

Abrupt Cessation Telephone Counseling Manual

Session 1 (Day 0)

Before call, determine lozenge dose by following instructions on lozenge tracking form.

- Ask for the participant

“Hello, may I please speak to _____.”

- Re-introduce yourself

“Hi, this is _____. I’m calling from the Nicotine Lozenge Study. As you know, I’m a smoking cessation counselor, and I’d like to help you quit by talking with you on the phone periodically. My first phone call with you will take about 30 minutes. All the others will last about 15 minutes. Is this still a good time to talk for about 30 minutes?”

(If not, schedule another time.)

- Clarify the help they will receive

“Let me begin by telling you about what you’ll receive from this program. As you know, participants in this study are asked to quit smoking either by gradually cutting down first or by not cutting down first. You’ve been assigned by chance to quit smoking without first cutting down. That means I’ll be asking you to maintain your usual level of smoking until a quit day that you select. I’ll help you prepare for that quit day, and I’ll send you free nicotine lozenges to help you quit and stay quit. My role is to help you succeed, and I’ll be doing that by talking with you today and then four more times on the phone. There may be times when another counselor calls you if I am not able to. Do you have any questions at this point?” (Answer questions.)

- Ask about smoking history

“I’m curious, have you ever tried to quit before?”

(Explore most recent quit attempt: how they did it (gradually versus abruptly; any treatments used); how long they quit; what caused relapse. Acknowledge responses; stress the advantage of having tried before.)

- Ask about pros and cons of smoking now

“Can you tell me what your smoking is doing for you? What do you get out of smoking? (Record what they say; probe for more: “Anything else?”)

“What concerns you about your smoking? Why are you thinking about quitting?”

(Record what they say; probe for more; repeat their concerns and acknowledge that they are good reasons for wanting to quit.)

- Assess plans and concerns about quitting

“So, I’m wondering, is it still your plan to quit smoking?”

(If yes: Reinforce decision. If no: Tell them that that would remove them from the study, and we wouldn’t be able to give them free lozenges and support. Ask if they would like to reconsider. If no, thank them, tell them they can call again up to two weeks from now if they change their mind, otherwise we will not be able to give them free lozenges and support; end call.)

“Do you have any concerns about quitting?”

(Acknowledge concerns, write them down, and reassure them that you’ll assist them during the process.)

- Do timeline follow-back (TLFB)

“I’d like to get a clear sense of your cigarette smoking over the past week beginning with the number of cigarettes you smoked a week ago.” (Plug in timeline follow-back instructions here and record smoking. Take average cigs per day from past week and record as baseline CPD on counselor log)

- Emphasize that the best way to quit is by setting a quit date

“We know that the way most people successfully quit is by setting a quit date, getting support, and using medication like the nicotine lozenge. I’m going to provide support and send you the nicotine lozenges, so what we need you to do is set a quit date. It would be best if the quit date is at least 7 days from now so I can be sure to get the lozenges to you, but within 21 days, so that your motivation to quit is still strong. What would you like to pick as your quit date?”

“Great, so your quit date will be on (day of week and date). I’m going to write that date down so I keep track of it. You might jot it down as well. I also want to mention that if you decide to postpone or delay your quit date, it may mean that you are not able to get more lozenges from us.”

- Begin preparation for quitting by focusing on social support

“I’d like to begin helping you prepare for quitting. We know that folks who have others around them who provide support and encouragement for quitting are more likely to be successful. Can you think of someone who is around you regularly who can support you through the process of quitting?”

“What would you like that person to do to support you?” “Is there anything that you’d like them to say to you while you’re quitting?” (Provide suggestions if they have none.)

“Would you be willing to ask them to do that?”

- Determine if there are other smokers around them and problem-solve ways to reduce exposure

“One thing that makes it harder to quit is to be around other people while they’re smoking. That makes it harder to quit because you can see and smell the cigarettes and because they’re readily available. Are you around other cigarette smokers?”

(If no: acknowledge this advantage. If yes: problem-solve ways to reduce the exposure or risk of being around someone while they’re smoking.)

- Review what you’ve talked about today and schedule next call

“You’ve already made some headway toward quitting. You’ve identified some reasons why you want to quit smoking; you’ve set a quit date for _____; you’ve picked out someone who you’ll ask to support you while you’re quitting; and you’ve thought about ways to reduce the chances of being around other smokers while they’re smoking. Are you feeling pretty comfortable with this?” (If not, address their concerns.)

“I’d like to call you again a few days before your quit date to help prepare you for that day and to go over how to use the nicotine lozenges. Could we schedule a call for _____ at _____?” (If that won’t work, arrange another.)

“Before that date, I’m going to send you a brochure that gives some suggestions for quitting smoking, and a questionnaire that I’d like you to fill out and mail back to us right away. I’ll also send you your first batch of nicotine lozenges. You’ll be receiving a supply of _____ mg lozenges. You’ll get these a few days before your quit date, but please don’t start using the lozenges until your quit date. Also, please read the information that comes with the lozenges. I’ll be available to answer any questions about the lozenges at our next phone call.”

“In addition, _____ from our study will be contacting you again to set up an appointment to collect another breath sample from you. To remind you, the breath sample will only measure your carbon monoxide level which is an indication of your cigarette smoking. The appointment will take about 5-10 minutes and can either be done at your home, work or at a public place in your community. _____ will be calling you during the week before your quit date to set this up. It’s an important part of our study to collect the breath sample, so we appreciate your cooperation with this. You will receive compensation for providing this breath sample.”

- Encourage them to continue to smoke their usual number of cigarettes until their quit date

“Finally, I recommend that you continue to smoke your usual number of cigarettes until your quit date. There are several reasons I’m recommending that. It’s the way that most smokers successfully quit smoking, and it’s what most experts recommend. Additionally, there’s concern that some people who cut down may inhale more deeply which would be harmful. There’s also

concern that cutting down may cause you to suffer withdrawal symptoms even before you stop smoking. The final reason I'm asking you to NOT cut down before quitting is that in order for us to test whether gradual or abrupt quitting works best, we need your cooperation in stopping abruptly. Are you okay with that?" (Acknowledge any concerns, remind them it's a study, and/or thank them for their cooperation.)

