NAQC Issue Paper

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

Calculating Quit Rates, 2015 Update

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EXECUTIVE SUMMARY

Background

This Executive Summary highlights findings from a 2015 update to the 2009 North American Quitline Consortium (NAQC) Issue Paper, *Measuring Quit Rates*. The full paper is intended to be a stand-alone document to support efforts to produce a standard NAQC quit rate. While randomized controlled trials have established the efficacy of quitlines, quit rates can assess the effectiveness of quitlines in real-world settings, under certain conditions or with different populations. Standardized quit rates can help quitline managers make better quitline purchasing decisions and provide evidence of program effectiveness; they can also be used to explore trends and facilitate discussion among NAQC members. It is important to have a standard quit rate definition so that when quit rates are compared over time or between quitlines, any differences observed are not due to differences in research methods. To make recommendations in this paper that balance the interests of multiple stakeholders, the authors used the criteria of methodological rigor, real-world feasibility, and the potential for use of findings. We make **recommendations** for decisions in the most important areas with the strongest evidence, and **suggestions** to consider in areas we think are important but less critical or supported by weaker evidence.

Use of Terms

In this paper, use of the word "tobacco" refers specifically to the use of manufactured commercial tobacco products and not to sacred, medicinal and traditional use of tobacco by American Indians, First Nations and other groups. Authors use the term conventional tobacco when referring to combustible tobacco products (such as cigarettes, cigars and cigarellos), smokeless products and pipes.

Definition of Abstinence, Quit Rate Calculations, and ENDS

Regarding the definition and measurement of abstinence from conventional tobacco products, our literature review resulted in no compelling evidence to change most recommendations in the 2009 NAQC Issue Paper. The 2009 NAQC standard quit rate for conventional tobacco use has become a widely used measure to assess quitline performance and can be used to assess trends over time. However, use of electronic nicotine delivery systems (ENDS) has increased steadily since 2009, and reflects a critical change in the landscape of tobacco control. It is important to consider that NAQC is both a science- and practitioner-based member organization. During recent deliberations of the Minimal Data Set (MDS) Workgroup on ENDS, NAQC learned that some state quitlines are changing their practice to match the evolution of ENDS products by providing standard cessation protocols designed for conventional tobacco use to ENDS users. Moreover, NAQC is committed to advancing knowledge in the field of tobacco control and quitline treatment, and is in a unique position to foster discussion and learning among member quitlines on the emerging topic of ENDS.

Taken together, we believe that the need to assess quitline performance is as important as learning about ENDS. Therefore, **we recommend calculating two standard NAQC quit rates: one based on conventional tobacco only using a 30-day point prevalence measure recommended by MDS; and a second, separate quit rate that considers abstinence from both conventional tobacco products plus ENDS at follow-up using items recommended by the MDS Workgroup on ENDS.** The conventional tobacco products plus ENDS quit rate would be used for learning and exploratory purposes, and to help advance knowledge about ENDS among

quitlines. Because the ENDS products and research is changing rapidly, we recommend that the NAQC Advisory Council revisit this recommendation in three to five years.

Who to Include in the Quit Rate

The 2009 NAQC Issue Paper recommended criteria by which tobacco users would be included and excluded from the standard NAQC quit rate. We conducted a literature review to re-examine these criteria and found no compelling evidence to change our original exclusions. In sum, **we recommend including in the standard NAQC quit rates all tobacco users who register for services, consent to follow-up, receive some phone counseling or were sent medications or medication vouchers, and have not been quit at intake for more than 30 days.** When calculating supplemental quit rates for non-telephone technologies, we suggest including only those participants who actively engaged with the program (e.g., at least one web login or response to a text).

In recent years, technologies to deliver tobacco cessation assistance have proliferated. Cessation help is now available through web, text, interactive voice response (IVR), email, and smartphone apps and games. Of these many types of interventions, it is important to define which should be included in the standard NAQC quit rate. We considered ways to produce intervention-specific quit rates (e.g., web only or text only). However, many quitlines allow participants to use more than one intervention mode at a time so isolating the effectiveness of any one type is very difficult. In addition, while each technology has some evidence of effectiveness, it is not clear which functions make them effective when they are shown to be so. This information is necessary to define minimal, evidence-based treatment in the quit rate calculation. Finally, asking quitlines to report quit rates for each intervention is resource intensive.

Based on these considerations, **we recommend that the standard NAQC quit rates include only those who have received treatments with the strongest evidence base, which we identify as any amount of telephone counseling and/or having been sent U.S. Food and Drug Administration (FDA)-approved medications.** Medications may be provided by any technology (e.g., ordered by telephone, web, etc.) and may be sent directly or as a voucher. If individuals receiving these evidence-based services also happened to receive cessation services from a technology with a weaker evidence base, like web or text, they would be included in the standard NAQC quit rates.

Supplemental Quit Rates

We understand that the standard NAQC quit rates likely will not meet all individual quitlines' evaluation needs, especially for those who enroll a large number of participants in cessation programs using non-telephone technologies. **We suggest that each quitline consider calculating <u>supplemental</u> quit rates according to their own information needs.** Supplemental quit rates may include participants with specific demographic characteristics (e.g., women only), different levels of program use (e.g., single vs. multiple sessions), or for service groups of particular interests (e.g., all web participants, some of whom were sent medications and/or used the phone program). These supplemental quit rates would be for a quitline's internal quality control and evaluation purposes and would not be reported to NAQC.

Conducting Follow-up Surveys

We continue to recommend conducting follow-up seven months post-enrollment. Since publication of the 2009 NAQC Issue Paper on measuring quit rates, the challenges to conducting a high quality telephone survey have increased. To partially address these challenges, **we recommend selecting a rolling, random sample of enough participants to produce n=400 completed survey responders for the standard NAQC quit rates. Additionally, we recommend attempting to achieve a response rate between 50% and 70%.** While some quitlines have struggled to achieve this response rate, many others are successful. A lower response rate will likely result in biased results that do not reflect a quitline's effectiveness with sufficient accuracy. Spending resources to achieve the recommended response rate may not be warranted, depending on the groups included in the survey (for example, it may not be realistic to expect a 50% response rate for a quitline primarily serving homeless tobacco users). Focusing more resources on surveying fewer participants with a higher response rate (and a more accurate quit rate) is a more cost-effective use of resources than sampling and surveying more participants with a lower response rate. Surveying on an ongoing, rolling basis is ideal for monitoring and ensures quitlines will always have recent data available for making program decisions. However, **we recommend that if resources are limited quitlines should forego continuous measurement and instead direct evaluation resources toward conducting more rigorous studies periodically, obtaining quit rates at least once every three years.**

Please note that **we suggest quitlines consider basing supplemental quit rates (e.g., among text enrollees only) on a smaller minimum number of surveys, n=75, in order to conserve resources.** A quitline's desire to survey certain specific groups of tobacco users (e.g., demographic, program use, or service type groups) may impact sampling decisions and should be considered during evaluation planning, and again when weighting the survey data.

The full 2015 Issue Paper on calculating quit rates presents best practices to conduct quitline follow-up surveys including: sending pre-notification letters, using incentives, training interviewers, and considering using mixed-mode follow-up surveys (phone + mail; phone + web). Many options are not resource intensive, and are cost-effective ways to achieve a higher response rate. **We recommend selecting a combination of survey administration strategies appropriate to a quitline's unique context and resources in order to achieve a response rate of 50% or greater.**

Calculating and Reporting Quit Rates

When calculating a quit rate, we recommend using a responder rate, which is the number who quit based on the follow-up survey, divided by the number of follow-up survey respondents. When presenting estimated quit rates, **we recommend reporting a 95% confidence interval** in order to represent the uncertainty inherent in surveying. The confidence interval provides a range of values in which the true quit rate very likely falls.

Many factors influence quit rates, including nicotine dependence, indicators of social disadvantage, demographic characteristics, level of program use, and contextual factors like cigarette tax rate and clean air regulations. Therefore, **we recommend reporting basic information about participants' characteristics and level of service use along with quit rates. Use caution when comparing results across quitlines, and consider the similarity of the quitline programs and context as well as the characteristics of respondents.**

Taken together, calculating high quality standard NAQC quit rates and sharing these with NAQC represents an exceptional opportunity for NAQC and quitlines to demonstrate the effectiveness of quitline interventions, and to compare quitline performance for vendor selection and other quitline management purposes. Calculating high quality supplemental quit rates that are responsive to a quitline's unique local context gives quitlines the power to demonstrate program accountability and proactively improve services according their unique needs and context.

SECTION 1: BACKGROUND

Preface

This paper is an update to the 2009 North American Quitline Consortium (NAQC) Issue Paper, *Measuring Quit Rates*.[1] It is intended to be used as a stand-alone document to support efforts to produce the standard NAQC quit rates[a]. Recommendations provided within each section serve to guide measurement of program outcomes for quitline services. While the standard NAQC quit rates are the focus of this paper, we understand that individual quitlines have their own unique data and information needs. To this end, we suggest supplemental quit rates and additional measures (see Section 7) that could be used to meet the unique needs of quitlines, beyond the standard NAQC quit rates.

What is a Quit Rate?

In tobacco cessation, an ideal quit rate is the proportion of tobacco users that participated in a tobacco cessation intervention that were able to quit using tobacco after participating in the intervention, as calculated from all tobacco users that participated in that intervention. For quitlines, the quit rate helps illuminate the extent to which quitline cessation programs are effective under certain conditions or with different populations. Data collected to produce quit rate calculations can be combined in different ways to better understand the effectiveness of specific cessation interventions, such as varying levels of service intensity. The standard NAQC quit rates, described in this paper, are also designed for this purpose. They do not, however, attempt to establish *if* telephone quitlines are effective (as in a clinical trial).

Why do We Need to Measure Quit Rates?

The efficacy of telephone counseling with or without nicotine replacement therapy (NRT) for tobacco cessation has been demonstrated in multiple randomized controlled trials and quasi-experimental studies.[2,3,4] All tobacco users in North America have access to quitline services. In Canada, there are 11 quitlines that provide services to all provinces[5] and in the U.S. a single toll-free number (1-800-QUIT-NOW) exists to triage tobacco users to state-based cessation services. Why should quitlines continue measuring quit rates if there is ample evidence to show the efficacy of quitlines and all states and provinces provide quitline services?

Quit rates are important for several reasons. First, they help purchasers of quitline services (e.g., states and provinces) make choices between potential quitline providers during bidding (and re-bidding) processes. Secondly, they help stakeholders (e.g., health department administrators, legislators, etc.) make the case for continued funding. Quit rates can also provide evidence of the effectiveness of quitline services to large

[a] For more detail regarding the differences from the 2009 paper, see the Implementation Guide.

employers and health plans that may be considering sharing costs of quitline services for employees or members. Additionally, purchasers of quitline services often seek to compare the quit rates they are observing within their state or province with that of neighboring states or provinces in order to assess the performance of their quitlines. Finally, quit rates can provide information to monitor emerging issues, such as electronic nicotine delivery systems (ENDS), across quitlines in order to facilitate discussion and assist in planning action to move forward.

Why do We Need Standard Quit Rates?

Having a standard for quit rate measurement across quitline services allows for more fair and valid comparisons of quitline service outcomes across service providers, states/provinces, and years of service provision (e.g., benchmarking). Without a standard measure, differences in quit rates may be artifacts of quit rate calculation methods and not reflect differences in service quality. Standard quit rates give quitline funders better tools to bid quitline contracts, provide more defensible quit rates to external audiences, and allow meaningful comparisons of services across states and provinces.

Why Now?

This issue paper is a continuation of efforts of the NAQC's Quality Improvement Initiative which seeks to define a set of quality standards for quitline performance and measurement in the U.S. and Canada. NAQC spearheaded this work in 2005 with the introduction of the Minimal Data Set (MDS) for intake and follow-up across quitlines.[6] This was followed by numerous conversations, webinars and NAQC issue papers intended to guide North American quitlines toward use of best-practices for cessation service provision as well as standardized measurement of service use and outcomes.[1,7,8,9,10,11,12] It has been six years since the creation of the first quit rate issue paper and in that time the landscape of tobacco cessation service provision has changed in ways that have the potential to impact quit rates.

First, newer technological mediums or "service modes" through which cessation content is delivered, such as email, text message, or web are now being more widely used.[13] These modes have variable content, are delivered at differing intensities, and are used alone or in combination with other cessation interventions. The landscape for cessation services has become more complex and quit rates need to evolve to meet this challenge.

Second, ENDS have emerged as an important issue facing tobacco control advocates and researchers. Use has increased steadily, and research is beginning to address important questions about the safety of these devices, their impact on smoking initiation and behaviors; quitting; and ENDS' impact on changing norms surrounding tobacco use. Anecdotally, some quitlines are using standard tobacco cessation interventions to help ENDS users quit. ENDS have been described as a disruptive technology and tobacco control advocates and researchers are engaged in a lively debate on how to respond to ENDS in comprehensive tobacco control efforts.

Finally, funding for quitlines is, in many cases, decreasing or under threat of being sequestered for other purposes; at the same time in the U.S., the Affordable Care Act (ACA) has set forth language that requires health plan coverage of preventive services including tobacco cessation counseling and medications.[14] Quitline service provision has simultaneously expanded beyond government-managed (state or provincial) services to include private health plan quitlines and wellness services of which tobacco cessation is a component. This presents a significant challenge to the tobacco control community in that the quality of services provided by private quitlines is unclear and is not currently being tracked by most state or provincial entities; this has

typically not been within their jurisdiction and private cessation service representatives have not typically been involved in NAQC or its quality improvement efforts.

Within this context health departments may find increasing incentives to act as quality assurers of public health service provision among both publicly and privately administered quitlines, as the private sector will begin serving a larger proportion of their citizenry than in the past. The ACA will impact where different populations of tobacco users receive services which will impact quit rates in the U.S. One likely scenario, for example, is that tobacco users of higher socio-economic status may be more likely served by quitlines supported through private insurers. State quitlines would then likely see a greater proportion of Medicaid-insured participants, participants with multiple co-morbid conditions, and, generally, tobacco users that have a harder time quitting. Under this scenario, state quitlines may have a harder time reaching the standard NAQC quit rate benchmark of 30%. Quit rate calculations should be refined so that they can respond to such scenarios.

