



NORTH AMERICAN  
**QUITLINE**  
CONSORTIUM

# Quitline Services: Current Practice and Evidence Base

*NAQC Quality Improvement Initiative*

2016

## **ACKNOWLEDGMENT AND RECOMMENDED CITATION**

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NAQC would like to acknowledge and thank the author, Chris Anderson, for his time, effort and expertise in developing this excellent paper.

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NAQC's Advisory Council (listed below) conceptualized the scope of this paper, oversaw its development, reviewed the draft and approved the final paper. We would like to acknowledge the important role played by the Advisory Council and to thank them for their contributions. Special thanks are extended to Jack Boomer, Paula Keller and Hilary Tindle who served as primary reviewers for this paper and contributed a great deal of time and expertise to ensuring a high quality product.

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NAQC also would like to acknowledge and thank the key staff involved in this project. Linda Bailey managed the project. Maria Rudie provided research support. Natalia Gromov provided support for layout and dissemination.

### **Funding Source**

Funding for this project was provided to NAQC through a cooperative agreement with The Centers for Disease Control and Prevention. The contents of this publication are under the editorial control of NAQC and do not necessarily represent the official views of the CDC.

### **Recommended Citation**

North American Quitline Consortium (2016). *Quitline Services: Current Practice and Evidence Base, 2016*. (Anderson CM). Phoenix, Arizona.

### **Corrections**

Please notify NAQC of any errors by e-mail at [naqc@naquitline.org](mailto:naqc@naquitline.org).

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## **INTRODUCTION AND EXECUTIVE SUMMARY**

### **Background**

Quitlines are widely recognized as an effective means of helping tobacco users quit. They provide evidence-based tobacco cessation treatment, according to the U.S. Public Health Service (Fiore 2008) and the Community Preventive Services Task Force (Guide to Community Preventive Services 2014). They are a key element in the U.S. Department of Health and Human Services' strategic action plan for tobacco control (USDHHS 2010) and are recommended by the Centers for Disease Control and Prevention as a best practice for statewide comprehensive tobacco control programs (CDC 2014). All states in the U.S., all Canadian provinces, and certain territories of both nations have implemented quitlines, as have many other states and nations around the world.

The service most responsible for quitlines' positive reputation is also their most longstanding: telephone counseling. Indeed, the telephone component is why such programs were called quit "lines". Yet quitlines have changed dramatically since they were first introduced in the U.S. in the early 1990's. At that time, telephone counseling and mailed information were the only services quitlines offered (Anderson 2007). Since then they have evolved into more complex programs that also offer medications and technology-based behavioral supports, such as text messaging and online chat, and they have become more integrated with health care systems (Rudie 2016). The growing suite of services is transforming the industry standard and expanding the definition of "quitline".

There has so far been no systematic review describing the broader scope of quitline services and the evidence for each. This paper attempts to fill that gap by providing an overview of current quitline practice in the U.S., a review of the scientific evidence for each category of service, and a discussion of major considerations related to implementation and evaluation of the service. Information on current quitline practice comes mainly from the North American Quitline Consortium (NAQC) Fiscal Year (FY) 2015 Survey, which was fielded in the U.S. only, due to Canadian funding constraints.

### **Who Should Use This Paper**

This NAQC issue paper is for all consortium members and stakeholders who want to expand their knowledge of quitline services, especially:

- Purchasers—public and private officials who fund quitline services and who play critical roles in determining what services are developed and offered
- Service providers—professionals who operate quitlines and who develop and implement new quitline services
- Researchers and other professionals who evaluate and report on quitlines
- Health care system leaders who are considering establishing a closer connection with quitlines

## **How the Paper is Organized**

Table 1, below, provides a synopsis of much of the content of the paper, including the extent to which various quitline services have been adopted, key findings from the literature, a characterization of the level of evidence for each service, and recommendations for the field.

The main body of the paper, entitled *Quitline Practice and Evidence Base*, is organized to allow the reader to become familiar with one service at a time. It has nine sections, one for each service category, grouped according to their underlying function or technology:

- Enrollment services, including intake and self-help materials
- Telephone-based services, including telephone counseling, IVR, text messaging, and mobile apps
- Web-based services
- Medications
- Referral

Within each category, there is a detailed discussion of the service, including:

- Definition of terms
- How widespread the service is among U.S. quitlines
- How it is used or implemented, with other potential uses if any
- Why quitlines offer the service
- Review of the evidence, with key findings in **bold**
- Guidance on evaluation of the service
- Considerations for purchasers
- Level of evidence and recommendations for the field, in *italics*

Following the discussion of individual quitline services is a series of short discussions on topics that cut across multiple services. The paper ends with a list of proposed topics for future quitline research and development.

## **A Word About Evidence**

In reviewing the evidence for each quitline service, this paper focuses on peer reviewed studies with the strongest experimental designs: randomized, controlled trials reporting quit outcomes at 6 months or longer. These are the studies from which conclusions can be drawn about the efficacy of quitline services. The paper relies in large part on meta-analytic reviews of these trials, for those service categories in which recent, high-quality reviews are available. By aggregating the results from multiple similar trials, reviews produce estimates of effectiveness that are often more reliable than those of individual studies. However, the paper also considers individual studies, some of which were included in the cited reviews and others that were published later, through September 2016 when this paper went to press. For each category of quitline service, the paper attempts to determine whether the preponderance of evidence from these trials supports a finding that the service is effective at helping tobacco users quit long-term.

Results in this paper are expressed as risk ratios rather than as quit rates, consistent with the methodology used in the meta-analytic reviews that the paper cites. Quit rates may vary widely across studies even within a service category, due to differences in the populations served,

differences in intervention design, and measurement differences. For that reason meta-analytic reviews generally express the difference in outcomes between the control and intervention conditions in terms of relative probability, which is what a risk ratio conveys. A risk ratio is an estimate of the probability of a particular event—in this case quitting tobacco—occurring in an intervention group relative to a control group. That is, if the odds or “risk” of success for control group participants are arbitrarily set at 1.0, a risk ratio indicates the relative odds of success for intervention group participants. For example, a risk ratio of 1.4 indicates that the intervention may increase the probability of success by 40%, relative to the control condition. Risk ratios in this paper are expressed as estimates within a 95% confidence interval, meaning that there is a 95% chance that the true figure falls within that range. If the interval does not overlap with 1.0, results of the intervention are considered to be significantly different from those of the control. The higher the risk ratio and the farther from 1.0 the bottom of the confidence interval is, the stronger the result. This is how the cited meta-analytic reviews report on the effectiveness of the services discussed in this and the same methodology is used throughout this paper.

Quitline services whose efficacy has been demonstrated in this way are identified as **research-validated best practices**. Those that have not, but that have a compelling rationale from widespread practice, are identified as **field-tested best practices**. Those that have one or more isolated examples of success in practice are identified as **promising practices**. Where strong examples are lacking both in the literature and in quitline practice, the paper indicates that there is so far **insufficient evidence to recommend the practice**.

**Table 1. Quitline Services: Adoption, Findings, Practice Level, and Recommendations**

Service and Extent of Adoption	Findings	Practice Level	Recommendations
<p><u>Intake</u> 100% of quitlines have implemented this practice.</p>	<p>1. There is no evidence that intake in itself helps tobacco users quit.</p>	<p>Universally adopted by quitlines as a practical necessity, intake is a field-tested best practice.</p>	<ul style="list-style-type: none"> <li>• <i>Employ cost-efficient means to register new participants, while ensuring data accuracy and user satisfaction with the process.</i></li> <li>• <i>To the extent possible, reduce the length and burden of intake by eliminating unnecessary questions and streamlining eligibility criteria.</i></li> </ul>
<p><u>Self-help materials</u> 96% of quitlines offer them.</p>	<p>1. Printed self-help materials in themselves can improve quit outcomes, though the effect just barely reaches statistical significance. 2. Self-help materials confer no measurable benefit as an adjunct to personal contact or NRT. 3. Tailored self-help materials can improve quit outcomes, but the effect may be due to personal contact in which data used to tailor the materials are gathered, as opposed to the materials themselves. 4. There is little evidence that providing self-help materials to quitline participants improves quit outcomes.</p>	<p>By the standard of widespread adoption, sending printed self-help materials is a field-tested best practice.</p>	<ul style="list-style-type: none"> <li>• <i>If sending printed self-help materials to participants produces meaningful program benefits short of improved outcomes, provide concise, professionally produced materials that are culturally and linguistically appropriate and that meet health literacy standards.</i></li> <li>• <i>Consider replacing printed materials with web-based or other technological interventions designed specifically for those media, with input from e-health and health literacy experts and from members of the target audience.</i></li> <li>• <i>To the extent possible, reserve program funds for other quitline services that have stronger evidence.</i></li> </ul>
<p><u>Telephone counseling</u> 100% of quitlines offer it.</p>	<p>1. Proactive, multisession telephone counseling is effective for smokers who call quitlines, the population which represents the largest category of quitline users. 2. Telephone counseling is also effective for smokers who do not call quitlines themselves, such as patients referred by a health care provider. 3. Telephone counseling is efficacious</p>	<p>Providing telephone counseling for tobacco cessation is a research-validated best practice.</p>	<ul style="list-style-type: none"> <li>• <i>Offer multisession, proactive telephone counseling as a standard quitline service, as it has the strongest evidence of any common quitline practice.</i></li> <li>• <i>If reverting to a single-call protocol becomes necessary during times of heavy demand, supplement the counseling with another evidence-based service such as free NRT.</i></li> <li>• <i>Exercise caution when comparing the quit rates of two or more quitlines, as results may</i></li> </ul>

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Service and Extent of Adoption	Findings	Practice Level	Recommendations
	<p>either by itself or as an adjunct to other treatments such as face-to-face counseling or NRT.</p> <p>4. Low-intensity telephone counseling does not have a measurable impact on quit outcomes; unless proven otherwise, a single call protocol—in the absence of other evidence-based treatments such as NRT—should be assumed to produce no significant effect on outcomes.</p>		<p><i>only be comparable if the populations treated, types of services provided, quality assurance procedures, and evaluation methods are similar.</i></p>
<p><u>Interactive Voice Response (IVR)</u> 87% of quitlines use it to triage calls.</p>	<p>1. IVR may not be effective as an adjunct to other high-intensity treatments.</p> <p>2. IVR can increase re-engagement by quitline participants.</p> <p>3. IVR can be an effective tool for recruiting smokers identified in the EHR.</p> <p>4. The efficacy of IVR may depend on how well it encourages participants to access other evidence-based treatments.</p>	<p>Use of IVR in connection with other evidence-based quitline services is a promising practice.</p>	<ul style="list-style-type: none"> <li>• <i>Consider uses of IVR beyond the basic triaging of incoming calls, such as asking intake and evaluation questions, recruiting new participants, re-engaging previous participants, promoting or supplementing the use of other quitline services, or helping tobacco users quit.</i></li> <li>• <i>Carefully evaluate any innovative use of IVR for its effects on program costs, use of other services, and participant satisfaction, and disseminate the findings.</i></li> </ul>



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Service and Extent of Adoption	Findings	Practice Level	Recommendations
<p><u>Text messaging</u> 62% of quitlines offer it, including:</p> <ul style="list-style-type: none"> <li>• 11% that offer one-way messages</li> <li>• 32% an interactive program</li> <li>• 19% both</li> </ul>	<ol style="list-style-type: none"> <li>1. Text messaging programs can be effective with smokers recruited online, through traditional advertising, or in health care settings.</li> <li>2. Text messaging can be effective either by itself or as an adjunct to in-person counseling.</li> <li>3. It is unknown whether text messaging is effective with quitline users, or in combination with other quitline services.</li> </ol>	<p>Offering text messaging programs to quitline participants is a promising practice.</p>	<ul style="list-style-type: none"> <li>• <i>If a text messaging program is offered, ensure that it is closely based on interventions proven effective. Such interventions generally feature content scheduled around a quit date, frequent messages, extended duration, and basic interactivity and tailoring.</i></li> <li>• <i>Design and promote the text messaging program as a stand-alone service to attract tobacco users who may be less inclined to use traditional quitline services such as telephone counseling. For participants who are willing to use other quitline services, provide links from the text messaging program to telephone counseling and NRT.</i></li> </ul>
<p><u>Mobile apps</u> Extent of adoption unclear; the two largest service providers offer them</p>	<ol style="list-style-type: none"> <li>1. There is no evidence to date that mobile apps help tobacco users quit.</li> </ol>	<p>There is insufficient evidence of efficacy to recommend that quitlines offer mobile apps.</p>	<ul style="list-style-type: none"> <li>• <i>Monitor the scientific literature for emerging evidence of the efficacy of mobile apps for tobacco cessation.</i></li> <li>• <i>If offering a mobile app, take steps to ensure that it adheres to the USPHS clinical practice guideline for tobacco dependence treatment, makes sophisticated use of smartphone technology, has features important to providers and smokers, and is highly rated by users.</i></li> </ul>
<p><u>Web-based services</u></p> <ul style="list-style-type: none"> <li>• 98% offer websites with basic info</li> <li>• 96% self-help</li> <li>• 81% chat rooms</li> <li>• 77% email</li> <li>• 64% online counseling</li> </ul>	<ol style="list-style-type: none"> <li>1. Web interventions may be effective for adult smokers and young adult smokers, but it is unknown if they are effective with adolescents.</li> <li>2. Web interventions are probably not more effective than counseling.</li> <li>3. Web interventions may not be effective as an adjunct to counseling.</li> </ol>	<p>Offering a web-based intervention that is closely based on the evidence from successful trials is a promising practice.</p>	<ul style="list-style-type: none"> <li>• <i>If web-based services are offered, ensure that they are closely based on interventions proven effective in randomized, controlled trials. In general, such interventions are multimodal, intensive with respect to the frequency of messages, interactive, and tailored.</i></li> <li>• <i>Continue to monitor the scientific literature for emerging evidence of the efficacy of web-based interventions for tobacco cessation.</i></li> </ul>

Service and Extent of Adoption	Findings	Practice Level	Recommendations
<p><b>Medications</b></p> <ul style="list-style-type: none"> <li>• 96% provide nicotine patches</li> <li>• 81% nicotine gum</li> <li>• 60% nicotine lozenges</li> <li>• 15% varenicline</li> <li>• 13% bupropion</li> <li>• 8% nicotine inhalers</li> <li>• 8% nicotine nasal spray</li> </ul>	<ol style="list-style-type: none"> <li>1. NRT, combination NRT, bupropion, nortriptyline, varenicline, and cytisine are all effective.</li> <li>2. No form of NRT is more effective than another, except that sprays and inhalers are slightly more effective than gum.</li> <li>3. Combination NRT is more effective than single formulation NRT, and nearly as effective as varenicline.</li> <li>4. Neither bupropion nor nortriptyline is effective as an adjunct to NRT.</li> <li>5. Varenicline is more effective than either single formulation NRT or bupropion.</li> <li>6. Despite earlier concerns about varenicline and bupropion possibly triggering adverse neuropsychiatric events, they have been proven to be safe, including for individuals with psychiatric disorders.</li> <li>7. Medication in combination with counseling significantly improves outcomes, relative to a control of usual care or minimal intervention.</li> <li>8. Behavioral support significantly improves long-term rates of abstinence over medication alone.</li> <li>9. The effect of telephone counseling is not subsumed by the effect of medication.</li> <li>10. NRT is effective as an adjunct to telephone counseling, and combination NRT is more effective in this context than single formulation NRT, but the optimal duration of NRT provision for quitline participants is unknown.</li> </ol>	<p>All 7 FDA-approved medications, and nortriptyline and cytisine, are research-validated treatments, as is combination NRT. Providing medication as an adjunct to telephone counseling is a research-validated best practice.</p>	<ul style="list-style-type: none"> <li>• Offer at least a 2-week starter kit of single-form OTC NRT to all quitline participants for whom NRT is indicated.</li> <li>• If the budget allows, offer combination NRT or varenicline instead of single-form NRT, as they have the strongest documented effect on quit outcomes.</li> <li>• If the budget allows, offer at least 6-8 weeks of medication, as longer courses may be more effective than shorter ones.</li> <li>• Offer telephone counseling to all participants provided medications, but do not require it.</li> </ul>

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<b>Service and Extent of Adoption</b>	<b>Findings</b>	<b>Practice Level</b>	<b>Recommendations</b>
<p><u>Referral</u></p> <ul style="list-style-type: none"> <li>• 100% accept fax referrals</li> <li>• 85% email or online referrals</li> <li>• 36% eReferrals</li> </ul>	<p>1. Interventions that incorporate referral to a quitline can significantly improve long-term quit outcomes.</p>	<p>Promoting referrals to the quitline is a research-validated best practice.</p>	<ul style="list-style-type: none"> <li>• <i>Offer a range of direct and indirect referral options to allow providers in various settings to refer tobacco users to the quitline, and make patient materials freely available to encourage provider participation.</i></li> <li>• <i>Develop the capacity to accept eReferrals from a range of certified EHR's and to return automated, patient-specific reports.</i></li> </ul>

## **QUITLINE PRACTICE AND EVIDENCE BASE**

### **Intake**

Intake is the process of enrolling or registering new participants for service. It usually takes the form of a telephone interview or online questionnaire. In contrast to mental health settings where it may encompass diagnosis and treatment planning, intake by quitlines is generally limited to basic data collection and an offer of service, with counseling or other services provided afterward (often immediately afterward).

