Feasibility of Delivering Varenicline Through A Telephone Quitline
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Note: Pfizer funded the NRT and Varenicline used for the pilot study
1. Learn about the feasibility of distributing varenicline through a Quitline.

2. Review data findings comparing cessation activity between those receiving mail-delivered varenicline with standard mail-delivered nicotine replacement therapy (NRT).

3. Discuss strategies for improving participant attrition in the varenicline delivery protocol.
Introduction

• Telephone quitlines are an easily accessible and effective means for delivering cessation services (1,2).

• Varenicline (VAR), available in the U.S. by prescription only, shows superior quit rates to the nicotine patches, (3,4) but has not been routinely delivered by quitlines.(5)

Primary Aims

1) To assess the feasibility of distributing varenicline through the New York State Smokers’ Quitline (NYSSQL);

2) To compare cessation activity between those receiving mail-delivered varenicline compared to standard mail-delivered nicotine replacement therapy (NRT).
Method

- Participants in the VAR arm (n=200) were instructed to contact their primary care physician (PCP) to obtain a prescription for varenicline, fax it back to a designated pharmacy, which would prompt NYSSQL to mail.

- Participants in the NRT arm (n=100) were mailed patches using an existing protocol.

- All participants were scheduled to receive 12 weeks of free pharmacotherapy, shipped in 3 mailings.
Randomization was conducted in a 2:1 ratio due to the fact that we anticipated a higher rate of attrition in the VAR Arm given the extra steps needed in this condition to obtain the study medication.

The NYSSQL IT staff programmed the randomization method into the Quitline’s online data collection system.
“I’d like to invite you to help us. We’re conducting a study to develop better ways to provide treatment for quitting smoking to quitline callers. If you decide to participate, you will receive specific health education information and may also receive either 12 weeks of the prescription medication varenicline (Chantix®) or 12 weeks of nicotine patches by mail........”
“You will complete a brief telephone survey today, then you will receive follow-up telephone calls around your quit date and 4 months from today to ask additional questions. All follow-up calls will only take between about 10 and 20 minutes each. Pfizer has provided the medications used in this study. Your participation is completely voluntary, and your responses will be confidential. Would you be willing to participate in the study?”
1) Are you under the care of a primary care physician?
2) Have you ever been diagnosed with or treated for a mental health problem like Major Depression, Bipolar Disorder, Dysthymia, or Schizoaffective Disorder?
3) Have you ever had serious thoughts of killing or hurting yourself, ever have any intention or plan to carry out these thoughts, or actually attempted to kill yourself?
4) Have you ever had an allergic reaction or intolerance to varenicline (Chantix)?
5) Are you currently on hemodialysis?
6) Do you have any drug allergies (e.g., antibiotics, aspirin, codeine)?
Procedures

• Intake: caller received general smoking cessation coaching (standard protocol)

• Nicotine Arm: Participants in the NRT Arm were sent 3 mailings of 4 weeks of nicotine patches per the standard quitline protocol for NRT delivery.

• Varenicline Arm: Participants in the VAR Arm were asked to call their PCP as soon as possible to have their doctor submit a prescription for varenicline via an e-script or fax to the State University of New York [SUNY] at Buffalo pharmacy.
Standard Protocol

- Intake
- Coaching call, including NRT eligibility assessment
- NRT Check call - if NRT mailed
- Quit date coaching call, including reassessment for additional NRT
- Third Coaching call, including reassessment for additional NRT
In addition to standard protocol:

- Collect PCP’s name and contact information
- Fax an information letter to the patient’s physician
- If reported no doctor, assist to locate a provider through Federally Qualified Health Center website (http://findahealthcenter.hrsa.gov/#)
- Review timeframe for coach calls and specified requirements around follow up
- Mail instructional information
Followed up with participants about the status of their prescription 7-10 days from the date of enrollment

Attempted to reach up to 4 times.

If answered provided assistance around filling prescription

Instructed on the amount they will receive and how to take it correctly to achieve desired results
### Overall Participant demographics

<table>
<thead>
<tr>
<th>Variable</th>
<th>VAR</th>
<th>NRT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>47.18 ± 13.89</td>
<td>46.05 ± 13.78</td>
</tr>
<tr>
<td>% White</td>
<td>77.20%</td>
<td>84.10%</td>
</tr>
<tr>
<td>% Hispanic or Latino</td>
<td>10.20%</td>
<td>13.00%</td>
</tr>
<tr>
<td>% Female</td>
<td>46.50%</td>
<td>47.00%</td>
</tr>
<tr>
<td>Cigarettes per day</td>
<td>23.8 ± 9.8</td>
<td>22.3 ± 7.7</td>
</tr>
<tr>
<td>Years smoking</td>
<td>25.78 ± 13.72</td>
<td>24.92 ± 13.16</td>
</tr>
<tr>
<td>Smoke in first 30 min of waking</td>
<td>91.70%</td>
<td>90.90%</td>
</tr>
</tbody>
</table>

*Note.* No significant differences in demographics between treatment arms.
Data Analyses

• Feasibility was assessed by
  • Counting the number of medication kits successfully dispensed for each prescription
  • Evaluating self report reasons for not filling a prescription.