Who is the Audience for This Paper?

The primary audience for the 2009 NAQC Issue Paper was quitline funders. There are multiple potential stakeholders to consider for this 2015 update, many of whom have differing needs. Additionally, there are more cessation services that may or may not be integrated with a quitline (web, text, in-person, etc.), and more and different types of quitline funders (e.g., employer cost sharing). Given the current context of quitlines and the multiple stakeholders involved, no one set of recommendations on calculating quit rates is likely to meet the needs of all quitline stakeholders. The authors of this paper, therefore, decided to prioritize audiences. Audiences have been categorized into primary, secondary, and tertiary audiences depending on their use of quit rates. This paper has been written for those listed as primary audiences in Table 1 below.

Table 1. Classification of NAQC Quit Rate Issue Paper Stakeholders

Classification	Definition	Stakeholders
Primary	Those who calculate quit rates and send their quit rate information to NAQC	• NAQC (the organization) • Quitline funders • Quitline service providers (especially as data collectors) • Evaluators of quitlines
Secondary	Those who may calculate quit rates and are potential users of a standard quit rate calculation, but who do not report to NAQC	• Managers of non-quitline tobacco cessation interventions • Health plan quitlines • Tobacco control researchers • Centers for Disease Control and Prevention
Tertiary	Consumers of quit rate information	• Health insurers (private and public, some may have quitlines) • Large employers with employee health insurance plans • Practicing health professionals • Health systems • Large public health entities (U.S. Department of Health

		and Human Services, Health Canada) • Government decision makers • General public

Considering Rigor, Feasibility, and Use

In addition to balancing the needs of multiple stakeholders, this paper must balance the interests of methodological rigor, real-world feasibility, and use of findings. Resource-constrained states and provinces may not be able to meet all the requirements of the highest levels of methodological rigor. At the same time, quit rates need to be accurate and useful not only to states and provinces but to the larger stakeholder group of NAQC members and to NAQC as an organization, which serves as a promoter of quality quitline services. Finally, information may be useful, even when validated measures are not available for certain areas of interest. This paper takes these real-world considerations into account and provides strategies that can help balance issues of feasibility while still producing accurate and useful results.

Paper Organization

The following section of this paper (Section 2) discusses in greater detail emerging trends that cross-cut several areas for recommendations in this paper. This section provides some necessary background on three key emerging trends that inform recommendations made in subsequent sections of the paper.

Sections 3 through 6 describe various aspects of how to calculate a quit rate. Because we understand that the standard NAQC quit rates (as specified in Section 3) may not meet all quitlines' information needs, Section 7 provides guidance on supplemental quit rate calculations that stakeholders may find helpful to consider and implement, such as quit rates for different services and service combinations, and other additional cessation measures. Section 7 also provides guidance on understanding variation in quit rates between quitlines, and steps quitlines can take to better understand their quit rates.

In each of these sections, the paper presents **recommendations** in calculating quit rates, which can be found in blue boxes within each section. Some aspects of calculating quit rates are important but less critical; additionally, research is not always sufficient to definitively inform certain decisions regarding quit rates. In these cases, we make **suggestions** for quitlines to consider, which have been bolded in the text. Finally, the Implementation Guide provides support to implement the recommendations within this paper. It includes a checklist of key items needed to calculate the standard NAQC quit rates, an example of how we recommend quit rates be presented visually, a suggested format for collecting NAQC annual survey data elements, as well as a description of changes in recommendations from the 2009 NAQC Issue Paper.

SECTION 2: EMERGING TRENDS IMPACTICING QUIT RATES

Since the publication of the 2009 NAQC Issue Paper on measuring quit rates, three issues have emerged which directly impact the calculation of quit rates. The first is the challenge of obtaining high response to telephone follow-up surveys, which are the primary method of quit rate data collection. The second is the proliferation of new technologies used to promote cessation, such as web-, text-, and email-based interventions, as well as interactive voice-response (IVR) programs and smartphone cessation apps and games. The final challenge is the rapid adoption of ENDS. These issues cross-cut many of the recommendations made in this issue paper. This

section briefly outlines key background on the specific challenges that each of these issues poses, which informs the solutions to these challenges presented in later sections.

Sub-section 2.1: Challenges Facing Telephone Follow-up Surveys

Telephone surveyors continue to face new barriers in attaining high response rates. An increase in wireless-only households, unsolicited calls, and the rise of caller ID functions all have negative impacts on the success of telephone surveys. Telephone response rates are declining nationally across many populations and for many survey topic areas. For example, a Pew Research study reported that surveys of all types are experiencing a decline in response rates; in 1997 typical telephone surveys from Pew Research had a response rate of 36% compared to 9% in 2012.[15]

The changing landscape of telephone ownership is one factor influencing surveyors' ability to reach participants. Many U.S. households are switching from landline telephones to cellular phones and the pace of this change is accelerating. Data from the National Health Interview Survey (NHIS) show that the percentage of adults living in wireless-only households has been steadily growing. In 2003, only 4% of U.S. adults lived in wireless-only households. In 2008, adults living in wireless-only households grew to 16%, and by 2013 it was 38%.[16] This trend is likely to affect telephone surveyors' ability to successfully contact quitline users for follow-up as quitline participants' move from landline to wireless-only households. The same NHIS report found that adults living in poverty are more likely to live in wireless-only households; which could make reaching this important quitline population more difficult.[16] Even when callers' telephone numbers remain active, the increased practice of screening calls using caller ID and voicemail reduces the probability of connecting with potential survey respondents.[17]

In the past when quitlines were primarily providing telephone interventions, telephone follow-up surveys matched follow-up mode to the intervention. In light of new quitline program offerings delivered using other technologies (web, text messaging) and continuing challenges faced by telephone surveys, mixed-mode surveys—any combination of telephone, mail, or online surveys—are now more commonly employed to increase response rates.[18,19] High response to follow-up surveys remains a critical component in producing quit rates that are precise measures of program success. See Section 5.7 for more information on survey modes and Section 5 in general for further discussion on improving response rates to follow-up surveys.

Sub-section 2.2: New Technologies Used for Cessation Service Provision

Since publication of the 2009 NAQC Issue Paper on measuring quit rates, one of the biggest changes is the explosion of different technologies used to provide cessation services. Results from the 2013 NAQC Annual Survey of Quitlines reported that a majority of U.S. quitlines (76%) provided self-directed web-based interventions to help tobacco users quit. Further, 48% of U.S. quitlines provided text messaging services and 5% reported using IVR technologies to provide treatment to tobacco users.[13]

These new interventions present several important questions regarding how quit rates can and should be calculated. First, it is important to note that new cessation interventions vary widely, even if the basic technology is the same. For example, website and text interventions exist on a continuum of being completely self-directed to intensively interactive, and from being one-size-fits-all to uniquely tailored to each program participant. This means that a combined quit rate for all web programs in the U.S. and Canada, for example, would include very different interventions, so results are not generalizable to a single intervention.

A second consideration is that quitlines that offer tobacco users a choice of several different kinds of cessation programs (e.g., telephone, web, text messaging) often allow participants to opt in to as many of those programs as they wish. Therefore, a quit rate based on all participants who used text programs, for example, will likely be influenced by the additional telephone and perhaps web programming that some participants engaged in.

Third, research on the effectiveness of new cessation technologies is currently emerging and provides a shifting platform for decision-making. The content and features of web-based cessation programs vary so much that the tobacco cessation literature has not yet convincingly determined what kind of web site is effective.[20,21] The effectiveness of text programs appears perhaps more favorable than web-based interventions, given that the U.S. Community Preventive Task Force has named them a promising practice and a recent randomized trial found evidence for relative efficacy of a text cessation program.[22,23] However, a review of the literature shows that text interventions possess a similar problem to web-based programs: there are not yet enough high quality studies to suggest which features of text-based interventions make them effective.[23] IVR-based interventions have recent evidence of effectiveness[24]; however, more study is needed to establish effectiveness overall. The lack of research to support effective web, text, and IVR interventions is especially problematic because there is little guidance to define minimal, evidence-based service, which is necessary if these new technologies are to be included in the quit rate.

A final challenge is that technologies are constantly emerging, as are the tobacco users' use of those technologies. It appears that programs on mobile devices may be more popular and more used than programs available through desktop or laptop computers. Smartphone apps are likely to proliferate, with a wide range in content and quality. Given the pace of technological innovation, it is important that any decisions about how quit rates are calculated be flexible over time to respond to technology and use pattern changes as they occur.

The main issue that new technologies present to the calculation of quit rates is which interventions should be included. How many quit rates should be calculated, and in what combination, to reflect quitline progress and effectiveness? For example, how, if at all, should self-directed website intervention participants be included in quitline quit rates? A related consideration is the burden of data collection on quitlines that such recommendations would produce. Section 3 will weigh all of the considerations above and make recommendations for who should be included in the standard NAQC quit rates. In addition, Section 7 describes our suggestion that each quitline calculate supplemental quit rates of different service combinations that best meet individual information needs.

Sub-section 2.3: ENDS

ENDS are rising in popularity and much is still unknown about these products. Tobacco users are increasingly using these devices in addition to or instead of other tobacco products.[25,26] Use of ENDS has the potential to impact (for better or for worse) tobacco users' ability to quit.[27,28,29,30] Awareness and ever use of ENDS increased among U.S. adults from 2010 to 2011, and use was significantly higher among current smokers compared with both former and never-smokers.[26]A recent survey of U.S. quitline callers found that nearly one third (30.9%) reported using or trying ENDS.[25] The rapid rise in use, particularly among tobacco users trying to quit, requires that quitlines and researchers consider how to account for ENDS use when calculating quit rates.

While increased use of ENDS is undisputed, almost every other area regarding ENDS is evolving. First, nearly all quitline service providers in the U.S. have protocols in place to address ENDS use, and as of July 2014 no service provider recommends ENDS as a cessation aid.[12] However, it is important to note that not all quitline

service providers provide treatment to help callers quit ENDS use.[12] This may be in response to anecdotal evidence that few callers have proactively expressed an interest in quitting ENDS[12], and because there are no evidence-based treatments identified for doing so to date. Instead, anecdotal evidence suggests that some quitlines are applying cessation protocols designed for conventional tobacco products to help callers quit ENDS.

Second, ENDS have been marketed both as a cessation aid and a safe (or safer) alternative to combustible tobacco. However, evidence of the efficacy of ENDS as a cessation aid is conflicting.[31,32] Similarly, studies about the safety of ENDS is decidedly mixed, and the products have not been in use long enough to study their long-term health risks or benefits, especially given that they are currently unregulated.[33,34,35] Finally, the regulation of ENDS is still evolving. Canadian authorities have determined that ENDS will be regulated as a drug; while the U.S. Federal Courts have ruled ENDS to be tobacco products and the U.S. Food and Drug Administration (FDA) has issued a proposed rule (currently pending), with no regulations specified at the time this paper was written.

Finally, the measurement of ENDS use is evolving. NAQC has developed required and optional measures of ENDS use to be incorporated into the MDS for the purpose of facilitating information gathering on this important topic. However, no items have been demonstrated to collect valid and reliable results. Not only do the nicotine levels within ENDS products vary greatly[36], but new products and variations continue to come to market. Also, puff strength and patterns of use of ENDS evolve as consumers learn more about the products and as products change. Some currently used survey and intake measures over-estimate use, particularly by failing to differentiate experimental from established use.[37] Other survey items produce underestimates, often due to the wide variety in products and names used to describe them.

In summary, the landscape of ENDS is rapidly evolving, creating a dynamic environment in which products are constantly emerging and research is struggling to catch up to inform decision-making. The only constant factor in the landscape of ENDS to date is their increased use, especially among tobacco users, suggesting the importance of better understanding quit rates for ENDS users. Section 4.3 will weigh these considerations and challenges, as well as recommendations made by the MDS Workgroup on ENDS, and provide recommendations for addressing ENDS in calculating quit rates.

SECTION 3: WHO IS INCLUDED IN THE STANDARD NAQC QUIT RATES

In tobacco cessation, an ideal quit rate is the proportion of tobacco users that participated in an intervention that were able to quit using tobacco, as calculated out of all tobacco users that participated in that intervention. Based on this definition, it is important to define exactly who is included in the standard NAQC quit rates. Of the many types of tobacco cessation interventions, which intervention's participants should be included in the quit rate? What level of use of an intervention is sufficient for participants to be included? What other specific characteristics should participants possess to be included in the quit rate? This section provides recommendations and suggestions to clarify these issues.

Sub-section 3.1: Services to Include in the Standard NAQC Quit Rates

Many quitlines use web and text services in addition to telephone counseling and medications.[13] Emerging technologies for cessation include IVR and smartphone apps. Quitline funders at state and provincial

governmental agencies frequently coordinate different kinds of interventions to provide a varied program of cost-conscious cessation alternatives to tobacco users in their region.

As a membership body, NAQC has been moving in the direction of embracing new technologies that may facilitate cessation in order to reach more and different tobacco users, and to provide potentially more cost-effective services for cessation in an era of limited resources.[11] To remain relevant in a landscape of changing technologies and resources, the standard NAQC quit rates should acknowledge technologies beyond telephone counseling. It is certain that technologies and tobacco users' patterns of service use will continue to evolve rapidly, so the standard NAQC quit rates should be flexible to these changes over time.

Section 2.2 discussed some challenges that emerging technologies for cessation bring to calculating quit rates. First, interventions are not standardized, so, for example, web technologies from one state or province to another can vary widely in the features they offer and the extent to which they are tailored to each participant. Second, many quitlines allow participants to use more than one technology at once, so isolating the effectiveness of any one technology is very difficult. Finally, while text interventions are often considered a promising intervention[38] and there is some evidence of the effectiveness of web[20] and IVR[24] interventions, the literature is not currently strong enough to clearly support any specific functions or content[21,23] that could be used to define minimal, evidence-based treatment, which is necessary for calculating a quit rate (see the subsection 3.2 immediately following for more details on this measure). While the evidence base for emerging technologies is growing, the evidence base for telephone counseling[3] and NRT and other FDA-approved tobacco cessation medications[39] is strong and specific enough to support definitions for minimal, evidence-based treatment. Additionally, vouchers have been demonstrated to be effective in increasing access to NRT.[40,41]

It is important to remember that the purpose of the standard NAQC quit rates is not to understand if telephone quitlines are effective (like a clinical trial would), but instead it is to understand quitlines' effectiveness under certain conditions, such as varying levels of implementation or for different populations. Quit rates may also help quitline funders judge the quality of their quitlines against a set standard, and to compare them to other states or provinces. It is equally important to acknowledge that creating a quit rate measurement for every type of intervention and permutation of combinations of services used can be extremely resource intensive.