All state quitlines conduct intake, in order to:

- Enroll new participants and enable future contact with them.
- Determine service preferences and eligibility, and triage accordingly.
- Gather information in the NAQC Minimal Data Set (MDS) for evaluation of reach (Campbell 2007).
- Obtain baseline data for outcomes evaluation.

There is no evidence for intake because it is never tested as an intervention in its own right. In quitline trials, intake precedes randomization due to the need to screen, consent, and register trial participants. It is possible that intake itself enhances outcomes, and it has been observed that quit rates tend to be higher among quitline callers who receive no counseling than among smokers in the general population. However, this observed difference may be due to self-selection; quitline callers may be more motivated to quit, on average, than smokers in the general population. In any case, **there is no evidence that intake in itself helps tobacco users quit.**

### *Evaluation of Intake*

Notwithstanding the lack of evidence of efficacy, quitlines understand that intake is an important part of the service delivery process, and take steps to make sure it helps and does not hinder their efforts to deliver evidence-based treatments. For this purpose, quitline should focus on process questions, such as:

- What percentage of incoming calls received during business hours are answered?
- How promptly are voice mail messages returned?
- What percentage of unique callers (as indicated by Caller ID) complete intake?
- At what rates do participants who complete intake opt for and receive evidence-based service?
- How long are intake interviews, on average?
- Is there evidence that the length of intake is a barrier to treatment? Are reasonable steps being taken to reduce this barrier?
- How satisfied are participants with the intake process? (For example, do they feel they received good customer service?)
- Does satisfaction vary by type of intake (e.g., telephone, IVR, web-based)?
- How soon after intake, on average, do participants receive evidence-based service?
- To what extent are intake data used in service delivery (e.g., to inform tailoring)?

Many quitlines have adopted a set of measures derived from the standard business practices of call centers. For a detailed treatment of this topic, see the NAQC issue paper, “Call Center

Metrics: Best Practices in Performance Measurement and Management to Maximize Quitline Efficiency and Quality” (NAQC 2010).

Intake is also the basis for measuring promotional reach, or the percentage of the total target population who take a “first step” of registering with a quitline. It is important for evaluating (1) the effectiveness of the selected promotional strategies at driving demand for service, (2) awareness of the quitline and buy-in among the target population, and (3) awareness and buy-in among health care providers and other professionals who are in a position to refer. By implementing the standardized MDS questions, quitlines ensure that their promotional reach results can be compared with those of other quitlines. However, it should be noted that this need can be met by asking the MDS questions of a random sample of participants, provided the sample is large enough to yield stable estimates for the variables of interest.

A full discussion of reach is beyond the scope of this paper. Readers who are interested in this topic should consult other NAQC issue papers:

- “Measuring Reach of Quitline Programs” (NAQC 2009)
- “Increasing Reach of Tobacco Cessation Quitlines: A Review of the Literature and Promising Practices” (NAQC 2009)
- “The Use of Quitlines Among Priority Populations in the U.S.: Lessons from the Scientific Evidence” (NAQC 2011)

### *Considerations for Purchasers*

The fact that intake is not itself an evidence-based service has important implications for those who fund quitline services. Most purchasers understandably want rich and accurate information about the people who use quitline services. Toward this end they may ask service providers to add questions to intake for a variety of reasons, for example, to gather fine-grained data about demographic sub-populations, to learn more about types of tobacco used, or to ensure that participants meet certain eligibility criteria before receiving a given service. But rich data come at a cost, especially if resources are limited: the greater the resources that are spent on intake, the fewer that are available for evidence-based services such as counseling and NRT.

This situation can become more problematic when there is a substantial increase in call volume. At such times quitlines may dedicate more staff time to handling the extra incoming calls, leaving less time for counseling. Obviously, this contradicts the primary purpose of quitline promotional campaigns, which is to increase use of evidence-based cessation treatments.

It is important to remember that intake is very time-consuming when conducted as a one-on-one interview. It can take 10 minutes or more per person, depending on the number of questions asked in addition to the MDS, and on any additional intake processes such as recording and verifying the participant’s insurance plan. This represents a real burden on staffing. Just as important, quitline service providers have observed that the longer the intake process, the more likely it is that participants will become frustrated and impatient, which could reduce both data quality and service utilization.

These considerations argue for quitlines to take steps to make intake less resource-intensive, such as:

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- Limiting the number of intake questions, especially in times of high call volume.
- Using sampling to collect MDS data on a representative sample of participants.
- Making intake available online.
- Streamlining eligibility requirements so there is less need to screen participants.
- Moving questions that are asked primarily for clinical reasons into the first counseling call.
- Testing Interactive Voice Response (IVR) for its suitability to handle all or part of a streamlined intake call (see the later section on IVR).
- Using dedicated, lesser trained staff for those parts of intake that are still conducted live.

### *Recommendations on Intake*

Despite the lack of evidence that intake improves quit outcomes, it is a practice universally adopted by quitlines as a practical necessity and can be considered a field-tested best practice.

Following are specific recommendations relating to intake:

- *Employ cost-efficient means to register new participants, while ensuring data accuracy and user satisfaction with the process.*
- *To the extent possible, reduce the length and burden of intake by eliminating unnecessary questions and streamlining eligibility criteria.*

### **Self-help Materials**

In quitline practice, self-help materials refer to psychoeducational literature sent to tobacco users or their friends and family. The literature is intended to guide them through the quitting process, either on their own or in conjunction with counseling or other services. Such materials have traditionally been mailed in printed hard copy format, but they may instead be sent electronically and/or rendered in audio or video formats.

Nearly all state quitlines (96% or 46/48 of those responding to the FY2015 NAQC survey) mail a packet of printed self-help materials to program participants (Rudie 2016). These are often called a “quit kit” or “quit pack.” Quitlines send these materials in order to:

- Encourage a quit attempt.
- Increase understanding of the steps of quitting, for the recipient’s immediate and future use.
- Provide a basic level of assistance to all participants, who may or may not receive other, more intensive services.
- Serve as an aid in counseling sessions.
- Create a favorable impression of the quitline as a helpful, free resource.

Packets are usually sent immediately after intake to all who are willing to receive them. Some quitlines send additional mailings later.

Packet contents vary among states, but most include a pre-printed quitting manual. The manual may have been developed in-house by the quitline service provider or purchased from a third party. It is usually provided in English or Spanish, or in some cases other languages. For example, the national Asian Smokers’ Quitline provides materials in Traditional Chinese, Simplified Chinese, Korean, and Vietnamese (Kuiper 2015). The manual may be tailored to

other characteristics besides language, such as age (e.g., specialized materials for teens or seniors), race/ethnicity (e.g., “Pathways to Freedom” for African American participants, Robinson 2003), or sexual orientation/gender identity (e.g., specialized materials for LGBT participants).

The packet may include other materials, such as a cover letter (either tailored or generic), a list of local cessation programs, fact sheets or brochures on particular topics, and non-printed items such as a “worry stone” or stir stick, to be used as a coping strategy. The packet may also include a voucher for medications or medications themselves, or these may be sent separately. Provision of medications is discussed in a later section.

*The Evidence for Self-help Materials*

As one of the earliest tobacco cessation intervention strategies, printed materials have been the subject of numerous published studies. A recent review by Hartmann-Boyce and colleagues considered 74 published trials of such materials (Hartmann-Boyce 2014).

**Table 2: Pooled Results from Trials of Self-help Materials**

<b>Studies</b>	<b>Intervention vs. Control Comparison</b>	<b>Risk Ratio &amp; 95% CI</b>
11 trials (N=13,241)	Printed self-help vs. no printed self-help, with no face-to-face contact in either group	1.19 (1.04-1.37)
5 trials (N=3,866)	Printed self-help vs. no printed self-help, with brief contact in both groups	1.17 (0.96-1.42)
11 trials (N=5,365)	Printed self-help vs. no printed self-help, with face-to-face advice in both groups	0.97 (0.80-1.18)
4 trials (N=2,291)	Printed self-help vs. no printed self-help, with NRT in both groups	1.05 (0.88-1.25)
31 trials (N=40,890)	Tailored materials vs. no service or non-tailored materials; intervention group may have received more personal contact than the control group	1.28 (1.18-1.37)
10 trials (N=11,024)	Tailored materials vs. no service or non-tailored materials; both groups received similar amounts of personal contact	1.06 (0.94-1.20)

*Source: Hartmann-Boyce 2014. CI=confidence interval.*

As shown in Table 2, the reviewers pooled 11 trials (N=13,241) in which an intervention of printed self-help was compared to a control condition of no service, and in which there was no face-to-face contact. They found that **printed self-help materials in themselves can improve quit outcomes, though the effect just barely reaches statistical significance.**

Two other analyses considered whether self-help materials were effective when there was also personal contact with participants. One included 5 trials (N=3,866) in which there was brief contact with all participants, and the other included 11 trials N=5,365) in which all participants received face-to-face advice. Neither found a significant effect. These findings suggest that **printed self-help materials confer no measurable benefit in addition to that of personal contact.**

Likewise, the reviewers looked at 4 trials (N=2,291) that studied NRT with and without self-help materials and found that **printed materials confer no measurable benefit in addition to that of NRT.**

Hartmann-Boyce and colleagues also examined the evidence for tailored materials. They pooled 31 trials (N=40,890) that compared tailored materials to either no service or non-tailored materials. “Tailored” in this context means making use of participant characteristics to provide an individualized intervention, or providing individual written feedback. The reviewers note that most of these trials used more than one mailing, and many involved personal contact in the intervention group in order to gather the information needed to tailor the materials, which may at least partly explain the difference in outcomes. They found a significant effect with this subgroup of studies, but a separate analysis with a different subgroup of 10 trials (N=11,024) in which the control and intervention groups received the same number of contacts found no effect. These findings suggest that **tailored self-help materials can improve quit outcomes, but the effect may be due to personal contact in which data used to tailor the materials are gathered, as opposed to the materials themselves.**

Most of the trials considered by Hartmann-Boyce and colleagues were not conducted in quitline settings. Focusing on just those trials that were conducted in a quitline setting and that provided telephone counseling to the intervention and control groups at similar rates, while varying only the type or intensity of self-help materials, yields discouraging results.

In two such studies (Davis 1992, Orleans 1998), quitline callers were given telephone counseling before being sent materials that were either tailored or not. Neither study found a significant effect.

One study (Borland 2003) recruited smokers who called an Australian quitline seeking written materials and not counseling, and compared a standard packet of materials to the standard packet plus three additional tailored letters. It found no effect from the added mailings. A later study by the same group (Borland 2004) was similar except that some participants in both groups received brief reactive counseling before enrollment. The later study did find an effect, but because the intervention group received telephone assessments which the control group did not receive, it is unclear if the effect was due to the added materials or to the telephone contact.

One study (Smith 2004) recruited quitline callers into a 2x2 factorial study comparing two levels of materials (a 44-page booklet versus a pamphlet) and two levels of counseling. There was no difference in outcomes between the two levels of materials.

One study (Strecher 2005) recruited callers to the NCI Cancer Information Service who were interested in quitting and compared an untailored single booklet to 3 conditions of multiple tailored materials. Another study (Sutton 2007) recruited callers to the U.K. quitline and compared two packets of information, one with a standard letter and the other with a 3-page tailored letter. In both of these studies, all participants received counseling. Neither study had a significant effect.



These quitline-specific findings indicate **there is little evidence that providing self-help materials to quitline participants improves quit outcomes.**

**Table 3. Summary of Findings on Self-help Materials**

1. Printed self-help materials in themselves can improve quit outcomes, though the effect just barely reaches statistical significance.
2. Self-help materials confer no measurable benefit as an adjunct to personal contact or NRT.
3. Tailored self-help materials can improve quit outcomes, but the effect may be due to personal contact in which data used to tailor the materials are gathered, as opposed to the materials themselves.
4. There is little evidence that providing self-help materials to quitline participants improves quit outcomes.

### *Evaluation of Self-help Materials*

In the absence of clear evidence that providing self-help materials to quitline participants improves outcomes, if they are provided evaluation should focus on developmental or process questions, such as:

- How do the materials rate against best practice standards for reading level and health literacy?
- Are the materials culturally and linguistically appropriate for the target audience?
- What features of printed materials are perceived by the target audience as most attractive and/or helpful (e.g., testimonials from relatable individuals, tips on what to do instead of smoking, workbook format)?
- Short of improved outcomes, do the materials produce other meaningful benefits? For example:
  - Better understanding of the quitting process
  - Greater likelihood of making a quit attempt
  - Greater likelihood that enrolled participants will use counseling or NRT
  - Assurance that all enrolled participants receive at least a basic level of service
- Do alternate protocols for mailed materials (e.g., repeated mailings throughout the year after a participant first engages with the quitline) produce desirable effects such as re-engagement with the quitline, use of other quitline services, or additional quit attempts?
- Are participants as satisfied or more so with self-help materials in other formats (e.g., video, e-book, interactive web material)?
- How do mailed materials compare with other communication strategies such as emailing, texting, IVR calls, or personal calls, with respect to engagement with the quitline?

### *Considerations for Purchasers*

If a decision is made to provide printed self-help materials, cost is a key consideration. The resources required to produce, warehouse, and disseminate materials are substantial. Factors that increase cost may be acceptable if they make the materials more attractive or useful to the target audience, such as professional design and production, focus group testing, full color printing, and first class mail delivery. However, other factors that increase cost may actually weaken the overall product, such as unnecessarily long text and a packet cluttered with nonessential items. These should be avoided.

Other ways to reduce the cost of self-help materials include:

- Using address validation software to reduce mis-deliveries.
- Using a fulfillment center that follows best practices for timely and efficient fulfillment.
- Posting non-essential materials (e.g., fact sheets on particular topics) online and directing participants where to find them.
- Providing materials only to participants who do not opt for counseling or who do not receive it immediately after intake.
- Sending materials electronically to participants who are able to receive them in that format.

The easiest way to start providing materials electronically is to convert existing print materials into PDF files and email them. However, participants may not consider such files to be truly useful. A better approach is to design new electronic content specifically for the selected medium, with input from e-health and health literacy experts and from members of the target audience. Ideally, such an effort would be subsumed under the quitline's efforts to develop web-based interventions. See the section on web-based interventions later in this paper.

### *Recommendations on Self-help Materials*

Despite the lack of evidence that sending printed self-help materials to participants improves outcomes, quitlines have almost universally adopted the practice. This may be due to historical precedent or because it produces other program benefits, such as ensuring that participants who do not use counseling or NRT receive at least a basic level of service. By the standard of widespread adoption, sending printed self-help materials appears, for now at least, to be a field-tested best practice. This may change if new evidence demonstrates the efficacy of these materials for quitline participants, or if, as seems more likely, quitlines replace printed materials with web-based or other technological interventions.

Following are specific recommendations relating to self-help materials:

- *If sending printed self-help materials to participants produces meaningful program benefits short of improved outcomes, provide concise, professionally produced materials that are culturally and linguistically appropriate and that meet health literacy standards.*
- *Consider replacing printed materials with web-based or other technological interventions designed specifically for those media, with input from e-health and health literacy experts and from members of the target audience.*
- *To the extent possible, reserve program funds for other quitline services that have stronger evidence.*

## **Telephone Counseling**

Telephone counseling for tobacco cessation refers to live, one-on-one support delivered over the phone to help tobacco users quit. It is designed to provide support and encouragement for behavior change by helping tobacco users prepare for a quit attempt and avoid relapse. It is often referred to as “coaching,” and telephone counselors may be referred to as “quit coaches.”

Since the establishment in 1992 of the first statewide quitline in the U.S., telephone counseling has been the hallmark service of American quitlines (Anderson 2007). It has been, and continues

to be for most quitlines, their most resource-intensive service. In general, it is also their best-evaluated service, with respect to both the scientific literature and real-world program evaluation.

