with smoking: “I am impressed with your strong desire to be free from addiction to nicotine.”
For Smokers Who Are Unwilling to Quit Now

Use *Motivational Interviewing* techniques

- Accept the patient’s resistance to change related to quitting.

  - Be open to the patient’s ambivalence and reasons for not quitting.
  - Back off if the patient expresses resistance: “You are tired of people trying to get you to quit – I can understand that.”
  - Tell the patient that you hear and respect his or her misgivings: “Because medication did not help you before, you think a different medication will not help you now.”
  - Ask permission to help: “May I tell you what I think will help you quit?”
For Smokers Who Are Unwilling to Quit Now

Use *Motivational Interviewing* techniques

- Support the patient’s self-efficacy with respect to quitting.
  - Build on past successes: “You were able to stop smoking for a couple of weeks the last time you tried – that means that you really have the skills to fight urges and resist temptation.”
  - Give the patient choices and control over how to proceed: “Which of these treatments sounds good to you?”
For Smokers Who Are Unwilling to Quit Now

Encourage smoking reduction plus nicotine-replacement (nicotine gum) therapy.

- Consider the use of nicotine-replacement therapy for 2–6 mo.
- Help the patient formulate a smoking-reduction plan, including a reduction in daily smoking as much as possible and elimination of smoking entirely in key environments and activities (e.g., in the car and while watching television).
Using Nicotine Replacement Medications When the Patient is Not Yet Ready to Quit
Optional Medications Before Smoking Cessation

For the patient who is unwilling to quit now, but willing to reduce smoking and use nicotine-replacement therapy

- Nicotine patch
- Nicotine gum
## Optional Medications Before Smoking Cessation – Nicotine Gum

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
<th>Comments</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Nicotine Gum</td>
<td>2-4 mg, up to 10 times/day, daily for up</td>
<td>Pair medication with counseling to reduce the number of cigarettes smoked/day as much as possible; see patient every 4 wk to assess interest in quitting and to conduct counseling</td>
<td>May result in increased attempts to quit and increased likelihood of cessation at 3-6 mo</td>
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Treatment Extenders

- Quitlines
- Smokefree.gov
eHealth and mHealth Approaches to Cessation

- NCI leads the nation
- Smokefree.gov and related websites, text message programs, social media, and mobile apps
- Numbers for FY-2015:
  - Website visits: ~ 2,350,000
  - Facebook followers: ~ 57,000
  - Twitter followers: ~ 19,400
  - Mobile Application downloads: ~ 65,000
  - SFTXT lifetime subscriptions: ~ 120,000
Engaging the Unmotivated Smoker: Innovative Approaches

Key Points:

- 70% of smokers may not be ready to quit
- Counseling can make a difference
- Pre-quit nicotine gum can be effective
- Take advantage of treatment extenders
Acknowledgements

- Michael Fiore (PI)
- Timothy Baker (PI)
- Daniel Bolt
- Linda Collins
- Douglas Jorenby
- Robin Mermelstein
- Bruce Christiansen
- Kathi Diviak
- Meg Feyen
- David Fraser
- Todd Hayes-Birchler
- Chris Hollenback
- Paul Kohn
- Madeline Oguss
- Megan Piper
- Holly Prince
- Tanya Schlam
- Stevens Smith
- Nick Wiley
- 14 Health Counselors