With these considerations in mind, we recommend that the standard NAQC quit rates include participants enrolled in telephone counseling and/or who were sent FDA-approved cessation medication(s) from any source (e.g., telephone, web, text, IVR, email, smartphone app or game, etc.). Participants who receive vouchers for medications should be included in the standard NAQC quit rates, along with those who are sent medications directly. A quit rate based on this criterion reflects the strongest evidence-based standard and is similar to the quit rates recommended by the 2009 NAQC Issue Paper.

We understand that the standard NAQC quit rates likely do not meet all the evaluation needs of individual quitlines, especially of quitlines that enroll a large number of participants in non-telephone technology cessation interventions. **We suggest that each quitline consider calculating supplemental quit rates for these other interventions according to their own information needs.** These supplemental quit rates would be for internal quality control and evaluation purposes, and would not be reported to NAQC. Please see section 7.2 for additional discussion of factors to consider in calculating supplemental quit rates.

Recommendation

The standard NAQC quit rates include participants enrolled in telephone counseling and/or who were sent FDA-approved tobacco cessation medication(s) or medication vouchers from any source (telephone, web, text, IVR, email, smartphone cessation apps or games, etc.).

Sub-section 3.2: Who to Include in the Quit Rate: Group Characteristics

This section describes other inclusion and exclusion criteria for the standard NAQC quit rates. It is very similar to the recommendations made about who to include in the quit rate denominator in the 2009 NAQC Issue Paper. A review of the literature found no substantive evidence to suggest changes to the exclusions recommended in 2009. Table **2** and Figure 1 below describe the various subgroups calling a quitline, starting with the most inclusive group then excluding groups one by one. These groups include:

1. All those requesting a quitline or medication service. In addition to current and former tobacco users, this group includes proxies, wrong numbers, and pranks;
2. All conventional tobacco users;
3. All *recent* conventional tobacco users;
4. All recent conventional tobacco users *seeking treatment;*
5. All recent conventional tobacco users seeking treatment *who register for services;*
6. All recent conventional tobacco users seeking treatment who register for services and *consent to the evaluation; and,*
7. All recent conventional tobacco users seeking treatment who register for services and consent to the evaluation and *receive at least minimal, evidence-based treatment.*

Table 2. Potential Groups to Include and Exclude and the Pros and Cons of Excluding Them

Group	Those Excluded	Pros	Cons
All callers requesting quitline/ medication service	None	Simple to count	Includes non-tobacco users who would artificially lower the quit rate. Non-registered callers often do not have information critical for the evaluation.
All conventional tobacco users	All non-tobacco users including those calling to assist friends or family, medical providers, the public seeking information, or exclusive ENDS users at intake	The group reflects only those who use tobacco, the target audience of quitline services	Includes those not seeking services, which would artificially lower the quit rate. Non-registered callers often do not have information critical for the evaluation. Excludes ENDS-only users at intake, so a quit rate cannot be calculated for this excluded group.
All recent	All non-tobacco users	Research suggests that	If a program specifically

Group	Those Excluded	Pros	Cons
conventional tobacco users	Tobacco users who are quit from conventional tobacco for more than 30 days prior to intake or registration	including those who were quit for more than 30 days would bias quit rates upward, so it is best to exclude this group	seeks to serve those already quit for more than 30 days at intake or registration, this group should be included in the denominator. Non-registered callers often do not have information critical for the evaluation.
All recent conventional tobacco users seeking treatment	All non-tobacco users Tobacco users who are: 1) quit from conventional tobacco for more than 30 days prior to intake or registration, 2) are not ready to quit	This group reflects a primary target audience for most quitlines: tobacco users ready to quit.	If a program specifically seeks to serve those not ready to quit, this group should be included in the denominator. Non-registered callers often do not have information critical for the evaluation.
All recent conventional tobacco users seeking treatment who register for services	All non-tobacco users Tobacco users who are: 1) quit from conventional tobacco for more than 30 days prior to intake or registration, 2) are not ready to quit, 3) failed to register / complete intake	This group reflects the primary target audience for most quitlines. Excluding those without intake is important because intake is necessary to provide treatment. Without intake, participants may not receive intervention, and may not have information critical for the evaluation.	Some callers may not complete intake due to technological or other problems. A quitline may have intended to serve those without intake, even if it may be unable to do so.
All recent conventional tobacco users seeking treatment who register for services and consent to the evaluation	All non-tobacco users Tobacco users who are: 1) quit from conventional tobacco for more than 30 days prior to intake or registration, 2) are not ready to quit, 3) failed to register / complete intake, 4) declined to participate in the evaluation	This group reflects those who the quitline primarily intends to target and who agree to follow-up. This group represents the "intention to treat" group and closely approximates the group that a clinical trial model would define as the "treatment" group. Those agreeing to follow-up will be more amenable to follow-up, likely resulting in a higher quit rate. Consent is required in clinical trials.	Non-consenters include participants quitlines would like to follow-up; however, they have declined to participate. This is not a clinical trial but a real-world evaluation group; there has been no randomization to be selected for this treatment; callers have self-selected themselves for the intervention. This group may or may not have actually received

Group	Those Excluded	Pros	Cons
			treatment.
All recent conventional tobacco users seeking treatment who register for services and consent to the evaluation and receive at least minimal, evidence-based treatment	All non-tobacco users Tobacco users who are: 1) quit from conventional tobacco for more than 30 days prior to intake or registration, 2) are not interested in quitting, 3) failed to register / complete intake, 4) declined to participate in the evaluation, 5) did not receive minimal treatment (defined below)	This group received some portion of the intended treatment, which allows a more credible assessment of the association between their service use and the quit rate	Given a proven, strong dose-response relationship, this group will over-estimate the quit rate. It also fails to meet criteria for the "intention to treat" model because the quitline intended to serve more callers than are included in this group.

Defining "minimal evidence-based treatment" is an important and final step to understanding who to include in the standard NAQC quit rates. This inclusion criterion was added in order to ensure that the quit rate produced reflects some amount of intervention that is known to impact quit rates. Quitlines may experience a separate problem of failure to deliver counseling or treatment services to tobacco users who register for service. We view this as a quitline quality issue that should be addressed separately.

We considered several factors to define minimal, evidence-based treatment for telephone counseling. To start, literature in tobacco control has demonstrated a dose-response relationship, with more counseling resulting in higher quit rates.[42] Further, numerous studies where a single, reactive call is a comparison arm provide evidence that even a very small amount of quitline telephone counseling is effective in helping tobacco users quit.[11] Finally, it is sometimes difficult for quitlines to obtain exact data about the number of exact counseling minutes, so defining minimal, evidence-based service as a specific amount of minutes of counseling (e.g., 10 minutes) presents practical challenges. Based on these considerations, we recommend that any amount of counseling beyond intake and registration be set as the level of minimal, evidence-based service.

The standard NAQC quit rates may also include having received NRT or another FDA-approved medication. Numerous studies suggest that providing medication via quitlines and by website, even absent of counseling, increases quit rates.[43] Therefore, we recommend defining minimal, evidence-based treatment for medications as having sent medication to a participant. Additionally, evidence suggests providing vouchers for medications increases tobacco users' access to them, so providing vouchers is also considered an evidence-based strategy.[40,41]

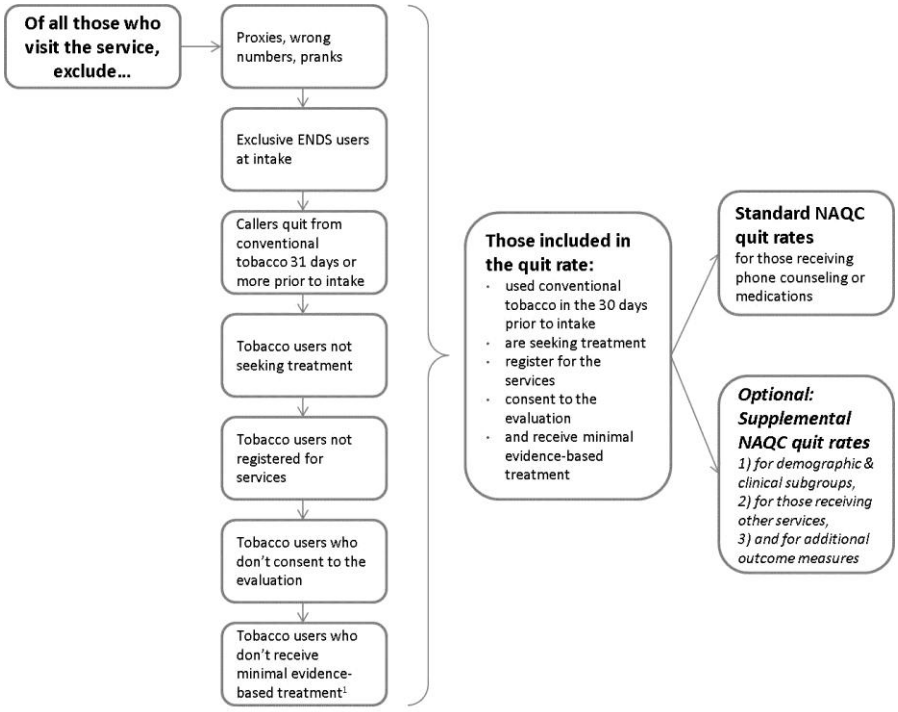
Finally, the concept of minimal, evidence-based treatment is relevant to considering whether or not ENDS should be considered in calculating the standard NAQC quit rates. At this time, there is no evidence-based

treatment for ENDS use. This finding is considered more fully, along with other evidence on ENDS, in section 4.3.

Recommendations

- *Include all conventional tobacco users who register for services, consent to follow-up, receive minimal, evidence-based treatment, and have not been quit from conventional tobacco at intake or registration for more than 30 consecutive days.*
- *Define minimal, evidence-based treatment as receiving any amount of telephone counseling or being sent medication (including vouchers).*

Figure 1. Potential Groups to Include in the Quit Rate: Excluded Subsets



[1] Minimal evidence-based treatment is having received any amount of phone counseling and/or having been sent any FDA-approved medications or medication vouchers from any source (web, text, IVR, smartphone app, etc.).

SECTION 4: HOW DOES NAQC DEFINE ABSTINENCE?

Abstinence may be defined by considering biochemical verification, as well as specifying when data is collected and the duration of abstinence. A literature review was conducted to assess relevant research published since the 2009 NAQC Issue Paper, and little evidence was found to suggest changes to the 2009 recommendations. New ideas have been developed, however, in how to operationalize definitions of abstinence in survey questions. Additionally, ENDS have emerged as a major issue that impacts how quit rates are defined. Therefore, this section revisits 2009 recommendations regarding timing of follow-up, duration of abstinence, and biochemical verification. New survey items are considered and we recommend how to account for ENDS use in quit rates based on our best knowledge to date.

Sub-section 4.1: Timing of Follow-up

Specifying the timing of follow-up is an integral part of defining abstinence and requires two decisions. The first is the reference point, or the time from which follow-up begins; second is the length of follow-up, or the time from the reference point to follow-up. Each is discussed below.

Reference Point

The ideal reference point for a quit rate is the true quit date for each participant. Unfortunately, using this strategy is difficult in practice. Alternatively, the advantage of starting to measure abstinence at the date of enrollment is that this information is usually easily available for all enrollees. One disadvantage of defining abstinence from the date of enrollment is that the measure includes the time when the enrollee was supported by the quitline and may not yet have made a quit attempt. Adjusting the length of follow-up can help to mitigate this disadvantage.

Length of Follow-up

Tobacco cessation researchers frequently measure abstinence at both six- or 12-month follow-up. In its MDS, NAQC recommends follow-up at seven months after enrollment, assuming a one-month treatment and follow-up six months post-treatment. The disadvantage of this approach is that brief, one-call programs are followed up later than is desirable. Additionally, newer technologies, such as text messaging programs, may engage participants for longer or shorter periods than the assumed one-month treatment period. Despite these considerations, NAQC's recommended seven-month follow-up corresponds closely with a six-month follow-up, which is commonly reported. The seven-month follow-up also allows an initial one month grace period to initiate both treatment and a quit attempt.

Recommendation

*Conduct follow-up **seven months** after quitline **enrollment**.*

Sub-section 4.2: Duration of Abstinence

The duration of abstinence needed to be counted as a treatment "success" has received considerable attention in the tobacco research community.[44,45,46] While individual researchers and academic work groups vary in the duration of abstinence they measure, point prevalence measures have some important advantages as compared to continuous and prolonged measures. Point prevalence abstinence measures describe the proportion of callers who are abstinent for a relatively shorter period of time immediately prior and through the follow-up evaluation as compared to continuous and prolonged measures.[b]

The first advantage of a shorter-term abstinence measure like point prevalence is a high degree of correlation between point prevalence and prolonged abstinence measures. For example, Velicer and Prochaska (2004) found a high correlation between 30-day point prevalence and six-month prolonged abstinence (r=0.85).[47] A second advantage of using point prevalence abstinence is consistency with outcome measures used to conduct the meta-analyses for the Public Health Service (PHS) Clinical Practice Guideline, Treating Tobacco Use and Dependence: 2008 Update.[2] The Guideline authors indicated point prevalence was preferred to continuous abstinence for several reasons. These included the frequency of studies reporting point prevalence abstinence (vs. more prolonged measures), the potential of continuous abstinence measures to underestimate the percentage of individuals who eventually obtain abstinence (i.e., recycle) and that most relapse begins soon after the initial quit attempt and these individuals are most likely to report continued tobacco use at a later follow-up. Finally, asking about point prevalence via survey may be less cognitively difficult as opposed to continuous or prolonged abstinence.