All state quitlines responding to the FY2015 NAQC survey provide telephone counseling (Rudie 2016). All provide reactive counseling in at least some situations. Nearly all (94% or 45/48) provide proactive counseling. On a literal level, the terms reactive and proactive indicate “who called whom.” If the participant calls, it is reactive; if the quitline calls, it is proactive. More broadly, reactive counseling is provided whenever a participant reaches out for help, whereas proactive counseling is provided on a pre-determined schedule and initiated by a counselor. In practice, most quitline participants receive counseling that has both reactive and proactive elements. For example, in the most common scenario—a smoker calls the quitline for help to quit and gets immediate assistance—the first session is reactive and all subsequent sessions are proactive.

The fact that quitlines provide most counseling sessions proactively is by design. Proactivity communicates caring and support, while creating accountability by suggesting an expectation of follow-through on the participant’s part. It also allows sessions to be scheduled according to the probability of relapse, more frequently in the beginning when the probability of relapse is high and less frequently later when the probability of relapse is lower (Zhu 1995). On a more basic level, proactivity helps to increase the number of sessions completed, because quitline staff are less ambivalent than participants about the quitting and counseling process.

Quitlines offer telephone counseling for a number of reasons:

- To assist those who feel they cannot quit on their own.
- To increase the odds of participants making a quit attempt, and reduce the odds of relapse.
- To complement the efforts of health care providers who ask their patients if they use tobacco and advise those who do to quit, but who lack the time or training to provide behavioral support for quitting.
- To balance other parts of tobacco control programs which may be perceived as judgmental or anti-smoker, by offering positive, nonjudgmental support to become tobacco-free.
- To reduce disparities in tobacco use or access to evidence-based treatment, such as those experienced by racial and ethnic minority communities, those of low socioeconomic status (especially Medicaid and the uninsured), persons with behavioral health conditions, and other priority populations, such as lesbian, gay, bisexual, and transgender (LGBT) individuals and military personnel.

### *The Evidence for Telephone Counseling*

As an intervention strategy that has been in use for over a quarter century, telephone counseling for tobacco cessation has been the focus of numerous studies and several meta-analytic reviews. One such review by Stead and colleagues has been updated repeatedly, most recently in 2013 when the authors considered 77 published trials of telephone counseling (Stead 2013).

**Table 4: Pooled Results for Trials of Telephone Counseling**

<b>Studies</b>	<b>Intervention vs. Control Comparison</b>	<b>Risk Ratio (95% CI)</b>
12 trials (N=30,182)	Multisession telephone counseling vs. self-help, for smokers who call a quitline	1.38 (1.28-1.49)
51 trials (N=30,246)	Multisession telephone counseling vs. self-help, for smokers who do not call a quitline (i.e., who are recruited in other ways)	1.27 (1.20-1.36)
30 trials (N=19,134)	Telephone counseling vs. self-help or other minimal intervention	1.34 (1.22-1.46)
11 trials (N=3,520)	Telephone counseling vs. a control that receives a brief intervention or face-to-face counseling	1.41 (1.20-1.66)
11 trials (N=7,592)	NRT plus telephone counseling vs. NRT alone	1.14 (1.03-1.27)
9 trials (N=6,274)	Low-intensity telephone counseling (1-2 sessions) vs. self-help or minimal intervention	1.07 (0.91-1.26)
34 trials (N=19,736)	Medium-intensity telephone counseling (3-6 sessions) vs. self-help or minimal intervention	1.32 (1.23-1.42)
9 trials (N=4,480)	High-intensity telephone counseling (7+ sessions) vs. self-help or minimal intervention	1.29 (1.11-1.50)

*Source: Stead 2013. CI=confidence interval.*

As shown in Table 4, the reviewers pooled 12 trials (N=30,182) testing quitline counseling with smokers who initiated service themselves by calling a quitline. They found that **proactive, multisession telephone counseling significantly improves quit outcomes for smokers who call quitlines.**

A strength of meta-analyses is that by pooling results from multiple trials they increase the sample size, thereby increasing the ability to detect an effect. Yet 7 of the 12 trials in this analysis each detected an effect independently. Zhu and colleagues conducted three of these trials with adult smokers in California, including two with English- and Spanish-speakers (Zhu 1996 and Zhu 2002) and one with Asian language-speakers (Zhu 2012). Rabinus and colleagues conducted two others with callers to the American Cancer Society's National Cancer Information Center (Rabinus 2004 and Rabinus 2007). Borland and colleagues conducted a trial in the Australian state of Victoria (Borland 2001), and Hollis and colleagues conducted one in Oregon (Hollis 2007). Three smaller trials that did not detect a significant effect nevertheless had results that favored the intervention (Borland 2003, Smith 2004, and Sims 2013). Only two of the 12 trials had results that did not favor the intervention (Gilbert 2006 and Ferguson 2012).

Stead and colleagues pooled 51 other trials (N=30,246) that tested telephone counseling with participants who were recruited into the service by other means. They found that **telephone counseling also significantly improves quit outcomes for smokers who do not call quitlines themselves.**

The reviewers conducted subgroup analyses with the same 51 studies. One included 30 trials (N=19,134) in which the control group received only self-help or other minimal intervention. Another included 11 trials (N=3,520) in which the control group received a brief intervention or face-to-face counseling. Telephone counseling had significant effects in both. A third sub-

analysis with 11 trials (N=7,592) that tested telephone counseling as an adjunct to NRT found a modest but significant effect. These findings indicate that **telephone counseling is efficacious either by itself or as an adjunct to other treatments such as face-to-face counseling or NRT.**

Stead and colleagues conducted another sub-analysis with the 51 trials mentioned above, regrouping them by the intended number of sessions per protocol. With the caveat that the number of sessions received was often less than the number intended, there were 9 trials (N=6,274) in the low intensity group (1-2 sessions), 34 trials (N=19,736) in the medium intensity group (3-6 sessions), and 9 trials (N=4,480) in the high intensity group (7 or more sessions). The reviewers found no effect in the low intensity group, but significant effects in the medium and high intensity groups. These results suggest that **low-intensity telephone counseling does not have a measurable impact on quit outcomes.**

The reviewers note that individual trials have demonstrated a significant effect from a single-call protocol (Zhu 1996) or a two-call protocol (Hollis 2007), but point out that the sessions provided in these trials were long: 50 minutes in Zhu and 30-40 minutes for the first session in Hollis, followed by a second, briefer call. Hollis also included tailored mailings. Therefore, these exceptions help prove the rule that telephone counseling must reach a certain threshold of intensity before it has a measurable impact on quit rates. Where that threshold lies likely varies by protocol, but few researchers have proven that telephone counseling works with just one call. For that reason, unless it has been proven otherwise, it should be assumed that **a single call protocol—in the absence of other evidence-based treatments such as NRT—produces no significant effect on quit outcomes.**

A few studies published after the 2013 review by Stead and colleagues provide further support for the efficacy of telephone counseling. One trial (Schuck 2014) recruited 512 Dutch smokers through their children's primary schools and randomly assigned them to receive either a self-help brochure or up to 7 proactive counseling sessions and supplementary materials. Both the counseling and the supplementary materials were tailored to smoking parents. The intervention significantly improved quit outcomes at 12 months. A second trial (Fu 2016) recruited socially disadvantaged members of a publically funded health plan in Minnesota (N=2,406) and randomly assigned them to receive either usual care or intensive outreach, which consisted of tailored mailings, proactive telephone counseling, and NRT. Participants in the intensive outreach condition had significantly greater prolonged abstinence at 12 months. A third trial (Cummins 2016) recruited pregnant smokers (N=1,173) who called the California quitline and randomly assigned them to receive either self-help materials or self-help plus up to 9 telephone counseling sessions that were tailored to pregnant smokers. The counseling significantly improved quit outcomes both at the end of pregnancy and at 6 months postpartum.

Based largely on studies in the Stead review, the Community Preventive Services Task Force recommends quitline counseling (Guide to Community Preventive Services 2014).

There is little evidence in the literature indicating which elements of telephone counseling are responsible for its effects, but some quitlines that have validated their protocols have also published papers describing the content of those protocols. For example, California has described its protocols for English and Spanish speaking adult smokers (Zhu 1996b), Asian language

speakers (Tedeschi 2013), and pregnant smokers (Cummins 2007). Likewise, there is little evidence indicating the extent to which counseling protocols should be tailored. Most validated counseling protocols are structured but allow for tailoring to individual characteristics at the discretion of the counselor.

**Table 5. Summary of Findings on Telephone Counseling**

1. Proactive, multisession telephone counseling is effective for smokers who call quitlines, the population which represents the largest category of quitline users.
2. Telephone counseling is also effective for smokers who do not call quitlines themselves, such as patients referred by a health care provider.
3. Telephone counseling is efficacious either by itself or as an adjunct to other treatments such as face-to-face counseling or NRT.
4. Low-intensity telephone counseling does not have a measurable impact on quit outcomes; unless proven otherwise, a single call protocol—in the absence of other evidence-based treatments such as NRT—should be assumed to produce no significant effect on outcomes.

*Evaluation of Telephone Counseling*

Nearly all quitlines evaluate outcomes from their counseling service on an ongoing or at least occasional basis. However, few distinguish between participants who received counseling only, medications only, or both. Questions of relative effectiveness among services are usually better left to studies with randomized designs to reduce the chance of bias from self-selection or other factors.

Some quitlines use counseling protocols that were previously validated in randomized, controlled trials and can therefore compare the quit rates obtained through ongoing evaluation to their original trial results. While the two sets of results are not exactly comparable, if the populations treated, services provided, quality assurance procedures, and evaluation methods are similar, a similarity in results may be highly suggestive of ongoing program effectiveness.

Some quitlines use counseling protocols that have not been validated and should be especially careful when interpreting their evaluation results, as differences in measured quit rates relative to other quitlines may be due in part to population differences or differences in how the evaluation was conducted, rather than to differences in the counseling. They could also be due to differences in medications or other services provided.

As a way of illustrating the need for caution when comparing quit rates, here are two examples of quitlines that would be expected to obtain higher quit rates than other quitlines even if there was no real difference in the effectiveness of the treatments they provide:

- A quitline that is less successful at reaching patients referred from health care, has a lower live answer rate on its incoming phone lines, and is less successful in persuading prospective participants to enroll in evidence-based services may have an evaluation sample that was more motivated to quit, on average, than those of other quitlines.
- A quitline that relies on a convenience sample of participants rather than on an appropriately selected random sample, or that makes fewer attempts and reaches a smaller percentage of selected participants, may weigh too heavily the responses of those who are most enthusiastic about being evaluated.

To help guide evaluation of quitline outcomes, NAQC developed an evaluation standard in 2009 and updated it in 2015. The updated standard calls for calculation of two quit rates: one based on abstinence from conventional tobacco use only, and another based on abstinence from both conventional tobacco and electronic nicotine delivery systems (ENDS), commonly referred to as e-cigarettes. The recommended measure is 30-day point prevalence abstinence at 7 months post-intake, using a random sample sufficient to produce at least 400 complete responses with a 50% or better response rate. Included in the calculation are participants who received any treatment that has a strong evidence base, currently limited to telephone counseling and medications, though subjects may also have received other services. For a detailed description of the standard, please see the NAQC issue paper, “Calculating Quit Rates, 2015 Update” (NAQC 2015).

Evaluation of telephone counseling should also address process questions to ensure that the service is delivered as planned, such as:

- Of the participants who opt for counseling, what percentage receives it?
- How much counseling do participants receive, with respect to the number of sessions and total number of minutes? How long are sessions on average?
- What percentage of participants sets a quit date?
- What percentage of participants makes a serious quit attempt (i.e., an attempt lasting a day or more)?
- How does use of counseling relate to use of other services? For example:
  - Do participants who receive medications (or who receive refills) complete more counseling sessions on average than those who do not?
  - Do counseling participants use medications for a longer time?
- How satisfied are participants with counseling?
- Does satisfaction vary by timeliness of service, number of sessions received, use of other services, success in quitting, or other measures?

### *Considerations for Purchasers*

Purchasers of quitline services may have questions related to telephone counseling when drafting requests for proposals (RFP).

One such question is, should service providers bidding on contracts be required to offer a research-validated counseling protocol? A research-validated protocol is one that has been tested in a clinical trial and found to produce a significantly higher quit rate, relative to a randomly assigned control condition such as self-help materials. Ideally, the trial results are subjected to scrutiny by fellow scientists who did not participate in the research and are published in a peer-reviewed journal. A protocol that has scientifically proven its efficacy has a good chance (but is not assured) of being effective in real world application.

Alternatively, purchasers may require bidders to offer an evidence-based counseling protocol. An evidence-based protocol may or may not have been research-validated itself, but is at least based on the best available evidence, i.e., evidence that was generated by those protocols that did go through the research validation process. In actual usage, however, the term “evidence-based” denotes a range of interventions that may be closely or only loosely based on the evidence.

Naturally, the more closely a protocol is based on the best available evidence, the more likely it is to have an effect similar to those described in published studies.

Quitline purchasers may require bidders to offer a research-validated protocol, rather than simply an evidence-based protocol, but this may disqualify some otherwise well-qualified service providers. A better approach is to require an evidence-based protocol and to put the onus on bidders to explain exactly how their protocol reflects the best available evidence, and how the service will be evaluated to ensure fidelity to the evidence.

Another question that purchasers may have is whether bidders should be required to follow a case management model. Case management, in which the same counselor handles every session with a given participant—barring absence due to sickness or vacation—is the norm in most counseling settings. Yet many quitlines use a shared caseload model, in which progress notes are stored in a database that all counselors can access so that any available counselor may counsel a given participant. Quitline partners and purchasers may prefer the case management model because it is more familiar, but is it really superior to the shared caseload model?

The published literature on proactive telephone counseling provides evidence supporting both models. For example, Zhu 1996 used the case management model and Borland 2001 used the shared caseload model (Zhu 1996a, Borland 2001). Both achieved a significant effect, so it is clear that either model may be effective. Unfortunately, there are no published trials directly comparing these two ways of providing follow-up support, so it is not known if one is more effective than the other.

The argument for the case management model is that having the same counselor contact the participant each time is therapeutically preferable as it may engender stronger rapport and accountability. However, the shared caseload model may also be therapeutic if it conveys to participants that they have a whole team supporting them.

The shared caseload model also has some practical advantages, as it:

- Offers more flexibility for scheduling appointments.
- Eliminates the need to reassign cases when a counselor is sick or on vacation.
- Is easier to implement with an autodialer system, which automatically queues up outbound calls and distributes them to available counselors.
- Helps to equalize the work load among counselors.
- May result in better adherence to the call schedule and a greater number of sessions completed.

Given that both models are effective and each has advantages, instead of requiring bidders to offer one or the other model, a better approach is to ask bidders to explain which model they use and why.

### *Recommendations for Telephone Counseling*

Based on the available evidence, providing telephone counseling for tobacco cessation is a research-validated best practice.



Following are specific recommendations relating to telephone counseling:

- *Offer multisession, proactive telephone counseling as a standard quitline service, as it has the strongest evidence of any common quitline practice.*
- *If reverting to a single-call protocol becomes necessary during times of heavy demand, supplement the counseling with another evidence-based service such as free NRT.*
- *Exercise caution when comparing the quit rates of two or more quitlines, as results may only be comparable if the populations treated, types of services provided, quality assurance procedures, and evaluation methods are similar.*

### **Interactive Voice Response (IVR)**

Interactive Voice Response or IVR is not a service per se, but rather a technology that can enable or facilitate a range of processes and services. It is a feature of some telephony systems that allows a computer to interact with users in a semi-conversational manner. It differs from an auto-attendant, which allows users to make menu selections or answer simple questions (yes/no or multiple choice) via their key pads, in that IVR also recognizes speech. IVR is therefore a more powerful tool for data collection. It may also be experienced by users as more convenient and closer to a real conversation than auto-attendants, and therefore as representing better customer service than auto-attendant systems. Finally, whereas auto-attendants are typically only used for inbound calls, IVR may also be used in proactive, outbound applications.

According to the FY2015 NAQC survey, 87% (41/47) of U.S. quitlines use IVR to triage incoming calls (Rudie 2016). Triage calls may be as simple as asking callers to specify their preferred language before transferring them to a live agent.

Only two quitlines reported using IVR in other ways, but there are many potential uses:

- Replace all or parts of intake, i.e., beyond the basic triaging of calls. IVR could potentially be used to ask all MDS questions and others in the intake protocol. (As a half-way step, the system could let callers choose either the IVR or a live agent.)
- Recruit new participants. For example, a health system may review data in its electronic health records (EHR) and use IVR to consent patients to be transferred to the quitline for treatment. Or the quitline itself may acquire lists of likely smokers and use IVR to screen them for interest in receiving service.
- Send upcoming call reminders.
- Supplement telephone counseling (e.g., for relapse prevention).
- Re-engage previous participants.
- Use as a bridge from other automated services (e.g., text messaging programs and phone apps) to telephone counseling.
- Use for evaluation (e.g., to assess satisfaction immediately after a call).

