

Gradual Cessation Telephone Counseling Manual

Session 1 (day 0)

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

- **Begin call**

“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 by first cutting down. That means I’ll be asking you to decrease your smoking gradually 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 reduce and to 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.)

- **Gather info on prior quitting and plans to quit**

“Before I begin, I’d like to ask some questions about your smoking. Have you tried to quit before? Have you ever tried to quit by cutting down first?”

(If yes) “When you last tried to quit by cutting down first, how did you decide which cigarettes not to smoke? How did this go?”

“Have you ever used any treatments like medications or counseling to help you quit? Was this helpful?”

“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.)

- **Gather info on normal smoking**

“Now I’d like to get an idea of how much you smoke each day by asking you about your smoking on each day in the past week.”

Do TLFB for CPD for last 7 days and quickly estimate mean CPD. Record this as baseline CPD on counselor log.

“Now I have some questions to help me understand your smoking situation. Do you work or go to school? Can you smoke at work or school? Can you smoke in your household?”

- **Setting of Quit Date**

“I’d like to discuss setting a quit date. We will be asking you to reduce your smoking prior to quitting and we have found it best to have smokers cut down over a 3 week period. We recommend to cut down by 25% by the end of the first week, then by 50% by the end of the second week and then by 75% by the end of the third week. Your quit date should be at least 3 weeks from now to allow time for you to cut down, but not longer than 5 weeks from now so your motivation to quit is still strong. What would you like to pick as your quit date?”

“OK, so _____ (day of week) _____ (date) will be your quit day. 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.”

“Now that you have a quit date, we need to decide three things: 1) your goal for cutting down for the first week, 2) which method to use to cut down and 3) how to use the nicotine lozenges to help you cut down.”

- **Setting of goal for first week**

(Determine what 25% reduction from baseline CPD is.)

“25% of your current average cigarettes per day is _____, so for this week we recommend you try to reduce from _____ to _____ cigs/day by the end of next week. Does this sound like a good goal for you or do you want to make a different goal?” (Negotiate goal and record on counselor log.)

- **Summarize methods of reduction**

“Okay, now I’d like to describe some different methods to help you cut down. We have found three methods to cut down work and they are all equally effective. You might want to write down these three methods: Timed Reduction, Selective Reduction-Easiest First and Selective Reduction – Hardest First.”

“With the timed reduction method you would gradually increase the time between cigarettes. I would help you figure out the amount of time you should wait between cigarettes so that you can make your goal for the first week. I realize that no one really smokes on a clock, but by setting a minimum time between cigarettes and gradually increasing it, you will smoke less. Some people like this strategy because it takes any decision-making out of their hands. But

it does mean that you cannot have two cigarettes in a row, or close together. Any questions about this method?"

"With the second method, Selective Reduction-Easiest First, you eliminate the cigarettes that you think are easiest for you to give up. I would help you choose the ___ cigarettes of each day that are easiest to give up. This method is good for people who have specific times and situations in which they smoke. But you do have to remember which cigarettes not to smoke. Any questions about this method?"

"The third method, Selective Reduction- Hardest First, is the same but you decide to forego the hardest to give up cigarettes first. Some smokers like this one because they believe they might as well do the hard part first when they are very motivated and then reducing will get easier over time. On the other hand, some smokers like to get some successes first before tackling the harder cigarettes to give up. Any questions about this method?"

"With all these methods you will be using nicotine lozenge to help out. But before we talk about the lozenge, I'd like you to choose a method to reduce. Do you have any questions before you choose one of these methods to reduce? So which method do you want to use?" (record choice on counselor log)

IF CHOSE SELECTIVE REDUCTION- EASIEST OR HARDEST FIRST, skip to page 4.

IF CHOSE TIMED REDUCTION, continue here:

"Okay, to figure out what your minimum time between cigarettes should be, I need to know what time you usually have your first cigarette of the day and what time you have your last cigarette of the day. Please wait just a minute while I do a calculation."
(Calculate the total hours between first and last cigarette and round off to nearest 30 min. Then use Timed Reduction Table to determine the minimum time between cigs to reach reduction goal).

"To cut down to ___ cigs/day, you would need to wait at least _____hrs/min between cigs. So you are not trying to smoke at specific times of the day, but rather you are trying to wait at least _____ hrs/min between cigs."

"If you smoke sooner than _____hrs/min after your last cigarette, don't worry about it, just try to wait another _____hrs/min before your next cigarette. When you have problems waiting that amount of time, we recommend you use the nicotine lozenge which we will discuss later. We recommend you use at least _____ lozenges each day. The main thing is to make your goal of smoking ___ cigs/day and this is just one way to do it, so you should focus more on making the goal than on doing this method exactly right. Do you have any questions about how you'll use this method?"

