NAQC Issue Paper

NAQC's Issue Papers aim to provide critical knowledge on important quitline topics and guidance for decision making.

Quitline Service Offering Models: A Review of the Evidence and Recommendations for Practice in Times of Limited Resources

INTRODUCTION

Now more than ever, public entities responsible for funding quitlines are working to determine what service offerings, or combinations of service offerings, move them closer to reaching the stated goals of their quitlines in the most cost-efficient manner. With evidence to guide decision-making mounting, this paper summarizes the data and makes recommendations for most effectively using limited resources when determining quitline service offering options.

Since the initiation of the first U.S. quitlines in the early 1990s, the scientific evidence establishing quitlines as an effective intervention for assisting tobacco users has grown considerably. This evidence has been translated into effective practice, with practitioners using the science to guide protocols development, training, and continuous quality improvement. Today quitlines exist in all 50 states, the District of Columbia, the Commonwealth of Puerto Rico, and the Territory of Guam; in each of the ten Canadian provinces and three Canadian territories; and, most recently, in Mexico. These quitlines, though varied in their service offerings, provide information, counseling, medication, and other support for people who want to quit using tobacco. Today, quitlines provide an effective, low-cost, and easily accessible public health intervention with capacity to serve large numbers of tobacco users.

There is a strong commitment to publicly funded quitlines in the U.S. as evidenced in funding support from state governments, the Centers for Disease Control and Prevention (CDC), and the National Cancer Institute (NCI), the recent creation of a National Quitline Data Warehouse, and designated funding for quitlines in the Prevention and Public Health Fund of the Affordable Care Act. Similarly, Health Canada has pledged support for provincial quitlines, providing funding to cover the cost of increased call volume resulting from the addition of a national telephone number on all cigarette packages in 2012. Increasingly, those involved with quitlines have been working to expand funding for quitlines through public-private partnerships.

At the same time, the environment continues to shift in ways that are straining resources. A recent report found that quitlines are reaching their highest levels of utilization at the same time that overall funding levels are decreasing. As a result, quitlines are having to reduce eligibility for services, counseling services, and or reduce or eliminate the provision of medication. With fewer resources, it is more important than ever to turn to the evidence to guide decisions to maximize efficiency and reach without sacrificing quality. In the following section, the challenges and opportunities impacting decisions around quitline service offerings are discussed.

Economic Challenges

The economic recession has negatively impacted funding for quitlines. Many states have made drastic funding cuts to their tobacco control programs, including quitlines. For example, in 2009 Wisconsin's state funding for smoking cessation was cut by 55%, which resulted in the quitline scaling back services for insured callers from four proactive calls to one. The state of Washington now provides quitline services only to Medicaid recipients as a result of state budget cuts, though some state funding is expected to be restored in July of 2012 (A. Malarcher, personal communication, June 28, 2012).

These states are not the exception. A recent analysis of utilization, budget, and quitline service trends found that from 2009 to 2010, 51% of state quitlines reported spending reductions, with 38% reporting reductions in service budgets, 36% cutting spending on medications, and 47% reducing funding for promotions. Of the 27 quitlines reporting funding reductions, two reported limiting eligibility for service, two reported reducing the number of counseling sessions from a five-call protocol to a one-call protocol, five reported reducing or eliminating nicotine replacement therapy (NRT), five limited eligibility criteria for NRT, and five reduced or eliminated promotions.

While revenues were greatly reduced by the recent economic recession, state governments continue to receive significant dollars from tobacco settlements and tobacco taxes. Despite \$25.6 billion tobacco dollars received in fiscal year 2012, states reduced funding for tobacco prevention and cessation programs 12% in the past year and 36% in the past four years. As a result, tobacco control funding is at its lowest level since 1999, when states first received settlement dollars. Many quitline programs, in particular, are severely underfunded. With a slow economic recovery, competing legislative priorities, and continued diversion of tobacco settlement dollars from their intended use, it is likely that adequate funding for quitlines will continue to be a challenge.

While state expenditures for U.S. quitlines have decreased, recent CDC funding has helped close the funding gap. Through American Recovery and Reinvestment Act dollars, the CDC funded state quitlines for \$44.5 million from 2010 to 2012. Additional Affordable Care Act funding (\$8.8 million) was made available from 2011 to 2012 and up to \$22 million in quitline funding for the Prevention and Public Health Fund of the Affordable Care Act will be awarded in 2012 (A. Malarcher, personal communication, June 28, 2012).

Increasing Consumer Demand

These economic challenges correspond to a period in which state and provincial quitlines are positioned to experience dramatic increases in consumer demand for their services. The Food and Drug Administration issued a final ruling in June of 2011 that beginning in September 2012 enhanced graphic health warnings would be required for cigarette packaging and advertisements. These larger, graphic health warnings will cover 50% of the front and back of cigarette packs, as well as 20% of all cigarette advertisements in the United States and include the national quitline portal number, "1-800-QUIT-NOW." The implementation date at this point, however, is uncertain due to ongoing legal proceedings in the case of *R.J. Reynolds Tobacco Co. v. U.S. Food and Drug Administration*. ¹³

In Canada, tobacco manufacturers and importers were required to use new warning labels beginning March 21, 2012, and retailers must ensure that all packages on their shelves feature the new labels by June 19, 2012. The new regulations include health information messages covering 75% of the front and back of cigarette and little cigar packages, with enhanced colors and graphics, a toll-free number (866-366-3667) for provincial quitlines, along with a website to inform tobacco users about the availability of smoking cessation services. ¹⁴

Despite the uncertainty in the U.S. regarding graphic warning labels, NAQC and the quitline community have been active in planning for eventual implementation. Quitlines will need to be prepared to adjust their service offerings to respond to what will likely be an historic opportunity to serve large numbers of tobacco users. Based on the experiences of other countries that have included quitline numbers in enhanced health warnings, a significant increase in calls can be anticipated. For example, Australia saw a doubling of call volume and the Netherlands experienced a 3.5-fold increase in calls when graphic warning labels with a quitline number were introduced. ^{15, 16} Similar results were seen in New Zealand. ¹⁷ In addition to these published findings, much will be learned in the coming months from the Canadian response to enhanced warning labels.

In the near term, the CDC launched the National Tobacco Education Campaign on March 19, 2012. Called "Tips from a Former Smoker," the goals of the campaign were to raise public awareness about the health consequences of smoking, encourage quit attempts, and promote cessation resources. The campaign targeted smokers with hard-hitting television, radio, print ads, and web content tagged with 1-800-QUIT-NOW or www.smokefree.gov. ¹⁸ While the

campaign's overall impact is currently being evaluated, reports indicate that nationally, call volume doubled during the first three weeks of the 12-week campaign.¹⁹

Expanding Access to Cessation Services

Health care reform efforts in the U.S. also have the potential to significantly impact quitlines. The Affordable Care Act requires coverage of tobacco cessation, in accordance with the U.S. Preventive Services Task Force A and B Recommendations. As a result, tobacco cessation is likely to be included in the essential health benefits in products available through the state health insurance exchanges. While the scope of covered services is not yet clear and will vary from state to state, the Affordable Care Act will likely open the door for new public-private, cost-sharing partnerships that support quitline sustainability and expand access to evidence-based cessation services for all tobacco users. In the shorter term, the Centers for Medicare and Medicaid Services changed its policy in 2011 to make tobacco cessation quitline services for Medicaid beneficiaries an allowable administrative cost expenditure, ²⁰ although it is unclear at this time how many state Medicaid offices will take advantage of this partnership opportunity.

Many quitlines are also engaged in efforts to implement health systems change. Health systems change, which includes improvements or modifications in health care policies, administrative procedures, and health care delivery processes, can play a key role in addressing tobacco use and increasing access to such treatments during every encounter in the health care system.³ This work also includes efforts to integrate tobacco user identification and referral to treatment (including quitlines) into electronic medical records (EMRs) as part of routine care delivery.

While the impacts of these many opportunities to support tobacco cessation have yet to be realized, they too have the potential to impact decisions around future service offerings for quitlines.

Overview of This Paper

The dynamic environment in which quitlines currently operate presents a tremendous challenge: How can tobacco users be served most effectively at a time with historically high utilization, limited resources, and a rapidly changing public health and health care environment? Many factors will influence decisions regarding service offerings. However, given the strong role that science has played in the creation and advancement of quitlines, it is critical that the evidence generated from research studies and evaluation of practice be used to inform efforts moving forward. This paper was created in response to a request from NAQC members to summarize the evidence and provide recommendations on how to most effectively use resources when determining service offering options. It is intended to serve as a resource for the multiple audiences involved with tobacco quitlines, including decision-makers within state, provincial, and national organizations that fund quitline services, service providers who offer guidance to their clients, and other quitline and cessation professionals. In addition, providers and payers of privately funded quitlines may find this paper relevant given current efforts to promote public-private partnerships for quitline services.

This paper addresses the following questions:

- 1) How effective are different service offering models regarding quitline utilization, tobacco abstinence rates, and costs? Are there points at which the return on investment diminishes in terms of amount of counseling (attempted and completed) and medication provided?
- 2) What impact does the provision of medications through quitlines have on reach and quit rates? Which mechanisms for dosing and delivery of medications are most cost-effective and/or provide other efficiencies?
- 3) Is there evidence to support the use of advanced technologies (web, interactive voice response [IVR] and texting) to expand quitline service offerings? Are these approaches cost-effective? What other efficiencies are achieved?

This paper is based largely on a review of the published literature. In areas where there is little published evidence, examples from practice are included. This paper is organized into four sections. Section One summarizes the evidence and provides recommendations for four service offering models:

- 1) Reactive counseling;
- 2) Reactive counseling with medications;
- 3) Reactive/proactive counseling; and
- 4) Reactive/proactive counseling with medications.

Section Two summarizes the evidence and provides recommendations for pharmacotherapy, including methods of NRT delivery. Section Three summarizes the evidence and identifies important considerations for quitline practices related to technology advances. Section Four provides an overall summary of the recommendations for practice and research.

The tables included in Sections One (service model offerings) and Two (pharmacotherapy) of the paper present selected study elements abstracted from a larger summary table in Appendix A. Readers are encouraged to access the summary table for additional elements of the research studies, including study design and sample sizes. Studies reviewed for Section Three (technology advances) are summarized in the body of the paper only.

Literature Review

The review of the literature for this paper focused on three broad areas: 1) quitline service offerings; 2) pharmacotherapy offered through quitlines; and 3) technological advances to support quitline service offerings. The articles reviewed for this report were identified primarily through PubMed searches. Key search terms included: quitlines, tobacco cessation programs telephone, nicotine replacement therapy smoking cessation, nicotine replacement therapy quitlines, cost effectiveness quitlines, tobacco cessation programs internet, and interactive voice response cessation. Additional studies were identified from the reference lists of published articles and from NAQC issue papers.

The body of published research on quitlines is substantial; this paper focused on those studies most relevant to the purpose of this paper.

- This review focused on the literature most applicable to the real world experience of quitlines where smokers are initiating contact with a quitline. It included both **randomized** and **non-randomized** studies.
- This review did **not** include studies that examined the effect of offering telephone counseling proactively in other settings (i.e., recruited participants through health care settings, work sites, or communities). While these studies contribute to the overall evidence base for the effectiveness of quitlines, the outcome data offered by these studies did not as directly address the questions posed in this paper. In addition, in these studies, smokers did not initiate calls to the quitline. For similar reasons, this review did **not** include studies that examined the effect of providing access to telephone counseling to smokers as part of a larger cessation intervention or tobacco control initiative.
- This review did **not** focus on which populations are best served by various models. Readers are encouraged to access the 2011 NAQC Issue Paper, *The Use of Quitlines Among Priority Populations in the U.S.: Lessons from the Scientific Evidence*, ²¹ for further information regarding this topic.
- This review included studies of the effectiveness of fax-referral programs (as a component of a proactive service models) since this tool is standard practice for the majority of quitlines.
- This review did **not** include the literature on active recruitment (cold calls) of tobacco users to quitlines.
- This review did **not** include the literature on the effectiveness of media promotions and quit-and-win contests in increasing quitline reach. Readers are encouraged to access the 2009 NAQC Issue Paper, *Increasing the Reach of Tobacco Cessation Quitlines*, ²² for a review of this evidence.
- The review of technology advances (web, IVR, texting) focused on those studies most relevant for integration of these tools with quitline services.

Defining Effectiveness

Three categories of effectiveness - quitline utilization, tobacco abstinence, and cost - were examined in reviewing the literature (Table 1). Both reach and quit outcomes that were abstracted were based on what was reported in the research and are not necessarily reflective of NAQC standards for calculating reach or quit rates. 23, 24 Measures of quitline utilization included call volume and reach, though reach was reported much less frequently than call volume. The number of calls completed and the amount of medication reported used were also examined. The quit rate at sixmonth follow-up, using the measure of seven-day point prevalence and an intention-to-treat analysis (where all nonresponders are assumed to still be smoking), was the most commonly reported tobacco abstinence measure across studies. Other studies presented quit rates in terms of continuous, sustained, repeated, or prolonged abstinence (vs. point prevalence) and used different follow-up periods. Some studies reported responder rates which calculate quit rates only on those contacted at follow-up. These distinctions are carefully noted in the tables. Cost effectiveness was most typically presented as cost per quit. Cost per quit is calculated as the total cost of delivering the quitline service divided by the number of quitline participants who successfully quit. Some studies provided cost per additional quitter or incremental cost-effectiveness ratios (ICER). Cost per additional quitter is the cost for each additional quitter achieved through the intervention condition as compared to the control or comparison condition. The ICER is the difference in costs for the intervention and control (or comparison) groups divided by the change in effectiveness measured by the difference in quit rates or life-years saved in the two conditions.

Table 1. Measures of Effectiveness

Quitline Utilization	Tobacco Abstinence	Cost
 call volume quitline reach calls completed amount of NRT reported used 	 6 month follow up/ 7 day point prevalence (PP)/intention-to-treat (ITT) or responder rate (RR) other abstinence measures as reported 	 cost per quit cost per additional quitter incremental cost-effectiveness ratios (per quit or per life year saved) [ICER]

Reviewing these measures of effectiveness across studies is useful in drawing conclusions based on patterns of findings. Readers, however, are cautioned against making direct comparisons of outcomes from one study to another. While there are some consistencies in quitline metrics, much variation remains. There are different methods for calculating and reporting quitline reach. Studies with lower response rates at follow-up present more conservative intent-to-treat estimates of quitting than studies with higher response rates. The calculations of cost per quit vary tremendously (and are not adjusted for inflation), with some studies accounting for total costs including media promotions and others limiting the analysis to the direct cost of services. In addition to variation in measures, studies included in this review were conducted with a wide range of tobacco user populations. Study populations differed in their levels of motivation, tobacco dependence, treatment and quitting history, and other social and psychological dimensions that are related to quitting success. These differences may limit the generalizability of findings specific to a particular study population to the broader population of quitline callers.

Context for Interpreting Recommendations

There are several contextual factors to consider in interpreting the recommendations offered in this report. While quitlines have much in common, there is much diversity. A "quitline" may be a single state or provincial quitline, a single state quitline operating alongside others but not coordinated, or may be multiple, coordinated state quitlines. Levels of funding and goals differ, as do smoker characteristics and target populations. The state environments in which quitlines operate also vary. For example, states differ in terms of Medicaid coverage for tobacco-dependence treatment, prevalence of tobacco use, numbers and types of health plans, levels of tobacco control program funding,

funding specifically for media campaigns, and tobacco control policies.^{12, 25} Funders, service providers, and quitline professionals will need to consider their unique circumstances when considering the recommendations for practice offered in this paper.

