2012 Special Webinar

Implications for North American Quitlines of a Recent Study on NRT and Quitline Counseling in England[1, 2]

April 26, 2012

Summary

Welcome and Introductions

Jessie Saul, PhD

NAQC's Director of Research, Jessie Saul, PhD, welcomed everyone to the call and introduced the speakers: Bruce Baskerville, PhD, Senior Scientist at the Propel Center for Population Health Impact, University of Waterloo; and Shu-Hong Zhu, PhD, Professor at the Department of Family and Preventive Medicine, School of Medicine, University of California, San Diego and the Director of the UCSD Center for Research and Intervention in Tobacco Control (CRITC).

Summary of the Study Design and Findings

Jessie Saul, PhD

(Dr. Saul's presentation slides are available on the NAQC website at http://www.naquitline.org/?page=CallInformation).

- Study setting: National quitline, England
- Participants: 2591 non-pregnant adult (16+) smokers, called quitline and agreed to set a quit date
- Randomization: participants assigned to one of four conditions
    - standard support (no NRT) (n=648)
    - proactive support (no NRT) (n=648)
    - standard support (NRT) (n=648)
    - proactive support (no NRT) (n=649)

Standard Support condition consisted of:

- Initial enrollment call

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[1] Ferguson, J., Docherty, G., Bauld, L., Lewis, S., Lorgelly, P., Boyd, K. A., McEwen, A. & Coleman, T. (2012). Effect of offering different levels of support and free nicotine replacement therapy via an English national telephone quitline: randomised controlled trial. *BMJ;* 344:e1696 doi: 10.1136/bmj.e1696.

[2] As a result of this webinar, NAQC has developed a *formal position (*http://naquitline.site-ym.com/resource/resmgr/Research/NAQC_position_stmt_Ferguson_.pdf) on the implications of Ferguson et al. for North American quitlines.

- Messages sent before, on, and after quit date (1, 3, and 6 months) by email, letter, or text (opt-out)
- Four proactive telephone support calls offered. If accepted, contacted -1week, on quit date, +2days, +3weeks. Calls were brief and unstructured.

Proactive Support condition consisted of:

- Initial enrollment call
- Messages sent before, on, and after quit date (1, 3, and 6 months) by email, letter, or text (opt-out)
- Six to seven proactive telephone support calls (no opt-out) at -2weeks, -1week, quit date, +3days, +7days, +14days, +21days. Calls were highly structured and tailored to the quit process.

Within each of the standard and proactive support conditions, participants were randomized to receive free NRT or not.

- Those who were **NOT** provided with free NRT through the quitline were given information about how to obtain support (including NRT) from National Health Service (NHS) sources.
- Those who **WERE** provided NRT through the quitline were provided 21 days of patches (15mg). To obtain the patches, participants had to call the NHS pharmacy (toll-free number) to have the NRT mailed. A 2nd 21-day supply was available in the same way.

Results

- Response rates and baseline characteristics were similar across conditions.
- 19.6% of those in the standard support condition reported prolonged cessation at 6 months, compared to 18.2% of those in the proactive support condition (difference was not statistically significant).
- 20.1% of those who were NOT offered free NRT through the quitline reported prolonged cessation at 6 months, compared to 17.7% of those who were offered free NRT through the quitline (difference was not statistically significant).
- The mean number of calls received by participants was 2.44 for the standard support condition, and 3.35 for the proactive support condition (less than one call difference).
- While it appears that more people in the free NRT condition used NRT, it is impossible to tell whether participants who sought non-study medications were the same or different people than received NRT through the quitline. Of those in the free NRT condition, less than half (42.9%) received NRT through the study.

Discussion

- In England, cessation medications are freely available through the NHS and standard care includes information about how to access them.
- Similar numbers of participants completed calls in each group.
- Similarity between services received by both groups “probably explains the similarity in outcomes achieved.” (Ferguson et al., 2012, p. 5)

Conclusion and Policy Implications

- "In England, where support for smoking cessation (i.e., counseling and NRT) is available to all smokers either free or at relatively low cost, adding additional proactive telephone counseling or an offer of free nicotine replacement therapy to usual quitline care did not affect smoking cessation rates. On the basis of this study, providing these through a quitline is not recommended." (Ferguson et al., 2012, p. 5)

Formal Response

N. Bruce Baskerville, PhD
Propel, University of Waterloo

Dr. Baskerville was asked to review the summary of methods, assess the quality of the study and highlight some of its strengths and limitations.