IVR may also be used to provide recorded self-help messages. According to the FY2015 NAQC survey, 85% (41/48) of quitlines provide recorded messages (Rudie 2016). Recorded self-help messages may be made available as a reactive service (e.g., for after-hours callers), although for this use, as noted above, a basic auto-attendant may suffice.

IVR can also proactively deliver recorded messages at any time, to any audience in the quitline's database. For example, it can deliver messages as a supplement to telephone counseling or to a

text messaging program. Because of the interactivity component, the messages in IVR calls can be tailored according to input the users themselves provide. Recorded messages can also include an invitation to access other services as needed, for example to be transferred to a live counselor. It does not appear that any quitline is currently offering an intervention based primarily on IVR, but that is a future possibility, as some of the published research suggests.

#### *The Evidence for IVR-based Services*

There have been few studies on IVR-based interventions for tobacco cessation and no reviews. Here is what the published research so far has found:

Two studies used IVR to provide supplemental relapse prevention support. In one (McNaughton 2013), smokers who had been given a group counseling session, 12 weeks of varenicline, and 9 IVR calls and had quit smoking at 12 weeks were randomly assigned to receive either no further service or continued IVR in weeks 13-52. The sample was small (N=23) and there was no difference in outcomes. In the other (McDaniel 2015), participants who had quit for at least 24 hours (N=1,785) were randomly assigned to receive regular quitline service, quitline plus 10 IVR calls, or quitline plus 20 IVR calls. Quitline service included 5 counseling calls, medications, and web-based support. The IVR calls included relapse risk assessments and transfers back to counseling for those at risk. IVR assessments seemed to identify quitters at risk for relapse, but did not significantly improve outcomes. These studies suggest that **IVR may not be effective as an adjunct to high-intensity treatments**, although more research is needed to answer this question definitively.

Two studies used IVR to re-engage previous quitline participants. One (Carlini 2012) used IVR to call participants back and screen them for current tobacco use. Current smokers were then randomly assigned to receive either no further service or IVR messages to elicit and address their barriers to re-engagement. The messages significantly increased the percentage re-enrolling. In another study (Carlini 2015), individuals were randomly selected from a quitline registry to receive IVR calls, text messages, and a postcard inviting them to re-engage with the quitline. IVR calls allowed participants to transfer directly to the quitline. Compared to registry participants not randomly selected, the IVR group was significantly more likely to re-engage. Neither study was designed to test whether re-engagement improves quit outcomes, but they both clearly showed that **IVR can increase re-engagement by quitline participants**.

Other studies used IVR to reach out to smokers identified in health care settings. In one (Haas 2015), IVR was used to contact and consent low-SES patients identified as smokers in the electronic health record (EHR). Consenting patients were randomly assigned to receive either usual care or an intervention with telephone counseling, 6 weeks of NRT, and community referrals to address socio-contextual mediators of tobacco use, all of which was integrated into their normal health care via the EHR. Outcomes at 9 months were significantly higher in the intervention group than in the control. The study was not designed to show whether IVR itself improves outcomes, but it did show that **IVR can be an effective tool for recruiting smokers identified in the EHR**.

In another study (Rigotti 2014), patients who had received a tobacco dependence intervention in the hospital and wanted to quit smoking post-discharge received either standard information

about pharmacotherapy and counseling, or IVR calls plus their choice of cessation medication for 90 days. IVR calls were designed to promote cessation, help with medication management, and allow participants to access live counseling (not provided by a quitline). The IVR group used more counseling and pharmacotherapy, and their outcomes at 6 months were significantly higher than the control's. However, a later study by the same team using a comparable design but with telephone counseling provided by a quitline (Rigotti 2016) did not replicate these results. This may have been because the linkage from the IVR to the quitline did not support patient engagement as well as in the first study. The intervention successfully increased abstinence during the treatment period but did not improve quit outcomes at 6 months. The IVR component was well utilized in both trials, but neither was designed to evaluate the efficacy of IVR in itself. These studies suggest that IVR is a promising way to maintain contact with hospitalized smokers post-discharge, but that **the efficacy of IVR may depend on how well it encourages participants to access other evidence-based treatments.**

**Table 6. Summary of Findings on Interactive Voice Response (IVR)**

1. IVR may not be effective as an adjunct to other high-intensity treatments.
2. IVR can increase re-engagement by quitline participants.
3. IVR can be an effective tool for recruiting smokers identified in the EHR.
4. The efficacy of IVR may depend on how well it encourages participants to access other evidence-based treatments.

#### *Evaluation of IVR-based Services*

Since quitlines are not yet using IVR as an intervention in its own right, evaluation should focus on narrowly defined process questions based on how it is actually used, e.g., whether the programming to triage calls is correctly sorting and routing calls with an acceptably low percentage of abandoned calls.

But given the many potential uses of IVR, future evaluation could take many forms. For example, if quitlines experiment with using IVR as a substitute for all or part of the live intake interview, evaluation should address such questions as:

- What questions, if any, is it practical to ask via IVR?
- How does IVR compare to live agents with respect to data quality?
- What benefits are realized by using IVR (e.g., staff time savings, more timely service)?
- What are the tradeoffs (e.g., lower call completion rates, decreased satisfaction)?

Quitlines that develop tobacco cessation interventions in which IVR is a central component should carefully evaluate their interventions and publish the results, which would be very informative for the whole quitline field.

#### *Considerations for Purchasers*

With a dearth of evidence for the use of IVR systems in quitlines, there is little to guide purchasers' decision-making in this area. Rather than requiring the use of IVR in quitline RFPs, a better approach is to ask bidders to describe their experience with IVR and any plans to experiment with its use in the future to gather data, recruit or re-engage participants, promote or supplement the use of other quitline services, or help tobacco users quit. Bidders should also describe their plans to evaluate such uses and disseminate their findings.

### *Recommendations on IVR*

There has been little research to date on the use of IVR to help tobacco users quit, but what has been published suggests that IVR is at least a promising tool to engage or re-engage participants. In particular, IVR may be useful as a way to promote and increase the use of other quitline services such as telephone counseling and medications. Based on the available evidence, the use of IVR in connection with other evidence-based quitline services can be considered a promising practice.

Following are specific recommendations relating to IVR:

- *Consider uses of IVR beyond the basic triaging of incoming calls, such as asking intake and evaluation questions, recruiting new participants, re-engaging previous participants, promoting or supplementing the use of other quitline services, or helping tobacco users quit.*
- *Carefully evaluate any innovative use of IVR for its effects on program costs, use of other services, and participant satisfaction, and disseminate the findings.*

### **Text Messaging**

Text messages are brief electronic messages sent to mobile phones. They may follow either the Short Message Service (SMS) standard, which allows up to 160 characters of text, or the Multimedia Message Service (MMS) standard, which allows more than 160 characters of text, as well as images, video, and audio. In quitlines, a text messaging program is a tobacco cessation intervention comprised of multiple text messages delivered over an extended period.

Most U.S. quitlines include text messaging in their service offerings. About 62% of U.S. quitlines responding to the FY2015 NAQC survey use text messaging (Rudie 2016), including:

- 11% (5/47) that offer one-way text messages.
- 32% (15/47) that offer interactive text messages.
- 19% (9/47) that offer both.

A typical use of text messaging by quitlines is in a pre-programmed course of multiple communications intended to support the recipient through one or more quit attempts. In this use, participants may enroll on a website or by texting a shortcode, without ever having used other quitline services.

There are other potential uses for text messaging by quitlines:

- Support or supplement telephone counseling. For example:
  - Send upcoming call reminders or “sorry we missed you” messages.
  - Offer additional encouragement or advice for relapse prevention.
- Invite users to access additional counseling if they’re having difficulties.
- Recruit new participants via direct text marketing, in which the quitline or a third party sends promotional text messages to likely tobacco users.
- Use to promote other services (e.g., mobile app, website, telephone counseling).
- Re-engage previous quitline participants, either from the telephone counseling program or from the text messaging program itself.

*The Evidence for Text Messaging Programs*

Text messaging programs for tobacco cessation are the subject of a growing body of scientific literature, but the field is still new (dating from the early 2000’s), and the number of relevant trials is limited. With a few notable exceptions, most trials published to date have not found a significant long-term effect. A recent review considers 12 trials of what the authors, Whittaker and colleagues, refer to as “mobile phone interventions” (Whittaker 2016). All but one of the trials focuses on text messaging programs; the other focuses on an intervention in which participants were given a cell phone which they could use to receive telephone counseling. They are cited here as evidence for text messaging programs.

**Table 7: Pooled Results for Trials of Text Messaging Programs**

<b>Studies</b>	<b>Intervention vs. Control Comparison</b>	<b>Risk Ratio &amp; 95% CI</b>
12 trials (N=11,885)	Text messaging program vs. a less intensive control, ranging from no text messages to daily untailed messages	1.67 (1.46-1.90)
7 trials (N=9,887)	Text messaging vs. a less intensive control, with neither group receiving individualized counseling	1.69 (1.46-1.95)
5 trials (N=1,995)	Text messaging vs. a less intensive control, with both groups also receiving individualized counseling	1.54 (1.12-2.11)

*Source: Whittaker 2016. CI=confidence interval.*

As shown in Table 7, the reviewers pooled 12 trials (N=11,885) testing mobile phone-based interventions and found that quit rates at 6 months were significantly higher with the intervention than in the control, despite the fact that a minority of the trials found an effect themselves (Rodgers 2005, Free 2011, Abroms 2014, Naughton 2014).

In fact, two large trials of a program developed in New Zealand (Rodgers 2005) and modified for use in the U.K. (Free 2011) under the name “txt2stop” are responsible for most of the effect in the pooled results. The txt2stop program was the most intensive of all those tested, with respect to the number of text messages sent. Participants recruited online and through traditional advertising were randomly assigned to a control condition of short, biweekly text messages emphasizing the importance of study participation or to an intervention of more frequent, content-rich messages. These were sent 5 times a day for 5 weeks, then 3 times a week for 26 weeks. They were designed to boost motivation, provide information on the benefits of quitting and the consequences of continued smoking, teach behavior change techniques, increase understanding of how to quit and stay quit, encourage participants to identify and plan for challenges, explain the importance of avoiding tempting situations, encourage perseverance, provide positive feedback, and urge participants to reflect on their own success and on how others would approve of their success. The messages also promoted use of a quitline, NRT, and peer support. Participants received a core set of messages, supplemented by additional messages tailored to demographics and to concerns expressed at enrollment. The program was interactive insofar as participants could text keywords to obtain additional help, but they could not reset the program if they relapsed. The program was later adapted for the U.S. and marketed by Agile Health under the name “Kick Buts.”

Another successful trial tested the “text2quit” program, developed by George Washington University and Voxiva, Inc. (Abroms 2014). Participants recruited online were randomly assigned to a control of a link to a resource on [www.smokefree.gov](http://www.smokefree.gov), or to an intervention of frequent text messages. Messages were timed to the quit date, when they were most frequent at 5 per day. Frequency decreased to about 2 per day in the first week and then to about 1 per week three months into the program, when outgoing messages stopped but participants could still access additional help by texting keywords. Messages were tailored to the quit date, reasons for quitting, money saved, and use of medications. Participants could change their quit date at any time, resetting the program. The intervention also included infrequent emails (once a week or less) summarizing the text messages’ content and linking to a tailored website. The site and reactive help were available throughout the 6-month treatment period. Text2quit was later incorporated into the quitline service offerings of Alere Wellbeing (now Optum).

A fourth study tested the “iQuit in Practice” program (Naughton 2014), also called iQuit (not to be confused with a mobile app of the same name developed by NCI for adolescent smokers). The program is designed to be used with smokers recruited in clinical settings. Patients in the U.K. who completed a questionnaire during a clinical visit were randomly assigned either to usual care or to usual care plus iQuit. Participants received a 4-page advice report and a program of text messages, both tailored to answers on the questionnaire. Tailoring also took into account their quit status at 3 and 7 weeks. Participants received 0-2 messages per day for 90 days. Messages were designed to advise participants about quitting, address the consequences of smoking and expectations for quitting, offer encouragement, boost self-efficacy, maintain motivation, and help participants handle difficult situations without smoking. Participants could access additional help by texting keywords. Interestingly, the usual care condition was fairly intensive, including clinical counseling, measurement of expired-air carbon monoxide, a prescription for pharmacotherapy, and arranging for follow-up. The text messaging program had an effect over and above this intensive intervention.

These 4 trials were the only ones in the Whittaker review to find a long-term, significant effect. Among the remaining 8 that found no significant effect, the results favored the intervention in only 3 (Bock 2013, Borland 2013, and Haug 2013). While the reviewed studies vary widely in design and outcomes, taken together they indicate that **text messaging programs can be effective with smokers recruited online, through traditional advertising, or in health care settings.**

The reviewers conducted subgroup analyses with the same 12 studies, one with 7 trials (N=9,887) testing text messaging programs alone, and another with 5 trials (N=1,995) testing them in combination with individualized counseling. The interventions had significant effects in both. These findings indicate that **text messaging can be effective either by itself or as an adjunct to in-person counseling.**

Two studies published after the Whittaker review add a note of caution to the interpretation of findings. One recruited adult smokers in China (N=8,000) who used Nokia Life Tools (Augustson 2016). Participants were randomly assigned to receive either 1 to 3 messages per day with smoking cessation advice, encouragement, and health education information,

or 1 message per week with information on the effects of smoking. There was no long-term significant difference in outcomes between the two groups. Given its large sample and non-effect, inclusion of this trial in future reviews may substantially reduce the estimated risk ratio for text messaging programs.

The other study was conducted in a quitline setting, unlike the others discussed so far (Boas 2016). Using a quasi-experimental design, it compared an employer-based quitline service consisting of telephone counseling and NRT to the same quitline service plus a text messaging program. It found no long-term significant effect from the added service. To date, no other quitline-specific evidence has emerged, so **it is unknown whether text messaging is effective with quitline users, or in combination with other quitline services.**

Finally, readers may be interested in another trial published after the Whittaker review (Müssener 2016). It recruited Swedish university students (N=1,590) who were daily or weekly smokers willing to quit within a month. They were randomly assigned to receive either 157 text messages with smoking cessation content delivered over a 12 week period, or 1 text every 2 weeks thanking them for being in the study. Unlike studies in the review, it did not report outcomes at 6 months or longer, but the intervention group did have a significantly higher quit rate than the control at 4 months.

The Community Preventive Services Task Force recommends text messaging programs, based largely on studies in the Whittaker review (Guide to Community Preventive Services 2014).

#### **Table 8. Summary of Findings on Text Messaging Programs**

1. Text messaging programs can be effective with smokers recruited online, through traditional advertising, or in health care settings.
2. Text messaging can be effective either by itself or as an adjunct to in-person counseling.
3. It is unknown whether text messaging is effective with quitline users, or in combination with other quitline services.

#### *Evaluation of Text Messaging Programs*

It is not yet known whether text messaging programs are effective for quitline users, or whether they are effective in combination with other quitline services. Also unknown, for those programs that were validated in non-quitline settings, is what made them effective. However, certain broad features were common among the effective text messaging programs and often missing among the ineffective ones. So when evaluating a quitline-based text messaging program, it makes sense to start by asking, does it share these features?

- Thoughtfully designed content scheduled around a quit date
- High frequency of message delivery
- Program duration of 3 months or longer
- Basic interactivity and at least modest tailoring

For some evaluation questions, it can be helpful to solicit direct feedback from users in order to make the program more responsive to their needs:

- What types of messages do they perceive as most helpful (e.g., planning tips, encouragement, information about the harms of smoking or benefits of quitting,

medication management, information on withdrawal, testimonials, offers of additional services, etc.)? Do these vary by user characteristics?

- Compared to text-only content, are they as satisfied or more so with multimedia content such as links to web pages, images, audio, and video?
- What other features of the program do they perceive as most helpful (e.g., access to an online portal, tailoring, ability to reset the program by changing the quit date, ability to get additional help through keywords or other means, social media connectivity)?
- What messages or features would they add, change, or delete?

Process questions on user behavior can help illuminate engagement with the program, such as:

- Which types of text messages are most or least likely to be read?
- To what extent do messages requesting a response receive one?
- What percentage of users drops out before program completion? When do they drop out?
- Is there evidence of user fatigue before drop-out, and are there effective strategies for heading it off and keeping users engaged?
- What percentage of users opts in to other quitline services?
- Do users refer their friends and family?
- Are alternate timing protocols associated with different levels of engagement, such as higher or lower frequency, more or less front-loading of messages, and longer or shorter overall duration?

Questions about reach can help to design and promote a program that is appealing to users:

- How do new users hear about the text messaging program? How do they access it?
- When given a choice between telephone counseling and text messaging, who chooses the latter and why?
- What factors predict text messaging participants using other quitline services? What factors predict other quitline participants using text messaging?
- How do the demographics of text messaging users compare to those of other quitline users? To what extent does the service reach an audience not served by other quitline services?