In addition, the recommendations provided in this paper are built on research studies that for the most part tested one component of quitline service delivery at a time. In practice, quitlines typically provide multiple service delivery approaches (or a combination of approaches) that may not reflect the controlled conditions of the research studies reviewed for this paper. To that end, recommendations will need to be interpreted by each quitline within the context of their unique service delivery approaches.

Finally, it is important to recognize that the recommendations address service delivery to the general population of quitline callers, and that other considerations will need to be taken into account when defining service offerings for specific subpopulations of quitline users. Likewise, these recommendations are offered within a North American context and may not be generalizable to the broader international community of quitlines.

SECTION ONE: A REVIEW OF EXISTING SERVICE MODEL OFFERINGS

There is a significant literature that establishes the effectiveness of quitlines in providing counseling support and pharmacotherapy to smokers who are interested in quitting. To date, there are three current reviews of the quitline literature.

- The 2008 U.S. Public Health Service Guideline concludes that tobacco cessation counseling delivered via telephone is more effective than minimal or no counseling, or self-help materials (OR=1.6), and that providing both quitline counseling and medication is more effective than medication alone (OR=1.3).³
- A 2007 systematic review in *Tobacco Control* of interventions for smokers who contact quitlines provides evidence for the effectiveness of telephone counseling, concluding that multiple-call protocols improve quit rates over a single counseling call at first contact or self-help materials.¹
- A 2006 Cochrane Review on Telephone Counseling for Smoking (updated in 2009) included 65 studies that met the strict criteria for randomized or quasi-randomized controlled trials with no follow-up shorter than six months. These studies fell into three categories: 1) trials of interventions for people calling quitlines; 2) trials providing access to a quitline; and 3) trials of proactive counseling, not initiated by calls to quitlines. The overall conclusion, based on meta-analyses of all 65 studies, is that there is strong evidence for proactive counseling. There is also evidence of a dose-response relationship with one or two calls providing less benefit than three or more calls.

The 12 studies included in the first category of the 2006 Cochrane Review (trials of interventions for people calling quitlines) were included in this literature review on service model offerings. An additional 35 studies were identified that met the inclusion criteria for this review and contributed to the evidence base for service model offerings.

Reactive Counseling

When a tobacco user initiates contact with a quitline, any counseling provided from that user-initiated contact is considered reactive. Service is typically delivered in a single session to the caller but can occur through multiple user-initiated contacts with the quitline. Among U.S. quitlines, 71% provide single session counseling that is client initiated and 42% provide multiple-session services that are client-initiated (categories are not discrete). All Canadian quitlines report providing these two categories of reactive telephone counseling.

The evidence for the relative effectiveness of reactive counseling based on randomized trials is not strong.^{1, 2} The 2006 Cochrane Review of trials of interventions for people calling quitlines included three reactive counseling studies. One study compared reactive counseling (counseling at initial call with the option to call the quitline for repeated support) to mailed self-help materials and found no effect.²⁶ Two studies that examined reactive support for

callers during a single session at the initial call failed to detect an increased benefit from either tailored counseling for African Americans²⁷ or self-help materials for blue-collar workers. ²⁸ The relatively small number of controlled studies of reactive quitlines, however, should be considered before drawing definitive conclusions about the effectiveness of this service model. Many quitline providers have been unable to randomize callers to a service that is less than what is currently offered. As a result, there are few trials that directly test reactive counseling.^{2,7}

While the evidence from randomized studies is limited, an understanding of this service model is also informed by studies that included reactive counseling as a comparison arm (Table 2). Gilbert et al. reported an overall abstinence rate for a single session reactive call of 13.8% among callers to a United Kingdom quitline.²⁹ Zhu and colleagues found that 15.7% of those assigned to the single counseling intervention delivered through the California Smoker's Helpline reported having quit for at least six months, concluding that even a single pre-quit session can significantly increase quit attempts compared to self-help interventions.³⁰ Borland et al. reported a quit rate of 15% for callers to an Australian quitline who were assigned to the reactive call condition.³¹ Hollis et al. reported a quit rate of 12% for callers to the Oregon quitline who were assigned to the one call condition without NRT³² while Bush and colleagues reported a quit rate of 9.4% for callers to the Oregon quitline who received a single 30-minute counseling call (prior to the addition of free NRT).³³

Table 2. Reactive Service Models

Study (reference #)	Call Protocol	Quit Rates
Borland 2001	single call	6 month/ PP/RR
(31)		15% reactive vs. 23% multi-call
Bush 2008	30 minute call	6 month/7 day PP/ITT
(33)		9.3% pre vs. 17.0% post NRT
Gilbert 2006	10-15 minute	6 month/30 day prolonged abstinence/ITT
(29)	call	13.8% reactive vs. 15.1% multi-call
Hollis 2007	15 minute call	12 month/30 day PP/ITT
(32)		12% no NRT vs. 17% with NRT
Orleans 1998	single call	6 month/7 day PP/ITT
(27)		9.1% standard reactive vs. 10.1% tailored reactive
Sood 2009	single call	6 month/7 day PP/ITT
(26)		15% self-help vs. 15% reactive
Thompson 1993	single call	self-help vs. tailored reactive; no differences
(28)		
Zhu 1996	50 minute call	12 month/continuous abstinence/ITT
(30)		5.4% self-help vs. 7.5% single call

Together, these studies indicate that reactive quitline services produce quit rates that, while lower than those for other service models, are clinically effective. These quit rates compare favorably to estimates of baseline quitting in the population, where only 4-7% of those attempting to quit in a given year are successful.³ This conclusion is also consistent with the overall evidence for brief interventions where advice to quit smoking, as brief as three minutes, increases the odds of quitting (OR=1.3)³

Reactive Counseling with Medications

This service model includes the offer of medications in addition to reactive counseling. The U.S. Public Health Service Guideline reports that the combination of medication plus counseling is more effective than counseling alone (OR=1.7).³ In 2010, there were 39 U.S. quitlines that provided free quitting medications to callers.⁶ The evidence indicates that NRT combined with single-call reactive counseling is an effective service model (Table 3). A non-randomized evaluation of the Oregon free patch give away demonstrated that NRT in combination with a reactive,

single 30-minute counseling session was both clinically effective and cost-effective, and resulted in increased demand for services. Prior to adding a two-week introductory supply of NRT to a one call protocol, quit rates were 9.3%. Following the addition of free NRT, quit rates increased to 17.0%. Enrollments per month also dramatically increased from 257 pre-NRT to 2,592 post-NRT, with an increase in annual quitline reach from 1.2% to 2.6%. The cost per quit was \$1,050 with NRT compared to \$3,738 for single-call counseling without NRT (costs included those for the intervention and quitline promotions). A randomized, multi-arm study of the Oregon quitline found quit rates of 17% with a brief, 15-minute call intervention combined with NRT (up to eight weeks) compared to 12% without NRT. This study concluded that the brief call with NRT intervention was more cost-effective compared to an intensive call protocol without NRT (see Hollis, Table 5).

Table 3. Reactive Service Models with Medications

Study	Call	Medicatio	Increase in	Quit Rates	Cost
(reference #)	Protocol	n	Calls/Reach		
		Protocol			
Bush	30	2 wks	257 pre vs.	6 month/7 day PP/ITT	see Fellows
2008	minute	patch	2,592/month post	9.3% pre vs.	
(33)	call	mailed	NRT	17.0% post NRT	
Fellows 2007 (34)	see Bush	see Bush	6,428 pre vs. 13,646 annually enrolled post NRT; reach increased 1.2% to 2.6% post NRT	see Bush	\$3,738 pre vs. \$1,050 post NRT/cost per quit; \$174 cost per incremental quit (ICER)
Hollis 2007 (32)	15 minute call	5 wks patch (up to 8 wks) mailed	NA	12 month/30 day PP/ITT 12% no NRT 17% brief NRT	cost per incremental quit (ICER) relative to brief no NRT [actual costs=\$67] brief NRT: \$2467/add quit [\$107]

^{*}Shading denotes related studies.

Reactive/Proactive Counseling

Under the reactive/proactive counseling service model the user initiates the first contact with the quitline, which is followed up with proactive (counselor-initiated) counseling calls. Today, 92% of U.S. quitlines and 100% of Canadian quitlines provide multiple-session proactive telephone counseling to their callers. There is a more substantial evidence base for this service model as proactive counseling protocols can more easily be compared to less intense interventions under real-world conditions. Overall, there is strong evidence that multi-call proactive counseling sessions have greater benefit compared to self-help or single-session counseling (odds ratio of 1.41 for proactive vs. reactive support). The 2006 Cochrane review found that "compared to smokers who have only a single contact with the quitline, and are either sent self-help materials or receive brief counseling or both, those who are randomized to one or more additional calls increase their chances of quitting by 25-50%."

While the findings based on meta-analyses provide strong evidence for multi-call protocols, examining the individual studies provides for a finer grained-analysis of the impact of proactive counseling (Table 4). Several studies provide

support for proactive counseling compared to self-help. ^{30, 35-37} Four studies found more intense proactive protocols were associated with higher quit rates compared to less intense call protocols. ^{30-32, 38} In contrast, two studies reported that proactive calls were no better than a single reactive call²⁹ or print materials. ³⁹ In addition, a randomized trial of callers to England's national quitline found that offering additional proactive counseling did not result in increased tobacco abstinence, ⁴⁰ while a randomized study of callers to the New York State Smokers Quitline found no difference in quit outcomes at three months between a two-call and four-call protocol. ⁴¹

Table 4. Proactive Service Models

Study	Call Protocol	Calls Completed	Quit Rates
(reference #)		F · · · ·	
Borland 2001 (31)	multiple calls, first pre-quit, then according to need	80% of those offered callbacks received them; average of 2.8 calls completed	6 months/PP/RR 15% reactive 23% multi-call
Borland 2003 (36)	multiple calls, 10-15 minutes over 2-3 weeks; 1 st callback timed to quit date, then per request	67.8% of those offered callbacks received them; average of 3.3 calls completed	6 month/PP/RR 15.9% self-help 19.5% tailored 25.1% tailored + phone
Carlin- Menter 2011 (41)	1 st call 1 week before quit date; others scheduled per request; calls ave 8 minutes (NRT provided)	average callbacks = .96; of those in 4 call group, 14% completed more than 2 callbacks	3 months/7 day PP/ITT 13.6% 2 callbacks 14.0% 4 callbacks
Ferguson 2012 (40)	standard: initial call, messages before, on, and after quit data, 4 proactive calls offered intensive: plus 6-7 proactive calls	standard: 2.4 calls completed intensive: 3.3 calls completed	6 month/prolonged abst/ITT 19.6% standard 18.2% intensive
Gilbert 2006 (29)	5 proactive calls, 3 in wk 1, 1 in wks 2 & 4	73.7% those offered received multiple calls; ave of 2.7 calls completed	6 month/30 day prolonged abst/ITT 13.8% reactive call 15.1% multi-call
Hollis 2007 (32)	brief: 15 min call moderate: 40 mins with brief call 1-2 wks later intensive:30-40 mins, up to 4 add calls over 3 months	average calls completed: moderate: 1.7-2.0 intensive: 2.5-2.9	12 month/30 day PP/ITT brief: 12% no NRT vs. 17% NRT mod: 14% no NRT vs. NRT 20% int: 14% no NRT vs. NRT 21%
Rabius 2004 (37)	5 proactive calls, 2 pre quit date, 3 within 2 weeks	NA	6 month/prolonged abstinence/ITT 1.9% control vs. 8.8% proactive (18-25 yr olds) 4.1% control vs. 7.7% proactive (25+ yr olds)
Rabius 2007	1) 35-45 mins 10-14 days	approximately 1 in 10 completed	7 months/30 day PP/ITT
(38)	before quit, 2-3 days before	the number of sessions they were	self-help 7.6%

Study (reference #	Call Protocol	Calls Completed	Quit Rates
(rejerence #	quit; 1-2, 6-9, and 13-16 days post quit 2) 3 session protocol – first and last session eliminated 3) abbreviated 5 call protocol – each call reduced to 10 min 4) + 2, 15 minute boosters	assigned to; did not vary by group	(n=1,564) 5 sessions, 210 min 12.7% 5 session, 210 min + 11.7% 3 session, 105 min + 10.8% 5 sessions 50 min 10.0% 5 sessions 50 min + 14.1%
Smith 2004 (39)	moderate: 50 mins, quit date set, 2 calls at 2 & 7 days post quit vs. intensive: 4 further calls days 14, 21, 34, 40	76% in counseling group received at least 1 call; 22% intensive vs. 56% moderate received all calls	6 months/7 day PP/ITT 14% print only 15% telephone counseling
Zhu 1996 (30)	50 minute reactive vs. plus 5 further sessions (1,3,7,14, & 30 days post quit)	NA	12 month/continuous abstinence/ITT 5.4% self help 7.5% single call 9.9% multi-call
Zhu 2002 (35)	pre-quit plus 6 post quit calls within 3 months	72.1% of those assigned to counseling received at least one call	12 month/prolonged abstinence/ITT 6.9% self-help 9.1% multi-call

Intensity of Proactive Counseling

In considering this service model, it is important to note that while individual study outcomes have varied, the majority of studies testing the effects of proactive counseling have observed a dose response relationship between completed calls and quit success. ^{29-32, 35-41} Carlin-Menter and colleagues, for example, reported that quit success increased 60-70% for every additional callback session completed. ⁴¹

In many of these studies, the real differences in level of treatment received between those in the intervention and control groups were marginal and the number of calls completed, rather than the number assigned, was the stronger predictor of tobacco abstinence. For example, Hollis et al. reported that while one-year abstinence rates increased with more intensive follow-up calls, the difference between outcomes for the moderate and intensive conditions was modest. They attribute this to the fact that many of the callers in the five-call protocol did not complete all calls, which resulted in an intervention "dose" similar to those in the moderate condition. Similarly, Carlin-Menter et al. found no differences in the number of call-backs completed per group; only 14% of those assigned to the four-call group completed more than two call-backs. Ferguson and colleagues also noted that their failure to observe increased quit rates among those assigned to the intensive proactive intervention condition was likely due to the fact that there were similar numbers of completed calls in both the intensive and the standard groups. Two studies examined the level of counseling beyond which there is little added benefit. Borland et al. reported a decline in incremental benefit beyond one or two proactive calls, with effects disappearing after six or more calls. Rabius and colleagues concluded from a multi-arm study of different proactive call protocols that there is no evidence that cessation effects increase beyond 90 minutes of cumulative counseling time. Together, the pattern of findings across

these studies indicate that under real-world conditions, moderate-intensity protocols are likely to be as clinically effective as higher-intensity call protocols.

Cost Effectiveness of Proactive Service Models

Only a handful of studies reported cost outcomes for proactive protocols (See Table 5).^{31, 32, 41, 42} Hollis et al. calculated ICER relative to the brief, no-NRT condition and found that the moderate counseling conditions were more cost-effective compared to the intensive counseling conditions.³² Carlin-Menter and colleagues found no difference in cost per quit between those assigned to the two-call and the four-call conditions, which is not surprising given the similarity in the number of calls completed for both groups.⁴¹

As seen in Table 5, costs per quit vary widely, illustrating the variability in how measures of cost effectiveness are calculated. For example, the study by Carlin-Menter and colleagues used direct-services costs only (i.e., the costs for counseling, NRT, and shipping) in calculating costs per quit, while Hollis et al. included total costs for the intervention, including promotions.^{32,41} While these reported cost outcomes allow for comparisons across conditions within studies, in most cases direct comparisons across studies cannot be made.