• Logistic regression analyses were conducted to evaluate the effects of treatment arm on 7-day point prevalence abstinence at the 4 month follow-up

• An exploratory analysis of the effect of insurance status on varenicline prescription submission was conducted using logistic regression.
Feasibility Outcomes

Varenicline Arm Outcomes

- Did not fill Rx (n = 146)
  - Lost to or refused follow-up (n = 94)
  - Dr. would not prescribe (n = 12)
  - Changed mind/No follow through (n = 10)
  - Never received mailed info (n = 7)
  - Concerns about side effects (n = 7)
  - Could not see Dr. (n = 6)
  - Filled prescription on own (n = 5)
  - Process is too difficult (n = 3)
  - Used E-cigs instead (n = 1)
  - No address (n = 1)

- Rx Dispensed (n = 54)
  - Completed Study (n = 36)
  - Lost to or refused follow-up (n = 16)
  - Pregnant and discontinued (n = 1)
  - Did not fill prescription (n = 1)
### Participant demographics in Varenicline Arm (n=200)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Prescription for Varenicline</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dispensed (n=54)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>49.51 ± 12.75</td>
</tr>
<tr>
<td>% White</td>
<td>91.84%</td>
</tr>
<tr>
<td>% Hispanic or Latino</td>
<td>9.26%</td>
</tr>
<tr>
<td>% Female</td>
<td>46.30%</td>
</tr>
<tr>
<td>Cigarettes per day</td>
<td>22.83 ± 10.24</td>
</tr>
<tr>
<td>Years smoking</td>
<td>27.93 ± 12.49</td>
</tr>
<tr>
<td>Smoke in first 30 min of waking</td>
<td>88.50%</td>
</tr>
</tbody>
</table>

*Participants who were sent varenicline were more likely to be White compared to those who declined the medication (Chi-square p-value = 0.03)*
## Role of Insurance Status

### VAR group insurance status and number of prescriptions submitted

<table>
<thead>
<tr>
<th></th>
<th>Submitted prescription</th>
<th>Did not submit prescription</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
<td></td>
</tr>
<tr>
<td>Uninsured</td>
<td>7 (18.9)</td>
<td>30 (81.1)</td>
<td>37</td>
</tr>
<tr>
<td>Medicaid</td>
<td>11 (17.2)*</td>
<td>53 (82.8)</td>
<td>64</td>
</tr>
<tr>
<td>Medicare</td>
<td>4 (23.5)</td>
<td>13 (76.5)</td>
<td>17</td>
</tr>
<tr>
<td>Private</td>
<td>21 (33.3)</td>
<td>42 (66.6)</td>
<td>63</td>
</tr>
</tbody>
</table>

Note. The * indicates p < 0.05 when compared to private insurance.
## Treatment Outcomes

### 7-day point prevalence abstinence at the 4-month follow-up

<table>
<thead>
<tr>
<th>Analysis</th>
<th>varenicline group (No. abstinent/No. in sample)</th>
<th>NRT group (No. abstinent/No. in sample)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITT</td>
<td>11% (22/200)</td>
<td>23% (23/100)</td>
<td>0.007</td>
</tr>
<tr>
<td>Per protocol</td>
<td>36% (13/36)</td>
<td>46% (23/50)</td>
<td>0.36</td>
</tr>
</tbody>
</table>
Satisfaction Outcomes

• Overall, how satisfied were you with the service you received from the Quitline?*

• To what extent has the Quitline met your quitting needs?*

• If you were to seek help again, would you contact the Quitline?

• If a friend were in need of similar help, would you recommend the Quitline?

* Refers to questions that reflected differences between study arms
Overall, how satisfied were you with the service you received from the Quitline?

- Control
- Varenicline

Satisfaction Level
To what extent has the Quitline met your quitting needs?

- Control
- Varenicline

None of my needs have been met
Only a few of my needs have been met
Most of my needs have been met
Almost all of my needs have been met
Discussion points

- Feasibility
- Insurance status
- Randomized controlled trial
- Barriers
- Study limitation
Lessons Learned

- Perceptions of quitline resources
- Addressing participants with differing levels of SES
- Coach training and biases
- Operations management: adjusting to existing protocols
Suggestions for Improving Attrition

- Streamline the process
- Specialize recruitment
- Promote doctor-patient communications
- Provide online resources educating about study
- Address quitline norms up front
- Promote cost savings
- Be aware of potential guilt around declining
- Enhance training minimizing fears associated with Varenicline
Improving Engagement and Decreasing Barriers

- Continue to enhance timely follow up
- Boost response rates by providing multiple modes for completing follow up
- Strengthen Varenicline and other medication protocols
- Provide more messaging around doctor-patient communications
- Align more with Healthcare Centers and Federally Qualified Health Centers
- Explore cost sharing options
This research was supported by an Investigator Initiated Research Grant from Pfizer, Inc. The content is solely the responsibility of the authors and does not necessarily represent the official views of Pfizer, Inc. Portions of these data were presented at the Society for Research on Nicotine and Tobacco annual convention in February 2015. The senior author (BAT) had full access to all data in this study and had final responsibility for the decision to submit the paper for publication. Scientific and grant personnel from Pfizer, Inc. were permitted to read the manuscript before we submitted the paper, but no changes were made to data analytics or reporting of the data analysis. This research was also supported by NIH grants T32-DA007238 (to Dr. Rojewski).

Conflicts of Interest:

Dr. Toll reports the following activities for the past 3 years: Recipient of the grant for medicine only from Pfizer, Inc. that was used for this study. Pfizer, Inc. provided the 12 weeks of varenicline and 12 weeks of NRT administered in this study.
Questions