Given that some text messaging programs have been proven effective (though not yet in a quitline setting), a quitline that offers such a service may also consider collecting outcomes data from a random sample of users. This assumes the quitline has the resources to evaluate sufficiently large numbers of both regular quitline participants and text messaging users to produce meaningful quit rates for both. NAQC currently recommends that a quitline's standard reported quit rate should include only those who receive counseling and/or medications, whether or not they also receive text messages, so the supplemental quit rate would be primarily for internal use. For more on this topic, see the NAQC issue paper, "Calculating Quit Rates, 2015 Update" (NACQ 2015).

The foregoing assumes that the text messaging service is a free-standing program designed to support users through one or more quit attempts, even if they use no other quitline services. Quitlines that make more limited use of text messages should focus their evaluation on more narrowly defined process measures based on how they actually use them. For example, a quitline that uses text messages to remind participants of upcoming counseling appointments could



evaluate whether the messages improve adherence to the call schedule or increase the number of sessions completed.

### *Considerations for Purchasers*

Although text messaging programs have so far been proven effective only in non-quitline settings, there are good reasons to believe they could be effective in quitline settings as well. First, some quitlines use the same programs that were proven effective in non-quitline settings. Second, many quitlines promote their text messaging programs via a website or with digital advertising, just as the research-validated programs did, so they may be reaching a similar audience. Third, use of the text messaging program is not conditioned on participation in other quitline services, which would be expected to drive some participants away for whom text messaging is particularly well suited. Finally, even if they are not effective in themselves, it is possible that quitline-based text messaging programs may help those who want telephone counseling or medications by helping them access these evidence-based treatments.

Even so, given the wide-ranging results from published trials of text messaging programs, purchasers would be wise to ask service providers bidding on their contracts to explain how their text messaging programs are based on the best available evidence. Specifically:

- Is their content similar to those of the research-validated programs?
- Do they have the same features, described above, that were common among the programs proven effective?
- Do they serve a similar population (e.g., recruited online)?

Purchasers who are less concerned about efficacy and more concerned about reach and cost savings should consider using SmokefreeTXT, a text messaging program provided by the National Cancer Institute and promoted on [smokefree.gov](http://smokefree.gov) (NCI 2016). The program is not research-validated but is free and comes from a credible source.

### *Recommendations on Text Messaging Programs*

A few text messaging programs have been shown to improve smoking cessation outcomes in non-quitline settings, and some of the text messaging programs offered by quitlines are based on these research-validated programs. Also, by linking to counseling and medications, a quitline-based text messaging program may increase use of these other evidence-based services. For these reasons, offering text messaging programs to quitline participants can be considered a promising practice.

Following are specific recommendations relating to text messaging programs:

- *If a text messaging program is offered, ensure that it is closely based on interventions proven effective. Such interventions generally feature content scheduled around a quit date, frequent messages, extended duration, and basic interactivity and tailoring.*
- *Design and promote the text messaging program as a stand-alone service to attract tobacco users who may be less inclined to use traditional quitline services such as telephone counseling.*
- *For participants who are willing to use other quitline services, provide links from the text messaging program to telephone counseling and NRT.*

## **Mobile Apps**

Mobile apps are software applications that can be downloaded to a smartphone or tablet from a distribution platform such as the Apple App Store or Google Play. Once downloaded, they can be used without an internet connection, though some features may be fully functional only while online. For purposes of this overview, mobile apps may also include:

- Web applications that employ responsive design for easy viewing in browsers of any size, including those of smartphones and tablets. In many ways these are like mobile apps, except that they do not reside on the phone itself and can only be accessed with an internet connection.
- Facebook apps, designed to exploit networking possibilities of the social media platform. These can only be used while logged into Facebook.

The FY2015 NAQC survey did not specifically ask if quitlines offer mobile apps and no respondents mentioned such a service under “other services offered” (Rudie 2016). However, the two largest quitline service providers in the U.S., Optum and National Jewish Health, both offer mobile apps.

Researchers and advocates have noted that mobile apps for tobacco cessation have great potential, owing to their relative low cost, wide reach, easy accessibility, convenience, ability to deliver a personalized experience, and ability to capitalize on social media to increase social support (McClure 2016).

### *The Evidence for Mobile Apps*

Despite the potential offered by this type of service, evidence of efficacy is so far lacking. There are hundreds of mobile apps for tobacco cessation, but they do not seem to be well informed either by best practices for tobacco dependence treatment or best practices for mobile app design.

Abroms and colleagues analyzed 98 of the most popular iPhone and Android apps, which were downloaded from 310,800 to 1,248,000 times per month worldwide (Abroms 2013). They noted that most were simplistic tools with basic functions. Categorizing each app by its primary approach to cessation, they found that calculator apps were the most common category, accounting for 38.8% of apps, followed by hypnosis apps (17.3%), rationing apps (15.3%), trackers (12.2 %); informational apps (6.1%), games (3.1%), lung health testers (2.0%), and others (5.1%). The lung health testers purported to be able to assess lung health by having users blow into their speakers. Most of the apps categorized as “others” aimed to alter users’ associations with smoking. The researchers also found low levels of adherence to the U.S. Public Health Service guidelines, giving apps an average 12.9 score on a 42 point adherence index. As examples of missed opportunities to support best practices, only 4.1% of the apps recommended using approved medications, and none recommended calling a quitline.

Hoepfner and colleagues analyzed 225 Android apps and found that on average they only addressed 2.1 of the “5 A’s” (Ask, Advise, Assess, Assist, Arrange) and only addressed 0.7 of them in a tailored way (Hoepfner 2015). However, they also found that covering more of the 5 A’s and tailoring were associated with app popularity and user-rated quality. They concluded that, “Publically available smartphone smoking cessation apps are not particularly ‘smart’: they commonly fall short of providing tailored feedback, despite users’ preference for these features.”

McClure and colleagues surveyed providers (n=264) and smokers (n=40) on how important they believed 21 hypothetical design features are to include in mobile apps for tobacco cessation (McClure 2016). Both groups rated these features as very or extremely important: free or low cost, keeping information private, matching individual needs and interests, adapting as the user's needs and interests change, helping to manage nicotine withdrawal symptoms and medication side effects, and allowing users to track their progress. Several other features were rated as somewhat or very important to one or both of the groups. The authors fault current apps for not being designed to reflect best practice treatment or to take full advantage of smartphone and tablet technology.

For their meta-analytic review of mobile phone interventions, Whittaker and colleagues found several high-quality trials of text messaging programs (as discussed above), but none on mobile apps (Whittaker 2016). However, several study protocols have been published recently, indicating that trials are planned or under way.

The seemingly great potential of mobile apps to provide cost-effective treatment to large numbers of tobacco users has thus far not been realized. **There is no evidence to date that mobile apps help tobacco users quit.**

#### *Evaluation of Mobile Apps*

In the absence of a clear set of best practices for mobile apps for tobacco cessation, quitlines that offer mobile apps can still take steps to evaluate them in ways that may identify opportunities to improve them.

- Rate them against the scales and coding schema in Abroms 2013, Hoepfner 2015, and McClure 2016.
  - What is their overall approach to cessation?
  - How well do they adhere to U.S. Public Health Service guidelines for tobacco dependence treatment?
  - How tailored is the feedback they provide?
  - To what extent do they incorporate features that providers and smokers have said are important?
- Rate them against other best practice documents for behavior change apps.
- Review actual usage data.
  - How often do users open the app, how long is the average session, and what is the total time used?
  - What features are used most?
  - To what extent do app users also use other quitline services?
- Solicit additional user feedback.
  - How well does the app meet users' expectations for helpfulness, ease of use, personal relevance, etc?
  - Were they able to access additional personalized help as needed?
  - What features would they add, change, or delete?
  - Would they recommend it to a friend?

With their many years of experience providing evidence-based treatment to hundreds of thousands of tobacco users, quitlines have a unique opportunity to help inform the development of mobile apps that are truly evidence-based. A quitline that is seriously engaged in such an effort should consider partnering with researchers to test it for efficacy. A quitline may have good reason to think a trial is warranted if its app:

- Adheres to the U.S. Public Health Service (USPHS) clinical practice guideline for tobacco use treatment (Fiore 2008).
- Takes full advantage of smartphone technological capabilities.
- Has features that providers and smokers have rated as important, including providing tailored feedback and adapting to the user's changing needs over time.
- Is well utilized and rated highly by users.

Results from such research would be of great interest to the entire quitline field.

### *Considerations for Purchasers*

Purchasers who are primarily concerned about efficacy have little reason at present to consider funding a mobile app, unless they are in a position to fund the development and rigorous testing of such an app, as described above.

Purchasers who are less concerned about efficacy and more concerned about reach and cost savings should consider using QuitGuide and quitSTART, two mobile apps provided by the National Cancer Institute and promoted on [smokefree.gov](http://smokefree.gov) (NCI 2016). As with SmokefreeTXT discussed earlier, the apps are not research-validated but are free and come from a credible source.

### *Recommendations on Mobile Apps*

Although there are hundreds of mobile apps for tobacco cessation, there are no published studies documenting successful trials, and most apps do not reflect best practices for tobacco dependence treatment or for mobile app design. For these reasons, there is insufficient evidence of efficacy to recommend that quitlines offer mobile apps.

Following are specific recommendations relating to mobile apps:

- *Monitor the scientific literature for emerging evidence of the efficacy of mobile apps for tobacco cessation.*
- *If offering a mobile app, take steps to ensure that it adheres to the USPHS clinical practice guideline for tobacco dependence treatment, makes sophisticated use of smartphone technology, has features important to providers and smokers, and is highly rated by users.*

## **Web-based Services**

Web-based services constitute a broad category of interventions encompassing all means of communication over the internet, including:

- Webpages and websites, along with the text, links, documents, images, videos, and other resources that are hosted there.
- Interactive communication tools that use the internet, such as email, instant messaging (IM), chat, video chat, and internet forums.

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- Social media services, such as blogs and microblogs, forums, video sharing, and social networks.

As mentioned in the section on mobile apps, there is some overlap between mobile apps and web apps, as the latter can be designed for easy viewing on smartphones and tablets, thus mimicking apps that reside on the phone itself.

Nearly all state quitlines make use of one or more web-based technologies (Rudie 2016):

- 98% (46/47) of quitlines responding to the FY2015 NAQC survey have websites that provide information about the quitline and cessation.
- 96% (45/47) offer web-based self-help tools.
- 81% (38/47) offer chat rooms.
- 77% (36/47) offer automated email messages.
- 64% (30/47) offer web-based interactive counseling, such as instant messaging or emailing with a counselor.

The FY2015 NAQC survey did not specifically ask if quitlines provide service on social media platforms and no respondents mentioned such a service under “other services offered” (Rudie 2016).

Quitlines use web-based technologies for many reasons, not all of which apply in every case.

First, quitlines use websites to promote themselves, by:

- Making it easy for community members to find accurate information about tobacco use and the quitline.
- Branding the quitline as the preeminent cessation resource in the state.
- Competing for market share with other cessation programs, including some that are not evidence-based or that charge for their services.
- Reaching out to a large and growing audience that consumes more online media than traditional media (e.g., youth and young adults).
- Supporting digital advertising efforts (i.e., providing landing pages for digital ad campaigns).

They also use websites to facilitate partnerships, by:

- Linking to community groups and local resources.
- Encouraging and enabling referrals.
- Providing information about tobacco use and cessation for health care providers, behavioral health professionals, and others in the community who interact with tobacco users (e.g., fact sheets, patient hand-outs, CME training).

Quitlines also use websites to help tobacco users quit, by serving as a gateway to the quitline’s suite of services. On a typical quitline website, tobacco users can register for telephone counseling, sign up for a text messaging program, read about how to quit, access online chat or other web-based communication tools, and even in some cases order medication. All of these services may be accessed from the website, but the term “web-based services” refers to those that are specifically built for the internet. Following are some common types of web-based services.

- Online self-help for quitting. Online self-help may range from static information to interactive and tailored content. On the upper end of that spectrum, the website may allow users to create and update a profile containing personal information such as their name, gender, age, years of tobacco use, type of tobacco, quit date, and email, which it then uses to provide a personalized and tailored experience. The site may have questionnaires, quizzes, and other interactive features which elicit further information from users and return timely, personalized feedback based on their responses. The site may track users' progress through steps in the quitting process, and provide new activities appropriate to where they are in that process, adapting to relapse as needed.
- Automated email messages. These may be organized into an intervention capable of standing on its own, consisting of multiple messages that are personalized and tailored to the user's unique circumstances. The content of email messages may be similar to those of the IVR and text messaging programs discussed above, but because the email format can accommodate lengthier text, it may be especially suitable for users who enjoy reading. However, the content need not be limited to text since other types of content such as images, video, and audio can also be sent via email.
- Chat rooms. These enable users to exchange information with each other, and in the process to give and receive peer support. Chat rooms may be monitored or not.
- Web-based interactive counseling. This can be done via instant messaging (IM), one-on-one chat, or email. The goal common to all is to allow users to access help from a real counselor. One difference is that offering IM or chat suggests that responses will be provided in real time, whereas with email a lag before responding may be tolerated. The ability to access help in this way may be presented to users as an added feature of systems that are otherwise fully automated.

The question of whether web-based services can play a role in helping tobacco users quit is a matter of acute interest in the tobacco control community. They seem to have enormous potential for a number of reasons. First, they can be accessed 24/7, from anywhere with an internet connection, by people who might not consider using telephone counseling. Fully automated web-based programs, once developed, can serve large numbers of people at lower cost than behavioral interventions delivered by clinicians or counselors. Even partially automated services (e.g., an automated email service that also allows users to send and receive personal emails as needed) may be less resource-intensive than an entirely non-automated service. Finally, reported quit rates for web-based interventions are often comparable to those of other interventions that have a strong evidence base. So there is great interest in learning whether such services actually help tobacco users quit.

#### *The Evidence for Web-based Services*

Web-based interventions for tobacco cessation are the subject of a growing body of scientific literature, but the field is still fairly new (since the early 2000's). There is tremendous variety among web-based interventions, and the evidence is not equally strong for all types. In some cases there are methodological issues that lead to uncertainty about study findings. Despite these challenges, numerous reviews of web-based interventions have been published. One recent review with rigorous methodology is by Civljak and colleagues, who considered 28 published studies (Civljak 2013). The reviewers found 7 trials which all compared some form of a web

intervention for adults to a minimal control. However, there was too much heterogeneity in this group, so they split the studies into subgroups, summarized in Table 9:

**Table 9: Pooled Results for Trials of Web-based Services (Part 1)**

Studies	Intervention vs. Control Comparison	Risk Ratio (95% CI)
2 trials (N=686)	Interactive, tailored intervention of email, web, IVR, and text messages vs. a self-help booklet	2.05 (1.42- 2.97)
3 trials (N=3,631)	Interactive, tailored intervention of various web-based components vs. assessment only	1.41 (1.11-1.78)
1 trial (N=1,112)	Interactive, non-tailored web intervention vs. a self-help booklet	0.87 (0.63-1.20)
1 trial (N=140)	Non-interactive, non-tailored web intervention vs. a self-help booklet	1.11 (0.54- 2.27)

*Source: Civljak 2013. CI=confidence interval.*

Two pooled trials (N=686) tested the Happy Ending program, an interactive, tailored web intervention for Norwegian smokers (Brendryen 2008a and b). The program included over 400 contacts by email, web, IVR, and text message. Tailoring was based on data gathered via IVR. In both trials, the program was tested against a self-help booklet. In the first, all participants also received NRT. Both studies had an effect and pooled results showed the program was effective at 6 months.

Three pooled trials (N=3,631) tested interactive, tailored web interventions. One randomized German rehabilitation inpatients to online assessment only or to assessment plus 7 sessions with a computer expert system, informational web pages, and a message board (Haug 2011). Another randomized Dutch smokers to 3 emailed assessments, or to assessments plus 3 emailed feedback letters (Smit 2012). A third randomized Dutch smokers to either emailed assessments or to assessments plus a baseline feedback report, 6 or 11 “action planning” assignments, and the same number of feedback reports (Elfeddali 2012). Only Haug 2011 had a significant effect at 6 months, but the pooled result was also significant. The reviewers found that all 3 studies were at high risk of bias, and there was a high level of statistical heterogeneity.

One trial (N=1,112) tested an interactive, non-tailored web intervention with Korean American smokers (McDonnell 2011). It consisted of stage-based content on the web, compared to the same content in a booklet. It had no effect at 6 months.