Table 5. Cost Outcomes for Proactive Service Models

Study (reference #)	Call Protocol	Cost
Borland 2001	multiple calls, first pre-quit, then according	Australian \$650 cost per
(31)	to need	incremental quit (ICER)
		service costs: Australian \$46
		proactive vs. Australian \$13
		reactive
Carlin-Menter 2011	1 st call one week before quit date; others per	\$445 2 calls
(41)	request; calls average 8 minutes (NRT	vs. \$442 4 calls cost per quit
	provided)	service costs:
		intake + 2 wk NRT + ship=\$37
		additional 4 wk NRT + ship=\$48
		completed callback session=\$10
Hollis 2007	<u>brief</u> :15 mins	(ICER) cost per incremental quit
(32)	moderate: 40 mins with brief call 1-2 wks	relative to brief no NRT [actual
	later	costs=\$67]:
	intensive: 30-40 mins, up to 4 additional	brief NRT: \$2467/add quitter
	calls over 3 months	[\$107]
		mod no NRT: \$1912/add quitter
		[\$132]
		mod NRT: \$2109/add quitter
		[\$193]
		int no NRT: \$2641/add quitter
		[\$242]
		intensive NRT: \$2112/add quitter
		[\$268]
McCalister 2004	5 calls, 2 before quit, 3 within 2 wks (Rabius	\$1,300 cost per incremental quit
(42)	2004)	(ICER)

Number and Timing of Proactive Calls

The 2006 meta-analysis by Stead et al. found that three or more proactive calls demonstrated a stronger dose-response relationship than one or two brief calls.² The meta-analytic evidence considered along with the individual study

findings reviewed for this paper suggest that at this point, two to three completed proactive calls may be sufficient, from both a clinical and cost perspective, to achieve desirable outcomes. ^{2, 31, 32, 41} As seen in Table 4, many of the participants in the studies of proactive counseling completed fewer than the number of assigned calls, suggesting many callers do not want or feel they need the extra calls. It has also been suggested that the relationship between calls completed and quit success that has been observed may be the result of those who are succeeding in their quit attempts (or are more highly motivated) being more likely to receive the additional calls offered, rather than the value of additional counseling. ^{1, 41} While further research is needed to understand the relationship between calls completed and quit outcomes, the evidence to date indicates that counseling resources may be better used to reach a greater number of callers with fewer proactive calls.

Further research is also needed to identify the optimal timing of proactive calls. Zhu and colleagues have noted that the first week after quitting is the critical period for the counseling intervention.³⁰ Borland et al. confirmed the importance of frequent calls around the quit date.³¹ Stead et al. concluded from their 2007 meta-analysis that "the counseling protocols that showed clearest effects included at least one, pre-counseling session, and further calls scheduled close to the quit date but with flexible schedules."¹

Call Attempts to Complete Proactive Calls

While numerous studies have investigated the issue of how many proactive calls are most effective, the science is largely silent on the issue on how many attempts should be made to contact smokers to complete these calls. A handful of the studies included in this review noted that three to four attempts were made to contact participants before the attempt was deemed unsuccessful. ^{40, 41, 43} This review, however, found no studies that examined the points at which additional attempts to complete proactive calls with smokers were no longer effective. Indeed, Stead and colleagues noted in their 2007 review of quitlines that identifying the optimum number of attempts to complete calls that is most cost-effective remains challenging. Given the usefulness of this information for informing service model delivery, this represents a much-needed area for future research.

Content of Proactive Calls

Consideration must also be given to how content of proactive calls works to support tobacco abstinence. Zhu et al. found that the follow-up sessions provided to subjects in the multi-call condition had little effect on their probability of making a quit attempt, and that the dose-response relationship between additional calls completed and quitting was achieved primarily by reducing the relapse rate. Borland and colleagues also found support for this relapse-sensitive call protocol. Future research will be needed to understand which components of the multi-call protocols are most critical to support quitting and prevent relapse so that decisions to truncate either the number or length of counseling sessions preserve the most critical aspects of behavioral counseling delivered through quitlines in the remaining sessions.

Fax-Referral Programs for Proactive Quitlines

Fax-referral programs provide an opportunity to extend the reach of proactive quitlines. For states that do not have resources to promote their quitlines through mass media, fax referrals provide an important channel for reaching smokers. Fax-referral programs also work to connect quitlines with efforts to implement health systems change by expanding tobacco users' opportunities and access to treatment during health care encounters. ⁴⁴ Currently, 49 U.S. quitlines and seven Canadian quitlines accept fax referrals from health professionals who have delivered a brief intervention to tobacco users during an office visit. ⁶ While most provider referrals are faxed, NAQC Annual Survey Data reveals that email and EMR transmittal methods are now also being used. ⁶

Overall, there is strong evidence for the effectiveness of fax-referral programs, though the magnitude of outcomes varies across studies (Table 6). A 2006 study compared fax referral with providing a brochure to connect patients to a quitline. This study reported a 59% contact rate for those who were fax-referred to the quitline compared to a 19%

contact rate for the group receiving a brochure instructing them to call the quitline. Of those in the fax-referral condition who were eventually contacted by the quitline, 90% accepted a one-time counseling call. Program costs for the first year were \$15-\$22 per patient connected with the quitline and in subsequent years decreased to \$4-6 per patient. Similar findings were reported in an Australian study, with 64% of patients accepting an offer for fax referral and 74% of those referred being contacted. The cost was less than \$2 per person. Four additional studies reported similar levels of success in contacting those referred to the quitline. In contrast, Willet et al. found that only 40% of individuals fax-referred to a quitline could be reached for enrollment and that fewer than one quarter of all referrals resulted in an enrollment. Two other studies reported similar, lower rates of contact. 252,53

Table 6. Fax-referral Programs

Study	Source of	Contact Rates	Quit Rate or Provider
(reference #)	Referral		Impact
Bentz	primary care	19% contact rate brochure vs.	NA
2006	clinics	59% fax referral; of those	
(45)		contacted, 90% accepted at	
		least 1 call	
Borland	general practices	47.5% referred; of those	3 month/30 day sust
2008		referred 76.8% contacted; of	abstinence/ITT
(48)		those contacted, 73.5%	6.9% in-practice vs.12.3%
		accepted service	referral
Ebbert	dental practices	60% enrolled and received at	6 month/7 day PP/ITT
2007		least one call	27.3% brief counseling vs.
(50)			25.0% fax referral
Gordon	dental practices	35% agreed to referral; among	3 month/RR
2007		those 70% contacted; 85%	Usual care 6.3%
(47)		enrolled	5As 8.3%
			Fax referral 7.2%
Mahabee-	emergency	46% connect rate; of those	3 month/7 day PP/ITT
Gittens	rooms	contacted 84% enrolled	5.9% usual care 11.4% fax-
2008			referred
(52)			
Rothemich	primary care	NA	40.7% smokers in intervention
2010	clinics		clinics received cessation
(54)			support vs. 28.2% in control
			clinics
Sheffer	primary care	NA	Average number referrals
2012	clinics		greater in intervention clinics
(56)			(8.5) vs. control clinics (1.5);
			intervention clinics had greater
			average quality referrals (4.8)
			vs. control clinics (.86)
Shelly	community	41% contact rate	intervention sites 2.4 times
2010	health clinics		more likely to provide
(53)			referrals, 1.8 times more likely
•			to offer medication counseling
			and/or prescriptions
Sherman	VA health	45% contact rate	11% those referred and 25%
2008	administration		those receiving counseling

Study (reference #)	Source of Referral	Contact Rates	Quit Rate or Provider Impact
(49)	sites		were quit; providers at intervention sites referred more patients
Willet 2009	hospitals and providers	40% contact; 23.6% of referrals overall resulted in	NA
(51)	providers	enrollment	
Wolfenden	pre-operative	64% accepted an offer; among	NA
2008	clinics	those accepting 74% were	
(46)		contacted	

Other studies have looked at the impact of fax referral on quitting success. Borland et al. found that fax-referred patients were twice as likely to report sustained abstinence as those in counseling in the in-practice counseling condition. In contrast, a randomized trial comparing usual care to quitline referral did not find significant differences in quit rates at three month follow-up. Similarly, Ebbert et al. found no evidence for greater abstinence for those in a fax-referral condition (brief counseling plus referral) in dental practices compared to those in a brief counseling condition. Gordon et al. found that quit rates were not significantly higher for those fax-referred compared to those who received a 5A's (ask, advise, assess, assist and arrange) intervention.

The impact of fax-referral programs on provider behavior has also been examined, with two studies concluding that the option of referring to quitlines increases provider engagement with the cessation process. A study examining usual care to usual care plus fax referral to the New York State Smokers' Quitline reported greater provider adherence to the 4 A's (ask, advise, assess and assist) in the intervention sites with increased rates for referrals and offers of medications compared to providers in control clinics.⁵³ Rothemich et al. found that clinics in an expanded vital sign intervention that included fax referral had a significantly higher percentage of smokers reporting that they received cessation support compared to those in the control clinics.⁵⁴

The research to date suggests that fax referral of smokers to quitline services is acceptable to both providers and many of their patients across a variety of health care settings. This approach, which extends the reach of quitlines, can be extremely cost-effective; however, there may be challenges involved in achieving high rates of contact and enrollment. A recent study suggests that efforts to overcome these challenges are a good use of quitline resources. A study of over 11,000 clients fax-referred to the Arizona Smoker's Helpline between 2005 and 2010 found that smokers who were referred by a health care provider were more likely to quit smoking than those who were self-referred (10.6% vs. 7.1%, seven-day point prevalence at seven-month follow-up, intent to treat), suggesting that many of those referred by a health care provider stand to benefit from enrollment in quitline services.⁵⁵

Sheffer and colleagues provide a model for advancing both numbers and quality of fax referrals through academic detailing which includes on-site training, technical assistance, and performance feedback.⁵⁶ In a randomized trial of clinical sites, the mean number of referrals was 5.3 times greater and the mean number of referrals resulting in enrollment 5.6 times greater in clinic sites that received enhanced academic detailing in support of fax referral compared to the fax-referral-only sites. Costs per referral were \$8.18 in the academic detailing clinics compared to \$9.75 per referral in the fax-referral-only sites; cost of quality referrals were similar in both academic detailing and fax-only sites (\$15.52 and \$15.07 respectively). Several of the fax-referral studies that reported increased provider referral also included training, technical assistance, and systems changes as part of the intervention condition.^{49, 53, 54}

Further research is needed to identify which aspects of training and technical assistance are needed to ensure high rates of quality referrals. In addition, there is a need to identify the optimum number and timing of attempts to contact those referred through these programs. The number of attempts made to contact referees ranged from three to five and

was reported in only three of the studies. ^{46, 49, 53} Willet et al. reported that 58.5% of referees were unreachable after three attempts. ⁵¹ Currently, quitlines are making between three and four attempts to reach fax or e-referred patients. ⁶

Additional research is also needed to understand how fax-referral programs can be effective in reaching populations not typically served by quitlines. Despite low rates of enrollment overall, Willet and colleagues noted that the fax-referral program reached a lower socio-economic status population than typically served.⁵¹ Given the strength of the evidence for fax-referral programs and the opportunities they provide for extending quitline reach and sustainability, they are likely to remain an important component of quitline service delivery.

Reactive/Proactive Counseling with Medications

The evidence for reactive/proactive models combined with medications is presented in Table 7. Several studies examining the addition of NRT to proactive quitline counseling have found that the offer of free NRT increases call volume ⁵⁷⁻⁶² as well as quit rates ^{57, 59-63} compared to a period prior to the addition of NRT. Two New York-based studies found a similar pattern of increased call volume and quit rates with the provision of NRT; however, in these studies it should be noted that while NRT was administered through the quitline (callers were screened and registered) the provision of NRT was not necessarily tied to counseling. ^{64, 65} In addition, several of the studies from New York have established the addition of NRT as cost-effective. ^{61, 64, 65} Hollis et al. found that offering NRT produced similar increases in quit rates across all three levels of counseling intensity (brief, moderate, intensive) and that combining NRT with proactive counseling is cost-effective. ³²

Table 7. Proactive Service Models with Medications

Study	Call Protocol	Med Protocol	Increase in Calls/	Quit Rates
(reference #)			Reach	
An	multi-call per	8 wks patch	155 calls month pre	6 month/7 day PP/ITT
2006	caller request	gum mailed	vs. 679 post NRT	10.8% pre vs. 21.7% post
(60)				NRT
Bauer	NA	voucher 2 wks	median calls/day	4-6 month/7 day PP/RR
2006		patch gum	6 pre vs. 148 post	12% pre vs. 22% post
(64)			NRT	NRT
Cummings	6 wk condition	voucher 2 wks	reach ranged from .5	4 month/7 day PP/RR
& Fix 2006	(NYC) - 1 f/up	patch/gum	to 4.8 (NYC)	12% no NRT
(65)	call	1 wk patches		27% 2 wk voucher
		2 wk patches		21% 1 wk mail
		6 wk patches		24% 2 wk mail
		mailed		33% 6 wk mail
Cummings	1 f/up call	6 wk patch mailed	5% of NYC smokers	6 month/7 day PP/RR
2006			reached	22.3% no NRT vs. 33.2%
(62)				NRT
Cummings	1 callback 2-4	2 wks/4 wks/6	NA	12 months/7 day PP/ITT
2010	post shipping	wks/		19.1% 2 wk
(69)	6 wk group -	6 wks/8 wks		12.9% 4 wk
	NRT	patch mailed		7.0% 6 wk
	contingent on			23.1% 6 wk
	receiving up to			22.6% 8 wk
	4 proactive			
	calls			
Miller	calls 3 wks, 14	6 wks patch	5% of NYC smokers	6 months/7 day PP/RR
2005	wks post intake	mailed	reached	6% pre vs. 33% post NRT

Study	Call Protocol	Med Protocol	Increase in Calls/	Quit Rates
(reference #)			Reach	
(61)				
Burns	NA	8 wks vs. 4 wks	NA	7 months/7 day PP/RR
2010		split shipment		37.2% 8 wks vs. 29.4% 4
(67)				wks
Campbell	initial call and	4 or 6 wks NRT	ave 397 calls/wk pre	6 months/7 day PP/ITT
2008	5 sessions	single shipment	712 calls/wk post	9.0% 4 wks vs. 12% 6 wks
(68)				
Cummings	single callback	2 wks/4 wks/6 wks	NA	7 months/7 day PP/ITT
2011	(10-15 min) 2	patch mailed		14.8% 2 wks
(43)	wks after			17.1% 4 wks
	initial call			17.5% 6 wks
Ferguson	standard: one	vouchers for 21	NA	6 month/prol
2012	wk pre quit,	day supply patch;		abstinence/ITT
(40)	day of quit, 2-3	2 nd 21 day supply		20.1% no NRT vs. 17.7%
	days post	available		NRT
	intensive:			
TT . 11°	3,7,14, 21 days	51 (t' f 0	A 11 -	12 v.1./20 .l DD/ITT
Hollis 2007	brief: 15 mins; moderate: 40	5 wks (option for 8	Average calls	12 month/30 day PP/ITT brief: 12% no NRT vs.
(32)	mins with brief	wks) patches mailed	completed: moderate: 1.7-2.0	17% NRT
(32)	call 1-2 wks	maneu	intensive: 2.5-2.9	mod: 14% no NRT vs.
	later;		Intensive. 2.3-2.7	20% NRT
	intensive: 30-			int: 14% no NRT vs. NRT
	40 mins, up to			21%
	4 add calls			
Maher 2007	5 calls	8 wks	call volume increased	3 months/7 day PP/RR
(57)				21% pre vs. 38% post
,				NRT
McAfee	2 calls – at call	8 wks vs. 2 wks	NA	6 months/7 day PP/adj ITT
2008	in and 1 wk	patches mailed		15.6% 2 wks vs. 21.9% 8
(66)	post quit			wks
Miller 2009	multi-call	1 wk NRT	NA	6 month/7day PP/ITT
(58)		vouchers 75% off		21.2% no NRT vs. 30.9%
		retail price		NRT
Swartz 2005	up to 3 calls	8 wks patch or	NA	6 month/30 day PP/ITT
(63)		gum mailed		12.3% counseling vs.
				22.5% counseling + NRT
Tinkelman	up to 5 calls	8 wks patch	2,351 calls month pre	6 months/PP/ITT
2007	after initial	mailed, split	vs. 3,606 post NRT	10.3% pre to 14.9% post
(59)	contact	shipment 4 + 4		NRT

^{*}Shading denotes related studies.