Study strengths include the following:

- The study is well designed with a clear description of rationale.
- The methods are very well described.
- The study included blinded data collectors.
- Good description of baseline characteristics of participants, along with losses and exclusions, was included.
- Authors included intent-to-treat analysis.
- Authors pointed out the limitations and highlighted potential sources for bias, including large attrition rate.

Study weaknesses include:

- *Didn't do allocation concealment.* It would be preferable to have used some procedure for insuring concealment, such as having a third party provide randomization. Possibility of bias exists when provider of service is doing the randomization. It didn't seem to be a factor here but the potential was there.
- *Blinding is almost impossible to do in a population size study.* The study authors did blind the data collectors, but the providers knew who was assigned to each group and could have done something differently when treating.
- *Power.* The study authors indicated that the study was powered to detect an odds ratio of 1.5 and they admit that the trial was perhaps underpowered in not being able to achieve any effects of this magnitude. The results did not show differences so this should not be a major drawback. As practitioners it could be clinically important; no, or a small, improvement in outcomes might have a big impact (e.g., reach). It is okay that they didn't have the massive sample size they wanted.
- *Number of participants lost to follow up* could have introduced bias despite their attempt for it not to. Authors should have mentioned or done a comparison of their dropouts against those who were still in the study (comparing baseline characteristics). Bias could have been introduced in sample because of loss to follow up.

Considerations:

- Context is VERY important to understanding the study results.
- England has a comprehensive and integrated tobacco control system, more so than the U.S. and Canada. Canada has inconsistent policies across its various provinces. For example:
    - British Columbia (BC) has 100% coverage – other provinces have programs that are not as systematic. In BC, people can get NRT at pharmacies.
    - Ontario offers NRT through a drug benefit program – participants have to meet criteria. Quitlines do not provide free NRT in Ontario but family physicians can provide it free to their patients.
    - Quebec has the longest standing free NRT system but NRT has to be prescribed by physicians or pharmacists.

Interpretation:
The study concludes that offering either proactive support or no-cost nicotine replacement therapy in addition to standard quitline care was not effective for smoking cessation in England. This is a likely conclusion to draw based on the findings. However,

- Participants were randomized to the standard or proactive counseling arms in the trial regardless of whether or not they wanted proactive counseling. Might have had some people getting calls who didn't want them and it could have made it challenging for advisors to provide that service to them. This may account for lack of differences between the treatment and the standard care group. The finding also runs counter to previously published meta analyses that showed proactive counseling does work (24 randomized control trials) (Tzelepis et al., 2011).
- It is possible that the high level of access to NRT outside of trial (all 4 arms of trial), as well as high levels of every day usage of NRT (approximately 50%) across all four arms of the trial, acted as a significant counter to being able to demonstrate a significant difference between those offered and not offered NRT. It seems that all four study groups were benefitting from free NRT.
- The study did not provide NRT dosage information or duration of use for those who obtained NRT outside of the study, which would have been helpful.

Conclusion: This study's findings hold true for the UK context however, further research is required to replicate this elsewhere.

Additional factors to consider:

- Possible resistance to (assigned vs. selected) proactive counseling and easy access to NRT. It is too early to say that these interventions are not effective in all contexts.
- In this study treatment groups were not that distinct for these two factors (proactive counseling and NRT).

Formal Response
Shu-Hong Zhu, Ph.D.

University of California San Diego
Dr. Zhu was asked to highlight strengths and weaknesses of the study and implications for quitlines in a U.S. context.

General Notes:

- The study was well-executed.
- No additional strengths or weaknesses to add to Dr. Baskerville's review.
- Dr. Zhu agrees with the conclusion that neither additional sessions nor NRT vouchers should be added to the current English NHS quitline operation.