One trial (N=140) tested a non-interactive, non-tailored web intervention with adult patients living with HIV (Humfleet 2013). It consisted of web-based content, compared to a self-help booklet. Most participants in both groups also received free NRT. There was no effect at 6 months.

Based on these 7 studies the reviewers found that **web interventions may be effective for adult smokers.**

The Civljak review also considered two trials that focused on young adult or adolescent smokers (summarized in Table 10). One trial (N=517) tested an intervention in which college students

received weekly financial incentives to visit an online magazine that provided personalized cessation messages and emailed peer support (An 2008). There was a significant difference in 30-day abstinence at 30 weeks, though how much of the effect was due to the incentives and how much to the rest of the intervention is unknown because the study was not designed to isolate their effects. Another trial (N=136) tested an Internet-based chat room for high school aged smokers providing real time support by a trained counselor (Woodruff 2007). It found no long-term effect on outcomes. Based on these two studies the reviewers found that **web interventions may be effective for young adult smokers, but it is unknown if they are effective with adolescents.**

**Table 10: Pooled Results on Trials of Web-based Services (Part 2)**

<b>Studies</b>	<b>Intervention vs. Control Comparison</b>	<b>Risk Ratio (95% CI)</b>
1 trial (N=517)	Weekly incentives to visit an online magazine with tailored content and emailed peer support vs. basic email; for college aged smokers	1.95 (1.42- 2.69)
1 trial (N=136)	Chat room with real-time support by a trained counselor vs. online measurement only; for high school aged smokers	0.93 (0.60-1.44)

*Source: Civljak 2013. CI=confidence interval.*

Civljak and colleagues considered (but did not pool) three trials that tested a web intervention against a control of counseling, either in-person or by telephone (Patten 2006, Swan 2010, Humfleet 2013). None of them found a long-term significant effect, indicating that **web interventions may not be more effective than counseling.**

They also considered (but did not pool) two studies that tested a web-based program in combination with counseling (Japuntich 2006 and Swan 2010). Neither found a long-term significant effect, suggesting that **a web-based service may not be effective as an adjunct to counseling.**

A trial published after the review by Civljak and colleagues used a 2x2 factorial design to assess the independent effects of a web intervention for smokeless tobacco users and telephone counseling (Danaher 2015). The web intervention consisted of access to ChewFree, an interactive and tailored website. The 7-day abstinence rate at 6 months was significantly higher for web than for non-web, but not significantly higher for counseling with web than for counseling without web. The results of this trial are consistent with findings from the review, that web interventions may be effective by themselves but not as an adjunct to counseling.

The Community Preventive Services Task Force has found insufficient evidence to recommend web-based interventions, based largely on studies in an earlier version of the Civljak review (Guide to Community Preventive Services 2014). The Task Force based this finding on the inconsistent results among studies. They also noted that big differences among interventions, the fact that control group participants often received evidence-based interventions, and substantial loss to follow-up in many studies, all made it difficult to interpret results.



**Table 11. Summary of Findings on Web-based Services**

1. Web interventions may be effective for adult smokers and young adult smokers, but it is unknown if they are effective with adolescents.
2. Web interventions are probably not more effective than counseling.
3. Web interventions may not be effective as an adjunct to counseling.

*Evaluation of Web-based Services*

These findings indicate that some, but not all, web interventions may be effective in helping tobacco users quit. The underlying studies were not designed to determine exactly what made certain web interventions effective. However, the research-validated interventions seemed to share several common characteristics. So when evaluating a web-based program, it makes sense to start by asking, does it share these features?

- A multimodal communication strategy (e.g., reaching out via email, web pages, IVR, and text messages)
- High frequency of communication
- Interactivity (i.e., participants truly participate and contribute information about their progress)
- Tailoring of the intervention based on the information that participants provide

As a corollary to the foregoing, it seems unlikely that static web content is any more effective than printed self-help materials, which as mentioned in that section, have an effect that just barely reaches statistical significance.

Given the many ways quitlines use web-based services, there is no universal approach to evaluating them. However, there are some basic questions that may apply, depending on whether the aim of a website is to promote the quitline and encourage referrals or to help tobacco users quit:

- If the aim is promotion and referrals:
  - Does the site consistently rank near the top of search results?
  - To what extent do participants report having heard about the quitline from the web? To what extent do they register online?
  - In surveys of consumers and providers who visit the site, does the quitline come across as a credible program that they would feel comfortable using themselves or referring others to?
  - To what extent do organizations link to it? Do they sign up for referral and/or download patient materials?
- If the aim is to help tobacco users quit:
  - What specific features does it offer that facilitate quitting (e.g., automated emails, chat)?
  - How well utilized are those features?
  - How are they rated in participant surveys?
  - To what extent do they increase engagement with the quitline and the use of other evidence-based services?

For some evaluation questions, it may be useful to gather feedback directly from participants to ensure that the program meets their needs:

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- What types of communications do they prefer?
- Is the program sufficiently interactive and appropriately tailored to their situation?
- What other features do they find most helpful?
- What messages or features would they add, change, or delete?

Quitlines that develop interventions in which a web-based service is the central component should consider testing them and publishing the results, which would be very helpful to the field.

### *Considerations for Purchasers*

Given the overall weak evidence for web-based interventions and the variability in the published literature, purchasers for whom treatment efficacy is a top priority may still take steps to increase the odds of obtaining an effective product:

- Recognize that quit rates obtained in uncontrolled evaluations may reflect population differences as much as treatment effects. For example, the fact that participants who self-select into a web program and participants who self-select into telephone counseling have similar quit rates does not mean the two programs are equally effective. They may be, but without a control and random assignment it is impossible to know.
- Require bidders to explain exactly how the web-based services they propose are evidence-based. For example:
  - What research-validated program or programs do they most resemble?
  - What features common to research-validated programs were incorporated into the services?
  - What additional steps were taken to increase the likelihood of effectiveness?
- Continue to monitor the literature for emerging evidence in this area and maintain close collaboration with your service provider to take advantage of new findings.

Alternatively, given the lower marginal costs of web-based interventions compared to telephone counseling, purchasers may have priorities other than treatment efficacy.

- If the priority is reaching an audience that is not well represented among users of the quitline's telephone counseling service, decision-making may focus on the proposed web service's likely impact on promotional reach. For example, will it help the quitline reach a younger demographic?
- If the priority is limiting state expenditures due to excess demand and a tight budget, decision-making may focus on how the web service will lessen the burden on more resource-intensive services.
- If the priority is using web services as a stepping stone to other services with a stronger evidence base, decision-making may focus on the pathways between services and efforts to transition users from one to the other, e.g., allowing web registrants to obtain free NRT and inviting them to speak to a live counselor.

Purchasers whose priorities reflect some combination of the above should require bidders to describe how their web services:

- Are based on the best available evidence for efficacy.
- Attract users less likely to use telephone counseling.
- Extend program resources.
- Enable users to move seamlessly between quitline services.

- Are evaluated to assess added value to the overall program.

### *Recommendations on Web-based Services*

Based on the available evidence, web-based interventions are too varied in their designs and inconsistent in their effects to be considered research-validated as a class. However, offering a web-based intervention that is closely based on the evidence from successful trials is a promising practice.

Following are specific recommendations relating to *web-based services*:

- *If web-based services are offered, ensure that they are closely based on interventions proven effective in randomized, controlled trials. In general, such interventions are multimodal, intensive with respect to the frequency of messages, interactive, and tailored.*
- *Continue to monitor the scientific literature for emerging evidence of the efficacy of web-based interventions for tobacco cessation.*

## **Medications**

Medications refer to pharmacological quitting aids provided to quitline participants. For many quitlines the options are limited to medications that the U.S. Food and Drug Administration (FDA) has approved as first-line therapies. These include several forms of nicotine replacement therapy (patch, gum, lozenges, inhaler, and nasal spray), bupropion (sold as Zyban) and varenicline (marketed as Chantix in the U.S. and Champix in Canada). Combination NRT refers to therapy that combines a long-acting form of NRT such as patches with a short-acting form such as gum or lozenges. Other effective therapies include nortriptyline, a second-line medication similar to bupropion, and cytisine, a medication similar to varenicline that is common in Eastern Europe but is not yet available in the U.S. or Canada. Medication provision or fulfillment refers to screening quitline participants for eligibility and contraindications, determining appropriate dosage, and sending either the medications themselves or a voucher redeemable for the medications.

According to a recent analysis of quitline profiles in the NAQC database, nearly all (98%, or 52/53) of U.S. quitlines provide at least one form of medication (Rudie 2016). Of these, the great majority, 90%, send the medication itself while the remainder send vouchers. A similarly high percentage, 89%, provide medications for free while the remainder provide them at a discount. Medications available over the counter (OTC) are more likely to be offered at no cost, while those available only by prescription are more likely to be offered at discount. Some quitlines face funding restrictions on their use of medications and are unable to offer them to all participants.

The three forms of NRT available OTC are the medications provided by the greatest number of quitlines:

- 96% (51/53) provide nicotine patches.
- 81% (43/53) provide nicotine gum.
- 60% (32/53) provide nicotine lozenges.

The four prescription medications are also provided by at least some quitlines:

- 15% (8/53) provide varenicline.
- 13% (7/53) provide bupropion.

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- 8% (4/53) provide nicotine inhalers.
- 8% (4/53) provide nicotine nasal spray.

The number and percentage of quitlines that provide combination therapy, i.e., more than one form of medication at a time, are not known.

Most quitlines provide medications in combination with one or more other services. Respondents to the FY2015 NAQC survey were asked if they provide “free NRT” with each of several services. Those that do represent:

- 96% (43/45) of those that offer proactive multisession counseling.
- 95% (42/44) of those that offer reactive multisession counseling.
- 39% (18/46) of those offering web-based self-help.
- 13% (5/38) of those offering chat rooms.
- 13% (4/30) of those offering web-based counseling.
- 8% (3/36) of those offering email.
- 4% (1/24) of those offering interactive text messaging.
- 0% (0/14) of those offering one-way text messaging.

The number and percentage of quitlines that require participants to use one of these services to obtain free or discounted medications are not known.

Quitlines offer tobacco cessation medications in order to:

- Encourage quit attempts and improve quit outcomes.
- Increase satisfaction and program adherence.
- Reach tobacco users who may not otherwise choose to use quitline services.
- Promote quitline services more cost effectively than with an offer of behavioral support alone.
- Encourage health care providers and systems to identify tobacco using patients and consistently refer them for treatment.

### *The Evidence for Medications*

The scientific literature demonstrating the effects of tobacco cessation medications is immense. A recent review by Cahill and colleagues consolidated the findings from 12 previous reviews of the various types of medications (e.g., NRT, antidepressants, nicotine receptor partial agonists, etc.), which in turn covered 267 trials (N=101,804; Cahill 2013). Key results from this review are summarized in Table 12.

**Table 12: Pooled Results for Trials of Medications for Tobacco Cessation**

Type of Medication	Comparison	Ratio <sup>1</sup>
Nicotine Replacement Therapy (NRT)	NRT vs. placebo control	OR 1.84, CredI 1.71-1.99
	Combination NRT vs. patch	OR 1.43, CredI 1.08-1.91
	Combination NRT vs. gum	OR 1.63, CredI 1.21-2.20

<sup>1</sup> The review by Cahill et al. reports results either as risk ratios (RR) with 95% confidence intervals (CI) or as odds ratios (OR) with 95% credible intervals (CredI).

	Combination NRT vs. other single NRT	OR 1.34, CredI 1.00-1.80
<b>Anti-depressants</b>	Bupropion vs. placebo control	OR 1.82, CredI 1.60-2.06
	Bupropion as adjunct to NRT	RR 1.23, CI 0.67-2.26
	Nortriptyline vs. placebo control	RR 2.03, CI 1.48-2.78
	Nortriptyline as adjunct to NRT	RR 1.29, CI 0.97-1.72
<b>Nicotine receptor partial agonists</b>	Varenicline vs. placebo control	OR 2.88, CredI 2.40-3.47
	Varenicline vs. patch	OR 1.51, CredI 1.22-1.87
	Varenicline vs. gum	OR 1.72, CredI 1.38-2.13
	Varenicline vs. other NRT	OR 1.42, CredI 1.12-1.79
	Varenicline vs. bupropion	OR 1.59, CredI 1.29-1.96
	Varenicline vs. combination NRT	OR 1.06, CredI 0.75-1.48
	Cytisine vs. placebo control	RR 3.98, CI 2.01-7.87

Source: Cahill 2013

Concerning Nicotine Replacement Therapy (NRT), Cahill and colleagues found that:

- **NRT is effective in increasing 6-month quit rates compared to a placebo control.**
- **No form of NRT is more effective than another, except that sprays and inhalers are slightly more effective than gum (not shown in table).**
- **Combination NRT (e.g., patch and gum together) is more effective than single formulation NRT.**
- **Combination NRT is nearly as effective as varenicline.**

Concerning bupropion and other anti-depressants, the reviewers found that:

- **Bupropion is effective compared to a placebo control, with an odds ratio similar to that of NRT.**
- **Nortriptyline (a second line medication) is also effective relative to a placebo control.**
- **Neither bupropion nor nortriptyline is effective as an adjunct to NRT.**

Concerning varenicline and other partial nicotine receptor agonists, the reviewers found that:

- **Varenicline is effective compared to a placebo control.**
- **Varenicline is more effective than either (1) single formulation NRT or (2) bupropion.**
- **Varenicline is as effective as combination NRT.**
- **Cytisine, similar to varenicline and not currently available in the U.S. or Canada, is effective compared to a placebo control.**

A large trial (N=8,144) published after the Cahill review examined the safety and efficacy of varenicline, bupropion, and nicotine patches relative to each other and to a placebo (Anthenelli 2016). The study was prompted by earlier concerns that varenicline and bupropion may trigger adverse neuropsychiatric events, especially in individuals with psychiatric disorders. Participants recruited in 16 countries, approximately half of whom had a psychiatric disorder, were randomly assigned to receive varenicline, bupropion, nicotine patches, or a placebo. All participants received brief weekly counseling in addition to the medication. Rates of 4-week continuous abstinence at 12 weeks were higher in the bupropion and patch groups than in the placebo group,

and higher in the varenicline group than in all others, confirming the efficacy findings of earlier trials. Importantly, the study found no significant increase in neuropsychiatric adverse events attributable to varenicline or bupropion, relative to either patches or placebos, demonstrating that **varenicline and bupropion have been proven to be safe, including for individuals with psychiatric disorders.**

The evidence for medications in combination with behavioral counseling is also substantial. A recent review by Stead and colleagues considered 53 trials combining these two treatments (Stead 2016). Pooling 52 trials (N=19,488), the authors found that **medications in combination with counseling significantly improve outcomes, relative to a control of usual care or minimal intervention** (RR 1.83; 95% CI 1.68 to 1.98). This finding was true regardless of:

- Treatment setting (i.e., health care or community settings).
- Whether subjects were selected for motivation to quit.
- Type of treatment provider.
- Number of sessions.
- Total length of contact.
- Degree of treatment uptake.

A separate review by the same group addressed the benefit of behavioral support as an adjunct to medications (Stead 2015). The reviewers considered 47 trials (N=18,682) comparing pharmacotherapy alone to pharmacotherapy plus more intensive behavioral support, most of which provided NRT and four or more sessions. They found that **behavioral support significantly improves long-term rates of abstinence over medications alone** (RR 1.17, 95% CI 1.11 to 1.24).

In a subgroup analysis, Stead and colleagues pooled 6 trials (N=5,311) in which the behavioral support was provided solely by telephone (RR 1.28, 95% CI 1.17 to 1.41). These studies show that **the effect of telephone counseling is not subsumed by the effect of medications.**

Several trials have investigated the effects of providing medications to quitline participants.

Hollis and colleagues employed a 3x2 design in a large trial with Oregon quitline callers (N=4,614) comparing three levels of counseling (one 15-minute call, one 30-minute call plus a follow-up call, or five proactive calls) and two levels of medication (no offer of free NRT or up to 8 weeks of free NRT) (Hollis 2007). The NRT offer and more intensive counseling were each associated with improved outcomes, although NRT appeared to contribute more to the overall effect than counseling did. The biggest difference was between the no-NRT + brief counseling cell and the NRT + intensive counseling cell. These findings support the quitline practice of offering both medications and counseling, as they show the treatments have separate effects, and that they are stronger in combination.

In another study with Oregon quitline callers (N=1,154), McAfee and colleagues used a simple 2-group design in a trial comparing two levels of medication (2 or 8 weeks of free NRT) (McAfee 2008). The quitline also attempted to provide 2 counseling sessions with participants in both groups. 30-day abstinence at 6 months was significantly higher in the 8-week patch group

than in the 2-week patch group. Participants in the 8-week group also completed more calls, used more NRT, and were more satisfied with the service.