Go to next page- "review use of lozenge"

IF CHOSE SELECTIVE REDUCTION-EASIEST FIRST

“Okay, so with this method we need to choose the easiest cigs to eliminate and substitute lozenge for these missed cigs. So that I can better understand your smoking, let’s go thru a normal weekday and track your smoking. Based on what you’ve told me (from TLFB) it looks like you typically smoke about _____ cigarettes on a weekday.”

Use Selective Reduction Daily Smoking Table and fill in number of cigarettes typically smoked during each time block as below

“Now I’m going to ask you about how much you smoke during different times of the day. What time do you get up in the morning? Okay, from the time you get up until _____(end of time block that includes waking time), how many cigarettes do you usually smoke?”
(Proceed through each time block and record typical number of cigarettes smoked in each.)

“So with this method you’ll need to select ____ cigs that you think would be easy to give up. So which ____cigs would you like to choose to give up first? Good, so you will not smoke (summarize cigs chosen to forego) and as we will discuss next, substitute at least ____ lozenges for these. So to review your typical day, (review each time block and how many cigs and lozenges will now be used in each).”

Go to “review use of lozenge” below.

IF CHOSE SELECTIVE REDUCTION-HARDEST FIRST

“Okay, so with this method we need to choose the hardest cigs to eliminate and substitute lozenge for these missed cigs. So that I can better understand your smoking, let’s go thru a normal weekday and track your smoking. Based on what you’ve told me (from TLFB) it looks like you typically smoke about _____ cigarettes on a weekday.”

Use Selective Reduction Daily Smoking Table and fill in number of cigarettes typically smoked during each time block as below

“Now I’m going to ask you about how much you smoke during different times of the day. What time do you get up in the morning? Okay, from the time you get up until _____(end of time block that includes waking time), how many cigarettes do you usually smoke?”
(Proceed through each time block and record typical number of cigarettes smoked in each.)

“So with this method you’ll need to select ____ cigs that you think would be the hardest to give up. Which ____cigs would you like to choose to give up first? Good, so you will not smoke (summarize cigs chosen to forego) and as we will discuss next, substitute at least ____ lozenges for these. So to review your typical day, (review each time block and how many cigs and lozenges will now be used in each).”

- **Review use of lozenge**

“Next I’d like to explain how to use the lozenge. The nicotine lozenge is a round tablet that you hold in your mouth as it slowly releases nicotine. It is currently available over the counter

for stopping smoking. You'll place the lozenge in your mouth and let it dissolve without chewing or swallowing it. It can take 20-30 minutes to dissolve completely. 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. You'll want to move the lozenge around in your mouth periodically."

"You may have heard that using a nicotine medication and smoking at the same time is dangerous. However, many scientific studies have tested this out and found out that you can use nicotine medications and smoke on the same day with very little risk of harm. Do you have any concerns about this?"

"The most common side-effects of the lozenge are sore throat and upset stomach; however it's rare when smokers can't take the lozenge due to side-effects. 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."

If has used med in past: "You told me earlier that you used ____ in one of your prior quit attempts. Nicotine lozenge is like this product(s) in that it _____ but is different in that _____."

<u>Product</u>	<u>Like lozenge</u>	<u>Lozenge differs</u>
Gum	Use as needed	Don't have to chew, less obvious to others, more socially acceptable, better taste
Inhaler	Use as needed	Less like smoking, less obvious to others, more socially acceptable
Patch	Has nicotine in it	Can use as needed for craving and tough situations
Zyban	Used to help smokers stop	Can use as needed for craving and tough situations

For all: "Based on our prior research, we recommend that for the next week you use at least ____ lozenges/day. We also recommend you use the lozenge whenever you have a craving or a withdrawal symptom such as mood problems, irritability, difficulty concentrating, insomnia or hunger or even if you just need some help to get through a period without smoking. The major mistake most smokers make is not using enough nicotine medication, so feel free to use more than the ____ lozenges if you think it will help. Do you have any questions about the lozenge or how we are asking you to use it?"

"We will be sending you lozenge today, so you will not get them for 2-4 days. You'll be receiving a supply of 72 _____ mg lozenges. We recommend you start trying to reduce now but if you want to wait till you get the lozenge that's fine. The rest of the information on using the lozenge to reduce will be in writing when you receive the lozenge and this will include a toll free number to call if you have any problems."