- End conversation

"I've enjoyed talking with you I look forward to talking with you again on _____."

- Complete counseling log
- Email Joanne and Amy with participant ID#, QD, date to send QD -7 day mailing (should be business day before QD -7), study group and lozenge dose.

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Session 2 (QD - 3 days)

- Ask for the participant and introduce yourself

“Hello, may I please speak to _____. Hi, this is _____. I’m calling to check in with you to see how you’re doing with your smoking. Is this a good time to talk for about 15 minutes?”

(If it’s not, schedule another time.)

- Do time-line follow-back for past 7 days and get smoking status since last counseling contact

“The first thing I need to do is get a clear idea of the number of cigarettes you’ve smoked each day over the past week.” (Do time-line follow-back and write this down. Praise them if they’ve smoked their usual level all week: “Good job staying at your usual smoking level over the week.” If they’ve reduced, “I see you’ve cut down. That’s okay, I’m just concerned that that may make things more difficult for you, but let’s see how it goes.” If they’ve quit, “Okay, I see that you’ve quit. Congratulations. We’ll talk about how you’re doing in just a minute.”)

- Ask if they received the brochure and the nicotine lozenges and about their use

“Did you get the brochure, the questionnaire, and the nicotine lozenges that we sent you through the mail?”

If no: verify address and make arrangements to send them again. Re-negotiate their quit date later in this protocol to occur a few days later so they will have the lozenges.)

If yes: ask about lozenges and questionnaire.

“Have you started using the nicotine lozenges yet?” (Write down yes/no. If no, reinforce. If yes, ask when they started using them, and do time-line follow-up back to determine use since they started using them.)

“Have you mailed in your questionnaire?” (If yes, thank them. If no, remind them to please mail it in right away.)

IF PERSON IS NOT CURRENTLY SMOKING, skip to Page 7.

IF PERSON IS CURRENTLY SMOKING, continue here:

- Ask about quitting

“The last time we talked, you set your quit day for _____. How are you feeling about that?” (Acknowledge response; confirm plans and reinforce or reschedule. If reschedule, continue with this protocol because there will be no other call before quit day.)

- Prepare for quit day

“I’d like to spend a little time thinking about how you can get through your quit day without smoking. You’re going to have the lozenges to use, and I’m going to go over how to use them in just a few minutes, but I’m wondering if you’ve got any particular plans to help get you through that first day?” (Reinforce their ideas. If they didn’t already mention the following, then add them as suggestions.)

“A basic principle is to make it hard to get access to a cigarette. You may have some cravings or urges to smoke, but if a cigarette isn’t readily available, you have a much better chance of resisting. Can you think of ways to make it hard to get access to a cigarette?” (Suggest getting rid of all cigarettes, including butts in ashtrays, in cars, etc., and avoiding being around others while they’re smoking. Check to see if they negotiated that since last session.)

“Many folks who succeeded in quitting say that it helps to stay focused on your reasons for quitting. Remind me again of your main reasons for quitting smoking?” (Encourage them to write those down and look at them throughout the day to sustain their motivation.)

“Last time we talked about having someone that you see regularly who will support you while you’re quitting. Did you talk with someone about that?” (If not, encourage them to do so.)

- Identify high risk for smoking situation

“When you think about your quit day, what do you think is going to be the most difficult part of the day to get through without smoking?” (Problem-solve around that situation.)

- Review use of the lozenges

“Okay, it sounds like you’ve got some plans for your quit day. Now, I’d like to go over the use of the nicotine lozenges with you because using the lozenges will also help you succeed. We sent you a package containing 2 bags, each containing 72 lozenges. On the morning of your quit day, you should stop smoking completely. Instead of smoking you’ll begin that day by substituting a nicotine lozenge every one to two hours. The lozenge will decrease your craving and withdrawal symptoms. Place the lozenge in your mouth and let it dissolve without chewing or swallowing it. When you first use the lozenge, it may have a slightly bad taste or cause a tingling feeling in your throat. Most people get used to that after trying the lozenge a couple of times. If the first few seem too strong, you can remove the lozenge before its done. Move the lozenge around in your mouth periodically. It’s important that you not use any other nicotine products, like cigarettes, while you are using the lozenges. Let the lozenges substitute for all of your cigarettes. We recommend that you use at least 9 lozenges a day. Please be sure to read the package instructions before you use any of the medication. Side effects from the lozenge are rare. The most common one is a sore throat. We have screened you to make sure that the

nicotine lozenge is safe for you to use. **Please do not share** your lozenges with others who are not in the study.

We have a phone number for you to call if you have any problems with the lozenges or if you begin to run out. That phone number is printed in large numbers on the instructions sheet that came with the lozenges. Do you have any questions about the use of the lozenges?"

(Address their questions.)

- Review what you've talked about today and schedule next call and end conversation

"It sounds to me like you're prepared for quitting. You've got excellent reasons why you're doing this, you've got some good ideas about how to get through your quit day, you've got support for quitting, and you've got the nicotine lozenges to take the place of your cigarettes and to help you with cravings. Do you have any questions or concerns at this point?" (Address them.)

"I want to let you know that I'll be calling you 3 more times after your QD and I'd like to talk with you no matter what happens. I'd like to schedule my next call with you for two days after your quit date to see how you're doing and to talk about any problems you may be having. Could we schedule a call for _____ at _____? (If that won't work, arrange another.)

"I've enjoyed talking with you and look forward to talking to you again on _____."

- Record information on Telephone Counseling Log.

IF PERSON IS NOT CURRENTLY SMOKING:

- Congratulate them on quitting and ask how it's going

"So, it sounds like you've already quit smoking. Congratulations. Should I put down __ (date) __ as your quit date?" (If not, "what date did you quit?")

"So, how's it going? What kinds of difficulties are you having?"

(Acknowledge response; use problem-solving process to help them deal with any difficulty.)

- Highlight strategies to help them stay quit

"I'd just like to highlight a few strategies that folks who are successful in quitting tend to use in case they might be useful to you. One basic principle is to make it hard to get access to a cigarette. You may have some cravings or urges to smoke, but if a cigarette isn't readily available, you have a much better chance of resisting. Can you think of ways to make it hard to get access to a cigarette?" (Suggest getting rid of all cigarettes, including butts in ashtrays, in cars, etc., and avoiding being around others while they're smoking. Check to see if they negotiated that since last session.)