Study Implications:

- The study shows that adding additional sessions does not increase quit rates but the additional sessions resulted in less than one additional call on average above the two calls that were provided through the standard care condition. In this study one is unable to tell whether the existing 2 sessions were good or bad. Perhaps the addition of one additional session through this study did not do anything.
- The study showed that sending NRT vouchers to participants (and their names to a pharmacy) did not increase quit rates. It did not show whether sending NRT directly to participants may make a difference. Sending a voucher for NRT, or requiring them to call a pharmacy to obtain NRT, is different than sending NRT directly to the participant.
- Most U.S. quitlines provide multiple-session counseling. Most U.S. quitlines are sending NRT directly to callers (tobacco users). The reference group of the study is similar to U.S. practice (in that there are 2.4 calls on average). The NRT condition in the study is different than most U.S. quitlines that are currently providing NRT, since most U.S. quitlines mail NRT directly to tobacco users. It is not clear for U.S. implications because the context is so different here in the US.

Conclusions:

- Quitlines in the U.S. should continue to provide multiple-session counseling and continue to send NRT. Our studies here have shown that both practices are effective at helping people quit!

Discussion:

- We have learned a lot from the paper. It makes us think.
- The study showed that adding one more session did not make a difference. Why is that the case? From 2.4 to 3.4 sessions is a big increase but they didn't see even a trend regarding improved outcomes. We should look into *how* we practice our counseling, what the content is, and how differences in counseling practices affect outcomes.
- If we get more people to use NRT it might not do anything. It was not clear from the paper how many people in each condition are using NRT, particularly in the condition assigned to receive NRT through the quitline/voucher. Just getting more people to use NRT may not have an impact on outcomes. The psychology of using NRT should be considered as well. We don't know what is going on

cognitively. What is the process – when did the people get the NRT, where was it in their quit attempt? Did they get it because counselors told them to go get and use the NRT, or was it just one more thing to do before making a quit attempt – it could have actually delayed the quit attempt. Were there too many steps? Did it make people wait before starting their quit attempt? Did the process of using the voucher/pharmacy system result in a delay or an effect? The people were motivated to quit at the start – and then may have had to delay to obtain NRT.

- We need to understand why some interventions work and others do not. We need to learn the *why* and this study did not explain that enough. My interpretation is that U.S. quitlines should continue to do what we are doing but we should monitor our delivery of protocols. We do not want to add more steps and delay quitting. Are we saying certain things within counseling sessions that allows smokers to delay their quit attempts –are we listening too much and not challenging them enough?

GENERAL DISCUSSION WITH THE WEBINAR PRESENTERS

Q: In the study, approximately 1200 people qualified for NRT and 500 received it (42%). Only about 75% of those who received it used it at an acceptable rate. What isn't reported in the study is whether those who were not offered NRT used the NRT they obtained from non-study sources. Motivation for using NRT may not be the same if they had to actively seek NRT on their own. How much NRT overall was used between the two groups? This may have been an issue in not detecting an effect in the study.

A: There is no documentation of dosage and length of use for those who were not part of the NRT use group. It is hard to draw a conclusion about whether or not NRT worked if only 30% of cohort used it. Also in this study we don't know if the smokers/participants were sticking to the guidelines of NRT use.

Q: In the editorial that accompanied the article in the journal it suggests that providing easy access to NRT may hinder quitting. What do the webinar presenters think about this?

A: Dr. Zhu doesn't see how this study leads to that conclusion. The control group had easy access as well as the intervention group. We don't know what the control group was doing with respect to duration of use or dosage of NRT. There was not a condition that was less intense in the study.

A: Dr. Baskerville didn't understand the editorial. He doesn't think the argument is defended by the study.

Q: Is it a waste of resources to make NRT available to those who are not ready to use it (randomization of NRT)? It might be better to use readiness to quit as a factor in getting NRT.

A: We need to understand where a smoker is in their quitting cycle and if there is benefit from learning more about where a smoker is and what protocol is right for them, we should use it.

Q: Are there similar studies going on in the U.S. around offering free NRT?