- **Closing**

“To summarize, you have set a quit date for _____ and your goal is to get down to - ___ cigs/day by this time next week. To do this you will use the _____ method and you will use at least _____ lozenges/day.”

“To finish, I want to remind you of why gradually reducing is a good way to quit smoking. First, many smokers find it easier to start with smaller goals and then progress to the large goal of quitting. Second, by reducing first, you should build up some successes and learn things that will help you when you do quit. Does this make sense to you?”

“Third, by reducing you begin to practice going for periods without smoking even when you are in situations in which you would normally smoke. This should teach your body to have less cravings when you are in that situation after you stop smoking. Fourth, by reducing you will be less addicted to nicotine when you do quit and this will help you quit.”

“Finally, by following the reduction plan as best you can you will help us find out whether for, some people, gradual cessation really is better than stopping abruptly. Do you have any questions at this point?”

“I will call you in one week to see how you are coming along with your reduction. Could we schedule a call for _____ at _____?”
(if that won't work, arrange another)

- Complete counseling log
- Email Joanne and Amy with participant ID#, QD, date to send QD -7 day mailing (should be the business day before QD -7), study group and lozenge dose.
- Send first batch of lozenges (1 bag of 72 with cover letter, green instructions and white half-sheet with refill instructions). Record on lozenge tracking form.

Gradual Cessation Telephone Counseling Manual Session 2 (7 days)

Be sure you know baseline CPD, reduction goal in CPD, gradual reduction method chosen and number of lozenges/day recommended before calling.

- **Begin call**

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

- **Do TLFB for CPD and lozenges per day for every empty day on calendar since last call**

“The first thing I need to do is get a clear idea of the number of cigarettes you’ve smoked and lozenges you’ve used each day since we last spoke.”
(Quickly estimate average CPD and lozenge and categorize into one of the following 4 groups)

IF THE PERSON DID NOT CUT DOWN AT ALL, skip to page 8.

IF THE PERSON CUT DOWN SOME, BUT DID NOT REACH THEIR GOAL, skip to page 9.

IF THE PERSON ALREADY QUIT, skip to page 10.

IF THE PERSON MET OR EXCEEDED THEIR REDUCTION GOAL, continue here:

“I see that you have made (or exceeded) your goal of _____ cigs/day. That’s great! Did you use the _____ method of reducing? Was it helpful? (if yes) How so? Did you have any problems in reaching your goal?”

“I see that you used about _____ lozenges/day.”

(If \geq recommended amount) “That’s great.”

(If $<$ recommended amount) “Why did you use less than the recommended _____ lozenges/day?” (encourage to use more)

“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)

- **Set goal for next week**

(determine what 50% of baseline CPD is)

“We need to think of a goal for next week. To stay on track with our recommendations, you would need to reduce to _____ cigs/day by the end of next week. Is that a reasonable goal

or do you think there should be another goal for next week?" (negotiate goal and record on counselor log)

"OK, this would mean that, for the next week, you reduce to _____cigs/day. Do you want to stick with your current method of reduction, _____?"

(If yes: Review reduction method and re-set parameters using smoking table or timed reduction chart)

(If no: Go back to session 1 page 2 and describe other methods and set parameters accordingly)

If goal is to quit next week, go to page 11.

"Also, be sure to use at least _____ lozenges/day."

- **End call**

"Do you have any questions at this point? Let's set up a call one week from now to see how you are coming along with your reduction. Is this a good time or is there a better time? Okay, so I'll call you on _____ at _____."

(record information on counselor log)

IF PERSON DID NOT CUT DOWN AT ALL:

"I see you have not cut down. Did you try to cut down?"

(If yes) "Did you try to use the _____ method? Why do you think that didn't work? What do you think you could do to help it work better for you?"

(If no) "Why didn't you try to cut down?"

"I see that you used about _____ lozenges/day."

(If \geq recommended amount) "That's great"

(If $<$ recommended amount) "Why did you use less than the recommended _____ lozenges/day?" (encourage to use more)

"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)

- **Set goal for next week**

"We need to think of a goal for next week. What do you think should be your goal to achieve by the end of the next week?" (negotiate goal and record on counselor log)

"OK, this would mean that, by the end of next week, you reduce to _____cigs/day. Do you want to stick with the current _____ method of reducing?"

(If yes: Review reduction method and re-set parameters using smoking table or timed reduction chart)

(If no: Go back to session 1 page 2 and describe other methods and set parameters accordingly)

If goal is to quit next week, go to page 11.

“Also, be sure to use at least _____ lozenges/day.”