Smith and colleagues used a 2x2x2 design in a trial with quitline callers in Wisconsin (N=987) comparing two durations of NRT (2 or 6 weeks), two types of NRT treatment (patch alone or patch plus gum), and two levels of telephone counseling (standard counseling or standard counseling + medication adherence counseling) (Smith 2013). Standard counseling consisted of four proactive sessions. The only factor that had a significant effect on abstinence rates at 26 weeks was combination therapy. Participants who received combination therapy for either 2 or 6 weeks had significantly higher quit rates than participants receiving only 2 weeks of patches. With no differences in outcomes between 2 and 6 weeks of combination therapy, offering 2 weeks of combination therapy appeared to be the more cost-effective approach. It is possible the study was underpowered to detect a difference between 2 and 6 weeks, but given that all participants received intensive, multisession counseling and 2 weeks of medication, it is also possible that providing additional weeks of medication does not produce an added benefit.

Ferguson and colleagues used a 2x2 design in a trial with quitline callers in England (N=2,591) comparing two levels of medication (no offer of free NRT or a voucher for 6 weeks of free NRT) and two levels of counseling (standard quitline support or multiple proactive sessions) (Ferguson 2012). Standard quitline support was unstructured, reactive counseling. Unlike Hollis 2007, this study found no difference in 6 month outcomes due either to NRT or to proactive counseling, and no combined effect. The authors speculate that the failure to detect an effect from the NRT could have been because tobacco cessation medications are freely available in England through the National Health Service. However, a subsequent analysis found that the non-effect was not explained by participants in the no-NRT condition obtaining medications on their own (Docherty 2014). It is possible that sending NRT itself instead of a voucher may have produced higher quit rates in the NRT condition.

Taken together, these trials suggest that **NRT is effective as an adjunct to telephone counseling, and combination NRT is more effective than single NRT**. However, with conflicting results from the comparisons of shorter and longer courses of NRT, they also show that **the optimal length of NRT provision for quitline participants is unknown**.

### **Table 13. Summary of Findings on Medications**

1. NRT, combination NRT, bupropion, nortriptyline, varenicline, and cytisine are all effective.
2. No form of NRT is more effective than another, except that sprays and inhalers are slightly more effective than gum.
3. Combination NRT is more effective than single formulation NRT, and nearly as effective as varenicline.
4. Neither bupropion nor nortriptyline is effective as an adjunct to NRT.
5. Varenicline is more effective than either single formulation NRT or bupropion.
6. Despite earlier concerns about varenicline and bupropion possibly triggering adverse neuropsychiatric events, they have been proven to be safe, including for individuals with psychiatric disorders.
7. Medication in combination with counseling significantly improves outcomes, relative to a control of usual care or minimal intervention.

8. Behavioral support significantly improves long-term rates of abstinence over medication alone.
9. The effect of telephone counseling is not subsumed by the effect of medication.
10. NRT is effective as an adjunct to telephone counseling, and combination NRT is more effective in this context than single formulation NRT, but the optimal duration of NRT provision for quitline participants is unknown.

### *Evaluating the Provision of Medications*

As a practice with strong evidence of efficacy, the provision of medications to quitline participants is evaluated primarily through outcomes. NAQC recommends that participants who receive medications be included in the standard calculation of a quitline's quit rate, regardless of whether they also receive other services such as telephone counseling. See the earlier section on telephone counseling for a brief discussion of outcomes evaluation and the NAQC issue paper, "Calculating Quit Rates, 2015 Update," for a more in-depth treatment of this topic (NAQC 2015).

Process evaluation may focus on such questions as:

- What percentage of registered participants screened negative for contraindications?
- Of them, what percentage was offered medications? What percentage accepted medications?
- Within the limits of the quitline's budget, what percentage received the most effective therapy available to participants (e.g., combination NRT or varenicline vs. single NRT)?
- If medications are provided by voucher, what percentage of recipients redeemed them?
- If medications are dispensed in more than one shipment, what percentage became eligible for a second shipment? What percentage received it?
- How much of their medications, on average, did participants use?
- To what extent did recipients also use other quitline services, especially telephone counseling?

For a more thorough discussion of this topic, readers should consult the NAQC issue paper, "Integration of Tobacco Cessation Medications in State and Provincial Quitlines: A Review of the Evidence and the Practice with Recommendations (2014 Update)" (NAQC 2014).

### *Considerations for Purchasers*

In deciding what medications to provide to quitline participants, if the only consideration is efficacy then the therapies with the strongest documented effects are varenicline and combination NRT. Of these two, combination NRT has a practical advantage for quitlines in that it can be provided using OTC products (patch and gum or lozenge), whereas varenicline requires a prescription. Prescription medications require more coordination with primary care providers and may entail greater legal liability for the quitline. Another advantage of combination NRT is that it has been tested in a quitline setting and found to outperform single-formulation NRT, as discussed above (Smith 2013). If varenicline and combination NRT are too expensive, patches or gum are reasonable alternatives. Purchasers should note, however, that with decreased upfront costs come lower long-term quit outcomes.



The next decision is, how much of the medication(s) to provide? Unfortunately, the optimal length of pharmacological treatment in a quitline setting is unknown, as studies have reached conflicting results. They have found that 8 weeks are better than none (Hollis 2007), and better than 2 (McAfee 2008). But they have also found that 6 weeks are *not* better than none (Ferguson 2012) and *not* better than 2 (Smith 2013). One might infer that a short course of NRT, e.g., 2 weeks, is better than no NRT when used as an adjunct to counseling, but strictly speaking this has not been proven. It is not known whether 2 weeks of NRT is long enough to be effective as an adjunct to telephone counseling.

With these unknowns, the safest way to ensure that medications provided by a quitline are effective as an adjunct to telephone counseling is to provide a longer course, i.e., at least 6-8 weeks, consistent with recommendations in the U.S. Public Health Service clinical practice guideline, *Treating Tobacco Use and Dependence* (Fiore 2008) and CDC Best Practices for Comprehensive Tobacco Control Programs (CDC 2014).

In practice, however, the decision about how many weeks of medication to provide often comes down to how many participants want it and how much funding is available to pay for it. Quitlines have to decide whether to make longer courses available to fewer participants, or shorter courses available to more participants. The CDC itself has at times imposed a 2-week per-person limit on NRT purchased with CDC funds, in order to serve more people. Although the efficacy of this approach is unclear, there is clear promotional value in being able to advertise that the quitline is offering free 2-week “starter kits” to all callers, which would be lost if the quitline were instead to provide 8-week kits to only a quarter of its callers. Opting for shorter courses for more participants can help with reach even if its effect on quit outcomes is unclear.

These considerations may lead quitlines to limit the amount of medications they offer to 2 weeks of a single form of OTC NRT. For quitlines with more funding for medications, offering either a longer course, combination NRT, or both would provide greater assurance of efficacy.

Another decision affecting the accessibility of medications is whether counseling should be required for those who receive medications. The USPHS clinical practice guideline recommends combining counseling and medication because of research showing that quit rates are highest when the two are used together (Fiore 2008). However, the guideline also acknowledges that if participation in counseling is infeasible or if the patient is not interested, counseling should not be required. Otherwise, counseling is a barrier to access to medications, which themselves are evidence-based treatments. Quit rates may be higher when counseling is required, but if treatment utilization is reduced, there may be less quitting overall. For this reason the American Lung Association also recommends that access to medications not be tied to participation in counseling (American Lung Association 2014).

In practice, quitlines may find that offering both treatments without making one conditional on the other leads to a high percentage of participants using both. Some counseling participants opt not to use medications, and some others who receive medications either opt not to receive counseling or cannot be reached for counseling after their first session. On average, however, offering free medications increases the amount of counseling used (McAfee 2008), so there is

little need for concern that medications will supplant counseling as the treatment of choice of most quitline participants.

### *Recommendations on Medications*

All 7 FDA-approved medications, and nortriptyline and cytisine, are research-validated treatments, as is combination NRT. Providing medication as an adjunct to telephone counseling is a research-validated best practice.

Following are specific recommendations relating to medications:

- *Offer at least a 2-week starter kit of single-form OTC NRT to all quitline participants for whom NRT is indicated.*
- *If the budget allows, offer combination NRT or varenicline instead of single-form NRT, as they have the strongest documented effect on quit outcomes.*
- *If the budget allows, offer at least 6-8 weeks of medication, as longer courses may be more effective than shorter ones.*
- *Offer telephone counseling to all participants provided medications, but do not require it.*

## **Referral**

Referral in quitline practice means either: (1) quitline staff helping participants access third-party services, such as mental health services or other tobacco cessation programs, or (2) professionals in the community helping tobacco users access the quitline, by giving them the quitline number and telling them to call (also known as indirect referrals), or by sending their contact information to the quitline so that quitline staff will proactively contact them (known as direct referrals). “Referral services” enable professionals in the community, whether in health care, behavioral health, social services, or other community agencies to make direct referrals to the quitline. These referrals may be made by phone (e.g., by transferring callers), by fax, by email, via a dedicated webpage, or electronically from within an EHR system. The term “eReferral” designates the last of these (although strictly speaking referrals made by email or online are also electronic).

Quitlines provide outbound referrals either to help participants access additional help to quit smoking (for example, by referring to local in-person cessation programs) or to help them manage other conditions beyond the quitline’s scope of practice. The FY2015 NAQC survey asked quitlines if they refer “to other cessation services offered by health plans,” and “to other health services for chronic conditions (i.e., diabetes, hypertension).” Nearly three quarters of U.S. quitlines (73%, or 35/48) do the former and 29% (14 of 48) do the latter (Rudie 2016). Quitlines that have eligibility criteria may also make outbound referrals for individuals who are ineligible for quitline service.

Regarding inbound referral services, information in the NAQC database indicates that all state quitlines have them (Rudie 2016).

- 100% (53/53) of quitlines accept fax referrals.
- 85% (45/53) accept email or online referrals.
- 36% (19/53) accept eReferrals.

Quitlines offer various services to support and encourage these referrals.

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- 96% of quitlines (51/53) offer quitline and/or referral brochures.
- 23% (12/53) offer customized referral/consent forms.
- 87% (46/53) offer patient progress reports.
- 85% (45/53) offer customized provider feedback reports.
- 43% (23/53) offer staff training.
- 8% (4/53) offer a quitline/referral program newsletter.

Quitlines accept inbound referrals in order to:

- Capitalize on the “teachable moment” when a tobacco user seeks health care treatment for a condition that may be caused or aggravated by tobacco use.
- Motivate health care providers to address tobacco use in their patients by giving them somewhere to send those who use tobacco.
- Facilitate health care systems change (e.g., the shift toward prevention).
- Reach tobacco users who may not respond to mass media advertising.
- Reduce the cost of promoting quitline services (e.g., the cost per caller).
- Reduce the variability in demand for quitline services throughout the year.

### *The Evidence for Referral*

Outbound referral is generally not viewed as an intervention in its own right, but rather as a way to give participants additional quitting options beyond what the quitline itself can offer, or to help keep sessions focused on cessation by sending participants elsewhere for concerns such as managing a chronic health condition or mental illness. Since evaluation does not focus on whether referring to third-party programs improves quit outcomes, the effect of such referrals on quit outcomes is unknown.

Similarly, accepting inbound referrals may not always be viewed as an intervention in its own right. However, early evidence for telephone counseling was based on subjects who take the initiative to call quitlines themselves. It was important to investigate whether it also helps subjects who are proactively recruited.

The review of telephone counseling trials by Stead and colleagues includes an analysis of 30 trials with participants (N=19,134) who did not call quitlines (Stead 2013). As mentioned in the section on telephone counseling, the intervention had a significant effect (RR 1.34; 95% CI 1.22 to 1.46). The authors did not perform a sub-analysis focused solely on trials with referral.

Four specific trials may offer insight on the issue of whether referring patients to quitlines increases their long-term odds of success in quitting. In one, hospitalized patients in the San Francisco Bay Area (N=2,024) were randomly assigned to (1) usual care, (2) in-patient counseling with 1 post-discharge telephone contact, or (3) inpatient counseling with 4 post-discharge contacts (Miller 1997). One-year cessation rates were significantly higher in group 3 than in group 1, and subgroup analyses show that the odds of quitting among patients with cardiovascular disease or other internal medical conditions were also greater in group 3.

In another study, eight community-based primary care clinics in Wisconsin were randomly assigned to usual care or an intervention (Katz 2004). A total of 2,163 adult smokers were enrolled. Staff at usual care sites received general information about the clinical practice

guideline. Intervention sites received a tutorial for intake clinicians, a vital signs stamp, and performance feedback. Intervention site subjects received an offer of free NRT and proactive telephone counseling. Intervention group patients were significantly more likely than usual care patients to be abstinent at 6 months.

In a third study, the practices of 69 primary care physicians in Australia were randomly assigned to usual care or to an intervention (Borland 2008). Recruited patients (N=1,039) all received the same in-practice support, while those in the intervention group were also referred to a quitline. Abstinence at 12 months was significantly higher in the intervention group than in usual care and the effect was mediated by the amount of help they received outside the practice.

In a fourth study, 68 dental clinics in Mississippi were randomly assigned to one of three conditions: (1) usual care, (2) an “Ask, Advise, Refer” intervention, or (3) a 5 A’s intervention, i.e., Ask, Advise, Assess, Assist, Arrange (Gordon 2010). A total of 2,160 patients were enrolled. Compared to usual care, those in the two intervention conditions combined were significantly more likely to be abstinent at 12 months. There was no difference between the two intervention groups. The intervention effect seemed to be due more to changes in clinicians’ behavior than to the quitline, since uptake of telephone counseling was low.

These studies suggest that **interventions that incorporate referral to a quitline can significantly improve long-term quit outcomes.**

### *Evaluation of Referral*

Directly referred participants who receive telephone counseling or medications are included in a quitline’s standard quit rate. If desired and if the sample is large enough, a supplemental quit rate based solely on these participants can also be calculated. However, care should be exercised when comparing quit rates of referred and non-referred participants since they may differ in important ways that cannot easily be controlled in the analysis. For example, directly referred participants may have greater self-efficacy for quitting smoking.

Process evaluation is critical to ensuring high quality in referral systems. A thorough evaluation requires the collaboration of referring organizations. It should focus on such questions as:

- Within a targeted health care system, what percentage of eligible providers participates in the direct referral program?
- What strategies are most effective for gaining their participation?
- Among participating providers, what percentage of patients is screened for tobacco use?
- Of these, what percentage receives the intended clinical intervention including referral?
- Is the number of within-practice referrals maintained over time?
- Are the number of referring providers and the total number of referrals changing?
- Are there differences in uptake by:
  - Referral source (i.e., health care providers vs. other professionals)?
  - Referral type (direct vs. indirect)?
  - Referral method (e.g., fax, email, eReferral)?
- How satisfied are referring providers with the program, including:
  - Patient materials and consent forms?
  - Progress and feedback reports?

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- Staff training and technical assistance?
- What percentage of direct referrals is contacted by the quitline, with how many attempts and over what length of time, on average?
- What percentage of contacted referrals opts for evidence-based treatment? What percentage receives it?
- What strategies are most effective at maximizing “treatment reach” among direct referrals (i.e., the percentage receiving evidence-based treatment)?
- To what extent do directly referred participants use other quitline services besides telephone counseling and medications?
- What proportion of participants who call the quitline themselves report that they heard about the service from a health care provider or other professional in the community (indirect referrals)?
- How do direct and indirect referral methods compare with respect to the cost-efficiency of recruiting participants into quitline service?

Readers who want to explore this topic in greater depth should consult the NAQC issue paper, “Quitline Referral Systems” (NAQC 2013).

### *Considerations for Purchasers*

Quitlines have been enabling and encouraging provider referrals for decades. But in recent years, health care reform has expanded the opportunities for referral. For example, patient health records are now more likely to be stored electronically than in paper format. With a mechanism for quitline referral embedded directly into EHR software, providers can quickly and easily consent and refer their tobacco using patients to the quitline. Just as important, health systems can set quality goals for the identification and treatment of tobacco users and track their progress in this area, earning credit for the “meaningful use” of patient data by referring smokers to the quitline. These conditions have increased interest in referral among health care providers and systems. At the same time, many North American quitlines have been developing their capacity to accept eReferrals and return automated progress reports to referring providers.

For public funders of quitline services, such as state or provincial governments, it makes sense to support eReferral not only because it is an effective way to drive quitline utilization, but also because it helps to normalize tobacco cessation intervention in health care. For private purchasers of quitline services, such as health plans and employers, eReferral represents an opportunity to increase the proportion of their members and employees receiving evidence-based tobacco dependence treatment, thereby speeding the decrease in their prevalence of tobacco use.

Readers who want to learn more about eReferral should consult the NAQC technical guidance document, *Guide for Implementing eReferral Using Certified EHRs* (2016).