[b] Continuous abstinence is measured from the beginning of the intervention (or quit date) through to the final follow-up evaluation. Prolonged abstinence is similar to continuous abstinence with the exception that a grace period is allowed to establish initial abstinence.[45]

The length of time required to be abstinent for point prevalence measures varies, but the most common periods are 24 hours, seven days and 30 days. For the standard NAQC quit rates, we recommend a 30-day point prevalence abstinence rate over a seven-day point prevalence rate because it is slightly more conservative and excludes very occasional smokers. In fact, in a systematic review by Hughes, Carpenter & Naud in 2010, which compared point prevalence (PP) and prolonged abstinence (PA) measures, point prevalence measures beyond seven days were excluded to, "prevent blurring of the PA/PP distinction, that is, an exceptionally long period of PP could be redefined as PA" (p. 757).[48] In that sense, using 30-day point prevalence abstinence provides a nice middle ground between the more conservative continuous or prolonged abstinence measures and the more liberal seven-day point prevalence measure.

Recommendation

*Measure and report **30-day point prevalence** abstinence.*

Sub-section 4.3: Definition of Abstinence

The standard quit rate calculations recommended in the 2009 NAQC Issue Paper were based on a definition of conventional tobacco products that included any use of the following: cigarettes, cigars, pipes, or smokeless tobacco (please see section 4.5 below for the exact item wording). The definition did not address the use of ENDS, which had recently come onto the U.S. and Canadian markets and were relatively unknown at that time. In the years since, the use of electronic cigarettes has increased rapidly. Given the widespread adoption of ENDS by current and former tobacco users[26], and particularly by quitline callers[25], it is important that we consider how to account for ENDS use when calculating quit rates.

Considering a Definition of Abstinence From Conventional Tobacco

It is important to keep in mind that the quit rate is intended to be a measure of the effectiveness of quitline services. At this time, not all quitlines provide specific treatment for ENDS using either existing or new protocols. According to NAQC's recent summary of quitline practices[12], most quitlines provide counseling to help participants stop using conventional tobacco products, not to help them stop ENDS use. Additionally, as described in Section 3.1, the quit rate should only include participants who received a *tobacco cessation treatment with a strong evidence base***,** namely telephone counseling and/or cessation medications as described in the PHS Guideline[2] and the 2006 Cochrane Review, *Telephone counseling for smoking cessation.*[49] Although it may be reasonable to expect that protocols for cessation of conventional tobacco products will be effective for cessation of ENDS, there are no evidence-based treatments for quitting ENDS at this time.

This combined evidence suggests that NAQC continue to recommend a standard quit rate measure based on abstinence from conventional tobacco products: cigarettes, cigars, pipes, or other smoked or smokeless tobacco. This measure would be used to assess the performance of quitlines and allows analysis of trends over time, as this measure is the same as the one recommended in the 2009 NAQC Issue Paper on calculating quit rates.

Considering a Definition of Abstinence From Conventional Tobacco Plus ENDS

It is important to consider that NAQC is both a science- and practitioner-based member organization. During the deliberations of the MDS workgroup on ENDS, NAQC learned that some state quitlines are changing their practice to match the evolution of ENDS products by providing standard cessation protocols designed for conventional tobacco use to ENDS users. Additionally, NAQC learned that state agencies and service providers are very interested in understanding the role of ENDS in their tobacco using populations. Moreover, NAQC is

committed to advancing knowledge in the field of tobacco control and quitline treatment, and is in a unique position to foster discussion and learning among member quitlines on the emerging topic of ENDS.

These considerations suggest that NAQC recommend a second standard quit rate calculation that considers abstinence from both tobacco products plus ENDS. This quit rate would be used for learning and exploratory purposes, to help advance the field and knowledge about ENDS.

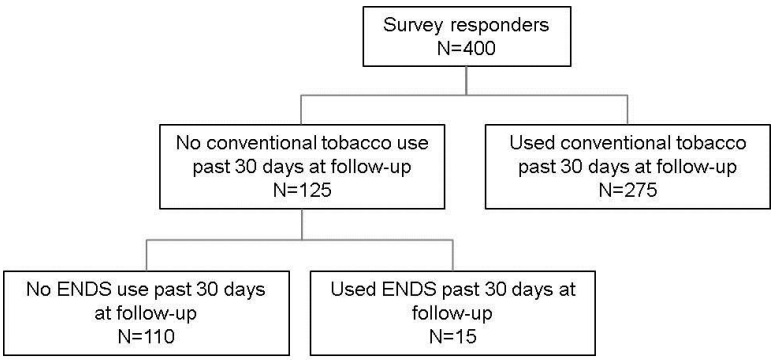
Considering a Dual Approach to Defining Abstinence

When considering a definition of abstinence based on conventional tobacco use versus tobacco use plus ENDS, it is helpful to reflect on the purpose and context of the definitions and the resulting quit rates. The purpose of a quit rate based on conventional tobacco use is to assess the performance of quitlines and trends over time. NAQC has a long history of supporting high quality performance assessment and continues to value this activity. ENDS use is, by contrast, an emerging issue. The purpose of a quit rate that considers tobacco plus ENDS is for learning and exploration, and to facilitate discussion among quitlines. Both NAQC and the authors of this paper assume that ENDS are a game-changer in the field of tobacco control, and are a force that NAQC and the field must learn about, grapple with, and address in order to ensure the continued success of quitlines.

In weighing these factors, we believe that the need to assess quitline performance is as important as learning about ENDS. Therefore, we recommend a dual approach to defining abstinence, and by extension, to calculating quit rates. We recommend calculating two standard NAQC quit rates: one based on conventional tobacco only, and one based on tobacco plus ENDS use, where ENDS use is defined as "an e-cigarette or other electronic 'vaping' product," per the NAQC Workgroup on ENDS.

Please review the example shown in **Error! Reference source not found.**2 below to further clarify the two quit rates. The standard NAQC quit rate for conventional tobacco use is 31.3%: those that quit conventional tobacco (n=125) divided by all survey responders (n=400). The standard NAQC quit rate for tobacco use plus ENDS is 27.5%: those that quit conventional tobacco and are not using ENDS at follow-up (n=110) divided by all survey responders (n=400).

Figure 2. Example Quit Status and ENDS Status for Calculating Conventional and Plus ENDS Quit Rates



It is important to acknowledge the rapidly evolving landscape of ENDS. Therefore, any recommendations in this area reflect the authors' current knowledge based on the science available. Moreover, the recommendations should be considered time limited; we expect that the NAQC Advisory Council may need to revisit the topic again in the next three to five years.

Recommendations

- *Calculate a quit rate for conventional tobacco use that defines abstinence based on the non-use of all of the following conventional tobacco products: cigarettes, cigars, pipes, and other smoked or smokeless tobacco. Use of electronic cigarettes should not be considered in the standard NAQC quit rate for conventional tobacco.*
- *Calculate a quit rate for tobacco plus ENDS use that defines abstinence based on the non-use of conventional tobacco as defined above, and the non-use of ENDS, defined as "an e-cigarette or other 'vaping' product" by the NAQC Workgroup on ENDS.*
- *The NAQC Advisory Council considers revisiting recommendations regarding conventional tobacco and ENDS quit rates in three to five years in light of changes in ENDS products and regulation, and recent research on ENDS and its measurement.*

Sub-section 4.4: Intake and Follow-up Questions

In order for abstinence rate calculations to be comparable between quitlines, the specific wording for survey items used to gather data for abstinence rates must be consistent. Further, on both the intake and follow-up surveys, items must have the same question phrasing for the stem (the question) and the response options available to the respondent. One of the most successful efforts to standardize question wording is NAQC's MDS. The MDS is a set of standardized questions to be collected at intake and follow-up that allow for data across individual quitlines to be compared and aggregated. The MDS is an ideal source of items for calculating quit rates because it is tailored for quitline use, it has been in the process of being tested and used for ten years, and many quitlines already use the MDS items.

This section specifically reviews MDS items critical to calculating quit rates and makes recommendations for precise question wording for the one outcome measure proposed in this paper, 30-day point prevalence.

Intake

Section 3.2 recommended that enrollees who have been quit from all tobacco for more than 30 days at enrollment should be excluded from quit rate calculations. MDS item SI 5, listed below in Table 3, is a required item that determines whether or not the enrollee used any tobacco in the last 30 days at the time of enrollment. Those who indicate "no" to all five types of tobacco listed in SI 5a-e should be considered to be abstinent at the time of enrollment and thus be excluded from both the numerator and denominator of quit rate calculations.

Table 3. MDS Items at Intake Related to the 30-day Abstinence Rate Calculation

SI 5	What types of tobacco have you used in the past 30 days?
SI 5a	*Cigarettes* ○ Yes ○ No ○ Don't know ○ Refused ○ Not asked

SI 5b	*Cigars, cigarillos, or little cigars* ○ Yes ○ No ○ Don't know ○ Refused ○ Not asked
SI 5c	*Pipe [Note: this is a conventional pipe, not a water pipe – see "water pipe" or "hookah" under "5e other" below.]* ○ Yes ○ No ○ Don't know ○ Refused ○ Not asked
SI 5d	*Chewing tobacco, snuff, or dip* ○ Yes ○ No ○ Don't know ○ Refused ○ Not asked
SI 5e	*Other* ○ Yes ○ No ○ Don't know ○ Refused ○ Not asked

Full information on the MDS can be accessed here: http://www.naquitline.org/?page=technical#final%20mds

Follow-up

At the time of the seven-month follow-up survey, there are two MDS items that we recommend be used to determine whether someone has achieved 30-day abstinence from conventional tobacco. The first is SF 2, which is listed verbatim below in Table 4. We also recommend that the item sequence of SF 4 and SF 4a-e be asked to confirm the response to SF 2. For example, if a respondent indicates that they did use tobacco per SF 2 (making them non-abstinent) they should also select at least one type of tobacco per SF 4a-e. This is a useful check because one possible explanation for a discrepancy between these two items is that some participants may be factoring in their use of ENDS when answering SF 2. As indicated previously in Section 4.3, ENDS use should only be factored in to the standard NAQC tobacco *plus* ENDS quit rate.

For a follow-up survey conducted over the telephone, an interviewer who encounters a discrepancy between SF 2 and SF 4 should follow-up to confirm which response is accurate and correct the discrepancy. This is more difficult to do via other follow-up methods, such as web or mail. If the discrepancy cannot be remedied, we recommend that abstinence be calculated based on the response to SF 4a-e ("no" to all types), as it is the more specific of the two items.

Table 4. MDS items at Follow-up Related to the 30-day Abstinence Rate Calculation

SF 2	Have you smoked any cigarettes or used other tobacco, even a puff or pinch, in the last 30 days? ○ Yes ○ No ***(Skip to SF 9)*** ○ Don't know ○ Refused ○ Not asked
SF 4	What types of tobacco have you used in the past 30 days?

SF 4a	*Cigarettes* ○ Yes ○ No ○ Don't know ○ Refused ○ Not asked
SF 4b	*Cigars, cigarillos, or little cigars* ○ Yes ○ No ○ Don't know ○ Refused ○ Not asked
SF 4c	*Pipe [Note: this is a conventional pipe, not a water pipe – see "water pipe" or "hookah" under 4e "other" below.]* ○ Yes ○ No ○ Don't know ○ Refused ○ Not asked
SF 4d	*Chewing tobacco, snuff, or dip* ○ Yes ○ No ○ Don't know ○ Refused ○ Not asked
SF 4e	*Other* ○ Yes (Continue to SF 4e-1) ○ No (Skip to SF 5a-e as indicated by "yes" to SF 4a-e above) ○ Don't know ○ Refused ○ Not asked
SF 9	Have you used an e-cigarette or other electronic "vaping" product in the past 30 days? ○ Yes ○ No ○ Don't know ○ Refused ○ Not asked

Recommendations

- *Use MDS intake items SI 5a-e to identify enrollees that were quit from conventional tobacco for more than 30 days at the time of enrollment. These participants should be excluded from the quit rate calculation.*
- *Use MDS follow-up item SF 2 and SF 4a-e to measure 30-day point prevalence for conventional tobacco, the proposed outcome measure in this paper. A response of "no" to SF 2 indicates 30-day abstinence.*
  - ***If there is a discrepancy between SF 2 and SF 4a-e ("yes" to SF 2 and "no" to SF 4a-e) that is not corrected during the survey process, calculate abstinence based on the response to SF 4.***
- *Assess ENDS use in the last 30 days at follow-up per recommendations made by the NAQC Workgroup on ENDS item SF 9.*

Sub-section 4.5: Biochemical Verification

Biochemical validation is one method for assessing smoking status and is considered to be the most objective because it is not subject to false reporting that may occur in participant self-report. However, biochemical

validation is costly (especially when used with large populations); more invasive than telephone, web and mail follow-up surveys; and according to the literature, not always necessary. According to a Society for Research on Nicotine and Tobacco (SRNT) subcommittee charged with making recommendations regarding the use of biomarkers, "in large-population, low-intensity trials, biochemical verification is neither feasible nor necessary."[50] The report suggests that the amount of quit rate inflation due to self-report measures is small, a finding that is supported by reviews of the literature[45] and other studies.[51] However, it is important to note there are some special populations for which misreporting may be higher,[51] such as adolescents who may misreport in order to avoid admitting to illegal activity, or because of elevated pressure to quit. In addition, pregnant smokers and medical patients may feel an elevated need to misreport since these special populations are likely to feel an increased pressure/expectancy to quit.

Recommendations

- *Do not conduct biochemical validation.*
- *Remain aware that self-reported quit rates are likely to include some small amount of inflation, and that this inflation is likely to be higher if the special populations you measured are facing an elevated expectancy to quit or feel a greater need to hide smoking behaviors.*

SECTION 5: CONDUCTING FOLLOW-UP SURVEYS

In Section 4.1 above, we recommend collecting abstinence at seven months post-enrollment. This section discusses some key components of conducting a high-quality follow-up survey. Topics covered include obtaining consent, sampling, the optimal number of completed surveys, response rates and addressing other non-response bias, frequency of follow-up, proven telephone survey practices, using other survey modes, data quality issues, and who should conduct a quitline's evaluation. This section addresses the components of a follow-up survey that should be prioritized for rigor (i.e., response rates and number of completed surveys) while providing solutions for achieving these priorities (e.g., frequency of follow-up and proven survey practices).