“Many folks who succeeded in quitting say that it helps to stay focused on your reasons for quitting. Remind me again of your main reasons for quitting smoking?” (Encourage them to write those down and look at them throughout the day to sustain their motivation.)

“Last time we talked about having someone that you see regularly who will support you while you’re quitting. Did you talk with someone about that?” (If not, encourage them to do so.)

- Review use of the lozenges

“Okay, it sounds like you’re doing well.”

If already using lozenges: “I know you’re already using the lozenges, but I’d like to go over their use with you just to make sure you’re getting the best benefit from them. “Have you had any problems since I last talked with you that might be due to the use of the lozenge?” Use adverse events sheet to document problems and then problem-solve.)”

If NOT yet using lozenges: “I know you haven’t started using the lozenges, so I’d like to go over their use with you just to make sure you get the best benefit from them.”

“We sent you a package containing 2 bags, each containing 72 lozenges. When you use the lozenges, you should stop smoking completely. Instead of smoking, substitute a nicotine lozenge every one to two hours. The lozenge will decrease your craving and withdrawal symptoms. Place the lozenge in your mouth and let it dissolve without chewing or swallowing it. When you first use the lozenge, it may have a slightly bad taste or cause a tingling feeling in your throat. Most people get used to that after trying the lozenge a couple of times. If it seems too strong you can remove the lozenge before its done. Move the lozenge around in your mouth periodically. It’s important that you not use any other nicotine products, like cigarettes, while you are using the lozenges. Let the lozenges substitute for all of your cigarettes. We recommend that you use at least 9 lozenges a day. Please be sure to read the package instructions with the medication. Side effects from the lozenge are rare. The most common one is a sore throat. We have a phone number for you to call if you have any problems with the lozenges or if you begin to run out. That phone number is printed in large numbers on the instructions sheet that came with the lozenges. Do you have any questions about the use of the lozenges?” (Address their questions.)

- Review what you’ve talked about today and schedule next call and end conversation

“It sounds to me like you’re on your way. You’ve got excellent reasons why you’re doing this, you’ve got some good ideas about how to stay away from cigarettes, you’ve got support for quitting, and you’ve got the nicotine lozenges to take the place of your cigarettes and to help you with cravings. Do you have any questions or concerns at this point?” (Address them.)

“I’d like to call you again in about 5 days to see how you’re doing and to talk about any problems you may be having. Could we schedule a call for _____ at _____? (If that won’t work, arrange another.)

“I’ve enjoyed talking with you and look forward to talking to you again on _____.”

- Record information on Telephone Counseling Log, noting that the next call will be **session 4**.

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Session 3 (QD + 2 days)

- Ask for the participant and introduce yourself

“Hello, may I please speak to _____. Hi, this is _____. I’m calling to check in with you to see how you’re doing with your smoking. Is this a good time to talk for about 15 minutes?”

(If it’s not, schedule another time.)

- Assess smoking status

“The first thing I need to do is get a clear idea of how you’re doing with quitting. Have you tried to quit smoking since we last talked?”

If yes: “When did you quit?” (Write down the date) “How many cigarettes have you smoked since you quit?” (Acknowledge response and write it down)

If no: “How many cigarettes a day are you currently smoking?” (Write this down)

Ask everyone: “How many lozenges a day are you using?” (Write this down)

IF PERSON SAYS TRIED TO QUIT BUT HAS SMOKED 1 OR 2 CPD SINCE QD, skip to Page 11.

IF PERSON SAYS DID NOT QUIT AT ALL OR THEY ARE SMOKING 3 OR MORE CPD, skip to Page 12.

IF PERSON IS ABSTINENT, continue here:

- Congratulate them on quitting and ask how it’s going

“Congratulations, you’re no longer smoking. Good job. How’s it going? What kinds of difficulties are you having?”

(Acknowledge response; use problem-solving process to help them deal with any difficulty.)

- Ask about cravings and problem-solve

“Have you been getting any cravings to smoke? What have you been doing to handle the cravings? How has that been working for you?” (Acknowledge responses.)

(If using at least 9 lozenges per day: Reinforce use. Ask: “Have you had any problems since I last talked with you that might be due to the use of the lozenge?” Use adverse events sheet to document problems and then problem-solve.)

(If using less than 9/day: Ask why they're using fewer than 9/day. Also ask: "Have you had any problems since I last talked with you that might be due to the use of the lozenge?" Use adverse events sheet to document problems and then problem-solve. Correct any misconceptions and encourage use, especially ahead of time when they know they will be facing a difficult situation. Remind them that the lozenges help decrease withdrawal symptoms such as anxiety, depression, difficulty concentrating, restlessness, hunger and impatience, as well as cravings to smoke.)

- Ask about social support

"What's your support person been doing to help you? What would you like them to do or say to you? Can you ask them to do that?"

- Discuss the use of self-rewards

"One way to see direct benefits from quitting is to come up with ways to reward yourself for not smoking. For example, some people take the money that they've saved each day and use it to buy something for themselves or to go out to dinner or to do something special they wouldn't otherwise do. Others find ways to include fun things into their days, like talking with a friend, watching a movie, working on a hobby. Can you think of some ways you can reward yourself for stopping smoking?"

- Ask about any high risk for smoking situations coming up in the next several days

"As you think about the next four or five days, can you think of any situations that are likely to put you at risk for smoking?" (Problem-solve the most risky situation mentioned.)

- Review what you've talked about, schedule next call and end conversation

"You're doing a great job stopping smoking. You've gotten through the difficult first couple of days, you've got ways to manage cravings including use of the nicotine lozenges, you're rallying your social support, you've got ideas about how to reward yourself for staying quit, and you've anticipated risky situations that may arise over the next several days. Do you have any questions or concerns at this point? (Address them.)

"I'd like to call you again in about 5 days to see how you're doing and to talk about any problems you may be having. Could we schedule a call for _____ at _____? (If that won't work, arrange another.)

"It's been good talking with you. I look forward to talking to you again on _____."