Amount of NRT Provided

While the evidence is strong for the effectiveness of NRT in combination with proactive counseling, the evidence regarding how much NRT to provide is mixed. A randomized study of callers to the Oregon quitline found that eight

weeks of NRT resulted in significantly higher quit rates than two weeks of NRT.⁶⁶ Burns et al. found that reducing NRT supplies to Colorado quitline line callers from eight to four weeks was associated with a one-fourth reduction in smoking abstinence rates.⁶⁷ Similarly, Campbell et al. found that increasing NRT supplies from four to six weeks for Montana quitline callers increased quitting success.⁶⁸

In contrast, findings from the New York quitline (which involved different conditions for distributing one, two, or six weeks of NRT) revealed no differences in quit rates by the amount of NRT distributed after controlling for differences between the groups. ⁶⁵ Similar results were seen when comparing two-, four-, six-, and eight-week supplies of NRT, where no clear dose-response relationship was seen. ⁶⁹ These two studies, however, were based on comparisons of nonequivalent groups (including uninsured, Medicaid enrollees, and privately insured) across a variety of geographic locations within New York, with some groups receiving some level of counseling and others receiving none. Stronger evidence is provided in a more recent study of callers to the New York State Smokers' Quitline randomly assigned to a two-, four-, or six-week supply of NRT combined with one 10-15 minute proactive call. This study confirmed earlier findings of no differences in quitting outcomes by the amount of NRT provided. ⁴³

Cost Effectiveness for Proactive Counseling with Medications

A summary of reported cost outcomes for proactive counseling combined with medications is presented in Table 8. McAfee and colleagues attempted to provide cost data from a state program perspective and were all-inclusive, including costs for training, facility space and supplies, and salary and benefits for interventionists, supervisory staff, and administrative personnel. In contrast, the cost estimates from the earlier New York studies (based on direct service costs and using responder rates that provide higher estimates of quitting) yield much lower costs per quit and costs per additional quit. The more recent randomized study from New York calculated relative cost estimates by subtracting out a historical baseline quit rate for counseling only. As noted earlier, the wide variations in how these measures were calculated make comparisons across studies difficult. In terms of cost effectiveness as it relates the amount of NRT provided, Cummings et al. identified the two-week supply as having the lowest cost per attributable quit though the differences were not significantly different. McAfee et al. found that while the quit rate for the eight-week condition was higher, the cost per quit was lower for the two-week condition.

Table 8. Cost Outcomes for Proactive Counseling with Medications

Study (reference #)	Cost
An 2006	\$1,362 vs.\$1,934 post NRT cost per quit (8 week)
(60)	Average cost per caller pre NRT \$136; average cost per caller
	post NRT \$352
Bauer 2006	\$210 cost per additional quitter (2 week)
(64)	
Cummings & Fix 2006	cost per additional quitter [actual service costs]
(65)	\$274 voucher [\$42]
	\$306 1 week mail [\$29]
	\$347 2 week mail [\$42]
	\$347 6 week mail [\$76]
Cummings 2006	\$420 cost per additional quitter (6 week)
(62)	
Miller 2005	\$464 cost per additional quitter (6 week)
(61)	
Cummings 2011	cost per quitter
(43)	\$891/2 week
	\$922/4 week
	\$1,022/6 week

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Study (reference #)	Cost
Fellows 2007	\$3,738 pre vs. \$1,050 post NRT cost per quit (2 week)
(34)	\$174 cost per incremental quit (ICER)
Hollis 2007	cost per incremental quit (ICER) relative to brief no NRT [actual
(32)	costs=\$67]: (5 week; up to 8 week)
	brief NRT: \$2467/add quitter [\$107]
	mod no NRT: \$1912/add quitter [\$132]
	<u>mod NRT</u> : \$2109/add quitter [\$193]
	<u>int no NRT</u> : \$2641/add quitter [\$242]
	intensive NRT: \$2112/add quitter [\$268]
McAfee 2008	\$1405 8 week NRT vs. \$1156 2 week NRT cost per quit
(66)	\$2,068 cost per incremental quit (ICER)
	Actual costs
	\$166 counseling and two weeks of NRT
	\$275 counseling and eight weeks of NRT
Swartz 2005	\$1,344 cost per quit NRT (8 week)
(63)	

^{*}Shading denotes related studies.

Reported Use and Willingness to Obtain Additional NRT

NRT-related quitline studies provide two additional important points of evidence for decision makers. First, many callers who receive free NRT are not using all of it. Cummings et al. found that only 51% of patches provided were reported used, with those receiving greater supplies reporting less use; those receiving a six-week supply reported using 33% of the NRT provided compared to 49% for the four-week supply and 61% for the two-week supply. A similar pattern was reported by Cummings and colleagues in an earlier study. Hollis et al. reported that while 80% of study participants requested the initial five-week supply of NRT, only 28% requested the additional three weeks of NRT that were available. Similarly, Ferguson and colleagues noted that 72% of those provided vouchers used them, but only 21% requested a second supply of vouchers.

Studies also suggest that some portion of callers – both insured and uninsured – are willing to obtain additional NRT on their own (See Table 9). Ferguson et al. reported that offering free NRT to callers to England's national quitline had no additional impact on smoking cessation. ⁴⁰ A careful look at this study, however, reveals that participants who were not offered NRT vouchers used the NRT that they had obtained on their own at higher rates than those offered NRT. These findings are not surprising given that in England NRT is readily available to all smokers and standard quitline practice includes advising all callers on how to use these medications. However, even in the U.S., where acquiring NRT is likely to involve out-of-pocket expenses or co-pays, some tobacco users are willing to acquire additional NRT beyond what is provided through the quitline. McAfee et al. included counseling messages explicitly encouraging participants to save the money they would have spent on cigarettes and use it to purchase additional NRT and found that uninsured callers who received only two weeks of NRT were 2.5 times more likely to purchase more NRT than those who received eight weeks. ⁶⁶ Indeed, several studies have found varying percentages of callers who obtained additional NRT. ^{33, 34, 64} One study found that the likelihood of obtaining additional NRT was in inverse relationship to the amount of NRT provided; however, it should be noted that there were differences in insurance status of the groups compared in this study that may have contributed to this finding. ^{43, 69}

Table 9. Obtaining Additional NRT

Study (reference #)	% Obtained Additional NRT	Caller Characteristics
Bauer 2006	Of those who redeemed the voucher, 21%	callers regardless of insurance status
(64)	obtained new supply after meds ran out	
Cummings 2010	2 wk 26%	2 wk – privately insured
(69)	4 wk 17%	4 wk – privately insured
	3 wk 17.8%	3 wk – Medicaid or uninsured
	6 wk 2.8%	6 wk – callers regardless of insurance
	8 wk 3.1%	status
		8 wk – uninsured
Bush 2008	47.2% using free patches obtained	uninsured callers
(33)	additional patches	
Cummings 2011	2 wk 16.8%	insured callers
(43)	4 wk 16.9%	
	6 wk 12.2%	
Ferguson 2012	Not offered NRT	callers to the English National Health
(40)	17.1% obtained without prescription	Service quitline
	19.6% obtained from health professional	
	Offered NRT	
	21.3% obtained without prescription	
	17.4% obtained from health professional	
McAfee 2008	2 wk 39.3%	uninsured callers
(66)	8 wk 16.2%	

^{*}Shading denotes related studies.

Recommendations for Practice Related to Service Model Offerings

The following recommendations are based on the review of the evidence for service model offerings. These recommendations address NRT as part of service model offerings; recommendations regarding medications more broadly are addressed in Section Two of this paper. Quitlines have established eligibility criteria to determine who is served. The following recommendations are not predicated on changes in these eligibility criteria, but rather on shifts in service offerings for eligible callers currently served.

- 1. If faced with the decision to add NRT or additional proactive counseling calls to a reactive quitline, the addition of NRT appears to be the more clinically effective and cost-effective choice. Furthermore, promoting the availability of free NRT has the potential added benefit of increasing call volume and extending quitline reach.
- 2. Quitlines offering proactive services should consider how many calls their callers are completing. While there is little literature to guide call-attempt protocols, unless a proactive quitline is willing to invest efforts in increasing the number of calls ultimately completed, the offer of a two- to three-call protocol with a high rate of completed counseling sessions may result in the same level of quit success as the offer of a four- to five-call protocol.
- 3. Combining NRT with proactive counseling results in the highest levels of quit success and has a positive impact on quitline reach. The evidence is currently mixed regarding the optimal amount of NRT to be provided to callers, with some studies demonstrating a benefit for extended supplies (beyond two weeks) and others suggesting that the trade-offs for quit rates with smaller supplies of NRT may be minimal. Limited evidence suggests that smaller NRT supplies are more cost-effective than extended supplies.
 - a. Under conditions of increased demand for services and limited resources, quitlines should consider providing two weeks of NRT to all eligible callers and reserving extended supplies of NRT (up to eight weeks) for those least able to afford it.

- b. Under conditions of adequate resources, quitlines should provide extended supplies of NRT (up to eight weeks) to eligible callers.
- 4. Quitlines that offer smaller amounts of NRT should include counseling protocols to support and encourage callers to acquire additional NRT.
- 5. Quitlines should continue to utilize fax-referral programs to reach tobacco users. These programs will be most effective when contact and enrollment rates are high. The quitline community should work together to identify which efforts have been most successful in contacting and enrolling individuals who are interested in and motivated to quit. Evidence suggests that investments in provider training, technical assistance, and systems changes may help to achieve the maximum impact of fax-referral programs.
- 6. While the body of evidence for reactive service offerings is limited, findings suggest they can be clinically effective, in particular when combined with medications.
- 7. Quitlines should be encouraged to carefully evaluate the impact of any changes made in service offerings. Reducing the amount of NRT provided will be cost-effective only if quit rates remain relatively stable; the addition of NRT offerings may drive up costs if more callers are enrolling in counseling services. Careful monitoring of the effects of changes in service offerings will be critical to maintaining quality.

Recommendations for Research Related to Service Model Offerings

This review of the evidence points to the need for additional research to answer several critical questions related to service model offerings.

- 1. <u>Reactive Service Models Quitlines</u> that have shifted from a proactive to a reactive service model due to decreased funding will be in a position to inform the field, and collaboration between these quitlines and tobacco control researchers should be encouraged. There is a need to examine:
 - a. The value-added benefit that is provided beyond the initial reactive call, when callers have the option to reactively contact the quitline at any time for additional support.
 - b. The cost effectiveness of reactive service models.
- 2. Proactive Service Models There is a need to examine:
 - a. The optimum number, length, and timing of completed calls.
 - b. Which call attempt protocols are most cost effective.
 - c. Which counseling elements are most critical to support quitting and prevent relapse and should be preserved under abbreviated proactive protocols.
 - d. Differences in the effectiveness of proactive protocols with different types of callers.
 - e. Methods for classifying callers into subgroups that would allow quitlines to more effectively allocate counseling resources.
 - f. The feasibility of providing a flexible menu of service options that callers can choose from. This includes investigating whether or not callers who would benefit most from a more intense call protocol (e.g., poorer quitting history, higher levels of dependence) would be more or less likely to choose it.
- 3. Fax-referral Programs There is a need to examine:
 - a. What impact fax-referral programs have on promoting quitlines, extending the reach of quitlines (in particular among those who otherwise would not be motivated to contact a quitline), engaging providers in the cessation process, and increasing rates of quitting success for those who are referred to quitlines.
 - b. Which approaches are most effective in achieving high rates of contact and enrollment.
 - c. How many attempts should be made to contact referrals and over what period of time they should occur.
- 4. Medications There is a need to examine:
 - a. How much NRT callers are using and how much is wasted.
 - b. How willing and able callers are to obtain NRT on their own.
 - c. The feasibility of limiting NRT to groups that are most likely to benefit from receiving it and methods for identifying which groups those would be.

SECTION TWO: EXPANDING SERVICE OFFERINGS THROUGH PHARMACOTHERAPY

The U. S. Public Health Service Guideline identifies seven first-line medications as reliably increasing long-term smoking abstinence rates: nicotine patches, nicotine gum, nicotine inhaler, nicotine lozenges, nicotine nasal sprays, bupropion, and varencline.³ The latest Cochrane Review for NRT for smoking cessation found that NRTs increase the rate of quitting by 50-70% regardless of setting.⁷⁰ In 2010, there were 39 U.S. quitlines that provided free quitting medications to callers. There were also three quitlines that offered discounted medications to callers. Five quitlines distributed vouchers for NRT products or prescription medications. All of the quitlines distributing free cessation medications offered the patch, followed by the gum and lozenges. Very few U.S. quitlines offered free bupropion or varenicline. Even fewer offered free nasal spray (one quitline) or inhalers (one quitline). Almost all U.S. quitlines providing free cessation medications had eligibility criteria for a caller to receive free medications. Most common were being a resident of the state, age criteria, readiness to quit, having no medical contraindications, and enrollment in quitline counseling.⁶

The provision of NRT in combination with reactive and reactive/proactive counseling service models was examined in the previous section. This section of the paper focuses on the overall impact of pharmacotherapy on quitlines, rather than by service model, and examines which mechanisms for medication dosing and delivery may provide efficiencies for service provision. The 2009 NAQC Issue Paper, *Integration of Tobacco Cessation Medications in State and Provincial Quitlines: A Review of the Evidence and the Practice with Recommendations*, ⁷¹ examines the topic of cessation medications and quitlines in depth and readers are encouraged to access that paper for additional information.

Providing Medications: A Review of the Evidence

Currently, the U.S. Public Health Service Guideline recommends no more than eight weeks for patches and up to 12 weeks for gum, lozenge, bupropion, and varenicline.³ The CDC recommends quitlines provide a minimum of two weeks of over-the-counter NRT for all callers and up to eight weeks for those financially disadvantaged.⁴⁴ Evidence is strong for offering free FDA-approved medications to quitline callers interested in quitting. According to the U.S. Public Health Service Guideline, quitline counseling added to medications is more effective than counseling alone (OR=1.3).³ There is also evidence for the cost effectiveness of providing medications through quitlines. Compared with counseling alone, the incremental cost per life-years saved is \$1,441-\$3,455 for NRT and \$920-\$2,150 for bupropion, with both being more cost-effective than many other accepted health-care interventions.⁷²

Several studies have demonstrated that providing NRT is effective in increasing call volume, ^{57-62, 64, 65} increasing tobacco abstinence, ^{57, 59-65} and is cost-effective. ^{32, 61, 64, 65} In addition, the evidence suggests that NRT provision is clinically effective across a range of amounts provided. ^{43, 65, 69} Evidence also suggests that many who receive larger supplies do not use it all and that some callers are willing to purchase additional NRT on their own. ^{33, 43, 64-66, 69}

Linking NRT to Enrollment in Proactive Counseling

A recent analysis of National Health Interview Survey data revealed that among those who tried to quit smoking in the past year and those who successfully quit in past two years, 30.0% used medications, while only 5.9% used counseling; among these individuals, 3.1% used a quitline. There is a public health benefit in making NRT widely available to smokers through quitlines and combining medication use with behavioral counseling to achieve maximum clinical benefit. Linking the provision of NRT to enrollment in telephone counseling has been shown to increase the amount of counseling calls completed; however, for many of these callers a primary motivation in calling the quitline is to obtain free NRT. Studies have shown that 80-96% of participants report that the provision of

free NRT was an important factor in their decision to try and quit smoking. ^{33, 60, 62} An important question from a service delivery perspective is: how critical is it to link the provision of NRT to enrollment in proactive counseling? As noted earlier, several of the NRT studies from the New York Smokers' Quitline did not tie the provision of NRT to enrollment in proactive counseling. Callers were screened and registered, NRT was administered through the quitline, and generally enrollment in counseling was not required. For most (but not all) of the participants in these studies, a callback was attempted four weeks from enrollment to counsel them about use of medications and support efforts to quit smoking. ^{62, 65, 69} In the 2006 study, quit rates of all of the NRT-only groups were higher compared to a sample of quitline-only participants from the previous year (between 21% and 27% for the NRT-only groups vs. 12% for the quitline-only group). ⁶⁵ While this observational study compared nonequivalent groups from different time points and geographic locations and could not control for external threats to validity (including the implementation of the New York City smoking ban during the period of the study), these data raise the possibility that the provision of NRT through quitlines combined with a brief intervention may produce outcomes comparable to extended quitline counseling with or without NRT.