Sub-section 5.1: Consent

Determining procedures for gaining caller consent to participate in an evaluation is an integral part of conducting quitline studies. Participation in a program evaluation should be a voluntary activity. As stated in the Program Evaluation Standards, evaluations should be designed and conducted to protect human and legal rights and maintain the dignity of participants and other stakeholders.[52] This means that evaluations must provide protection for human subjects; such protections begin with an informed consent process. The type of consent process used may be further impacted by the nature of the quitline study; some quitline studies are considered primarily evaluation while others are primarily research. Evaluation often allows for a simpler participant consent process than research studies, and quitline evaluations will often be determined to be exempt from review by an institutional review board. Federal policy regarding Human Subjects Protection (known as the Common Rule) defines research and evaluation and describes the types of studies that must be reviewed.[c] Even

[c] For more information on complying with human subjects protection guidelines, see the U.S. Department of Health and Human Services website: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html .

if quitline evaluations are often judged to be exempt, we feel it is prudent to follow the Common Rule and we recommend obtaining callers' consent to engage in the evaluation.

It is important to consider the time at which consent is obtained because consent timing contributes to the representativeness of consenting participants and survey results. Research indicates non-respondents to health and lifestyle questionnaires are more likely to be tobacco users.[53,54,55] Therefore, seeking consent for evaluation at the time of the six or seven-month follow-up survey call may result in a disproportionate number of callers refusing consent because they have not quit tobacco. We recommend seeking consent at the time of intake, before the result of the quit attempt is known, because this will produce a more representative sample of survey contacts.

Finally, most quitline follow-up studies will qualify as a very low-risk or no-risk activity for quitline callers. For this reason the consent process may be simple and straightforward. Consent rates for U.S. quitlines averaged 94% (range: 69% to 100%) in fiscal year 2013.[13] We recommend that quitlines strive to achieve a minimum of 85% of callers agreeing to participate in a follow-up study.

Recommendations

- *Obtain consent to participate in the follow-up survey; solicit consent early on such as at the close of intake or registration.*
- *Strive to achieve a consent rate of 85% or higher.*
- *Consider consulting a human subjects research board or institutional review board regarding consent procedures as appropriate.*

Sub-section 5.2: Sampling

Exhaustive and random sampling represent two approaches for selecting callers to participate in the follow-up evaluation. **Exhaustive sampling** attempts to follow-up with all callers who register and are eligible for the study. This strategy will produce the largest possible sample, although some proportion will still fail to complete the survey when it is administered. One important disadvantage of exhaustive sampling is that it can be expensive, possibly exhausting resources that could be used to achieve a higher response rate among a smaller group of participants. This results in less representative results, which can be an inefficient use of resources.

Random sampling attempts to follow-up with a random selection of callers who register and are eligible for the study. Just as with exhaustive sampling, a large enough random sample will be representative of the total population of callers prior to follow-up. Both methods will be subject to nonresponse bias as not all participants sampled will respond to the survey. The advantage of random sampling for quitlines that serve a large number of tobacco users is that it reduces evaluation costs by reducing the number of program participants that must be followed up. Cost savings may then be applied to increase survey response rates, which increases the representativeness of the results. If a quitline elects to randomly sample, a strategy must be developed to ensure that a representative sample is selected. One way to achieve a representative random sample is to assign each eligible participant a random number and rank them. The sample would be generated by selecting every fifth or tenth participant, for example.

Cohort and rolling sampling are two approaches to selecting a time period for the follow-up evaluation. In **cohort or time-limited sampling**, callers who register during a limited time period are followed up. While this

type of sampling can produce sufficient numbers of completed surveys to calculate a quit rate in a short period of time, this method has the potential to introduce bias depending on seasonal and environmental factors. Quitline call volumes tend to be higher in certain seasons, such as after New Year's and after certain environmental events like the federal tax increase in 2009.[56] In a **rolling sample,** a random sample of callers is selected on an ongoing basis, such as weekly or monthly. This method eliminates the influence of seasonal variation and environmental factors on caller characteristics. It allows quitlines to examine the impact of protocol changes or environmental events, and keeps costs down. The main limitation of this method is that it may yield a small number of completed follow-up surveys per sampling period (each week or month), which may result in delay before a quit rate can be produced. However, once a rolling sample and follow-up process is underway cumulative quit rates can be reported periodically, such as quarterly.

For the purposes of the standard NAQC quit rates, we recommend sampling for follow-up on a rolling basis with a random selection of participants that received quitline counseling and/or medication. Quitlines that serve a small number of tobacco users may need to exhaustively sample in order to achieve the desired number of completed surveys. If a cohort or time-limited sampling strategy is used instead of a rolling sample, we recommend being mindful of the enrollment window. For example, to achieve results that are representative of the overall quitline, try to select an enrollment time period for the study that does not overlap with a program change or large media campaign.

Please note that survey participants' responses may need to be weighted prior to calculating the standard NAQC quit rates if different sampling strategies are used for different groups enrolled during the same time period. Table 5 provides an example of weighted survey data. In this scenario, imagine a quitline was interested in exhaustively sampling participants who only received NRT and no phone counseling for an internal evaluation, but only randomly sampling a portion of the quitline participants to save costs. In order to achieve a quit rate that combines these two groups, the completed surveys will need to be weighted back to the enrollment level. See in Table 5 below that 25% of enrollments were NRT only and 75% were quitline participants. This differs from the proportion of survey responders, which is 37% for NRT only and 63% for quitline participants. Weighting is important because quit rates differ for the two groups: 30% for quitline participants compared to 23% for NRT only. Therefore, NRT only participants (with their lower quit rate) would be over-represented in the unweighted results. A weighted quit rate will ensure that the final, combined quit rate reflects actual service use patterns and their respective quit rates.

Table 5. Example of Weighted Quit Rate

Program	Number of enrollments in study period	Number sampled	Number of completed surveys	Weight	Number of quitters (unweighted)	Unweighted quit rate	Weighted number of quitters	Weighted quit rate
NRT only participants	500 (25%)	500	300 (37.5%)	0.666 (25%/37.5%)	70	23.3% (70/300)	46.6 (70*.666)	NA
Quitline participants	1,500 (75%)	1,000	500 (62.5%)	1.200 (75%/62.5%)	150	30.0% (150/500)	180.0 (150*1.2)	NA
Total	2,000 (100%)	1,500	800 (100%)	1.000	220	**27.5%** (220/800)	226.6 (180+46.6)	**28.3%** (226.6/800)

Recommendations

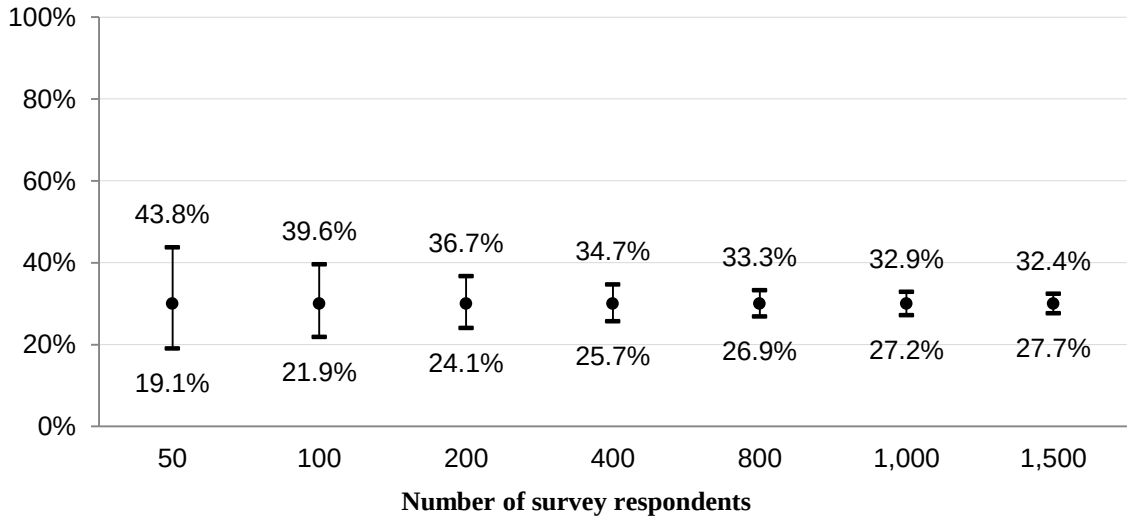
- *Ideally, conduct follow-up on an ongoing rolling basis, with a random sample of registered callers.*
- *If a rolling follow-up is not feasible, use multiple cohorts or time-limited sampling as a viable second choice.*
- *If weighting is necessary, use the comments section of the NAQC Annual Survey of Quitlines to communicate information pertinent to the reported quit rate.*

Sub-section 5.3: Power and Choosing a Sample Size

A common question in sampling is how many people to sample – in follow-up studies, the more completed surveys are obtained, the more accurate the results will be. Confidence intervals are a statistical methodology that can be used to help determine how many completed surveys are needed, given a desired level of precision. A confidence interval (noted using CI) illustrates the likely range of a "true quit rate" given survey error. A more detailed explanation of how to calculate and use confidence intervals when reporting will be discussed in Section 6.3.

Figure below illustrates how the number of respondents affects the width of the 95% confidence interval for a 30% quit rate. The main point to take from the figure is that in general, the more survey respondents, the narrower the range of the 30% quit rate is and therefore the more precise the quit rate estimate is. This is due to decreasing uncertainty in the estimate with an increase in the number of completed surveys. However, diminishing returns are seen with more and more additional respondents; as the number of survey respondents surpasses 800, the interval width of the 95% CI does not change much.

Figure 3. Confidence Interval Ranges for a 30% Quit Rate by Number of Respondents



We recommend the minimum number of survey respondents be N=400 for the standard NAQC quit rates, given the need for precision and resources available. The sample size needed in order to produce 400 completed surveys will depend on the survey response rate achieved. For example, if a 50% response rate is expected, then roughly twice as many quitline or medication users, or N=800, should be sampled in order to achieve the desired number of survey respondents and a corresponding CI width of approximately 9%.

In addition to the standard NAQC quit rates, quitlines will likely produce supplemental quit rates for other groups of interest and unique service groupings. In Section 7.1 we provide guidance for choosing a sample size for supplemental quit rates.

Recommendation

N=400 completed surveys should be obtained, yielding the desired confidence interval width of 9%. Assuming a survey response rate of 50%, approximately N=800 quitline or medication users should be sampled.

Sub-section 5.4: Response Rates and Reducing Bias in Quit Rates

Achieving a high response rate is critical to the precision and accuracy of quit rates. A response rate is a simple ratio as seen below:

$$\textbf{Response rate} = \frac{\text{Number of individuals who completed a survey}}{\text{Number of individuals who were sampled to be surveyed}}$$

The numerator is a subset of the denominator and should only include those who responded to the survey. Please note that the denominator should include everyone who was sampled for surveying, regardless of their final survey disposition (e.g., not contacted, deceased, number not in service, etc.). This includes all participants who were selected to be contacted, but were never called because the target number of completed surveys was reached.

A common question in the quitline community is, "what is an adequate response rate for a quitline study?" The 2009 NAQC Issue Paper on measuring quit rates recommended quitlines provide enough resources to achieve a 50% survey response rate.[1] This recommendation was a compromise between the realities of what quitlines were able to achieve and common knowledge that a higher survey response rate will produce a more accurate quit rate. The 2009 paper provided examples from two state quitlines showing a decrease in responder quit rates as survey response rates increased. This is a form of self-selection bias, where successful participants (i.e., those who quit using tobacco) are more likely than unsuccessful participants to respond to a survey.

While many quitlines are struggling to achieve survey response rates of 50% or higher, NAQC fiscal year 2013 Annual Survey of Quitlines results show that some quitlines are able to achieve this benchmark.[13] In addition, there is no new evidence since the 2009 NAQC Issue Paper that refutes the importance of survey response rates in producing accurate quit rates. Therefore, reducing the recommended survey response rate would send a misleading message that the response rate is not important and could ultimately increase bias in quitline studies. We recommend that quitlines attempt to achieve a survey response rate between 50% and 70%. Regardless of final response rate, we recommend that quitlines report the response rate along with the quit rate to help readers interpret the quit rate.

The best way to achieve a high response rate is to select an appropriate sampling method and sample size (see Sections 5.2 and 5.3 above) and use proven methods to achieve a high response rate (see Section 5.6). Several of the survey strategies suggested require a relatively small amount of resources to implement.

While survey response rate is very important, it is not the only factor influencing the generalizability of quitline outcome studies. Low consent rates can have the same effect as low response rates in introducing bias into

survey results. For example, imagine a quitline serves a large population of non-English speakers. If a smaller proportion of the non-English speakers consent to the follow-up study than English speakers, the sample – and survey respondents – may not adequately represent the non-English speakers. This becomes more critical to the accuracy of the quit rate if language is associated with quitting. We also recommend that quitlines report the consent rate for the study to help add context to survey accuracy.

In addition to consent and response rates, missing contact information can also be a threat to accuracy. Participants with missing telephone numbers, email addresses, and home addresses might be ineligible for the evaluation follow-up. If missing contact information is correlated with low socioeconomic status or some other factor that is associated with quitting, excluding these participants can bias the study results.

Finally, recognizing how bias limits a quitline evaluation is helpful to put results in context. **To assess nonresponse bias we suggest comparing registration and utilization variables of all survey responders from the study vs. all other participants who registered during the study time frame.** For example, if the enrollment period for the study was July 2013 through June 2014, compare the survey responders from this time period against all other participants who enrolled in these months. Compare the participants on factors from registration such as age, education level, number of counseling sessions completed, etc. We suggest using simple statistics such as chi-square for categorical variables or t-tests for continuous variables to test for statistical differences. Or, just look for any factors that show a 5% or 10% difference between these two groups (responders vs. everyone else). Understanding and reporting the limitations of your results is important and can add context to a quitline's evaluation.

Recommendations

- *Calculate the response rate by dividing the number of survey responders by the total number sampled. Do not exclude sampled individuals from the denominator due to death, non-contact, numbers not in service, or any other reason.*
- *Attempt to achieve a response rate between 50% - 70%.*
- *Report the study response rate along with quit rate.*
- *Report the study consent rate along with quit rate.*
- *Quit rates should be interpreted with caution. Low survey response and low consent rates can result in a responder group that does not well reflect the quitline population.*

Sub-section 5.5: Follow-up Frequency and Resource Limitations

The last two sub-sections described two key recommendations for calculating the standard NAQC quit rate: obtaining n=400 completed surveys and achieving a 50% - 70% response rate. However, many quitlines face resource limitations that make an ongoing, rolling quit rate that achieves a 50% response rate difficult to attain. This section provides recommendations on how often, and when, to conduct follow-up studies.