- Record information on Telephone Counseling Log.

IF PERSON TRIED TO QUIT BUT HAS SMOKED 1-2 CPD SINCE QD:

- Acknowledge smoking situation and ask what happened

“Okay, so it sounds like you’ve made some good headway with quitting, but you’ve also smoked. What’s going on?” (Ask about the specific situation in which they smoked, where were they, what motivated the lapse, what were they thinking or feeling, how did they get the cigarette, what did they try to do to avoid smoking?)

- Ask how they’re feeling about the situation and emphasize the value of the experience

“How are you feeling about your smoking situation right now?”

(Acknowledge response. If they sound discouraged, mention the tendency to want to give up when you have a slip; to just decide that you’re not ready to do this or this is too hard. The best treatment for those thoughts is to remind yourself why you wanted to quit in the first place. Ask if those reasons have changed.)

“The good news about this experience is that you’ve caught it early and you can recover from it, but it’s going to be important to find a way to avoid these slips because they are very risky. They’re what lead people back to smoking. Are you up for finding a way to manage them?”

- Problem-solve what they could have done differently to resist smoking in that situation

“What kinds of things could you have done differently to have avoided smoking?” (Reinforce these and add others as needed.)

- Ask about cravings and problem-solve

“Have you been getting many cravings to smoke? What have you been doing to handle the cravings? How has that been working for you?” (Acknowledge responses.)

(If using at least 9 lozenges per day: Reinforce use. Ask: “Have you had any problems since I last talked with you that might be due to the use of the lozenge?” Use adverse events sheet to document problems and then problem-solve.)

(If using less than 9/day: Ask why they’re using fewer than 9/day. Also ask: “Have you had any problems since I last talked with you that might be due to the use of the lozenge?” Use adverse events sheet to document problems and then problem-solve. Correct any misconceptions and encourage use, especially ahead of time when they know they will be facing a difficult situation. Remind them that the lozenges help decrease withdrawal symptoms such as anxiety, depression, difficulty concentrating, restlessness, hunger and impatience, as well as cravings to smoke.)

- Ask about social support

“What’s your support person been doing to help you? What would you like them to do or say to you? Can you ask them to do that?”

- Discuss the use of self-rewards

“One way to see direct benefits from quitting is to come up with ways to reward yourself for not smoking. For example, some people take the money that they’ve saved each day and use it to buy something for themselves or to go out to dinner or to do something special they wouldn’t otherwise do. Others find ways to include fun things into their days, like talking with a friend, watching a movie, working on a hobby. Can you think of some ways you can reward yourself for stopping smoking?”

- Ask about any high risk for smoking situations coming up in the next several days

“As you think about the next four or five days, can you think of any situations that are likely to put you at risk for smoking?” (Problem-solve the most risky situation mentioned.)

- Review what you’ve talked about, schedule next call and end conversation

“You’re making good progress. You’ve had some difficulty, but you sound resolved to keep going. You’ve got ways to manage cravings, you’re rallying your social support, you’ve got ideas about how to reward yourself for staying quit, and you’ve anticipated risky situations that may arise over the next several days. Do you have any questions or concerns at this point?” (Address them.)

“I’d like to call you again in about 5 days to see how you’re doing and to talk about any problems you may be having. Could we schedule a call for _____ at _____? (If that won’t work, arrange another.)

“It’s been good talking with you. I look forward to talking to you again on _____.”

- Record information on Telephone Counseling Log.

IF PERSON DID NOT QUIT AT ALL OR THEY ARE SMOKING 3 OR MORE CPD

- Acknowledge smoking situation and ask what happened

For people who didn’t quit: “Okay, so it sounds like you didn’t quit on your quit day. What’s going on?”

For people who quit but are back to smoking daily: “Okay, so it sounds like you quit initially, but you’re back to smoking daily. What’s going on?”

- Ask how they're feeling about the situation and emphasize the value of the experience

“How are you feeling about your smoking situation right now?”

(Acknowledge response. If they sound discouraged, mention the tendency to want to give up; to just decide that you're not ready to do this or this is too hard. The best treatment for those thoughts is to remind yourself why you wanted to quit in the first place. Ask if those reasons have changed.)

“The good news about this experience is that you've caught it early, and you can recover from it. The thing we know about quitting smoking is that people typically try multiple times before they're successful. Each time you make an attempt is like a practice session, and you get a better idea of what it's going to take to quit. The best strategy still remains getting focused on setting a new quit date, and I'm very happy to work with you if you're willing to give it another try. Are you up for doing that?”

(Acknowledge response. **If they don't want to set a new quit date now**, acknowledge that and ask if you can call them in another 5 days to see how they're feeling. Schedule the next call and end conversation. If they do want to set a new quit date, reinforce that and continue below.)

- Set a new quit day

“It's generally a good idea to set a quit day sooner rather than later because motivation can sometimes go down as time passes. Could you pick a day in the next 5 days for your quit day?”
(If new QD is within 5 days: Praise them for their commitment to a quit date; tell them you're going to write that date down and encourage them to do the same. **If new QD is more than 5 days from now:** Let them know that delaying their new QD may mean that they will not be able to receive more lozenges from us and may not receive any counseling calls after their QD. Ask them if they'd like to consider a QD that is sooner.)

- Prepare for quit day

“Knowing what you know now, I'm wondering if you've got any ideas about what might help you get through your quit day?”

(Remind them about making it hard to get a cigarette; avoiding being around others while they're smoking; staying focused on your reasons for quitting; asking for support.)

- Identify high risk for smoking situation

“When you think about your quit day, what do you think is going to be the most difficult part of the day to get through without smoking? (Problem-solve around that situation.)

- Encourage use of lozenges

“We recommend that when you quit, that you use at least 9 lozenges a day to avoid cravings and withdrawal symptoms such as anxiety, depression, difficulty concentrating, restlessness, hunger,

and impatience. It's especially useful to use the lozenge when you anticipate that you'll be facing a difficult situation in which you may want to smoke. We don't recommend using the lozenges while you're continuing to smoke. Do you have any questions about the lozenge use?" (Answer questions.)