A recent study by Zawertailo and colleagues examined quit outcomes for a group of callers to a toll-free number who received five weeks of NRT, self-help materials, and the number to the Ontario smokers' quitline. ⁷⁴ Callers received a brief 5A's intervention delivered at the initial call but no further counseling was provided. Outcomes were compared to a randomly sampled group of smokers concurrently recruited to participate in the Ontario Tobacco Survey. This study, based on a relatively large sample with an appropriate comparison group, reported six-month tobacco abstinence rates of 21.4% for the intervention group compared to 11.6% in the no-intervention group. The cost of the program per caller was Canadian \$179. These data provide additional evidence that the distribution of NRT through quitlines, combined with brief intervention, may be an effective strategy for quitlines to consider.

While there are no studies to date that have directly tested the effects of linking NRT provision to enrollment in counseling, there are quitlines that offer examples of how this has been implemented in practice. In New York, eligible tobacco users can obtain free NRT by calling the quitline or by completing an online application process. Residents are eligible to receive two, two-week rounds of NRT per year, provided the rounds are at least three months apart. Callers must provide a phone number so a quit coach can attempt to contact them by phone. NRT is sent out once eligibility is verified and then the client is contacted for a quit-date counseling call. If quit coaches are able to reach them, most clients will engage in a counseling session (P. Celestino, personal communication, April 5, 2012). In British Columbia, the provincial government recently launched a program that provides up to 12 weeks of free medications each calendar year (NRT and prescription medications). British Columbia residents can call HealthLinkBC at 8-1-1 where they select an NRT product that is either mailed to their home or they can pick up at their local pharmacy using a personal reference number. HealthLinkBC can transfer callers directly to the quitline, but they are not required to use the quitline service to obtain NRT. Callers are also encouraged to visit the QuitNow.ca website to use the NRT Assessment Tool if they are unsure of which NRT product to choose (J. Boomer, personal communication, April 2, 2012). The Arizona Smokers' Helpline has implemented a "medication only" protocol for periods when promotions for free NRT strain capacity. Under these conditions, callers are given the option to receive the medications rather than requiring them to enroll in proactive counseling. Up to three follow-up calls are made to assess medication use and offers are made for additional counseling if desired (S. Michael, personal communication, April 3, 2012).

Though quitlines remain committed to providing callers with counseling, further study is needed to understand if allowing callers access to NRT while encouraging (rather than requiring) them to enroll in proactive counseling may be a means to engage smokers in quit attempts they may not otherwise try. There may be potential cost savings if those who currently must enroll in services to obtain NRT have little intention of fully engaging with the counseling process. There may also be opportunities for increased reach to those tobacco users who are primarily interested in NRT. This issue should be examined carefully. While NRT is effective with or without counseling, "the absolute increase in success attributable to the use of NRT will be larger when the baseline chance of success is already raised

by the provision of intensive behavioral support."⁷⁰ There is also evidence to suggest that those who use NRT without counseling may be more heavily dependent on nicotine and have had more previous failed attempts,⁷⁵ which would suggest that this group may stand to benefit the most from extended counseling.

Adherence to NRT Protocols

While many of the studies reviewed noted how much NRT callers reported using, they did not address the question of whether or not the NRT was used as intended. The one exception was the study by Carlin-Menter et al., which found that 82% of those receiving NRT reported they did not smoke while using the patch, while 91% of those who still smoked reporting they had smoked now and again. This type of evidence is critical for the quitline community, as the public health benefit of providing NRT through quitlines will only be achieved if both utilization and adherence to medication protocols remain high.

Non-NRT Medications

To date, there are only two published studies examining the use of non-NRT medications with quitline counseling (Table 10). One of these studies found that the use of either 150mg/day or 300 mg/day doses of bupropion increased abstinence rates with telephone counseling enhancing these effects. The other study examined the provision of varenicline through a quitline. This study reported that tobacco abstinence at three months was higher among persons self-selecting varenicline compared to those self-selecting four weeks of NRT. After adjusting for other cessation predictors at three months, varenicline users were 28% more successful at being quit from tobacco, but at six months medication use was no longer predictive of quit outcomes. Varenicline users were more likely to be long-time tobacco users with a history of previous unsuccessful quit attempts compared with those choosing NRT.

Table 10. Non-NRT Medications

table 10. 1001-1001 incurcations			
Study	Medication Protocol	Quit Rates	Cost
(reference #)			
Biazzo 2010	4 wks NRT mailed vs.	6 month/7 day PP/ITT	caller pays \$75 for 12
(77)	varenicline \$25 co pay &	11% NRT (n=3,679) vs.	wks varenicline
	prescription for each of the 4	17% varenicline (3,116)	quitline pays \$270.75
	wks (option for up to 12 wks);		
	2 nd and 3 rd shipments tied to		
	calls		
Swan	bupropion SR (300 and 150 mg)	12 month/7 day PP/ITT	NA
2003		33.2% moderate counseling + 300	
(76)		mg; 31.4% moderate + 150 mg;	
		25.7% brief + 300 mg; 23.6% brief	
		+150 mg	

Distribution of Medications

There are few published studies that inform mechanisms for distributing medications (see Table 11). A study by Saul et al. found that a split shipment protocol (where an initial shipment of NRT is mailed with the second shipment tied to continued counseling) did not result in lower rates of satisfaction or quitting and was more cost-effective. Another study by Walker and colleagues in New Zealand reported on the results of an experiment with a sample box of NRT products. Subjects were randomized to receive two vouchers for up to eight weeks of NRT or a sample box of five different NRT products. Participants receiving the sample box were instructed to try each of the products and select the one that best met their needs. They were then provided a four-week supply of their chosen product. The study found no difference in quit rates between the two groups.

In current practice, the majority of quitlines provide medications through direct mail. This method of delivery is considered cost-effective, as once a distribution system is set up, costs are largely contained to the cost of the product and shipping (D. Tinkelman, personal communication, April 2, 2012). For those providing a full eight-week course of NRT, implementing a split-shipment protocol can reduce the amount of NRT that is wasted, and can be more cost-effective without lowering quit rates. Studies have shown that only about 20-30% of callers request the second shipment of NRT. 32, 40

Table 11. Medication Distribution

Study	Medication Protocol	Quit Rates	Cost
(reference #)			
Saul	5 wks NRT	7 months/30 day PP/ITT	single: \$1,350/quit
2011	5+3 wks split dosing NRT	18.1% 5 wks	vs.
(78)	8 wks NRT	28.8% 5+3 wks	split: \$1,242/quit
	patch gum mailed	28.3% 8 wks	
Walker 2011	2 vouchers mailed for 8 wks	6 months /7 day PP/ITT	NA
(79)	NRT	30% usual care vs. 29% sample	
	or mailed samples of NRT	box	
	products; one product selected		
	and 4 wk supply mailed		

Vouchers and discounts, while not as widely used, offer potential to reduce costs associated with providing medications. Cummings et al. found similar quit rates among those receiving vouchers for NRT (27%) compared to those who received NRT by direct mail (21-33%). With a voucher system, quitlines are only paying for the cost of the medication redeemed, the costs of procuring, storing, and shipping medications are avoided, and the additional step of having to go to a pharmacy may screen out those who are not highly motivated to use medication. Voucher systems, however, could prove to be too much of a barrier for even highly motivated tobacco users. This may have been the case for the Ohio quitline, where an evaluation revealed that a high percentage of callers who received vouchers never redeemed them. The quit rate was also lower for the group who were sent vouchers through the mail and asked to redeem them at local pharmacies compared to those receiving NRT through the mail, and while this difference could not be directly attributed to the voucher system, the decision at that time in Ohio was to shift all NRT delivery to direct mail (D. Tinkelman, personal communication, April 2, 2012).

Given the lack of published research in this area and the potential for cost savings, states that use medication delivery approaches other than direct mail were asked to share their experiences. The following is a summary of various distribution approaches that have been implemented and lessons learned (see Table 12) (J. McChord, S. Michael, S. Shulties, J. Smith, K. Wilson, personal communication, April 4, 2012). These lessons are shared as examples to learn from, rather than serving as a foundation for generating evidence-based recommendations.

Table 12. Medication Distribution Approaches Other than Direct Mail*

	**	
Arkansas Tobacco	Offers a \$50 voucher for varenicline. Callers are made aware of the voucher option	
Quitline	and if they elect to receive one it is mailed to their home along with a letter to	
	present to their physician. Callers provide the letter to a physician who writes a	
	prescription. Callers provide the pharmacy with the voucher when they pick up	
	their prescription.	
	Lessons Learned: This approach has been challenging as it requires individuals to	
	be seen by a physician and incur the cost of a doctor visit or co-pay. Additionally,	
	the cost of varenicline ranges from \$110-\$140 which presents financial barriers for	
	some callers.	

mes of Limitea Resources	
Arizona Smokers Helpline	Since 2003, the quitline has offered some form of NRT benefit. In 2006, the quitline offered a 50% discount on NRT and medications. A pilot program was implemented in 2006 in which all callers received 12 weeks of free NRT or NRT+ (bupropion and varenicline). The impact of offering 12 weeks of free NRT and NRT+ on quitline service utilization and cessation outcomes was evaluated. Findings showed that 83% of callers enrolled in the free NRT program, 80% of these callers said the offer of free medication was important in their decision to quit, and the quit rates for those who received varenicline were positive. Lessons Learned Mail distribution worked best for the over-the-counter medications. Vouchers resulted in many complications with pharmacies wanting to know why and how to deal with vouchers for over-the-counter medications. Vouchers worked best for prescription medications. In this case, working with local pharmacies was easier than training physicians in the prescription protocol with a centralized distribution pharmacy.
Oklahoma Quitline	Oklahoma offers \$30 varenicline discount cards. This benefit is not actively promoted but provided as available. The cards are provided by Pfizer. Callers learn about the discount card when discussing what forms of pharmacotherapy are available with the quit coach. Lessons Learned: This is a very popular offering. The only challenge is getting and keeping the discount cards in stock.
South Dakota Quitline	South Dakota residents are eligible for up to eight weeks of bupropion and varenicline (reduced from 12 to eight weeks due to funding cuts). Evaluation data was used to determine that 30% of callers did not use the third, four-week fulfillment of the prescription medication. Once enrolled in the program, the participant visits a healthcare provider who determines if the medication is safe and appropriate. The provider faxes a quitline prescription form to the Central Pharmacy. The quitline coach sends the Central Pharmacy notification of completion of the first, third and fifth coaching sessions in order for the participant to receive the medication. The medication is sent directly to the participant's home. Lessons Learned: Reach and quit rates increased since offering varenicline. Physician referrals increased to 44% of all quitline callers. The prescription medications are mailed directly to participant's home which alleviates barriers for those living in rural areas. Challenges are mostly administrative, including when: The provider sends the prescription to the pharmacy but the client fails to call the quitline to initiate cessation coaching. Prescriptions are signed but incomplete, illegible, or for the wrong medication amount. Prescriptions are faxed to a local pharmacy rather than the Central Pharmacy. There is a lack of follow through from the provider (no fax sent).
Utah Quitline	Utah offered a discount coupon for \$30 toward the purchase of varenicline that the quitline included in mailings for three months in 2010. Pfizer provided the coupons free of charge.

J	
	Lessons Learned:
	It was relatively easy for Pfizer to provide coupons to the quitline fulfillment center
	and for the quitline to include them in mailings.
Wyoming Quitline	If a caller enrolls in counseling, wants NRT, and passes a medical screening, these
	medications are sent directly to their home. If a caller wants bupropion or
	varenicline, they must first get a prescription for that medication from their
	provider. A voucher is then sent from the quitline to a participating pharmacy that
	is close to the caller's home. The caller then goes to the pharmacy with their
	prescription and the pharmacy fills the prescription. The voucher pays for \$120 for
	month one and \$90 for months two and three.
	Lessons Learned:
	The greatest challenge can be in getting pharmacies that are in close proximity to
	callers to participate in the program. Residents may drive many miles to be able to
	use a pharmacy that participates with the coupon program.

^{*}All of these quitlines provide NRT in addition to the other medications identified.

These approaches indicate that states are actively seeking innovative solutions for medication delivery. These examples from practice and lessons learned suggest that:

- Quitlines may experience success in collaborating with pharmaceutical companies to provide discounts for medications, which may be a viable option for other quitlines to consider. Quitlines should explore these and other partnerships to leverage discounts for medications.
- The cost benefit structure of voucher systems need to be further understood. If the goal is to ensure that medications are reserved for those who are most highly motivated to use them, vouchers may be effective in that costs will only be incurred for those who are motivated to redeem the vouchers at a pharmacy. If the goal is to use the offer of NRT to encourage and motivate quit attempts, vouchers may present too high of a bar. Furthermore, setting up voucher systems can be time and resource intensive.
- Given the challenges of accessing pharmacies in rural areas, quitlines that are considering voucher systems may want to use a combination of direct mail in rural areas and vouchers in more geographically dense locations.
- Based on quitline experience, the provisions of medications may increase physician referrals, extend reach with tobacco users who want to try to quit with prescription medications, and increase quit rates for some groups of tobacco users.

Recommendations for Practice for Expanding Service Offerings through Pharmacotherapy

- 1. Under conditions of increased demand for services and limited resources, quitlines should consider providing two weeks of NRT to all eligible callers and reserving extended supplies of NRT (up to eight weeks) for those least able to afford it. Under conditions of adequate resources, quitlines should provide extended supplies of NRT (up to eight weeks) to eligible callers.
- 2. Quitlines that offer smaller supplies of NRT should include counseling protocols to support and encourage callers to acquire additional NRT.
- 3. Quitlines providing extended supplies of NRT by direct mail may want to consider split-shipment protocols.
- 4. Quitlines with robust budgets may want to consider providing access to prescription medications.

Recommendations for Research for Expanding Service Offerings through Pharmacotherapy Areas for additional research include:

- 1. The impact of amount of medication supplied on quitline utilization, clinical outcomes, and cost effectiveness.
- 2. The impact of delivery mechanisms for medications (direct mail, vouchers, others) on quitline utilization, clinical outcomes, and cost effectiveness.
- 3. The impact of de-linking the provision of NRT from extended quitline counseling.

- a. Does connecting with tobacco users whose primary motivations are to obtain NRT provide an opportunity to encourage enrollment in quitline counseling as well as an opportunity for brief, effective interventions with those not opting for counseling?
- b. Are "medication-only" protocols used during times of high demand for services where callers are given the option to receive the medications (with additional follow-up calls to assess medication use) rather than requiring them to enroll in proactive counseling effective?
- 4. The impact of providing prescription medications (bupropion and varenicline) through quitlines.
- 5. The amount of NRT being used, the extent to which NRT is used correctly, and the impact of both of these variables on quit rates.