Conducting an on-going rolling sampling is ideal for monitoring and allows quitlines the ability to always have recent data for making program decisions. However, the standard NAQC quit rates are not required annually. It is more important to conduct a rigorous outcome study where evaluation resources are focused on obtaining 400 completed surveys and a 50% response rate, than to conduct less rigorous studies more often or on-going.

There are several situations where an updated quit rate should be considered:

- To achieve a baseline quit rate, or a baseline quit rate from a rigorous outcome study
- After programmatic changes to the quitline (e.g., changing from a five-call program to a three-call program)
- After changing quitline service providers
- After changes to eligibility of quitline participants
- When the demographics of the quitline population has shifted
- Three years since the most recent quit rate study

Recommendation

When an ongoing rolling survey of n=400 completed surveys and a 50% response rate is not feasible due to resource constraints, conduct a follow-up study of n=400 completed surveys and a 50% response rate at least once every three years.

Sub-section 5.6: Telephone Survey Practices

As discussed in Section 2.3, survey response rates are declining over time. Given that achieving a high response rate is critical to the precision and accuracy of quit rates (see Section 5.4 for a fuller discussion of this issue), it is important that quitlines carefully consider telephone survey follow-up protocols in order to achieve the highest possible response rate with the resources available for evaluation. Fortunately, an abundance of survey methodology research is available to simplify and guide the surveying process.[57] Dr. Don Dillman has been conducting scientific research for over 30 years on increasing response rates and is considered to be one of the major contributors in developing a scientific basis for survey research methodology. He recently released a fourth edition of his widely respected guide on survey methodology, *Internet, Phone, Mail and Mixed-Mode Surveys: The Tailored Design Method*.[19] The field of public opinion research has also contributed a large body of literature to optimizing random digit dial telephone surveys, though literature on random digit dial telephone surveys has somewhat less applicability to the listed samples used in quitline follow-up evaluations. The following section highlights potential strategies for increasing survey response rates from the literature on survey methodology, considering the strategies' cost effectiveness.

Pre-notification Letters

The literature supports the use of pre-notification or advance letters, sent by mail, as a cost-effective way to increase response rates.[58] Sending advance letters may help increase the chance of contact by differentiating the phone call from a sales call, and helping reduce any suspicion about the purpose of the call.[59] Additionally, social exchange theory suggests that advance letters may lead to increased response rates because they clarify the value and legitimacy of the survey, thereby encouraging cooperation.[19] The letters should be printed on the quitline and/or sponsoring agency letterhead and envelope to capitalize on participants' familiarity with the service. They should also be as brief as possible, yet engaging, and should provide an explanation for what will be asked of the respondent and what benefit they can expect to receive in return.[19]

Incentives

The literature on survey methodology demonstrates that providing incentives to survey participants increases response rates and can be an important part of increasing the representativeness of survey respondents.[60,61] Incentives are frequently provided in one of two forms: advance or promised. As the name suggests, advance

incentives are provided by enclosing a token amount (e.g., $2 to $5 cash or gift card) inside the pre-notification letter. Conversely, promised incentives are mentioned at consent and in the pre-notification letter and sent as a thank you gift after the respondent completes the survey. Compared to token advance incentives, amounts for promised incentives may be higher, such as $10 or $20 or an opportunity to be entered into a drawing for a larger prize. Promised incentives exemplify an economic exchange model, or paying participants to complete the survey. In contrast, the token advance incentive is considered to be part of the social exchange; it is a thank-you and acknowledgement for the time and effort expended to complete the survey. Advance incentives have been found to be more effective than promised incentives in raising response rates.[62] However, the lack of an available mailing address and transiency among the quitline population can make advance incentives problematic or even impossible for some quitlines. In these cases, promised incentives may be a good alternative.

While incentives are known to be effective to increase response rates and representativeness of survey respondents, less is known about the cost effectiveness of incentives overall and particularly the cost effectiveness of advance versus promised incentives. In our own experience with seven-month follow-up surveys for tobacco cessation programs, PDA has found that small advance incentives result in modest reductions in survey implementation costs. We have concluded that, in most circumstances, small advance incentives are a critical tool in obtaining a high response rate with limited resources. The type and amount of incentive a quitline chooses should depend on the unique qualities of a quitline's population, the contact data available for that population, and the budget allocated for follow-up.

Survey Introduction

The introduction of the survey to evaluation respondents presents an additional opportunity to increase response rates. A study by the National Organization for Research at the University of Chicago (NORC) found that the inclusion of an introductory statement identifying a government sponsor (which many quitlines have) increased participation.[63] Dillman has postulated the following principles regarding the survey introduction: it should be brief, identify the survey's topic and length, and provide a reminder of any incentive or previous agreement to participate.[19] Quitlines should carefully consider the follow-up survey introduction because this strategy has almost no cost associated with it, but is an opportunity for boosting response.

Converting Soft Refusals

Converting soft refusals is a critical element of obtaining the highest response rate possible and is a common practice among surveyors. However, little literature exists to guide quitline evaluators in developing a soft refusal policy. Since survey response is correlated with tobacco use status, quitline participants may decline to take the survey, giving reasons such as, "I didn't really use the quitline" or "I didn't quit smoking." Survey protocols may be developed to convert this type of soft refusal by assuring potential respondents that the quitline is interested in hearing about the experiences of all callers, regardless of how much or how little they used the quitline, and whether or not they are still using tobacco. While employing these methods it is important that soft refusal policies respect the right of respondents to decline the survey. A soft refusal protocol is a low-cost strategy to boost response; it requires no resources other than planning and interviewer training.

Number of Attempts and Length of Follow-up Period

Finally, the number of attempts surveyors make before closing out a contact strongly impacts response rates. The Centers for Disease Control and Prevention recommends 15 attempts for the Behavioral Risk Factor

Surveillance System. In PDA's experience, most quitlines will reach an adequate response rate by making between seven and 15 attempts per contact. Because a greater number of attempts requires more resources, quitlines should make as many attempts as possible given budget constraints, and adjust that number as needed to achieve an adequate response rate. The number of attempts needed to produce an adequate response rate varies by population. It is important to the extent possible that every participant in the sample be contacted an equal number of times regardless of the number of surveys completed until the calling period closes. This ensures that every sampled participant has an equal opportunity for being contacted. The calling period should close within a reasonable amount of time (usually a month or less from initial follow-up contact) so that the duration between registration and follow-up is uniformly near to the seventh-month mark across all respondents. This practice helps increase the representativeness of survey results. We also recommend that call attempts are made at varying times of the day and days of the week.

Recommendation

Select and test a combination of survey administration strategies appropriate to the quitline's unique resources and needs, and adjust strategies as necessary in order to obtain a follow-up response rate of 50% or greater.

Sub-section 5.7: Survey Mode

Common sense suggests that mode consistency is an important criterion in selecting a follow-up survey mode: telephone quitline callers would be best reached with a telephone follow-up survey, while participants of a web-based program would be best reached via a web-based survey. Not only are participants likely to have a preference for communicating via the mode they chose for services, but they are also most likely to have provided complete contact information for that mode. However, given decreasing response rates via telephone and the need for high response rates, researchers are increasingly recommending that mixed-mode surveys be conducted.[19,60] Mixed-mode surveys ask the same questions and offer the same response choices using two or more survey modes, such as internet, telephone, IVR, or mail. A key benefit of mixed-mode surveys is the potential to increase response rates.[64] Mixed modes can also help to reduce non-response error, which occurs when a significant number of people in the sample do not respond to the survey and have different characteristics (such as tobacco use status) than those who do respond. Providing more than one mode has the potential to better reach all types of participants.

Despite these advantages, mixed-mode surveys can also pose problems. One major concern is mode effect: people's answers to any particular question may differ depending on the survey mode.[65] Mode effects are caused by the presence or absence of an interviewer, differences between visual vs. aural communication, and whether the interviewer or the respondent controls delivery of the stimulus. Common problems include cognitive processing of scales, primacy – recency effects, and response bias due to social desirability. For the most part, mode effects are controllable when multi-mode surveys are thoughtfully developed. Dillman recommends using the same question text and format across survey construction, so that survey items are designed to be received by the respondent in a similar way regardless of the mode of delivery.[19] The MDS items recommended in Section 4.4 allow for exactly similar stem and item choice wording across verbal (telephone) and written (web, text) survey modes, reducing this concern for follow-up surveys to calculate quit rates. Dillman also advises using multiple modes of contact to increase response rate in multi-mode studies.

Cost is also a concern when selecting survey modes. Adding a second survey mode may increase costs due to the added time for developing the items and protocols, and for the additional survey and data management time.

Using software that is designed for multi-mode survey administration can dramatically reduce this cost. Another way that a mixed-mode survey can potentially reduce costs is if a less expensive mode (such as a web survey) is utilized first and a more resource-intensive mode (such as telephone surveying) is reserved for those who are harder to reach.[19] Finally, additional modes may require the collection of additional contact information at the time of enrollment.

Sub-section 5.8: Data Quality Issues – Quitline Service Provider

Just as we assume some amount of measurement error in our outcome survey results, we should assume some amount of measurement error in intake and utilization data provided by quitline service providers. Measurement error in outcome studies can be reduced by using questions that have been tested for validity and reliability such as the MDS follow-up questions. To reduce measurement error from intake and utilization data, we recommend that quitline funders monitor key data provided by quitline service providers, such as quit status at intake and consent. Request copies of the intake, utilization, and follow-up surveys from the service providers collecting information; monitor how service providers are asking key questions such as consent (at intake) and quit status (at follow-up). Look for high levels of missing data and unexplained changes in a variable's distribution of values over time. In addition, quitline funders should be aware of how service providers ask intake questions. Even small changes to the wording of a question can alter the meaning; it is important to understand what intake questions are being collected and how.

One substantial barrier to achieving high response rates is the number of quitline participants whose telephone number is not in service at follow-up. One reason for this is many U.S. households are changing from landline telephones to cell phones, and the pace of this change is increasing.[16] Quitlines can mitigate the damage of this trend by collecting as much contact information as is feasible during the first call. This includes asking for more than one telephone number (cell phone, work, home), a mailing address, which is necessary for sending a pre-notification letter (see Section 5.6 above for a discussion of the effectiveness of pre-notification letters), as well as an email address for web-based surveying, if necessary. As much contact information should be collected during intake as is feasible, weighing the benefit of additional information at intake against the length of the intake process and available data fields.

Recommendation

Monitor intake and follow-up data for high levels of missing data and abrupt changes in the distribution of values for key variables.

Sub-section 5.9: The Evaluation Team

In the preceding sections we have made detailed recommendations regarding the calculation of quitline quit rates. We have also made detailed recommendations regarding the appropriate methods for conducting follow-up surveys and highlighted the importance of survey response rates in interpreting quit rate findings. Due to the potential complexity of these issues, we believe it is important that the evaluation be conducted by persons with experience in quitline evaluation or research. Quitline funders may elect to rely upon external evaluators or researchers, or their internal evaluation staff. It is also possible for the evaluation to be conducted by the quitline provider. In any case, evaluators should abide by the Guiding Principles for Evaluators as set forth by the American Evaluation Association, which states that "evaluators should disclose any roles or relationships they have that might pose a conflict of interest (or appearance of a conflict) with their role as an evaluator," and that

any actual or perceived conflicts "should be clearly articulated in reports of the evaluation results."[66] In cases where outcome evaluation is performed by the quitline service provider, quitlines should follow CDC recommendations that evaluation staff must be entirely separate and independent of the counseling staff.[67] Potential evaluators should be judged upon the transparency of their reporting (e.g., clearly defined sample selection, survey methods employed, number lost to follow-up and causes of loss to follow-up) and demonstrated ability to achieve adequate response rates on follow-up evaluation surveys. *Please note that the authors of this NAQC Issue Paper wish to acknowledge that they are from an independent evaluation firm whose scope of work includes evaluating quitlines.*

Recommendations

- *Use an evaluator or researcher with experience in quitline evaluation.*
- *Evaluation may be conducted by an external evaluator or researcher, or internally by quitline service providers as long as the individuals conducting the evaluation are entirely separate from, and independent of, the counseling staff.*
- *Select an evaluation team based upon transparency of reporting and demonstrated ability to achieve adequate response rates on follow-up evaluation surveys.*

SECTION 6: HOW TO CALCULATE QUIT RATES

This section provides detailed recommendations on how to calculate quit rates for conventional tobacco and conventional tobacco *plus* ENDS. Each calculation is mathematically composed of a numerator and a denominator.

$$\textbf{Conventional Tobacco Quit Rate} = \frac{\text{\# survey respondents abstinent from conventional tobacco}}{\text{Total \# survey respondents}}$$

$$\textbf{Conventional Tobacco plus ENDS Quit Rate} = \frac{\text{\# survey respondents abstinent from conventional tobacco and ENDS}}{\text{Total \# survey respondents}}$$

Section 4 (How to Define Abstinence) clarified some critical details about the numerator. Namely, that abstinence should be measured seven months post-enrollment using a 30-day point prevalence measure. Section 3 (Who to Include in the Quit Rate) recommended which groups of individuals should be included in the denominator, and Section 5 (Conducting Follow-up Surveys) discussed sampling.

This first part of this section provides further clarification on whether the denominator should include only survey respondents or all those sampled as a part of a follow-up survey. Additionally, this section addresses what to do when data necessary for a quit rate is missing, and how to calculate a confidence interval with a quit rate.

Sub-section 6.1: ITT vs. Responder Rate

A key task in calculating quit rates is to ensure that the rate includes as little bias as possible due to non-response to follow-up surveys. As discussed in Section 2, telephone survey response rates have been declining over time, and it is inevitable that some of those selected to be surveyed in a seven-month follow-up survey will not respond (please see Section 5.2 for more details on recommended sampling strategies for the follow-up survey). Even after substantial efforts are made to increase follow-up survey response rates, as described in Section 5.6, there will be sampled participants who do not complete a survey. How to address potential bias introduced by non- respondents is a key decision in calculating quit rates.