- Review what you've talked about today and schedule next call and end conversation

"It sounds to me like you're ready to give this another try. You've got solid reasons for quitting, you're better prepared for your quit day than you were before because you know more; you've got support for quitting, and you've got the nicotine lozenges to substitute for your cigarettes and to help you with cravings. Do you have any questions or concerns at this point?" (Address them.)

"I'd like to call you again in about 5 days to see how you're doing and to talk about any problems you may be having. Could we schedule a call for _____ at _____? (If that won't work, arrange another.)

"I've enjoyed talking with you and look forward to talking to you again on _____."

- Record information on Telephone Counseling Log.

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Session 4 (QD + 7 days)

Before call, look at Adverse Events form to identify any reported symptoms or problems with the lozenges that need follow-up.

- Ask for the participant and introduce yourself.

“Hello, may I please speak to _____. Hi, this is _____. I’m calling to check in with you to see how you’re doing with your smoking. Is this a good time to talk for about 15 minutes?”

(If it’s not, schedule another time.)

- Assess smoking status

“The first thing I need to do is get a clear idea of how you’re doing with quitting. Have you smoked any cigarettes since we last spoke on _____?” (Acknowledge response)

If yes: “How many cigarettes a day are you currently smoking?” (Write this down)

Ask everyone: “How many lozenges a day are you using?” (Write this down)

IF PERSON HAS LAPSED SINCE THE LAST SESSION, skip to Page 17.

IF PERSON HAS RELAPSED (BEEN SMOKING DAILY), skip to Page 19.

IF PERSON IS ABSTINENT, continue here:

- Congratulate them on abstinence and ask how it’s going

“Congratulations, you’re not smoking. Well done. How’s it going? What kinds of difficulties are you having?”

(Acknowledge response; use problem-solving process to help them deal with any difficulty.)

- Discuss coping with negative emotions (if you didn’t just discuss this above)

“I want to mention to you one situation that can put people at risk for going back to smoking after they’ve quit. A lot of relapses back to smoking happen when an ex-smoker is feeling some sort of negative emotion. It can be a “high energy” negative emotion like anger, stress, anxiety, or frustration. Or it can be a “low energy” negative emotion like loneliness, boredom, sadness, or depression. The reason these negative feelings can be risky is because some smokers have learned to use cigarettes as a way to help manage negative emotions. Smoking doesn’t take the negative feeling away completely, but it seems to temper it slightly, making it less aversive. When they stop smoking, they eliminate that coping strategy, so it’s important to find other ways

to reduce negative emotions; ways that don't have harmful side effects. Is there a particular negative emotion that you think might put you at risk for smoking?"

(Problem-solve ways to handle whichever negative emotion they mention. If they don't mention one, then problem-solve ways to handle stress.)

- Ask about their reasons for quitting

"How are you feeling about your reasons for quitting? Remind me what your reasons are."
(Reinforce them.)

- Ask about any high risk for smoking situations coming up in the next several days

"As you think about the next week, can you think of any situations that are likely to put you at risk for smoking?" (Problem-solve the most risky situation mentioned.)

- Comment on use of lozenges

(If using at least 9 lozenges per day: Reinforce use. If reported problems with lozenge at prior call, ask about past symptoms or problems with lozenge: "Last time we spoke you mentioned _____. Is this still occurring?" If no problems from previous call, ask: "Have you had any problems since I last talked with you that might be due to the use of the lozenge?" Use adverse events sheet to document problems and then problem-solve.)

(If using less than 9/day: Ask why they're using fewer than 9/day. If reported problems with lozenge at prior call, ask about past symptoms or problems with lozenge: "Last time we spoke you mentioned _____. Is this still occurring?" If no problems from previous call, ask: "Have you had any problems since I last talked with you that might be due to the use of the lozenge?" Use adverse events sheet to document problems and then problem-solve. Correct any misconceptions and encourage use, especially ahead of time when they know they will be facing a difficult situation. Remind them that the lozenges help decrease withdrawal symptoms such as anxiety, depression, difficulty concentrating, restlessness, hunger and impatience, as well as cravings to smoke.)

For everyone: "I need to check in about your supply of the nicotine lozenge. How much lozenge do you have left?" (Assess how many bags or sheets they have and whether they need more based on daily use. If not enough, send more and inform participant that you will do this)

- Review what you've talked about, schedule next call and end conversation

"You're doing a terrific job not smoking. You've already gone _____ days at this point which is excellent. You've got ways to deal with difficult situations that may arise, you've got good ideas about how to handle some negative emotions without smoking, and you continue to have great reasons for wanting to stay quit. Do you have any questions or concerns at this point?"
(Address them.)

“I’d like to call you again in about 5 days to see how you’re doing and to talk about any problems you may be having. This next call will be our last one. Could we schedule a call for _____ at _____? (If that won’t work, arrange another.)

“It’s been good talking with you. I look forward to talking to you again on _____.”

- Record information on Telephone Counseling Log, send more lozenge if needed.

IF PERSON HAS LAPSED SINCE LAST SESSION

- Acknowledge smoking situation and ask what happened

“Okay, so it sounds like you’re doing quite well most days, but you’ve also smoked. What’s going on?” (Ask about the specific situation in which they smoked, where were they, what motivated the lapse, what were they thinking or feeling, how did they get the cigarette, what did they try to do to avoid smoking?)

- Ask how they’re feeling about the situation and emphasize the value of the experience

“How are you feeling about your smoking situation right now?”

(Acknowledge response. If they sound discouraged, mention the tendency to want to give up when you have a slip. The best way to renew your motivation is to remind yourself why you wanted to quit in the first place. Ask if those reasons have changed. Reinforce them.)

“You’re at a critical point in your quitting process because you’re generally doing well, but you’re putting yourself at risk by slipping. It’s going to be very important to find a way to avoid these slips because slipping leads people back to smoking. Are you up for thinking about some ways to avoid them?” (Reinforce them.)

- Problem-solve what they could have done differently to resist smoking in that situation

“What kinds of things could you have done differently to have avoided smoking?” (Reinforce these and add others as needed.)