A: There are some studies that show that providing free NRT does work in a U.S. context (e.g., McAfee et al., 2008; An et al., 2006). But a recent study by Cummings et al. comparing 2 weeks of NRT vs. 4 and 6 weeks of NRT produced no results (Cummings et al., 2011). We do know that sending vouchers vs. sending NRT is a big difference – the method of receiving NRT does make a difference.

Q: The editorial suggests that providing easy access to NRT has an unintended consequence - communicating that quitting is easier than it really is and undermining the perceived value of NRT to smokers. I don't see how the study findings support this.

A: The editorial is in line with Dr. Zhu's opinion- that simply making NRT easier to access may not do anything. Free access may not solve all our problems. This comment is supported by the Ferguson study and he agrees with it. We can't just blindly send out free patches assuming that making them available for free solves all our problems.

A: Canadian quitlines don't have the ability to send out or provide NRT. To provide NRT, there are many links in the process. The links can be broken during the process and they don't know if the smoker got what they needed. Dr. Baskerville is trying to study it (in a new study) this fall to see if the smokers benefit more.

Q: What is the upper limit of consumer acceptance of more intensive interventions/protocols? We see that reflected in the kinds of services received in the U.S. (2.5 calls on average) and Canada (3.5 calls on average). What can we take away regarding counseling services? What is that upper limit of how many calls smokers will accept? Is it 3.4 (like in the study)?

Discussion:

- Quitlines have to counsel so many people with limits on funding so we may only be able to provide the 2.5 to 3.5 calls per participant. What if we counseled fewer people with more counseling sessions?
- The meta-analysis done last year (24 studies included in the analysis) showed that proactive counseling did benefit smokers (Tzelepis et al., 2011) but the question remains, how many sessions to have? It is a good question!
- Data from Canada shows that the number of sessions and quitting status is correlated. This says yes, proactive counseling is a good thing – but how many sessions are good? What is cost effective? What is needed to achieve that impact? More is better but how much more? More research needs to be done to find this number.

- Number of calls is one thing, but also length and content of each call should also be considered.
- I found it telling that the study didn't see an increase in effectiveness with the additional call – they didn't see even a trend in the findings. Interesting. They should see some difference between study arms where people received 2.4 vs. 3.4 calls. What is the break- even point? Where do we see the effect?
- Dr. Baskerville said his research demonstrated a significant difference after 4 proactive calls. But we need to more carefully research this to determine where we do not yield any benefit at all.
- There was a study in Arizona that looked at callers to the quitline with depression. Standard (3.5 call) protocol vs. enhanced protocol (6.7 calls) – they asked both groups if that was too many or not enough calls. Most in both groups said it was just right. Interesting. What is that top limit?

Question/comment: Not all smokers come in at the same place in their quit attempt. That also makes it hard to determine the number of calls that would be effective. We shouldn't set a number. There is one quitline funder who doesn't limit tobacco users to a maximum number of calls per caller. We see a similar result as was reported by Dr. Baskerville, that somewhere between 4 and 12 calls people are the most successful. What is different about these people in their quit attempts? Maybe we shouldn't set a limit on the number of calls – people should be able to ask for more if needed. How are people different when making their quit attempt? Where are they in their quit history? These things may make a difference.

Q: Are quitlines asking people about their planning processes i.e., how "spontaneous" was their effort to reach out to the quitline versus whether calling in was an action planned over some period of time? Several studies have shown spontaneous quitters demonstrate more abstinence in the long run, so if we can show counseling and NRT make a difference, maybe we need to put more effort into prompting spontaneous calls to the quitline.

A: Should we encourage more spontaneous calls? This is hard to study and show in a RCT. Most people who call quitlines by definition are all planning to quit.

A: Some quitlines offer services to those who have already quit (Canada).

Additional response: I disagree with Dr. Zhu who said that calling a quitline, "by definition," is a planned event and would argue that a proportion of people calling into the quitlines may be doing so fairly immediately after deciding to quit (e.g., they see a quitline promotion, it triggers their desire to quit and they pick up the phone). Since there are studies out there that show this "spontaneity" in quit attempts may lead to more successful long-term outcomes, I think it is important for quitlines to try to capture that information. It may turn out that this phenomenon moderates the impact of NRT/counseling/etc., and therefore would need to be controlled for when conducting future studies.

References

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