There are two straightforward approaches to calculating quit rates from studies with non-respondents. First, quit rates may be based only on those that respond to the survey, which is referred to as a responder rate (RR). Conversely, an intention-to-treat (ITT) approach may be employed, where all non-respondents are considered to be tobacco users (non-abstinent)[68] and which may be more accurately labeled as penalized imputation. The major advantages of both the RR and ITT rates are that they are simple to implement and explain. These advantages are important as quit rates are shared with quitline stakeholders, the media, and the public.

At the same time, it is important to acknowledge limitations of both the RR and ITT approaches in quit rate calculation. It is unavoidable that each of these simple approaches results in some degree of systematic error. It is well established in the conduct of clinical research that individuals who do not complete the treatment protocol or are otherwise "lost to follow-up" have worse outcomes than individuals who complete all aspects of the treatment and follow-up evaluation. The RR approach ignores this association and thus likely leads to a systematic overestimate of the true quit rate. The ITT approach addresses this issue by adopting an extreme position that all individuals who do not complete the follow-up evaluation are considered treatment failures. This likely leads to a systematic underestimate of the true quit rates.

In the conduct of clinical trials, the ITT approach has long been the dominant (though not exclusive) strategy for reporting quit rates. This is based upon the belief that the ITT approach is the most conservative when testing the hypothesis that a new treatment or program is efficacious compared to a different treatment or no treatment. While this may be the appropriate approach for clinical trials, it is not at all clear that this is the best approach for the evaluation of quitlines in practice.

In considering this issue further, it is important to recognize that there are substantial downsides to both the overestimation and the underestimation of the true quitline quit rate. The major disadvantage of overestimation of the true quit rate is the creation of unrealistic expectations regarding program outcomes and the risk of a loss of credibility (of the evaluation and perhaps of the overall program) if there is a large gap between reported and true program outcomes. The disadvantages of underestimation of true quit rates are the creation of overly pessimistic attitudes about quitline services that could negatively influence participation rates (i.e., tobacco users' interest in calling the quitline) and decisions by stakeholders regarding the continuation of funding or expansion of quitline programs.

NAQC's 2009 Issue Paper, *Measuring Quit Rates*, presented both hypothetical and real-world cases to assess whether the RR or ITT quit rate was a better approximation of the true (and unobtainable) quit rate.[1] The authors concluded that the RR quit rate is likely to be at least as accurate or perhaps more accurate than the ITT quit rate. A review of the quitline literature since 2009 did not uncover any new evidence to refute this conclusion. A caveat to these conclusions, and one that is addressed in the case studies from the 2009 paper, is

that the accuracy of the RR will improve as the survey response rate increases. Therefore, readers should cautiously interpret studies with low and very low survey response rate because the RR may not be more accurate than the ITT rate and neither rate may be very helpful in assessing the performance of a quitline. We recommend that a survey response rate always be reported with a quit rate so that the reader can better understand the quit rate presented.

There are certainly more sophisticated ways of handling missing information from non-respondents, such as those that involve imputation of missing outcome data based on the data that is available (e.g., intake data). Hall et al. (2001) discusses a number of different imputation models including "missing at random" and "missing completely at random".[69] Both of these models seem inappropriate for missing follow-up data in tobacco cessation modeling because the outcome data is clearly not missing at random. A more sophisticated approach considers "non-ignorable non-response" which means that the "missingness" is related to the outcome being measured. The ITT approach is an extreme case of this "non-ignorable non-response" in assuming a perfect relationship exists between using tobacco and having missing data. Finally a "selection model" which is based on generating propensity scores to predict who is missing and then using these scores in a model to help predict quitting could be employed. This type of model may use intake data such as respondent age, stage of readiness to quit, and level of addiction to predict outcomes. The advantage of a propensity score model is that it may be more accurate than the other calculation strategies mentioned above. The disadvantage of the propensity score imputation is that it requires a sophisticated research team and many hours to develop these models which have many additional assumptions that must be carefully delineated. Therefore, the use of propensity scores may not be practical in the evaluation of quitline quit rates in general practice.

Recommendation
Use the responder rate (RR) as the primary measure for reporting quitline outcomes. This is the number of quitters divided by the number of follow-up survey respondents.

Sub-section 6.2: How to Handle Item Non-response

This section offers guidance and recommendations on how to address non-response to follow-up survey items that are critical to calculating quit rates. The required items needed to calculate a quit rate using the recommendations in this paper include: consent; minimal, evidence-based treatment; quit status at intake; 30-day point prevalence tobacco status at follow-up; and 30-day ENDS status at follow-up. It is possible that a participant who responded to the follow-up survey and should be included in the quit rate calculation could be missing one or more of these required items. For each of the required items, we offer a recommendation for handling non-response. **In general, we encourage quitlines to work with survey interviewers and the quitline vendor to prioritize key items to reduce the incidence of missing information.**

Consent to Follow-up

This paper recommends asking quitline participants at the time of registration whether they consent to follow-up study participation (See Section 5.1). Some quitlines will ask consent at registration and others during follow-up survey administration. Regardless of when consent is asked, a participant could refuse to answer the consent question or the question could have been skipped accidentally by the survey interviewer. In either case, the participant should not be considered a survey responder and their record should not be included in standard NAQC quit rate calculations.

Note: For the purposes of calculating a response rate, those who refuse (or have missing) consent at the time of *follow-up* should be included in the denominator and considered a non-responder. Those who refuse consent (or have missing consent) at *registration* should not be sampled and will not be in the response rate denominator. The exclusion of those who refuse (or having missing) consent at registration is also discussed in Section 3, Who is Included in the Standard NAQC Quit Rates.

Minimal, Evidence-based Treatment

In Section 3.2, this paper recommends that participants who did not receive minimal, evidence-based treatment (e.g., at least some counseling or medication) are excluded from the standard NAQC quit rates. It is unlikely that there will be much missing for this required item, but any missing data should be treated thoughtfully. We recommend working with quitline service providers and medication providers to ensure that basic information regarding counseling sessions and medication shipments are available on all quitline participants. If missing data is identified before the survey is administered, questions could be added to the follow-up survey to ascertain whether minimal, evidence-based treatment was achieved (e.g., "Did you ever speak with a quitline counselor?", "Did you receive medication from the quitline program?"). While self-reported data is not ideal, it is preferable to the alternative of excluding participants with missing minimal, evidence-based treatment data from the standard NAQC quit rate calculations. If there is a lot of missing data for this item, excluding these individuals could bias the quit rate. This is especially true if the participants missing this item are not a random selection of participants but are related (e.g., pregnant women).

Quit Status at Intake

Similar to minimum treatment, participants who had no use of conventional tobacco in the 30 days prior to intake are excluded from the standard NAQC quit rates. It is possible that some participants will have missing data for the quit status questions at intake. If this is the case, work with the quitline vendor to improve data collection on this item. Alternatively, look for other intake questions that can be used as a proxy to estimate the quit status at intake field. If missing data is low on this item (5% or less of registrants), re-assign missing data to "not quit at intake." If data is missing for a larger proportion of participants (more than 5%), we encourage quitlines to be thoughtful about handling the missing data and to communicate with NAQC any assumptions that have been made regarding missing data.

30-day Point Prevalence for Conventional Tobacco

This is the only required item from follow-up surveys used to calculate the standard NAQC quit rates. Ideally, this important survey question is answered by the vast majority of survey responders. If this item is consistently missing for some participants, consider working with interviewers to prioritize the question to reduce its' future missing. Regardless of how many participants are missing this item, we recommend recoding missing to 'not quit'. While this seems conservative, excluding these participants from the quit rate denominator could inflate the quit rate.

30-day Point Prevalence for ENDS

ENDS use at follow-up is required to calculate the standard NAQC tobacco *plus* ENDS quit rate. If this item is missing, we recommend still including these participants in the standard NAQC tobacco *plus* ENDS quit rate calculation. To determine the numerator of the tobacco *plus* ENDS quit rate, we recommend examining those who quit conventional tobacco and answered the ENDS item. For this group, calculate the proportion who were

not using ENDS at follow-up. Next, apply this proportion to all those who quit conventional tobacco (both with and without ENDS data). The product of this calculation is the numerator for the tobacco *plus* ENDS quit rate. Please note that ENDS use is not used to produce the quit rate for conventional tobacco, so the calculations described above are not necessary for the standard NAQC conventional tobacco quit rate. In sum, no respondent should be excluded for missing ENDS data.

Recommendations

- *Exclude those missing consent (at intake) from quit rate calculations entirely.*
- *Assume those missing the 30-day point prevalence for conventional tobacco item are not quit.*
- *Include those missing the 30-day point prevalence item for ENDS in both standard NAQC quit rates. To calculate the numerator for the standard NAQC quit rate for tobacco plus ENDS, examine all those who quit conventional tobacco and answered the ENDS item at intake. For this group, calculate the proportion who quit ENDS. Then apply this proportion to all those who quit conventional tobacco (both those with complete and missing ENDS data).*
- *For minimum treatment and quit status at intake, thoughtfully deal with missing data and use the comment field of the NAQC Annual Survey to communicate how missing data was handled.*

Sub-section 6.3: Calculating Confidence Intervals

As discussed in Section 5.2 above, in order to conserve resources we recommend surveying a random sample of callers in a quitline evaluation. Measuring the true abstinence rate of all quitline callers may provide the most accurate measure of the quitline's performance, but it is very resource intensive to do so, and attempting to sample all quitline users may also lead to a lower response rate and thus an increased bias in the measurement. On the other hand, we can obtain an estimate of the true rate from our sample of follow-up responders. In addition to reporting the estimated rate, we recommend including a 95% confidence interval (CI), as an expression of uncertainty.[d] This interval provides a range of values that has a high probability of containing the true quit rate, and it is based on the normal approximation to the binomial probability distribution. As we saw in Section 5.3, the more completed surveys, the narrower the interval.

Confidence interval calculators for proportions are freely available at the VassarStats website (http://vassarstats.net/prop1.html). Many websites and statistical software programs provide this service, although some may use a slightly different underlying formula, so calculated confidence intervals may differ slightly.

Many quitlines would like to compare quit rates of various subsets of their callers. For example, you may wish to compare quit rates of those with a high level of program utilization to those with a low level. Confidence intervals may be used as a measure to determine if two quit rates differ from one another; if the confidence

[d] In Section 6.1, PDA recommends calculating a responder rate and not an intention-to-treat rate (ITT) for quit rates. However, the CDC encourages calculating both a responder and ITT rate. If quitline staff or evaluators elect to calculate an ITT rate, special attention should be paid to the confidence interval around that rate. The ITT rate assumes that all non-responders are smoking and includes them in the sample. This is problematic when calculating a CI because the usual 95% CI would assume the quit statuses for the entire sample are observed data points, which is incorrect. This assumption results in a CI with a smaller margin of error and is not sufficiently conservative. To remedy this issue, we recommend applying the calculated CI width for the responder rate to the ITT point prevalence rate by centering the width of the responder rate CI on the ITT rate.

intervals for two rates do not overlap at all, the two rates are significantly different. However, if the confidence intervals for the two rates do overlap, then they may be similar, or in some cases, significantly different. There is simply not enough evidence to determine whether the rates truly differ. Therefore, examining the overlap in confidence intervals will identify many, but not all, significantly different abstinence rates.

Recommendation

- *Include a 95% confidence interval along with the estimated quit rate in order to provide a range of values that has a high probability of containing the true quit rate of quitline callers.*
- *Use caution when determining significant differences in rates by comparing confidence interval overlaps.*

SECTION 7: USING QUIT RATES FOR INTERNAL PURPOSES

Standard quit rates have many benefits, but quitlines vary considerably in terms of the services they provide, the populations they serve, and a wide variety of factors associated with quitting in each state or province, like the tobacco taxation rates. These differences are particularly important as quitline staff use quit rates, satisfaction, and other data to manage their quitlines. This section discusses ways to consider these important differences between quitlines' quit rates; how to use the data collected to produce supplemental quit rates that may be of greater use for internal management; and some additional measures that individual quitlines may feel are useful for them to collect.

Sub-Section 7.1: Understanding and Addressing Variation in Quit Rates

Even after the measurement of quit rates has been standardized, different programs may have different results. Having a lower quit rate is not necessarily a sign of lower quality services; two identical quitline programs can yield widely different overall quit rates due to the differences in the specific populations they serve and the services they provide. Some key characteristics to consider are described next, followed by some suggested ways of examining data to make sense of these differences.

Characteristics to Consider

Nicotine dependence has been found to be a very strong predictor of quitting success, with those smoking fewer cigarettes per day and/or having a longer time period from waking to first cigarette having a higher rate of quitting.[70,71,72,73] Therefore, it is helpful to report participants' nicotine dependence characteristics along with quit rates, and to consider dependence when interpreting quit rates.

Indicators of social disadvantage have also been shown to influence quit rates. Many studies have reported that lower income, education, or socio-economic status (SES) is associated with lower quit rates.[70,72,73,74,75] Not surprisingly, these factors are highly correlated with one another. Co-morbidities such as having a mental health or substance use disorder have also been associated with lower quit rates.[74,76,77,78]

Additionally, several **demographic characteristics** have been shown to influence outcomes. One of the strongest predictors of quitting across studies is age, with older smokers more likely to successfully quit than younger smokers.[70,72,73,75] Gender has also been found to be associated with quitting success, with males having greater quit success than females,[70,72] but males are less likely to participate in self-selected, voluntary interventions such as quitlines. While some studies have found an increased chance of quitting for non-Hispanic

whites,[75] this finding is not consistent across the literature. Other studies have found no difference for race or ethnicity.[71,72,73,79]

It is important to note that many of the studies that discuss participant characteristics and how they affect quitting behavior are based on a general population of tobacco users rather than treatment-seeking tobacco users. It is possible that the relationship of predictors to outcomes found for the general population of tobacco users may not hold for those who proactively seek out cessation treatment. It is worth noting that predictors varied across the studies listed above; also, demographic trends in smoking cessation have changed over time.[80] Therefore, it is likely that predictors noted above may change or disappear and new predictors may appear.