- Discuss coping with negative emotions (if you didn’t just discuss this above)

“I want to mention to you one situation that can put people at risk for going back to smoking after they’ve quit. A lot of relapses back to smoking happen when an ex-smoker is feeling some sort of negative emotion. It can be a “high energy” negative emotion like anger, stress, anxiety, or frustration. Or it can be a “low energy” negative emotion like loneliness, boredom, sadness, or depression. The reason these negative feelings can be risky is because some smokers have learned to use cigarettes as a way to help manage negative emotions. Smoking doesn’t take the negative feeling away completely, but it seems to temper it slightly, making it less aversive. When they stop smoking, they eliminate that coping strategy, so it’s important to find other ways

to reduce negative emotions; ways that don't have harmful side effects. Is there a particular negative emotion that you think might put you at risk for smoking?"

(Problem-solve ways to handle whichever negative emotion they mention. If they don't mention one, then problem-solve ways to handle stress.)

- Ask about any high risk for smoking situations coming up in the next several days

"As you think about the next week, can you think of any situations that are likely to put you at risk for smoking?" (Problem-solve the most risky situation mentioned.)

- Comment on use of lozenges

(If using at least 9 lozenges per day: Reinforce use. If reported problems with lozenge at prior call, ask about past symptoms or problems with lozenge: "Last time we spoke you mentioned _____. Is this still occurring?" If no problems from previous call, ask: "Have you had any problems since I last talked with you that might be due to the use of the lozenge?" Use adverse events sheet to document problems and then problem-solve.)

(If using less than 9/day: Ask why they're using fewer than 9/day. If reported problems with lozenge at prior call, ask about past symptoms or problems with lozenge: "Last time we spoke you mentioned _____. Is this still occurring?" If no problems from previous call, ask: "Have you had any problems since I last talked with you that might be due to the use of the lozenge?" Use adverse events sheet to document problems and then problem-solve. Correct any misconceptions and encourage use, especially ahead of time when they know they will be facing a difficult situation. Remind them that the lozenges help decrease withdrawal symptoms such as anxiety, depression, difficulty concentrating, restlessness, hunger and impatience, as well as cravings to smoke.)

For everyone: "I need to check in about your supply of the nicotine lozenge. How much lozenge do you have left?" (Assess how many bags or sheets they have and whether they need more based on daily use. If not enough, send more and inform participant that you will do this)

- Review what you've talked about, schedule next call and end conversation

"You're doing well as long as you can get those slips under control. You've got ways to deal with difficult situations that may arise, you've got good ideas about how to handle some negative emotions without smoking, and you continue to have great reasons for wanting to stay quit. Do you have any questions or concerns at this point?" (Address them.)

"I'd like to call you again in about 5 days to see how you're doing and to talk about any problems you may be having. This next call will be our last one. Could we schedule a call for _____ at _____? (If that won't work, arrange another.)

"It's been good talking with you. I look forward to talking to you again on _____."

- Record information on Telephone Counseling Log, send more lozenge if needed.

IF PERSON HAS RELAPSED (BEEN SMOKING DAILY)

- Acknowledge smoking situation and ask what happened

“Okay, so it sounds like you’ve been smoking. What’s going on?”

- Ask how they’re feeling about the situation and emphasize the value of the experience

“How are you feeling about your smoking situation right now?”

(Acknowledge response. If they sound discouraged, mention the tendency to want to give up. The best way to renew your motivation is to remind yourself why you wanted to quit in the first place. Ask if those reasons have changed. Reinforce them.)

“The thing we know about quitting smoking is that people typically try multiple times before they’re successful. Each time you make an attempt is like a practice session, and you get a better idea of what it’s going to take to quit. The best strategy still remains getting focused on setting a new quit date, and I’m very happy to work with you if you’re willing to give it another try. Are you up for doing that?”

(Acknowledge response. **If no:** If they don’t want to set a new quit date now, acknowledge that and ask if you can call them in another week to see how they’re feeling. Schedule the next call and end conversation. If they do want to set a new quit date, reinforce that and continue below.)

- **If yes:** Set a new quit day

“It’s usually wise to set a quit day fairly soon so you keep the momentum going. Could you pick a day in the next 4 days for your quit day?”

(**If new QD is within 4 days:** Praise them for their commitment to a quit date; tell them you’re going to write that date down and encourage them to do the same. **If new QD is more than 4 days from now:** Let them know that delaying their new QD may mean that they will not be able to receive more lozenges from us and may not receive any counseling calls after their QD. Ask them if they’d like to consider a QD that is sooner.)

- Prepare for quit day

“Knowing what you know now, what do you think will be most helpful in getting you through your quit day?”

(Remind them about making it hard to get a cigarette; avoiding being around others while they’re smoking; staying focused on your reasons for quitting; asking for support; using the nicotine lozenges.)

- Identify high risk for smoking situation

“When you think about your quit day, what do you think is going to be the most difficult part of the day to get through without smoking? (Problem-solve around that situation.)

- Encourage use of lozenges

“We recommend that when you quit, that you use at least 9 lozenges a day to avoid cravings and withdrawal symptoms such as anxiety, depression, difficulty concentrating, restlessness, hunger, and impatience. It’s especially useful to use the lozenge when you anticipate that you’ll be facing a difficult situation in which you may want to smoke. We don’t recommend using the lozenges while you’re continuing to smoke. Do you have any questions about the lozenge use?” (Answer questions.)

For everyone: “I need to check in about your supply of the nicotine lozenge. How much lozenge do you have left?” (Assess how many bags or sheets they have and whether they need more based on daily use. If not enough, send more and inform participant that you will do this)

- Review what you’ve talked about today and schedule next call and end conversation

“It sounds to me like you’re ready to give this another try. You’ve got solid reasons for quitting, you’re better prepared for your quit day than you were before because you know more; you’ve got support for quitting, and you’ve got the nicotine lozenges to substitute for your cigarettes and to help you with cravings. Do you have any questions or concerns at this point?” (Address them.)

“I’d like to call you again in about 5 days to see how you’re doing and to talk about any problems you may be having. This next call will be our last one. Could we schedule a call for _____ at _____? (If that won’t work, arrange another.)

“I’ve enjoyed talking with you and look forward to talking to you again on _____.”

- Record information on Telephone Counseling Log, send more lozenge if needed.