SECTION THREE: EXPANDING QUITLINE SERVICE OFFERINGS THROUGH ADVANCES IN TECHNOLOGY

This section of the paper examines the evidence base for the use of integrated web, IVR, and text-based interventions as an adjunct to quitline services. ¹ While these tools represent emerging technology that has not been fully tested with quitlines, these innovations hold great potential for expanding quitline service offerings by reaching new populations, providing efficiencies in service delivery, and offering cost savings. These technologies can be implemented to specifically enhance quitline services or may be part of a larger constellation of cessation services being offered along with quitline services.

The Evidence for Integrated Quitline and Web-based Services

Currently, 75% of North American quitlines offer some type of web-based services for tobacco users. Evidence for the effectiveness of web-based cessation programs is growing. To date, there have been three meta-analyses on Internet-based cessation programs. A systematic review of 11 randomized trials found that tailored, interactive web-based cessation interventions have an odds ratio for tobacco abstinence of 1.8, compared to untailored booklet or email interventions. A 2009 meta-analysis of 22 studies found sufficient clinical evidence to support web-based smoking cessation programs for adult smokers. A 2010 Cochrane review concluded that "some web-based interventions can assist smoking cessation, especially if the information is appropriately tailored to the users and frequent automated contacts with the users are ensured," but also noted inconsistent effects across trials. This review also noted that web-based programs may have additional benefit when used with other interventions, and may be more attractive to young people who smoke. The Community Preventive Services Task Force recently concluded that the evidence for Internet-based interventions is insufficient due to inconsistent effects observed across studies. The Task Force noted that the studies were complicated by differences in Internet-based content and low response rates at follow-up.

In looking more specifically at the evidence base for integrated phone and web-based programs, there is a small body of mixed findings. One randomized study compared a basic web program, an enhanced web-based program consisting of interactive information, tools, and social support, and an enhanced web plus phone counseling program. ⁸⁴ The web plus phone condition significantly out-performed the two web conditions in terms of 30-day point-prevalence abstinence rates at 6 and 12 months (12.2% basic web, 14.4% enhanced web, and 19.7% web plus phone; at 6 months, intention-to-treat). At 18 months, the 30-day point prevalence abstinence rates were similar among the three groups: 19% (basic web), 17.4% (enhanced web), and 19.6% (web plus phone). In contrast, a randomized trial comparing phone, web, and combined phone and web, did not find higher quit rates among those receiving the integrated intervention (37% phone + web vs. 41% web, seven-day point prevalence at six months). ⁸⁵ Another study tracked 11,143 participants who enrolled in an integrated phone and web program between May 2006 and October 2007. ⁸⁶ All enrollees received up to five proactive calls and unlimited access to a website, with the program designed to

¹ Studies reviewed for technology advances are summarized only in Section 3 and are not included in the Appendix Summary Table.

encourage use of all program components rather than asking participants to choose. The study found that participants used phone services more than the web program and reported 30-day quit rates at six-month follow-up of 21% (intentto-treat). The study also found that web utilization was significantly associated with increased call completion and tobacco abstinence rates at the six-month follow-up.

Further research will be needed to inform whether or not it is cost-effective for quitlines to integrate web-based cessation interventions with phone counseling. None of the three studies above provided data on cost effectiveness, which would need to be carefully considered in conjunction with the clinical outcomes in making this determination. A better understanding of how these two evidence-based approaches – quitlines and web interventions – can work together to support tobacco users in their quit attempts is needed. Graham and colleagues speculate that the integration of phone and web may provide a synergistic benefit of encouraging greater immediate use of and adherence to the information and support provided, preventing early relapse through the timing of the calls, and providing social support via the web that allows the counselor to tailor the intervention to meet the smoker's needs.⁸⁴

Aside from fully integrated phone and web programs, there are many other ways in which quitline programs are currently using the Internet. These include providing general information on the quitline or other tobacco cessation services, automated e-mail messaging, chat rooms, and interactive counseling. In Minnesota, smokers who are interested in quitting can visit a website where they are provided information about both phone coaching and a web program. In addition, information about news and events of interest to smokers is provided, cessation ads are featured, and direct links to Facebook are posted.⁸⁷ Florida uses their website to provide video testimonials from quitters and quitting tips. 88 California's website provides quitline information in multiple languages 89 while Hawaii's website provides direct click-to-call functionality. 90 In British Columbia, web-based cessation programs serve as the gateway to other programs. Tobacco users can call the quitline directly, but to sign up for any of the other program features, such as text messaging, email or online services, tobacco users register online (J. Boomer, personal communication, April 2, 2012). Since 2006, eligible tobacco users in New York have been able to obtain free NRT by completing an online application process (P. Celestino, personal communication, April 5, 2012). Arizona has successfully piloted an online enrollment process that can be used during times of high call volume (S. Michael, personal communication, April 3, 2012).

There are many benefits associated with these broader uses of the Internet, including the potential to reach younger tobacco users, the ability to provide 24-hour access to information, ease in providing information in multiple languages, and efficiencies in providing information and answering questions for users before they directly engage with services. In addition, many of these approaches are relatively low-cost. While additional research is needed to understand the specific costs and benefits involved, current experience suggests that the future of quitlines is likely to be highly integrated with web-based technologies.

The Evidence for the Use of Integrated Voice Response with Ouitlines

Increasingly, quitlines have looked at IVR as a tool to expand service offerings. There are relatively few studies to date testing IVR as a smoking cessation tool and none that examine its integration with quitlines. Reagan et al. randomly assigned smokers who received inpatient counseling at an academic medical center to two intensities of IVR follow-up. 91 One group received four IVR calls post-discharge with the offer of a callback from a counselor. The other group received one IVR call two weeks post-discharge. The cessation rates between the two groups did not differ. Three Canadian studies have explored IVR as a tool to follow smokers after discharge as part of a comprehensive intervention (i.e., "Ottawa Model"). These studies have found evidence for the feasibility of IVR, establishing contact with 74% of patients post-discharge. 92 These investigators have also documented higher abstinence rates post-implementation than before the introduction of the Ottawa Model (29.3% vs. 18.3%);⁹³ however, the only study to date on the effects specific to IVR failed to demonstrate an increase in smoking cessation rates. 94 McDaniel and colleagues established that IVR can be an effective tool in gathering tobacco use data from patients prior to scheduled clinical appointment to better support treating their nicotine dependence in primary care

settings.⁹⁵ Ershoff and colleagues tested a booklet, booklet plus IVR, or booklet plus proactive telephone counseling with prenatal smokers and found no differences in quitting outcomes between the groups. ⁹⁶ Burke et al. reported that the majority of those using a fully-automated IVR tobacco cessation support line found it easy to use (78%), the instructions clear and helpful (90%) and said they would recommend it to someone else (84%), with 78% staying on the line to complete the intervention.⁹⁷

The use of IVR in the above studies varied considerably, ranging from a single IVR call to daily IVR messages. In addition, IVR was used in conjunction with other intervention approaches, which makes it difficult to isolate its relative impact. While the evidence to date is limited, it is likely that quitlines will increasingly consider IVR technology. For example, the Ontario Smokers' Helpline is currently collaborating with a hospital-based IVR program (G. Luciano, personal communication, April 3, 2012). Tobacco users who are discharged from the hospital can enroll in an IVR program to support their cessation process. If tobacco users are responding to IVR prompts in a way that indicates they would benefit from live counseling, they are triaged to the quitline. After providing live counseling, the quitline enters information back into the IVR system to document the nature and outcome of the call. This approach provides an opportunity to make hospital-based cessation initiatives more cost-effective (prior to this arrangement, nurses were providing the counseling). However, implementing and sustaining IVR programs within hospital-based settings can present challenges, including receiving administrative approvals, committing resources, and providing for ongoing costs. The Ontario Smokers' Helpline is also building IVR directly into their quitline systems as a tool for handling the expected increases in call volume due the new tobacco packaging warning labels in Canada. Initially, the focus will be on an inbound system that during times of high call volume will provide callers the option to complete an abbreviated assessment via the telephone and provide their contact information for a callback by a Quit Coach for counseling. Future efforts may include outbound capacity to assist in identifying those in greater need and flagging these individuals for a call from a quit coach (G. Luciano, personal communication, April 3, 2012).

Additional investigation into the use of IVR technology as an adjunct to quitline services is necessary and time-sensitive. The CDC recently announced that a new back-up IVR system (triggered when all lines to a state quitline are busy) went into effect on March 19, 2012. Beginning on April 4, 2012, the system is turned on during the hours when the California quitline is closed. Developed jointly by CDC and NCI, the system is intended to provide a safety net for state quitlines in the event that increases in call volume exceed a state's capacity. The system offers callers a menu of service options, including referral to the NCI cessation website smokefree.gov, pre-recorded cessation messages tailored to callers' needs, and a NCI text messaging program. The CDC reports that they will be exploring options to increase the usefulness of this IVR system after the testing phase with California is complete (NAQC, Email, April 3, 2012).

Further research and continued identification of how states are using IVR will be needed to further understand its effectiveness. In addition to the uses described here (extending the capacity of quitlines during times of high demand, identification and collection of information from smokers, extending hospital based-cessation support post-discharge), novel approaches to using IVR in conjunction with quitlines are likely to emerge. For example, Carlini and colleagues have used IVR to proactively reach relapsed smokers who had previously used a quitline and found that when reached, 36% accepted the IVR assessment and of those, 66% accepted the opportunity to re-enroll in quitline services.

The Evidence for the Use of Texting with Quitlines

Text messaging is an emerging technology for smoking cessation. The potential exists for text messages to serve as a reminder system for telephone counseling appointments, a means of sending out motivational messaging, and a means for participants to proactively request messaging around certain topics. The potential benefits of texting interventions include cost effectiveness, scalability to large populations, the ability to tailor messages that are time-sensitive and may distract users from cravings, and the ability to link smokers with others for social support. 99 Studies to date (non-specific to integration with quitlines) show that text messaging seems to be well received and that users are satisfied

with the programs. 100-104 The populations for these studies have focused largely on adolescents and young adults who are heavier users of this technology, 100, 102, 103, 105 though some studies have included other adult populations. 106, 107

With respect to cessation outcomes, a meta-analysis of mobile phone-based interventions for smoking cessation shows some short-term quit success, but no evidence to support a long-term effect on tobacco abstinence. The Community Preventive Services Task Force recommends mobile phone-based interventions based on sufficient evidence for increasing tobacco use abstinence for those interested in quitting. A trial of New Zealand's Txt2quit program demonstrated significant increases in quit rates at six weeks when compared to no messages (28.1% vs. 12.8%)¹⁰⁶ (See Table 13). A trial of the United Kingdom's txt2stop program found that abstinence at six months increased in the txt2stop group compared to the control group who received messages unrelated to quitting (9% vs. 4%). One study found increased quit success (26.1% in the intervention group vs. 11.2% in the control group) with equivalent quit outcomes in Maori and non-Maori populations. Two related studies testing an integrated program of Internet, email, and texting technologies reported a doubling of tobacco abstinence at 12-month follow up.

Table 13. Evidence for Cessation-Based Texting Interventions

Study (reference #)	Quit Rates	
Bramley 2005	6 week follow-up, intention to treat	
(104)	26.1% intervention group vs. 11.2% control	
Bredndryen 2008	12 month follow-up, intention to treat	
(109)	20% intervention vs. 7% control	
Bredndryen 2008	repeated 7 day point abstinence at 12 months, intention to treat	
(110)	22.3% intervention vs. 13.1% control	
Free 2011	6 months, biochemically verified continuous abstinence	
(107)	9% intervention vs. 4% control	
Rodgers 2005	6 weeks, 7 day point prevalence, intention to treat	
(106)	28.1% intervention vs. 12.8% control	

While there is a need for additional research to understand long-term outcomes, there is a significant level of program adoption already underway. Both the United Kingdom (NHS Service Stop Smoking Together program) and New Zealand (Txt2quit program) provide texting programs. In the U.S., NCI has developed SmokefreeTXT to support smoking cessation with a focus on teens and young adults (the texting service, however, can be used by all adults). SmokefreeTXT is segmented based on age and in the future will be segmented based on smoking pattern (regular smokers and weekend/social smokers). NCI has also launched a Spanish version of the texting program. In addition, NCI has developed QuitNowTXT, a library of text messages (including recommended timing and frequency) that is publicly available at http://www.smokefree.gov/hp.aspx.

Quitlines that are considering integrating text messaging to enhance services will need to consider a variety of factors. The first is the question of frequency of messaging, with the challenge of achieving a balance between effectiveness and not overburdening those who do not have unlimited text messaging (NCI also offers SmokefreeTXT Lite for people who have limited text messaging). The issue of message timing will also need to be considered. In the NCI program, users do not start receiving messages until two weeks before the quit date. The messages then ramp up in frequency up to the day before and the first week after quitting, then taper off over six weeks post-quit. Quitlines will also need to weigh whether or not they have the capacity to respond to participants who request help. Overall, texting programs can be relatively low-cost, with resources needed for startup (to modify vendor platforms to support the algorithm for what messages are delivered and when) and for messaging costs.

Considerations for Practice for Expanding Quitline Service Offerings through Advances in Technology

The emerging nature of the evidence for these new technologies as an adjunct to quitline services limits the ability to make science-based recommendations. This will be an area that will be fluid in terms of evolving technology and evidence, and readers will need to review up-to-date research before making service decisions. It is expected that quitlines will continue to innovate with these technologies and incorporate them into their cessation service offerings, and dissemination of experience-based findings among quitlines should be encouraged. Though relatively inexpensive, building systems to support these technologies does require some investment of resources and time. Quitlines should carefully consider the value added in adopting and integrating these technologies.

Based on the evidence to date, the findings of this review suggest:

- 1. There is no compelling evidence that integrating web-based cessation programs with phone counseling is more effective than phone counseling alone. Further research will be needed to more fully understand how these two programs can work together to support tobacco users in their quit attempts.
- 2. In practice, there are many uses of web technology that are being used in conjunction with quitline services. The future of quitlines will likely be highly integrated with web-based technologies. Innovations should be encouraged and experiences shared.
- 3. To date, IVR technology remains largely untested among quitlines. Those who are adopting IVR should be supported to evaluate these programs and share findings with the larger quitline community. Likewise, NCI should be encouraged to share findings based on the federal IVR system.
- 4. Texting appears to provide short-term cessation benefits. Given the potential for this tool to provide efficiencies in service delivery and its relatively low cost, quitlines should be encouraged to adopt and evaluate text-based interventions. An emphasis should be placed on encouraging quitlines to adopt and modify texting programs that are currently available rather than on developing new texting programs.
- 5. While this paper did not review the use of social media, several quitlines have integrated these tools (Facebook, Twitter) into their programs. Dissemination of experience-based findings should be encouraged.

Recommendations for Research for Expanding Quitline Service Offerings through Advances in Technology

- 1. Additional research is needed on the feasibility and effectiveness of quitline services coupled with automated text messaging, IVR, and web-based technologies. How are these technologies being used by quitlines? What role can these technologies have in extending reach to different groups of tobacco users, increasing tobacco abstinence, and lowering costs?
- 2. Research is needed to identify who is reached with these technologies that might not otherwise be reached and how users are engaging with these technologies to support their quitting process.
- 3. The cost effectiveness of these technologies should be investigated.
- 4. Randomized controlled trials may struggle to keep pace with the rapid emergence and evolution of new technologies. Quitlines currently using these technologies should be supported to evaluate these tools and disseminate their findings.
- 5. While not included in this review, there is a need for research on mobile applications to support quitlines. This area is important given a recent study that found that iPhone apps for smoking cessation have low adherence to evidence-based cessation, with few applications recommending or linking the user to quitlines, counseling, and/or pharmacotherpy.¹¹¹

SECTION FOUR: FINAL RECOMMENDATIONS FOR PRACTICE AND RESEARCH

The North American community of quitlines is well positioned to face the challenges and opportunities of the future. Given the accelerating pace of change, quitline stakeholders will need to remain closely connected to science to guide their practice. They will also need to continue to learn from each other regarding the impacts that service models, medication approaches, and technologies have on supporting tobacco users in their quitting process.