Finally, in addition to participant characteristics, a number of **program characteristics** are known to be associated with variability in quit rates. As discussed in Sections 3.2, the evidence for a dose-response effect is well documented. In addition to the number of telephone counseling sessions offered by the quitline being positively associated with higher quit rates,[42] studies have shown that there is also a strong association between the number of calls completed and tobacco abstinence.[3] A wealth of literature finds a strong positive relationship between both the availability of pharmacological therapy and its use.[3,81,82]

Reporting Quit Rates with Key Participant and Program Characteristics

Given the many factors associated with quit rates, evaluators and quitline funders can take several steps to help themselves and others understand their quit rates in greater depth. To start, for the tobacco users in each quit rate reported, we recommend reporting their demographic and clinical characteristics, the services available to them, and their level of service use. This helps give readers key information to better interpret a quitline's quit rate. Many of the participant characteristics listed above can be gathered using the MDS Intake Questions, including age, gender, race/ethnicity, education level, cigarettes per day, and time from waking to first cigarette. Income level and insurance status are not required items on the MDS; however, if available, these may also be reported and considered. In addition, any other characteristics that distinguish a quitline's population served from those of other quitlines should be reported. A description of the services a program provides is typically readily available and we recommend it be reported. However, information about participants' actual use of services can be more difficult to access and understand. Quitline service providers typically have this data available. We recommend working with them to obtain, understand, and report this information along with your quit rate.

Calculating Separate Quit Rates by Key Characteristics

We also suggest calculating supplemental quit rates for different sub-populations of tobacco users that are of particular interest to a quitline and its stakeholders. A comparison of quit rates for different groups of participants is a first glimpse at the extent to which a quitline is well serving all of the tobacco users it serves. For example, how similar are the quit rates for men and women? How different are quit rates between those who used 1, 2 or 3 or more sessions?

While we recommend studies obtain n=400 completed surveys to produce a standard NAQC quit rate in Section 5.3, we suggest using a smaller sample size for quit rates calculated for specific subpopulations in order to conserve resources. We suggest that quit rates for subpopulations be based on at least N=75 completed surveys, which results in a confidence interval width of approximately 20%. This is a much larger confidence interval width than for N=400, which we estimated in Section 5.3 as 9%. To determine the number of participants to sample to achieve N=75 completed surveys, divide 75 by the estimated response rate. For example, an

estimated response rate of 50% would mean you would need to sample N=150 participants to achieve N=75 completed surveys. As with the standard NAQC quit rates, we suggest that supplemental quit rates be reported with their associated 95% confidence interval so that the reader can understand the possible error in the reported quit rate (see section 6.3 for further discussion of this point).

Unfortunately, comparing the quit rates of different groups in order to assess the relative effectiveness of a quitline is rudimentary at best. Without further analysis it is almost impossible to know if the differences seen are by chance or reflect real differences in outcomes due to the characteristic in question. Statistical tests like chi-squares that are used in cross-tabulations can address this concern. Additionally, because participant characteristics are also often related to each other (e.g., education level is associated with income), it is also difficult to know the unique contribution that one characteristic makes to a quit rate.

Using Logistic Regression to Better Understand a Quit Rate

Despite these difficulties, understanding the effectiveness of a quitline for specific groups is often an important question for quitline funders and stakeholders. For example, a quitline funder may hear anecdotal evidence that one racial or ethnic group of callers is dissatisfied with services. A comparison of quit rates by racial and ethnic groups may show some small difference. Further chi-square tests may show the differences to be statistically significant. However, it may also be possible that the differences seen may be due to other factors, such as some groups using certain cessation services, like text-based programs, at greater rates than other groups. In cases such as this, we suggest conducting a logistic regression to better understand if there is a relationship between important factors such as participant race/ethnicity and a quit rate, and to better understand the strength of any relationship that exists.

Logistic regression is a statistical methodology that can show the relationship between an outcome (e.g., 30-day point prevalence abstinence) and multiple relevant factors simultaneously, such as program use and caller characteristics. By controlling for these factors, logistic regression results present abstinence rates in the context of the populations that quitlines serve and levels of service use.

Conducting logistic regressions requires a certain level of statistical expertise, which some quitlines may not have access to. Therefore, we suggest finding a partner experienced in this method if a quitline does not already have someone on staff to conduct the analysis. Consulting with an experienced professional is important because many factors contribute to quitting. A few examples are confidence and motivation to quit, family support, and counselor quality. Logistic regression results are only as good as the models they are based on, so we suggest planning the best statistical model possible. An expert can also explain the findings and present odds ratios, as well as more easily interpretable statistics like relative risk and predicted quit rate differentials.

When examining logistic regression results, please keep in mind that this analytic technique can help explain the relationship between various factors and quitting, but it does not prove that one factor caused another. A logistic regression can instead give more certainty that specific factors are associated with quitting, but not that they cause tobacco users to quit.

Taken together, it is important to remember that standardized quit rates are valuable because they allow one quitline to compare their quit rate to another, which provides important context and insight. However, many factors impact quit rates and quit rates should not be the only indicator of success and quality. We suggest that

quitline funders explore a variety of factors related to quitting so that they can better understand the quality of their quitline and have more information to help manage it appropriately.

Recommendations

- *Report quit rates with some basic information about participant demographic and clinical characteristics, program services available, and level of program use.*
- *Use caution when comparing your quit rate to those of other quitlines. Consider the similarity of the quitline programs, as well as the demographic and tobacco use characteristics of respondents.*

Sub-section 7.2: Calculating Supplemental Quit Rates for Different Service Combinations

As described earlier, one of the primary purposes of the standard NAQC quit rates is to allow NAQC members to compare their quit rates to one another. To create a comparable rate across quitlines, the standard NAQC quit rates are calculated for those who receive a service that has a strong evidence base (telephone counseling and/or medication).

While the standard NAQC quit rates are relatively easy to calculate and allow NAQC members to compare their quitlines to one another, it is very understandable that the standard NAQC quit rates may not meet quitlines' information needs for internal management purposes. Many state and provincial quitlines offer services beyond telephone counseling and medications, and quitlines may be interested in the quit rate of specific programs or program combinations regardless of their evidence base. For example, a program may wish to know the quit rate for all those who used web-based services, regardless if they received medications (included in the standard NAQC quit rates) or not (excluded from the standard NAQC quit rates). In short, the standard NAQC quit rates may have limited utility when quitlines want to investigate the quit rate for services with a less robust evidence base, or for different service combinations than what are recommended in this paper.

Luckily, the data collection procedures outlined in this Issue Paper provide quitline staff with all the information they need to calculate supplemental quit rates for different service groups that match each quitline's specific interests. **We suggest that quitlines consider which cessation services they are most interested in learning about, and calculate supplemental quit rates for participants enrolled in those service group(s) as needed.** When conducting these calculations, it is important to keep in mind that many programs allow participants to enroll in more than one program at a time, so a quit rate for all web-based program participants, for example, may include those who also used telephone counseling and/or text-based programs. Therefore, it may be challenging to understand the unique contribution of web-based services on quit rates. For cases such as this, it may be helpful to run a logistic regression model (described above).

We suggest that quitlines consider calculating supplemental quit rates following all relevant recommendations outlined for the standard NAQC quit rates in Sections 4, 5, and 6, with two exceptions. First, supplemental quit rates should be based on a minimum of n=75 completed surveys (not n=400), to conserve resources. We encourage quitlines to increase the number of completed surveys if stakeholders will demand a quit rate with a smaller margin of error.

Second, definitions for minimal, evidence-based service will need to be tailored to the specific technology (web, text, IVR, email, smartphone app, etc.). Unfortunately, less evidence is available to help define minimal, evidence-based service for these emerging technologies. Therefore, **we suggest that minimal, evidence-based**

service mirror the quality of "active engagement" that is found in the definition of minimal, evidence-based service for telephone counseling. We suggest that quitlines consider the following definitions of "active engagement" that were feasible and reasonable at the time this paper was written: at least one log-in for web-based programs, at least one response to a text, at least one response to a counseling-related item[e] via IVR. Because emerging cessation technologies evolve rapidly, we suggest that evaluators and quitline funders who produce the supplemental quit rates apply the principle of "active engagement" to new and changing technologies as needed, and allow definitions of minimal, evidence-based service to evolve along with the technologies.

Sub-section 7.3: Additional Measures

It is also possible that the standard NAQC quit rates measures (30-day point prevalence abstinence) may not meet all of quitline funders' information needs. Each quitline has its own set of unique questions to answer about the program's functioning and outcomes. There are several additional outcomes which may be of interest to quitline funders and stakeholders; some of these outcomes can be reported using standard MDS follow-up items, some using MDS optional items, and others require additional custom survey items. In this section, five alternative outcome measures and their potential applications are described along with a list of corresponding follow-up survey items.

24-hour Quit Attempt

Quitlines may find it useful to report the percentage of participants who make a quit attempt. This is defined as abstaining from tobacco for at least one full day, and reflects a purposeful attempt to stop tobacco use (as opposed to an involuntary abstinence resulting from circumstances which prohibit tobacco use, such as hospitalization). Making a quit attempt is an integral part of the quitline intervention process. Most quitline protocols encourage tobacco users to select a specific date to stop tobacco use, and counsel them to prepare for the quit date. Making a quit attempt signifies meaningful participation in the intervention process and documents achievement of the first step toward abstinence. For quitlines that serve tobacco users with mental illness or substance use disorders, a 24-hour quit attempt may be a primary outcome measure of interest because these groups experience increased barriers to quitting. Generally, a low rate of quit attempts may be a sign of potential service quality problems which need further investigation.

MDS item SF 9, shown below, is a single item that could be used to measure quit attempts on a follow-up survey:

> SF9. Since you first called the quitline on (Date of first contact), seven months ago, did you stop using tobacco for 24 hours or longer because you were trying to quit? (DO NOT READ, CHECK ONE ONLY)
>
> - Yes *(Continue to OF 9-1)*
> - No *(Skip to SF 10 or 10a-e)*
> - Don't know
> - Refused

[e] For example, a question about triggers for smoking rather than a demographic question (e.g., age).

- Not asked

In reporting this outcome, we suggest using the same subset of survey respondents included in the standard NAQC quit rates (those who consent, are not already quit at intake, and receive minimal, evidence-based treatment). Report the proportion who responded "yes" to question SF9, and provide 95% confidence intervals.

Prolonged Abstinence Measures

Prolonged abstinence (also called sustained or continuous abstinence) is typically defined as not smoking for a set period after a quit attempt. Sometimes, this is for the entire period of time between the quit date and follow-up; other times, it begins after an initial "grace" period that may or may not be specified. Although this paper recommends that quitlines collect 30-day point prevalence abstinence as the primary quit outcome, there are several advantages to prolonged abstinence measures which may be of value to quitline funders and their stakeholder groups: it is more stable, is a better proxy for lifelong abstinence, is a better proxy for health benefit, and has a closer temporal relationship to the intervention than point prevalence measures.[50] For quitlines that find value in these factors, we suggest collecting a prolonged abstinence measure from participants at follow-up.

The MDS does not provide a standard or optional item for assessing prolonged abstinence. In Section 4, we suggest follow-up items measuring prolonged abstinence are more cognitively difficult for survey respondents to answer, as compared to items about point prevalence. We suggest that quitlines that opt to assess prolonged abstinence should tailor the survey question to meet their individual evaluation needs while also considering potential measurement issues.

Relapse

Relapse – quitting for a sustained period and then returning to regular tobacco use – can be a valuable measure for understanding patterns of quitting behavior among quitline participants. For example, the timing of when relapse is most likely to occur could help identify opportunities for programmatic changes to quitlines to help support users in maintaining their quit. Unfortunately, there is currently no consensus in the field on how to define and measure relapse. Quitlines opting to assess relapse will need to select and collect both a prolonged abstinence measure and a measure of subsequent relapse that meet their needs.

Reduction

Reduction in the number of cigarettes smoked per day is a secondary outcome which may be used to demonstrate progress even when quitline participants have not successfully quit tobacco. Like the 24-hour quit attempt, reduction may be selected as an appropriate marker of progress for populations who may face greater challenges with quitting tobacco, or who may need longer-term intervention and support.

Two identical MDS items, collected at intake and follow-up, respectively, are used to calculate reduction: S I7a and SF 6a.

> SI7a./SF6a. How many cigarettes do you smoke per day on the days that you smoke?
> (cigarettes per day) ____
> - Don't know
> - Refused
> - Not asked

For each respondent, subtract the number of cigarettes reported at follow-up from the number reported at intake. Quitlines may choose to report the mean value of the change, or to report the proportion in categories, such as the percentage of respondents with increased values, no change in values, or decreased values. We do not recommend calculating reduction in the number or amount of cigars, pipes or smokeless tobacco due to the difficulty in collecting standard measures of the quantity of tobacco contained in these tobacco products, which can vary greatly. However, quitlines may also be interested in reporting reduction in conjunction with ENDS use. Such analyses may show the extent to which ENDS use replaces tobacco use among those who fail to quit completely.

CONCLUSIONS

Taken together, calculating a high quality standard NAQC quit rate for conventional tobacco represents an exceptional opportunity for NAQC and quitlines to demonstrate the effectiveness of quitline interventions, to monitor cessation trends over time, and to compare quitline performance for vendor selection and other quitline management purposes. By calculating the tobacco *plus* ENDS quit rate, individual quitlines and NAQC have the opportunity to make a substantial contribution to the field of tobacco control. Calculating high quality supplemental quit rates that are responsive to a quitline's unique local context gives quitlines the power to demonstrate program accountability and proactively improve services according to their individual needs and context.

It is important that quitline follow-up studies make the best use of available resources. One important test of the quality and cost effectiveness of a follow-up survey is the accuracy of the quit rate that is produced. Ideally, quitlines will conduct ongoing, rolling follow-up surveys that results in n=400 completes with a response rate of 50% of greater. Many quitlines achieve this goal, and this paper presents many options and tools to assit quitlines to do so. When the ideal follow-up survey design is not feasible due to resource constraints, we recommend conducting a follow-up study of n=400 completes and a 50% response rate less frequently, at least once every three years. When balancing priorities, it is more important to conduct a rigorous outcome study less frequently, where evaluation resources are focused on obtaining a 50% response rate, than to conduct less rigorous studies continuously or more frequently.

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