Abrupt Cessation Telephone Counseling Manual

Session 5 (QD + 12 days)

Before call, look at Adverse Events form to identify any reported symptoms or problems with the lozenges that need follow-up.

- Ask for the participant and introduce yourself

“Hello, may I please speak to _____. Hi, this is _____. I’m calling to see how you’re doing with your smoking. Is this a good time to talk for about 15 minutes?”
(If it’s not, schedule another time.)

- Announce that this is your last call and assess smoking status.

“I just want to remind you that this will be my last conversation with you, but a research assistant will call periodically to ask you some questions about your smoking. As before, I need to get an idea of how you’re doing with quitting. Have you smoked any cigarettes since we last spoke on _____?” (Acknowledge response)

If yes: “How many cigarettes a day are you currently smoking?” (Write this down)

Ask everyone: “How many lozenges a day are you using?” (Write this down)

IF PERSON HAS LAPSED SINCE THE LAST SESSION, skip to Page 23.

IF PERSON HAS RELAPSED (BEEN SMOKING DAILY), skip to Page 25.

IF PERSON IS ABSTINENT, continue here:

- Congratulate them on abstinence and ask how it’s going

“Congratulations, you’re not smoking. That’s terrific. How’s it going? What kinds of difficulties are you having?”

(Acknowledge response; use problem-solving process to help them deal with any difficulty.)

- As time and interest permit, check in with them about the following (if not already discussed above) and use the problem-solving process around any difficulty identified:
 - Others smoking around them
 - Dealing with negative feelings without smoking
 - Cravings for a cigarette
 - Other situations where you used to smoke regularly?
 - Weight concerns
 - Is there anything else that concerns you about your smoking?

- Ask about any high risk for smoking situations coming up in the next couple of weeks

“As you think about the next couple of weeks, can you think of any situations that are likely to put you at risk for smoking?” (Problem-solve the most risky situation mentioned.)

- Comment on use of lozenges and encourage continued use

(If using at least 9 lozenges per day: Reinforce use. If reported problems with lozenge at prior call, ask about past symptoms or problems with lozenge: “Last time we spoke you mentioned _____. Is this still occurring?” If no problems from previous call, ask: “Have you had any problems since I last talked with you that might be due to the use of the lozenge?” Use adverse events sheet to document problems and then problem-solve.)

(If using less than 9/day: Ask why they’re using fewer than 9/day. If reported problems with lozenge at prior call, ask about past symptoms or problems with lozenge: “Last time we spoke you mentioned _____. Is this still occurring?” If no problems from previous call, ask: “Have you had any problems since I last talked with you that might be due to the use of the lozenge?” Use adverse events sheet to document problems and then problem-solve. Correct any misconceptions and encourage use, especially ahead of time when they know they will be facing a difficult situation. Remind them that the lozenges help decrease withdrawal symptoms such as anxiety, depression, difficulty concentrating, restlessness, hunger and impatience, as well as cravings to smoke.)

For everyone: “I’d like to encourage you to continue to use the lozenges for at least 6 weeks after your quit date. After 6 weeks, you can either stop using them completely or you can slowly decrease your use, whichever you prefer. Very few smokers get withdrawal symptoms from stopping the lozenges after 6 weeks, so that shouldn’t be a problem for you. However, we can provide lozenges to you for up to 12 weeks after your quit date provided that you aren’t smoking. Do you have any questions about that?” (Address questions.)

- Anticipate the risk of slips

“I want to mention to you some thoughts that people who have quit smoking sometimes have that can set the stage for going back to smoking. I mention them to you because I want you to be prepared for them if they occur to you. Sometimes a person who has quit smoking gets curious about what it would be like to smoke a cigarette or what a cigarette would taste like. Or sometimes a person deludes him/herself into believing that he/she can have a cigarette and easily stop with just one. The point I want to make is that because you’ve been a smoker in the past, your brain is now sensitized to nicotine, and if your brain gets a quick hit of nicotine (faster than the lozenge supplies), there’s a very good chance that it will want more. So, having just one cigarette is like playing with fire. Most people who smoke after quitting, get hooked back in and relapse. So, I strongly encourage you to recognize those thoughts that might tempt you to have a drag off a cigarette and resist them because they are very dangerous. Does that make sense to you?”

- Ask about their reasons for quitting

“How are you feeling about your reasons for quitting? Remind me what your reasons are.”
(Reinforce them.)

- Review what you’ve talked about and end your calls

“You’re doing a great job not smoking. You’ve already gone ____ days, which is excellent. You continue to have strong reasons for staying quit, you’ve got ways to deal with difficult situations that may come up, and you know what kinds of thoughts can put people at risk for going back to smoking. Do you have any questions or concerns at this point?” (Address them.)

“I’ve really enjoyed talking with you over the past few weeks. This is my last call to you, so I want to wish you much success in your efforts. I really believe you can do it. I also want to mention that someone else from our program will be calling you in a couple of days to ask you some questions about your smoking and to see if you need more nicotine lozenges. You’re still in our study, so we’d appreciate it if you’d continue to answer questions about your smoking periodically. You will be compensated \$15 for each of those follow-up calls. It’s been good talking with you and I wish you success.”

- Record information on Telephone Counseling Log.

IF PERSON HAS LAPSED SINCE THE LAST SESSION

- Acknowledge smoking situation and ask what happened

“So it sounds like you’re doing well on most days, but you’ve also smoked. What’s going on?”
(Ask about the specific situation in which they smoked, where were they, what motivated the lapse, what were they thinking or feeling, how did they get the cigarette, what did they try to do to avoid smoking?)

- Ask how they’re feeling about the situation and emphasize the value of the experience

“How are you feeling about your smoking situation right now?”
(Acknowledge response. If they sound discouraged, mention the tendency to want to give up when you have a slip. The best way to renew your motivation is to remind yourself why you wanted to quit in the first place. Ask if those reasons have changed. Reinforce them.)

“You’re at a very important point in your quitting process because you’re generally doing well, but you’re putting yourself at great risk by occasionally smoking. The reason that is so risky is because, as an ex-smoker, your brain is now sensitized to nicotine, so if your brain gets a quick hit of nicotine (faster than the lozenge supplies), there’s a very good chance that it will want more. Having just one cigarette or even just one puff, is like playing with fire. Most people who smoke after quitting get hooked back in and relapse. So, I strongly encourage you to think about

your reasons for quitting when you have thoughts that tempt you to take a puff. Does that make sense to you?” (Reinforce them.)