This review set out to address a question of critical importance to those involved in quitlines: How can tobacco users be served most effectively at a time with historically high utilization, limited resources, and a rapidly changing public health and health care environment? While many of these questions are answered by the science, many additional questions remain. This section of the paper summarizes the implications of this review for service offerings, continued innovations, and research. As stated throughout this paper, recommendations address services to the general population of tobacco users and other considerations may apply when defining service offerings for special populations.

Recommendations for Service Offerings

The environment will continue to shift in unknown ways, challenging quitlines to be increasingly flexible in adjusting service models. There will be conditions in which resources are inadequate to meet the demand for services. There will also be times when adequate resources allow quitlines to consider expanding service offerings. Unfortunately, there are likely to be situations where quitlines are faced with very low levels of funding, and in those cases, stakeholders will need to determine if there is a point at which the costs of providing a very minimal service outweigh the benefits. The challenge facing all quitline stakeholders will be in balancing both reach and effectiveness when making critical service delivery decisions. Based on this review of the evidence, service delivery options are presented for conditions of both low and high resources.

Table 14. Service Delivery Options for Low and High Resources

Environment	Service Delivery Options	Evidence
Low	Scale back the number of	Evidence suggests that the offer of moderate
Resources	proactive calls	intensity protocols (2-3 calls with a high rate of
		completed counseling sessions) are as likely to
		be as clinically effective as the offer of higher
		intensity call protocols (4-5 calls). 31, 32, 38, 40, 41
		In addition, moderate counseling protocols are
		more cost-effective than high intensity
		protocols. ³²
	Scale back to one-call (reactive)	Evidence indicates that NRT combined with
	combined with NRT	single-call reactive counseling is an effective
		service model. ³²⁻³⁴
	Deduce the marriage of NDT to a	Chydiae have above that a true week marrielan
	Reduce the provision of NRT to a	Studies have shown that a two week provision of NRT is clinically effective ^{43, 62, 69} and cost-
	two week starter kit	
		effective. ⁶⁶
	If reducing the provision of NRT	Studies have shown that some callers are
	to two weeks, include counseling	willing to purchase NRT on their own, ⁶⁴ 33, 40, 43,

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Times of Limited Resources

Times of Limited	Resources	
	on how to obtain additional NRT	62 in particular if counseled to do so. 66
	Reserve extended supplies for those least able to obtain NRT on their own	Studies have shown that a longer course of NRT (up to 8 wks) results in higher quit rates than shorter supplies. 66-68
	Consider using split-shipments for distributing extended supplies of NRT	Evidence suggests that split shipment protocols for providing extended course of NRT may be more cost-effective than single-shipment protocols. ⁷⁸
	Increase resources for fax referral with an emphasis on achieving high rates of contact and enrollment	Evidence suggests that fax-referral programs are an effective tool for increasing quitline enrollments, 45, 46 increasing success in quitting, 48 and increasing provider engagement in the quitting process. 53 In addition, these programs are highly cost-effective. 45, 46, 56 Efforts to achieve high rates of contact and enrollment among those referred further enhance the effectiveness of fax referral. 56
High Resources	Add proactive counseling to a reactive quitline	There is strong evidence that multi-call proactive counseling sessions have greater benefit compared to single session counseling. ¹ ,
	Add free NRT if not already provided	Several studies have demonstrated that providing NRT is effective in increasing call volume, ^{57-62, 64, 65} increasing tobacco abstinence, ^{57, 59-65} and is cost-effective. ^{32, 61, 64, 65}
	Provide extended supplies of NRT	Studies have shown that longer course of NRT (up to 8 weeks) results in higher quit rates than shorter supplies. 66-68
	For quitlines with robust budgets, consider providing access to prescription medications	Evidence suggests that the provision of varenicline ⁷⁷ or bupropion ⁷⁶ through quitlines is clinically effective.

Recommendations for Continued Innovations

There are several areas of innovations that are prevalent in current quitline practice, despite limited scientific evidence. These areas should be identified as priorities for further research and those pursuing these innovations should be encouraged to share their experiences to advance the field.

1. Linking NRT to Enrollment in Proactive Counseling

Though quitlines remain committed to providing callers with counseling, further study is needed to understand if allowing callers access to NRT while encouraging (rather than requiring) them to enroll in proactive counseling is an effective service delivery model. This issue should be examined carefully through rigorous research. In the meantime, much can be learned from those quitlines that have adopted approaches to providing NRT in combination with brief interventions.

2. Medication Distribution

There is very little science to inform service models for distributing medications, yet a critical need to identify the cost-benefit structure of voucher systems (and other distribution mechanisms) exists. Again, those quitlines that are actively innovating in this area should be supported to share their experiences in an effort to identify opportunities for cost savings in the distribution of medications.

3. Partnerships

Partnerships with pharmaceutical companies are another area of innovation identified from current practice. Quitlines should explore opportunities to collaborate with pharmaceutical companies to leverage discounts for medications as well as pursue other potential partnerships that could extend resources and support sustainability.

4. Technology

While the science to support advances in technology is emerging, in practice technologies are currently being used in conjunction with quitlines. Given that these technologies hold great potential to expand quitline service offerings, the adoption of these innovations should be encouraged and experiences shared.

Recommendations for Research Priorities

Generally, quitline research has been underfunded and needs to be identified as a priority area for federal funding. This review identified several areas for further research which were summarized at the end of Sections One -Three. A summary of research areas viewed as highest priority for addressing quitline service model offerings are presented below.

Table 15. Research Priorities for Addressing Service Model Offerings

Reactive Service Models

How cost-effective are reactive service models?

Proactive Service Models

- What are the optimum number, length, and timing of proactive calls?
- Which call attempt protocols are most cost-effective?
- Which counseling elements are most critical to support quitting and prevent relapse and should be preserved under abbreviated proactive protocols?

Fax-referral Programs

- Which approaches are most effective in achieving high rates of contact and enrollment?
- How many attempts should be made to contact referrals and over what period of time should they occur?

Medications

- What impact does the amount of medication supplied have on quitline utilization, clinical outcomes, and cost effectiveness?
- What is the impact of de-linking the provision of NRT from extended quitline counseling?

• What impact does different delivery mechanisms for medications (direct mail, vouchers, other technologies) have on quitline utilization, clinical outcomes, and cost effectiveness?

Advances in Technology

- What is the feasibility and effectiveness of quitline services coupled with automated text messaging, IVR, and web-based technologies?
- What role can these technologies have in extending reach to different groups of tobacco users, increasing tobacco abstinence, and lowering costs?
- How cost-effective are these technologies when used in conjunction with quitlines?

ACKNOWLEDGEMENTS

Authors:

NAQC would like to acknowledge the lead author of this issue paper, Barbara Schillo, PhD. Dr. Schillo was responsible for conceptualizing and drafting the original paper and incorporating feedback of NAQC staff, NAQC Advisory Council members, and NAQC's general membership into the final version of the paper. Dr. Schillo would like to acknowledge Jessie Saul, PhD for her guidance on the literature review, as well as Lija Greenseid, PhD and Michael Luxenberg, PhD who both provided reviews of draft versions of the paper and advised on specific technical issues.

Contributors:

For managing the feedback and revision process, support of the author and editing NAQC would like to acknowledge Tamatha Thomas-Haase, MPA. For layout and design of the paper, NAQC would like to acknowledge Natalia Gromov. Linda Bailey, JD, MHS contributed important feedback that shaped the scope and content of the paper. NAQC would also like to acknowledge its Advisory Council members for their role in reviewing and approving this Issue Paper, most notably the three members who served as primary reviewers: Karen Brown, MPA, Ann Malarcher, PhD, MSPH, and Ann Wendling, MD. The feedback from NAQC members during the review and comment phase of the process was also invaluable.

Funders:

NAQC's Quality Improvement Initiative is made possible with funds from 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 funding organizations.

Recommended Citation:

NAQC. (2012). Quitline Service Offering Models: A Review of the Evidence and Recommendations for Practice in Times of Limited Resources. (B. Schillo, PhD). Phoenix, AZ.

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Appendix A

Appendix A Study (reference #)	Location	Service Model	Call Protocol	Med Protocol	Increase in Calls/ Reach	Calls Completed	Amount of NRT/Meds Used	Quit Rates	Cost	Study Design
	d Proactive So									
Borland 2001 (31)	Australia	Reactive & Proactive	Multiple calls, first pre-quit, then according to need	NA	NA	80% of those offered received callbacks; ave 2.8 calls completed	NA	6 month/PP/RR 15% reactive 23% multi-call	Australian \$650 per incremental quit (ICER): Australian \$46 multi-call vs. Australian \$13 reactive	2 arm RCT Reactive (n=501) Multi-call (n=497)
Borland 2003 (36)	Australia	Reactive & Proactive	Multiple calls 10-15 mins over 2-3 weeks; 1 st callback tied to quit date, then per request	NA	NA	67.8% of those offered received callbacks; ave 3.3 calls completed	NA	6 month/PP/RR 15.9% self-help 19.5% tailored 25.1% tailored + phone	NA	3 arm RCT Self-help (n=527) Tailored (n=523) Tailored + phone (n=528)
Carlin- Menter 2011 (41)	New York	Reactive & Proactive & Meds	First call 1 week before quit date; others scheduled per request; calls ave 8 minutes	All sent 2 wks, eligible for up to 6 wks patch	NA	Average callback = .96; of those in 4 call group, only 14% completed > 2 callbacks	No differences between groups; 9% did not use	3 month/7 day PP/ITT 13.6% 2 callbacks. 14.0% 4 callbacks	\$445 2 calls vs. \$442 4 calls Costs: intake + 2 wk NRT + ship=\$37 additional 4 wk NRT + ship=\$48 completed call back session=\$10	2 arm RCT 2 callbacks (n=961) 4 callbacks (n=962)
Gilbert 2006 (29)	United Kingdom	Reactive & Proactive	5 proactive calls, 3 in week 1, 1 in weeks 2 & 4	NA	NA	73.7% of those offered received multi calls; ave 2.7 calls completed	NA	6 month/30 day prol abst/ITT 13.8% reactive call 15.1% multi-call	NA	2 arm RCT Single reactive call (n=704) Multi-call (n=753)
Hollis 2007 (32)	Oregon	Reactive & Proactive & Meds	Brief: 15 min call Moderate: initial 40 min	5 wks; option for 8 wks patch (mailed)	NA	Average calls completed: Moderate: 1.7-2.0	80% requested 5 week supply, 28%	12 month/30 day PP/ITT Brief: 12% (no NRT) vs. 17%	(ICER) cost per incremental quit relative	3 X 2 RTC Brief (n=872) Brief NRT (n=868)

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			with brief call 1-2 weeks later Intensive: 30-40 minutes, offer of up to 4 add calls over 3 months			Intensive: 2.5-2.9	requested additional 3 weeks	Moderate: 14% (no NRT) vs. 20% Intensive: 14% (no NRT) vs. 21%	to brief no NRT [actual costs=\$67]: brief NRT: \$2467/add quitter [\$107] mod no NRT: \$1912/add quitter [\$132] mod NRT: \$2109/add quitter [\$193] int no NRT: \$2641/add quitter [\$242] intensive NRT: \$2112/add quitter [\$268]	Moderation (n=718) Moderate NRT (n=715) Intensive (n=720) Intensive NRT (n=721)
Orleans 1998 (27)	USA – 4 regions	Reactive	Single call	NA	NA	Median counseling min minutes 13 standard; 19 tailored	NA	6 month/7 day PP/ITT 9.1% standard vs. 10.1% tailored	NA	2 arm RCT Standard reactive call (n=437) Tailored reactive call (n=456)
Rabius 2004 (37)	USA	Reactive & Proactive	5 proactive calls, 2 before quit date, 3 within 2 weeks	NA	NA	NA	NA	6 month/prolonged abst/ITT 1.9% control vs. 8.8% proactive (18- 25 year olds); 4.1% control vs.7.7% proactive (25+ year olds)	See McAlister	2 arm RCT Self-help vs. Multi-call 3,522 participants; half randomized to each group
McAlister 2004 (42)	USA	Reactive & Proactive	5 proactive calls, 2 pre quit date, 3 w/in 2 wks	NA	NA	NA	NA	NA	\$1,300 cost per incremental quit (ICER)	2 arm RCT Self-help Multi-call
Rabius 2007 (38)	USA	Reactive & Proactive	1) 35-45 minute call 10-14 days before quit date, 2-3 days before quit date; 1-2	NA	NA	Approximately 1 in 10 completed the number of sessions they were assigned to; this did not	NA	7 months/30 day PP/ITT Self-help=7.6% 5 sessions, 210 min=12.7% 5 session, 210 min plus booster=11.7%	NA	7 arm RCT Half of each of the three proactive conditions randomized to two 15 minute

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			days, 6-9			vary by group.		3 session, 105		boosters vs. no
			days and 13-					min=8.5%		boosters
			16 days post					3 session, 105 min		Self-help
			quit date					plus booster=10.8%		(n=1,564)
			2) 3 call: first					5 sessions 50		5 sessions, 210
			and last					min=10.0%		minutes (n=749)
			session					5 sessions 50 min		Plus booster
			eliminated					plus booster=14.1%		(n=826)
			3)							3 sessions, 105
			Abbreviated							minutes (n=819)
			5 call: each							Plus booster
			call reduced							(n=812)
			to 10 minutes							5 sessions, 50
			each							minutes
			4) + 2, 15							(n=1,289)
			minute							Plus booster
			boosters							(n=263)
Smith	Canada; 10	Reactive &	Moderate:50	NA	NA	76% of those	NA	6 months/7 day	NA	5 arm RCT (632
2004	localities	Proactive	minute call,			in counseling		PP/ITT		participants
(39)			2 calls at 2 &			group received		14% print only		randomized)
			7 days post			at least one		15% telephone		Print only
			quit vs.			call; only 22%		counseling		50 minute initial
			<u>Intensive</u> : 4			in intensive vs.		Increased call		call plus 2, 5-10
			further calls			56% in		condition did not		callbacks
			at days 14,			moderate		result in increased		50 minute initial
			21, 34, 40			condition		quit rates		call plus 6 5-10
						received all				min call backs
						calls				(Call conditions
										crossed 2 types of
										pamphlets)
Sood	USA	Reactive	Single call	NA	NA	NA	NA	6 months/7 day	NA	2 arm RTC
2009	Illinois -							PP/ITT		Self-help (n=496)
(26)	Iowa							15% self-help		Reactive (n=494)
, ,								15% reactive		, ,
Thompson	USA	Reactive	Single call	NA	NA	NA	NA	No differences	NA	2 arm RCT
1993										Self-help (n=185)
(28)										Tailored reactive
										(n=197)
Zhu	San Diego	Reactive &	50 minute	NA	NA	NA	NA	12	NA	3 arm RCT
1996		Proactive	reactive vs.					month/continuous		Self-help (n=841)
1//0	L	110001110	1000110 15.		L			month continuous		Sen help (n=0+1)