### *Recommendations on Referral*

Based on the available evidence, promoting referrals to the quitline is a research-validated best practice.

Following are specific recommendations relating to referral:

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- *Offer a range of direct and indirect referral options to allow providers in various settings to refer tobacco users to the quitline, and make patient materials freely available to encourage provider participation.*
- *Develop the capacity to accept eReferrals from a range of certified EHR's and to return automated, patient-specific reports.*

## **CROSS-CUTTING ISSUES**

This review has so far focused on categories of quitline service, one at a time. Several issues that cut across multiple categories are discussed here. These are all key issues that may arise for purchasers as they weigh specifications for their quitline services.

### **The Challenge of Moving Toward Multimodal Service Delivery**

The movement in quitlines toward multimodal service delivery is driven by several considerations. For a growing portion of the tobacco using population, phone conversations are not the normal or preferred mode of communicating. To reach these tobacco users and avoid eventual obsolescence, quitlines need to change with the times and meet their target audience on its preferred platforms. Some of these platforms offer possibilities that did not exist with telephone counseling, such as the ability to share a much wider range of content. Some make it possible to achieve greater efficiency through automation, so that a quitline can engage many more users than it could with telephone counseling alone. Also, having a suite of different but related services may make it easier to re-engage participants over time. Taken together, these considerations make a powerful case for diversifying the quitline's service offerings.

Despite these advantages, however, the efficacy of telephone counseling does not automatically carry over to the newer services, even if their development was informed by the experience of providing that counseling. If program efficacy continues to be a high priority, how should multimodal quitlines address the unevenness in the evidence base? Here are two possible approaches:

One approach is to regard the services that do not yet have strong evidence of efficacy primarily as tools for increasing the quitline's reach. Their purpose is to attract a larger, more diverse pool of participants who may eventually—if they have a positive experience with the initial service—use other more evidence-based services. In this approach, the idea is to let users “get their feet wet,” consume content that they find engaging and useful, develop trust in the quitline as a credible and responsive organization, and receive occasional invitations to use other quitline services such as telephone counseling and medications. Some participants may make quit attempts while using the unproven services, and may even be successful. But because it can never be known to what extent, if any, the unproven services contribute to their quitting success, such participants are not counted as “treated” unless they also use the quitline's other, more evidence-based services.

Another approach is to put the services that do not yet have strong evidence on a pathway to efficacy. In this approach, the quitline continues their development, paying close attention to trials that have had either an effect or no effect, imitating the former and avoiding any mistakes of the latter, and conducting rigorous evaluations with the goal of continuous program improvement. When the service reaches a point that it reflects best practices for tobacco dependence treatment (e.g., as articulated in the clinical practice guideline), takes full advantage of the capabilities of the underlying technology, has features that providers and tobacco users believe are important, is well utilized and highly rated by users, and demonstrates strong outcomes in real world evaluations, the quitline might consider partnering with quitline researchers to test it in a randomized, controlled trial to obtain proof of efficacy. This would not

only give assurance that the service does actually help tobacco users quit, but would also help build the evidence base and drive improvement in the entire field.

These two approaches are not mutually exclusive. A quitline could work toward the goal of demonstrating effectiveness in all its newer services, while regarding them in the meantime as tools for increasing reach and for introducing participants gradually to the quitline's other, evidence-based services. In fact, if and when the newer services are proven effective, it may turn out that their effectiveness is due in part to their ability to get users to also use more traditional quitline services. Likewise, it could turn out that the effectiveness of traditional quitline services is enhanced by the adjunctive use of the newer services. The hope is that the quitline will serve a larger population *and* be more effective overall.

Each quitline must decide how much of its resources to spend developing and providing novel services that are as yet unproven, versus other services that have a strong evidence base. Information sharing among quitline stakeholders may help to develop consensus about the relative priorities of efficacy and innovation.

### **Determining the Target Audience**

The movement toward multimodal service delivery was driven in part by a desire to reach younger smokers, but most quitlines still aim to serve people of all ages, or at least adults of all ages. They try to ensure that tobacco users of racial/ethnic minority backgrounds are at least as well represented among quitline participants as among tobacco users in the general population. Some take steps to reach a disproportionately large share of tobacco users of low socioeconomic status (SES) and some even have tiered services, reserving the highest level of service for the uninsured or under-insured. Limiting services in this way reflects the prioritization of a more vulnerable population of tobacco users, but it also may be used to encourage insurers to cover the cost of tobacco cessation treatments themselves instead of relying on a public health-funded service to do it. Since enactment of the Patient Protection and Affordable Care Act of 2010 (commonly called the Affordable Care Act), insurers and employers in the U.S. have been required to cover the cost of cessation treatment for their populations.

Although target audiences are often described in demographic terms, in reality the target audience for most quitlines consists of those tobacco users who most need its help, or who think that they do. These are the ones most likely to respond to quitline advertising, referrals, and other promotional strategies. It is worth remembering, when planning quitline services, that the profile of those who actually use the services may be quite different from that of the average tobacco user in the broader community. They are more likely than tobacco users in general to:

- Be daily, heavy smokers.
- Be economically disadvantaged.
- Have mental illness.
- Have chronic disease.
- Have a disability.

This has some important implications. First, promotional and educational materials should reflect the quitline's target audience with respect not only to race, age, and gender, but also to other personal characteristics such as these. In their training programs, quitlines should ensure that



their staff understand and can empathize with the cultural perspectives and challenges that so many participants experience. There are also ways of thoughtfully addressing such challenges in program design, such as by providing online content on quitting smoking with diabetes or other physical and mental health conditions.

### **Ensuring Accessibility**

One of the great selling points of quitlines over the years has been their accessibility. Unlike face-to-face programs which may charge for attendance, pose transportation and childcare challenges, and be available only intermittently, quitlines are free to users and can be reached by anyone with access to a phone. Most have extended hours and are available year-round. These qualities have helped quitlines appeal to a large audience, especially the economically disadvantaged.

In recent years state quitlines have also become more accessible linguistically. With NCI's addition of a national Spanish quitline portal, and with CDC's funding of the national Asian Smokers' Quitline, there is now nationwide, toll-free access to quitline services in several of the nation's most commonly spoken languages:

- 1-800-QUIT-NOW     English
- 1-855-DEJELO-YA   Spanish
- 1-800-838-8917     Chinese (Mandarin and Cantonese)
- 1-800-556-5564     Korean
- 1-800-778-8440     Vietnamese

While intake, self-help materials, and telephone counseling are available in all of the languages above, other quitline services may only be available in English, and online there is much less information in the other languages. For telephone calls in languages other than the ones listed above, many quitlines engage third-party interpreters such as LanguageLine. This ensures a basic level of accessibility to participants who speak other languages, though the quality of the intervention is not as high as when speaking directly with participants. These linguistic limitations are important to keep in mind when deciding how broadly to promote the service.

Likewise, quitline services are not always optimized for people with disabilities, including the blind, the deaf or hard of hearing, and those with learning disabilities, and written information, whether in print or online, often does not follow best practices for health literacy (USDHHS ODPHP). To some extent, quitlines compensate for these deficits by offering help in a range of formats, enabling users to choose the ones most suitable for themselves. Ideally, however, quitlines would implement best practices for accessibility across all platforms, increasing comprehension and retention not only for those with disabilities or low literacy, but for all participants.

### **Considering 24/7 Operation**

The question whether it is better to offer service 24 hours a day, 7 days a week than during more limited hours affects both intake and counseling. Quitline advertising that airs late at night or on weekends may reach tobacco users, some of whom will respond by calling at those times. Even without advertising, there is a subset of potential participants who will contact a quitline at traditional off-hours. Therefore, being open 24/7 provides maximum flexibility to participants

and may help the quitline reach some who would not have called at more conventional times. However, there is a cost associated with staffing a quitline around the clock which may only be acceptable if there is a sufficient level of demand to keep staff busy during the late night hours. There is an opportunity cost as well, as staffing the late shift means fewer staff are available for busier shifts.

The question is more complicated for counseling. After the first session, most telephone counseling is provided on a proactive basis, meaning the quitline calls the participant. Quitlines avoid calling participants when they have reason to believe they are asleep. Therefore, in the late night hours counselors can only provide reactive (i.e., inbound) counseling, or call participants whom they know are available at those times. Therefore, as with intake, offering counseling on a 24/7 basis can help to reach those who would not have participated during more conventional hours, but it can be challenging to ensure that counselors have enough work to keep busy during the late night hours, and covering those shifts may make it more difficult to cover the busier shifts.

For these reasons, operating on a 24/7 basis makes sense only for those service providers that are large enough to experience substantial demand for service in the late night hours and have no trouble staffing around the clock (e.g., those that operate quitlines for multiple states, and that are active across several time zones). For purchasers, it makes sense to require 24/7 operation only if they plan to run substantial after-hours advertising and are willing to accept the tradeoffs described above.

### **Adapting Service Provision to Fluctuating Demand**

As the most resource intensive services offered by quitlines, intake and counseling are also the most challenging to adapt to fluctuating demand. The intensive, individualized nature of these services means that the number of participants requesting service is the key factor in determining the level of resources (i.e., staff hours) needed to provide them, and the number of participants requesting service may be highly variable. This is because proven mass communication strategies such as television advertising campaigns are used unevenly throughout the year. Overlapping campaigns run by different agencies (e.g., CDC and the state tobacco control program) may produce dramatic “peaks” in demand. Correspondingly, times when few or no major mass media campaigns are running can lead to “valleys” in demand.

To a limited extent, quitlines may cope with this challenge by obtaining greater efficiencies from their staff in times of high call volume. That is, they may ask staff to spend a greater percentage of their time on the phone with participants. This is not an ideal solution, because it suggests either that productivity was suboptimal before the period of high demand began, or that the quitline is risking burnout by exceeding the optimal level of productivity, which if continued for too long can reduce service quality and increase staff turnover. In either case, if over time there are big changes in staff productivity (as measured, for example, by the average percentage of time spent in session with participants), it may indicate a need to examine the quitline’s processes to achieve a baseline of greater productivity.

Quitlines may have other forms of flexibility with staffing, such as by offering extra hours to part-time or on-call staff, though this obviously has a financial cost.

There are other, more sustainable approaches for dealing with the challenge of uneven demand. First, quitlines should try to minimize fluctuations by:

- Coordinating with all partners who promote the quitline to achieve, to the extent possible, a year-round campaign.
- Partnering with health care providers and systems to generate referrals. Direct and indirect referrals can create a consistent base of demand that diminishes the impact of peaks or valleys in media-generated demand.

Second, quitlines may alter the service itself to better match available resources, for example by:

- Developing abbreviated intake and counseling protocols for use in high-demand periods or with subgroups of participants who are judged to need less help than others (e.g., because they have fewer risk factors for relapse).
- Increasing the role of NRT provision, which is a more scalable service than counseling.

A caveat to the last suggestion is a weakness in the evidence for single-call protocols (as discussed in the section on telephone counseling). It suggests that if efficacy remains a top priority even in times of high call volume, a quitline using a single-call protocol should first test it against a minimal intervention control in a randomized design, or should supplement it with medications.

A thorough examination of service models is beyond the scope of this paper. Readers who want to explore this topic further should consult the NAQC issue paper, “Quitline Service Offering Models: A Review of the Evidence and Recommendations for Practice in Times of Limited Resources”, which makes recommendations for several basic service models (NAQC 2012).

## **FURTHER RESEARCH AND DEVELOPMENT**

Following is a list of some key questions for further research and development, by type of service.

### **Intake**

- Given that conducting intake interviews is a resource-intensive activity with no evidence that it improves outcomes, what are the best practices for streamlining and automating the process while ensuring data accuracy and satisfaction among participants?

### **Self-help Materials**

- Traditionally, printed self-help materials are sent in a single mailing immediately after intake. Given the lack of evidence that they improve outcomes as an adjunct to telephone counseling, should they continue to be provided? Are there alternative formats and protocols that would make more of a contribution to quitting success?

### **Telephone Counseling**

- What components of telephone counseling protocols are most responsible for their effects?
- Quitline counseling typically follows a structured protocol, providing consistency and ensuring thoroughness in the intervention. But it is generally structured around a single quit attempt or series of quit attempts over a brief period (i.e., a smoker registers for service and undergoes counseling to plan and execute a quit attempt). Short-term slips and relapse are addressed, but as a rule there is no standard protocol for re-engaging with participants over the long term. Since relapse is more common than abstinence and most smokers must make multiple attempts before quitting for good, are there protocols that do a better job of helping tobacco users achieve abstinence over the long term?
- Are there telephone counseling protocols that do a better job of helping smokers who have already quit (whether intentionally or not) to remain abstinent, for example, discharged hospital patients?
- With the movement toward giving quitline participants access to help in a wide range of formats, some of which have weaker evidence of efficacy than telephone counseling, there is an effort to build linkages between services. For example, text messaging participants may receive occasional messages inviting them to speak to a live counselor, or there may be a keyword they can use as needed to get a callback from a live counselor. How proactive should the quitline be in promoting telephone counseling to these participants? Given the somewhat random nature of these cross-overs between services, what is the best protocol to use in these cases?
- Some of the trials of telephone counseling and medications appeared to show that medications make a greater contribution to quit outcomes than counseling. Is there a behavioral support protocol that would be more effective as an adjunct to medications, perhaps one that combines telephone counseling with newer technologies?
- Is there a good use for video telephony in quitline counseling?

## **IVR**

- Are there other good uses for IVR beyond the basic triaging of calls, such as:
  - Recruiting new participants and re-engaging previous ones?
  - Replacing all or parts of calls and supplementing telephone counseling?
- Can an IVR-based intervention used in a quitline setting, designed to stand on its own but with links to other services such as telephone counseling, significantly improve quit outcomes?
- What are best practices for IVR-based intervention design with respect to intensity, duration, interactivity and tailoring?
- How does use of IVR affect program costs, use of other services, participant satisfaction, and reach?

## **Text Messaging**

- Can a text messaging intervention used in a quitline setting significantly improve quit outcomes?
- Does multimedia content such as links to web pages, images, audio, and video increase participant engagement and satisfaction?
- What are best practices for text messaging program design with respect to intensity, duration, interactivity and tailoring?
- Are there other good uses for text messaging besides as a stand-alone program, such as:
  - Supporting or supplementing telephone counseling (e.g., sending upcoming call reminders or “sorry we missed you” messages; offering additional encouragement or advice for relapse prevention; inviting users to access additional counseling if they’re having difficulties)?
  - Recruiting new participants via direct text marketing?
  - Promoting other quitline services (e.g., mobile app, website, telephone counseling)?
  - Re-engaging previous quitline participants, either from the telephone counseling program or from the text messaging program itself?
- How does use of text messaging affect program costs, use of other services, participant satisfaction, and reach?

## **Mobile Apps**

- How can smartphone technology best be exploited to engage and assist tobacco users in quitting? What capabilities do smartphones and tablets have that the developers of existing tobacco cessation apps have not yet exploited?
- Can a mobile app designed as part of a suite of quitline services significantly improve quit outcomes?
- How does use of mobile apps affect program costs, use of other services, participant satisfaction, and reach?

## **Web-based Services**

- Is there a combination of web-based technologies and content which, when deployed in a quitline setting, significantly improves quit outcomes?

- How does use of web-based services affect program costs, use of other services, participant satisfaction, and reach?

### **Medications**

- What is the shortest duration of medication provision that is still effective for quitline participants, either as a standalone treatment or as an adjunct to telephone counseling? What is the most cost-effective duration of treatment?
- If nortriptyline and cytisine, which are usually cheaper than similar medications, become available for use in North America, should quitlines offer them? Are they effective as adjuncts to telephone counseling?
- What is the cost per successful quit of varenicline compared to NRT and combination NRT?

### **Referral**

- How do participant characteristics differ among those who self-refer, are indirectly referred, or are directly referred? How do they differ among those who are directly referred via fax, online, or e-referral? Are they associated with differences in treatment utilization, satisfaction, or quit outcomes?
- What strategies are most effective for gaining the participation of health care systems, providers, and other partners (e.g., community-based organizations) in making direct referrals to quitlines?
- What strategies are most effective at maximizing “treatment reach” among patients directly referred to quitlines (i.e., the percentage receiving evidence-based treatment)?

## **IN CLOSING**

Since quitlines were first introduced to North America in the early 1990's, they have grown in number, size, and complexity. This growth reflects both a widespread and continuing need for help with tobacco dependence and the quitline community's dedication to meeting that need with appealing and effective services. All NAQC members and stakeholders have roles to play in the ongoing improvement of quitline services, whether by funding and supporting development, identifying needs and opportunities, thoughtfully designing or redesigning interventions, building out and implementing services, carefully evaluating them, or disseminating findings.

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