- Problem-solve what they could have done differently to resist smoking in slip situation

“Let’s think about ways you could have resisted smoking in the situation in which you smoked. What kinds of things could you have done differently to have avoided smoking?” (Reinforce these and add others as needed.)

- As time and interest permit, check in with them about the following (if not already discussed above) and use the problem-solving process around any difficulty identified:

- Others smoking around them
- Dealing with negative feelings without smoking
- Cravings for a cigarette
- Other situations where you used to smoke regularly?
- Weight concerns
- Is there anything else that concerns you about quitting?

- Ask about any high risk for smoking situations coming up in the next couple of weeks

“As you think about the next couple of weeks, can you think of any situations that are likely to put you at risk for smoking?” (Problem-solve the most risky situation mentioned.)

- Comment on use of lozenges and encourage continued use

(If using at least 9 lozenges per day: Reinforce use. If reported problems with lozenge at prior call, ask about past symptoms or problems with lozenge: “Last time we spoke you mentioned _____. Is this still occurring?” If no problems from previous call, ask: “Have you had any problems since I last talked with you that might be due to the use of the lozenge?” Use adverse events sheet to document problems and then problem-solve.)

(If using less than 9/day: Ask why they’re using fewer than 9/day. If reported problems with lozenge at prior call, ask about past symptoms or problems with lozenge: “Last time we spoke you mentioned _____. Is this still occurring?” If no problems from previous call, ask: “Have you had any problems since I last talked with you that might be due to the use of the lozenge?” Use adverse events sheet to document problems and then problem-solve. Correct any misconceptions and encourage use, especially ahead of time when they know they will be facing a difficult situation. Remind them that the lozenges help decrease withdrawal symptoms such as anxiety, depression, difficulty concentrating, restlessness, hunger and impatience, as well as cravings to smoke.)

For everyone: “I’d like to encourage you to continue to use the lozenges for at least 6 weeks after your quit date. After 6 weeks, you can either stop using them completely or you can slowly decrease your use, whichever you prefer. Very few smokers get withdrawal symptoms from

stopping the lozenges after 6 weeks, so that shouldn't be a problem for you. However, we can provide lozenges to you for up to 12 weeks after your quit date providing you aren't smoking. Do you have any questions about that?" (Address questions.)

- Review what you've talked about and end your calls

"You're doing well with your smoking and are almost completely quit. You continue to have strong reasons for quitting, you've got ways to deal with difficult situations that may come up, and you know that slips can put you at risk for going back to smoking. Do you have any questions or concerns at this point?" (Address them.)

"I've really enjoyed talking with you over the past few weeks. This is my last call to you, so I want to wish you much success in your efforts. I really believe you can do it. I also want to mention that someone else from our program will be calling you in a couple of days to ask you some questions about your smoking and to see if you need more nicotine lozenges. You're still in our study, so we'd appreciate it if you'd continue to answer questions about your smoking periodically. You will be compensated \$15 for each of those follow-up calls. It's been good talking with you and I wish you success."

- Record information on Telephone Counseling Log.

IF PERSON HAS RELAPSED (BEEN SMOKING DAILY)

- Acknowledge smoking situation and ask what happened

"So it sounds like you've been smoking. Can you tell me what's going on?"

- Ask how they're feeling about the situation and emphasize the value of the experience

"How are you feeling about your smoking situation?"

(Acknowledge response. If they sound discouraged, mention the tendency to want to give up. The best way to renew your motivation is to remind yourself why you wanted to quit in the first place. Ask if those reasons have changed. Reinforce them.)

"The thing we know about quitting smoking is that people often try multiple times before they're successful. Each time you make an attempt is like a practice session, and you get a better idea of what it's going to take to be successful. You have the nicotine lozenges to help with that; however, I just want to let you know that we can continue to supply them only if you quit smoking completely. The best strategy still remains getting focused on setting a new quit date. I'm wondering if you're up for doing that?"

(Acknowledge response. If they don't want to set a new quit date now, acknowledge that and go to "end conversation". If they do want to set a new quit date, reinforce that and continue below.)

- Set a new quit day

“It’s usually a good idea to set a quit day fairly soon while your interest is still high. Could you pick a day in the next few days as your quit day?”

(Praise them for their commitment to a quit date; tell them you’re going to write that date down and encourage them to do the same.)

- Prepare for quit day

“Knowing what you know now, what do you think will be most helpful in getting you through your quit day?”

(Remind them about making it hard to get a cigarette; avoiding being around others while they’re smoking; staying focused on your reasons for quitting; asking for support; using the nicotine lozenges.)

- Ask about problems with lozenges

If reported problems with lozenge at prior call, ask about past symptoms or problems with lozenge: “Last time we spoke you mentioned _____. Is this still occurring?” If no problems from previous call, ask: “Have you had any problems since I last talked with you that might be due to the use of the lozenge?” Use adverse events sheet to document problems and then problem-solve.)

- Identify high risk for smoking situation

“When you think about your quit day, what do you think is going to be the most difficult part of the day to get through without smoking? (Problem-solve around that situation.)

- Review what you’ve talked about today

“It sounds to me like you’re ready to give this another try, and that’s excellent. You’ve got solid reasons for quitting, you’re better prepared for your quit day than you were before because you know more; and you’ve got support for quitting. We can continue to provide you with nicotine lozenges to substitute for your cigarettes and to help you with cravings provided that you are not smoking. Do you have any questions or concerns at this point?” (Address them.)

- End conversation

“I want you to know that I’ve really enjoyed talking with you over the past few weeks. This is my last call to you, so I want to wish you much success in your efforts. I also want to mention that someone else from our program will be calling you in a couple of days to ask you some questions about your smoking and to see if you are eligible for more nicotine lozenges. You’re still in our study, so we’d appreciate it if you’d continue to answer questions about your smoking periodically. You will be compensated \$15 for each of those follow-up calls. It’s been good talking with you and I wish you success.”

- Record information on Telephone Counseling Log.