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(30)			plus 5 sessions 1,3,7,14 & 30 days after quit					abstinence/ITT 5.4% self help 7.5% single call 9.9% multi-call		One call (n=1,143) Multi-call (n=1,046)
Zhu 2002 (35)	California	Reactive and Proactive	Pre-quit + 6, post quit date calls within 3 months	NA	NA	72.1% of those in counseling condition received at least one call	NA	12month/prolonged abstinence /ITT 6.9% self-help 9.1% multi-call	NA	2 arm RCT Self-help (n=1,309) Multi-call (1,973)
Pharmacoth	erapy									
An 2006 (60)	Minnesota	Reactive & Proactive & Meds	Multi-session – timed per request; not to exceed 12 weeks	8 wks patch gum mailed	155 average calls per month pre vs. 679 post NRT	Pre NRT – 77% one call; 23% multi Post NRT: 90% multi; 10% one call	NA	6 month/7 day PP/ITT 10.8% pre vs 21.7% post NRT	\$1,362 vs \$1,934 post NRT cost per quit Average cost per caller pre NRT \$136; average cost per caller post NRT \$352	Comparison to historical outcomes Pre NRT (n=670) Post NRT (n=596)
Bauer 2006 (64)	Western New York State (Erie and Niagara counties)	NRT administered through quitline but not tied to counseling	NA	Voucher (pharmacy) 2 wk supply of patch gum	Median calls/day pre 6; post 148	NA	85% redeemed voucher	4-6 months/7 day PP/RR 12% pre vs. 22% post NRT	\$210 cost per additional quitter	Comparison to historical outcomes Pre NRT (n=515) Post NRT (n=1,016)
Cummings & Fix 2006 (65)	New York State	NRT administered through quitline but not tied to counseling	In NYC (6 wk condition) – 1 f/up phone call	Voucher for 2 wk supply patches/gum 1 wk patches 2 wk patches 6 wk patches mailed	Reach ranged from.5 to 4.8 (New York City)	NA	2 wk voucher – 61% 1 wk – 56% 2 wk – 49% 6 wk – 23%	4 months/7 day PP/RR 12% no NRT 27% 2 wk voucher 21% 1 wk mail 24% 2 wk mail 33% 6 wk mail	cost per additional quitter [actual service costs] \$274 voucher [\$42] \$306 1 week mail [\$29] \$347 2 week mail [\$42] \$347 6 week mail [\$76]	Non equivalent comparison groups Pre NRT (n=515) 2 wk voucher (n=702) 1 wk mail (n=721) 2 wk mail (n=1,033) 6 wk mail (n=1,386)
Cummings 2006 (62)	New York City	Reactive & Proactive & Meds	One follow up call	6 wk patch mailed	5 of NYC smokers reached	NA	NA	12 months/7 day PP/RR 22.3% pre vs. 33.2% post NRT	\$420 cost per additional quitter	Comparison to historical outcomes Pre NRT (n=446)

			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					r Practice in Time		Post NRT (n=1,597)
Cummings 2010 (69)	New York State	Varied models Attempted callback 2-4 weeks post shipping with all callers	2 wk supply 4 wk supply 6 wk supply 6 wk supply 8 wk supply patch mailed	6 wk group - NRT contingent on receiving up to 4 proactive calls	NA	NA	Number of patches used did not differ	12 month/7 day PP/ITT 19.1% 2 wk 12.9% 4 wk 7.0% 6 wk 23.1% 6 wk 22.6% 8 wk	NA	5 non equivalent comparison groups 2 wk (n=490) 4 wk (n=588) 6 wk (n=731) 6 wk (n=1,386) 8 wk (n=707)
Miller 2005 (61)	New York City	Reactive & Proactive & Meds	Calls 3 weeks and 14 weeks post intake	6 wk patch mailed	5% of NYC smokers reached	55% NRT group received no counseling	NA	6 month/7 day PP/RR 6% pre vs. 33% post NRT	\$464 cost per additional quitter	Comparison to historical outcomes Pre NRT (n=506) Post NRT (2,150)
Bush 2008 (33)	Oregon	Reactive & Meds	30 minute call	2 wks patch mailed	257 pre to 2,592/month enrollment post NRT	NA	NA	6 month/7 day PP/ITT 9.3% pre vs. 17.0% post NRT	See Fellows (below)	Comparison to historical outcomes Pre controls (n=546) Post participants (n=1,201)
Fellows 2007 (34)	Oregon	Reactive & Meds	30 minute call	2 wks patch mailed	6,428 pre vs. 13,646 annual enroll post NRT; reach increased 1.2% to 2.6%	NA	NA	NA	Cost per quit \$3,738 pre vs. \$1,050 post NRT \$174 cost per incremental quit (ICER)	Comparison to historical outcomes Pre-initiative controls (n=546) Initiative participants (n=1,201)
Biazzo 2010 (77)	Montana	Reactive & Proactive & Meds	5 sessions	4 wks NRT mailed; Varenicline \$25 co-pay & script for each 4 wks (up to 12) 2 nd and 3 rd shipments tied to calls	NA	Varenicline: 37% 0-2 calls; 67% 3-5 calls NRT: 63% 0-2 calls; 33% 3-5 calls	NA	6 months/7 day PP/ITT 11% NRT vs. 17% Varenicline	Caller pays \$75 for 12 wks varenicline Quitline pays \$270.75	Comparison of callers self-selecting NRT (n=3,679) or varenicline (n=3,116)

Burns 2010 (67)	Colorado	Reactive and Proactive & Meds	NA	8 wks vs. 4 wks, split shipment	NA	44-53% - 1-2 calls 47-57% - 3-5 calls	NA	7 month/7 day PP/RR 37.2% 8 wks vs 29.4% 4 wks NRT	NA NA	Non equivalent comparison group 8 weeks (n=1,384) 4 weeks (n=326)
Campbell 2008 (68)	Montana	Reactive & Proactive & Meds	Initial call and 5 sessions	4 or 6 wks NRT single shipment	Ave 397 calls/wk 4 wks 712 calls/wk 6 wks	NA	NA	6 month/7 day PP/ITT 9.0% 4 wks vs 12% 6 wks NRT	NA	Comparison to historical outcomes 4 wks (n=1148) 6 wks (n=1,834)
Cummings 2011 (43)	New York State	Reactive & Proactive & Meds	Single call back (10-15 min) 2 wks after initial call	2 wks 4 wks 6 wks patch mailed	NA	58% completed proactive call; no differences between groups	2 wk 67% 4 wk 49% 6 wk 33%	7 months/7 day PP/ITT 14.8% 2 wk 17.1% 4 wk 17.5% 6 wk	Cost per quitter \$891/2wk \$922/4 wk \$1,022/6 wk	3 arm RCT 2 wk (n=923) 4 wk (n=929) 6 wk (n=949)
Ferguson 2012 (40)	United Kingdom	Reactive & Proactive & Meds	Standard: initial call, messages before, on and after quit data, 4 proactive calls offered (brief, unstructured) Intensive: plus 6-7 proactive calls (structured)	Vouchers for 21 day supply patches; 2 nd 21 day supply available	NA	Standard: 2.4 calls completed Intensive: 3.3 calls completed	71.9% redeemed vouchers; 21.0% requested second supply	6 month/prol abst/ITT 20.1% no NRT vs. 17.7% NRT 19.6% standard vs. 18.2% intensive	NA	RTC 2 levels of proactive counseling with or without free NRT standard support (no NRT) (n=648) intensive support (no NRT) (n=648) standard support (NRT) (n=648) intensive support (NRT) (n=648) intensive support (NRT) (n=649)
Maher 2007 (57)	Washington	Reactive & Proactive & Meds	5 calls	8 weeks	Call volume increased	NA	NA	3 month/7 day PP/RR 21% pre vs 38% post NRT	NA	Comparison to historical outcomes Pre= (114) Post= (218)
McAfee 2008 (66)	Oregon	Reactive & Proactive & Meds	Eligible for 2 calls; also ad hoc; 1 st on call in; 2 nd	8 wk vs 2 wk patch (mailed) Split	NA	Median no calls 1.6 - 2 wk 2.0 - 8 wk	Ave 6.3 wks NRT used in 8 wk condition;	6 month/7 day PP/adjusted ITT 15.6% 2 wk NRT 21.9% 8 wk NRT	\$1405 8 week NRT vs. \$1156 2 week NRT cost per quit	2 arm RCT Multi-call with 2 N=578) or 8 weeks NRT

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			wk after quit date	shipment			4.3 in 2 wk condition		\$2,068 cost per incremental quit (ICER) Actual costs \$166 counseling and 2 weeks of NRT; \$275 counseling & 8 wks NRT	(n=576)
Miller 2009 (58)	Australia	Reactive & Proactive & Meds	Multi-call counseling	1 wk worth NRT vouchers 75% off retail price	NA	NRT group received more callbacks (6.3 vs 5.5)	36.8% vouchers redeemed; those that received 80.9% used	6 month/ 7day PP/ITT 21.2% no NRT vs 30.9% NRT	NA	Two separate samples randomly recruited Counseling (n=1000) Counseling + NRT (n=377)
Saul 2011 (78)	Minnesota	Reactive & Proactive & Meds	Up to 5 calls	5 wks NRT 5+3 wks split dosing NRT 8 wks NRT mailed patch or gum	NA	Callers in split shipment completed more call (3.0) compared to those in 5 wk one shipment group (2.4) or 8 wk single shipment group	Split shipment used NRT ave 48.8 days; 5 wk, 1 shipment 28.9 days; 8 wk single shipment 33.5 days	7 month/30 day PP/ITT 18.1% 5 wks 28.8% 5+3 wks 28.3% 8 wks	Cost per quit Single \$1,350/quit vs. split - \$1,242	Nonequivalent comparison groups 8 wk single shipment (n=247) 5 week one shipment (n=94) 5+3 wk split shipment (n=66)
Swan 2003 (76)	Health Plan	Reactive & Proactive & Meds	NA	Buproprion SR	NA	NA	NA	12 month/7 day PP/ITT 150 mg + moderate phone = 31.4% 150 mg + brief = 23.6% 300 mg + moderate = 33.2% 300 mg + brief = 25.7%	NA	4 arm RCT Brief vs. moderate counseling X 2 dosing levels of medication 150 mg + moderate phone (n=382) 150 mg + brief phone (n=381) 300 mg + moderate phone (n=383(300 mg + brief

			100				J J	Tractice in Time	<i>J</i>	phone (n=378)
Swartz 2005 (63)	Maine	Reactive and Proactive & Meds	Up to 3 calls	Vouchers up to 8 wks patch gum	NA	NA	Of those eligible, 64.5% obtain NRT	6 month/30 day PP/ITT 12.3% counseling. 22.5% + NRT	\$1,344 NRT cost per quit	Comparison of 1,076 callers receiving counseling vs. counseling + NRT
Tinkelman 2007 (59)	Ohio	Reactive & Proactive & Meds	Up to 5 calls after initial contact	8 wk patch mailed; split ship 4 & 4	2,351 calls/month pre vs. 3,606 post NRT	NA	NA	6 month/PP/ITT 10.3% pre vs. 14.9% post NRT	NA	Comparison to historical outcomes Pre= (10,009) Post = (13,233)
Walker 2011 (79)	New Zealand	Reactive & Proactive & Meds	Multi-call counseling	2 vouchers wks NRT or NRT samples, 1 selected, 4 wk supply mailed	NA	Average of 3 support calls over 8 wks, each lasting 10-15 minutes	NA	6 months /7 day PP/ITT 30% usual care vs. 29% sample box	NA	2 arm RCT Vouchers for 8 wks NRT (n=704) vs. Sample box, with 4 week supply of chosen product (n=706)
Zawertailo 2012 (74)	Ontario	Reactive & Meds	Brief phone intervention (5 As) at initial call	5 wk patch gum mailed, self help materials and quitline number	NA	NA	NA	6 months/30 day PP/RR 11.6% no intervention vs. 21.4% NRT intervention group	Cost per quitter \$C1,720	Nonequivalent comparison group Comparison (random sample smokers) (n=4,501) NRT group (n=6,261)
Fax referral				_						
Bentz 2006 (45)	Oregon Primary Care Clinics	Reactive & Proactive	NA	NA	NA	19% contact rate brochure vs. 59% fax referral; of contacted, 90% accepted at least one call	NA	NA	\$15-\$22 per pt. year one; \$4-\$6 in following years	2 arm RCT 19 clinics Brochure (n=240) vs. Fax referral (n=496)
Borland 2008	Australia	Reactive & Proactive	NA	NA	NA	47.5% referred; of	NA	3 month/30 day sust abst/ITT		2 arm RTC In-practice

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(48)	General practices					those 76.8% contacted; of those 73.5% accepted service		12.3% referral vs. 6.9% in-practice		management (26 GPs, n=311) vs. Fax referral (43 GPs, n=728)
Ebbert 2007 (50)	Minnesota Dental practices	Reactive & Proactive	Brief call within 48 hours of fax; 1-2 wks post quit; up to 10 wks if requested	NA	NA	60% enrolled and received at least one call	NA	6 month/7 day PP/ITT 27.3% brief counseling vs. 25.0% fax referral	NA	2 arm RTC Brief counseling (n=22) vs. Brief counseling + fax referral (n=82)
Gordon 2007 (47)	Mississippi Dental practices	Reactive & Proactive	NA	NA	NA	35% agreed to referral; among those 70% contacted; 85% enrolled	NA	3 month/RR Usual care 6.3% 5As 8.3% Fax referral 7.2%	NA	3 arm RTC (n=2,177 randomized to 1 of 3 arms) Usual care vs. Dental delivered 5As vs. Advice to quit + fax referral
Mahabee- Gittens 2008 (52)	Ohio Emergency rooms	Reactive & Proactive	NA	NA	NA	46% connect rate; of those contacted 84% enrolled	NA	3 month/7 day PP/ITT 5.9% usual care 11.4% fax- referred	NA	2 arm RCT Usual care (n=119) vs. Fax referral (n=237)
Rothemich 2010 (54)	Virginia Primary care clinics	Reactive & Proactive	NA	NA	NA	NA	NA	40.7% smokers in intervention clinics received cessation support compared to 28.2% in control clinics	NA	2 arm RCT Control clinics (n=8) vs. "Vital Sign" Intervention clinics (includes fax referral) (n=8)
Sheffer 2012 (56)	Wisconsin	Reactive & Proactive	NA	NA	NA	NA	NA	Average number referrals greater in intervention clinics (8.5) vs. control clinics (1.5); intervention clinics had greater ave quality referrals (4.8) vs. control clinics	Cost per referral (less than \$10) and per quality referral (less than \$16) was similar for two conditions	2 arm RCT Control Clinics – Fax to Quit (n=25) Intervention Clinics – Fax to Quit + Enhanced Academic Detailing (n=24)

								(.86)		
Shelly 2010 (53)	New York Community health clinics	Reactive & Proactive	NA	NA	NA	41% contact rate	NA	Intervention sites 2.4 times more likely to provide referrals, 1.8 times more likely to offer med counseling and or a prescription	NA	Quasi- experimental 2 intervention CHC (usual care + fax referral+ training and feedback) vs. 2 comparison centers (usual care)
Sherman 2008 (49)	VA sites in California	Reactive & Proactive	NA	NA	NA	61% contact rate; 45% received quitline services	NA	11% of all referrals to quitline were abstinent at 6 month follow-up; providers in intervention clinics referred more patient in prior month (15.6 vs. 0.7)	NA	2 arm RTC Telephone care coordination including referral to quitline (n=10 clinics) vs. usual care (n=8 clinics)
Willet 2009 (51)	Ohio Hospitals and providers	Reactive & Proactive &	NA	NA	Increased from 68/month to 412/month following promotional effort	40% contact; 23.6% referrals overall resulted in enrollment	NA	NA NA	NA	Comparison to historical outcomes Comparison (n=36,273) Faxed (n=1,616)
Wolfenden 2008 (46)	Australia Pre- operative clinics	Reactive & Proactive	NA	NA	NA	64% accepted an offer; of these 74% contacted; enrolled ave 2.3 calls	NA	NA	Cost less than \$2/person	Single-group design (n=67)

^{*}Shading denotes related studies.