- **End call**

“Do you have any questions at this point? Let’s set up a call one week from now to see how you are coming along with your reduction. Is this a good time or is there a better time? Okay, so I’ll call you at _____ on _____.”

(record information on counselor log)

IF THE PERSON CUT DOWN SOME, BUT DID NOT REACH THEIR GOAL

“I see you have cut down some and that’s great, but I also see you did not make your goal. Did you use the _____ method of reducing? What seemed to be most helpful in cutting down? What kind of problems did you have in reaching your goal?”

“I see that you used about _____ lozenges/day.”

(If \geq recommended amount) “That’s great”

(If $<$ recommended amount) “Why did you use less than the recommended _____ lozenges/day?” (encourage to use more)

“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)

- **Set goal for next week**

“We need to think of a goal for next week. What do you think should be your goal to achieve by the end of the next week?” (negotiate goal and record on counselor log)

“OK, this would mean that, by the end of next week, you reduce to _____ cigs/day. Do you want to stick with the current _____ method of reducing?”

(If yes: Review reduction method and re-set parameters using smoking table or timed reduction chart)

(If no: Go back to session 1 page 2 and describe other methods and set parameters accordingly)

If goal is to quit next week, go to page 11.

“Also, be sure to use at least _____ lozenges/day.”

- **End call**

“Do you have any questions at this point? Let’s set up a call one week from now to see how you are coming along with your reduction. Is this a good time or is there a better time? Okay, so I’ll call you at _____ on _____.”

(record information on counselor log)

IF THE PERSON ALREADY QUIT:

“It appears you have already quit. That’s great!

“What made you decide to go ahead and quit rather than waiting and doing it more slowly?”

“I see that you used about _____ lozenges/day.”

(If \geq recommended amount) “That’s great”

(If $<$ recommended amount) “Why did you use less than the recommended _____ lozenges/day?” (encourage to use more)

“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)

“Since you’ve already quit, I’d like to go over the use of the nicotine lozenges to quit rather than reduce. How much lozenge do you have left?” (Assess how many bags or sheets they have)

“We will be sending you a new shipment of lozenge with new instructions, but it will take 2-4 days for these to get to you. In the package we will be sending, there will also be a booklet with some tips on quitting.”

“Once you receive the new instructions in the package we’ll be sending, you should throw away your old instructions for using the lozenge to reduce and read the new instructions for using the lozenge to quit. Now that you’ve quit, you should be substituting a nicotine lozenge every one to two hours. You should use the lozenge whenever you have a craving or a withdrawal symptom such as mood changes, irritability, difficulty concentrating, hunger or insomnia. We recommend you use it for 12 wks after your quit date. Most smokers do not use enough lozenge each day and do not use it for long enough. We recommend that you use at least 9 lozenges a day, but you can use up to 20.”

“Now that you’ve quit it’s important that you not use any other nicotine products, like cigarettes, while you are using the lozenges. 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 information sheet we will send with the lozenges. Do you have any questions about the use of the lozenges?”

- **End call**

“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. Since you quit early, this next call will be our last one. Could we schedule a call for _____ at _____?”

(If that won't work, arrange another.)

(Record information on counselor log, noting that the **next call will skip to session 5**. Send 2 boxes of lozenges with pink instructions sheet, Clearing the Air. Let study coordinator know about change of QD.)

IF PERSON WANTS TO QUIT NEXT WEEK:

"That's great you want to quit. We recommend you continue to reduce as much as possible before you quit. After you quit you will be using more lozenge than now. So that we can get more lozenges to you for quitting and a booklet on quitting tips, it would be best to set a quit day for sometime after 7 days from now but if you want to quit before then, that's okay. What do you think would be a good quit date for you? OK, so _____ will be your new quit day." (Write QD in TLFB).

IF QUIT DATE IS \geq 3 DAYS FROM NOW:

"I'd like to call you again 3 days before your quit date so I can help you prepare for quitting and teach you how to use the lozenge for quitting. I will be sending you a new shipment of nicotine lozenges that will have new instructions for how to use the lozenge for quitting rather than reducing plus a questionnaire to complete and send back in a stamped envelope. This is important information for us, so we would appreciate it if you can return the questionnaire as soon as possible. We will compensate you for completing and returning the questionnaire."

"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. Do you have any questions about this?"

- **End call**

"I'd like to set up another call for 3 days before your quit date. Can I call you on _____ at _____?"

(If that won't work, arrange another.)

(Record information on counselor log, noting that the **next call will skip to session 4**. Send 2 boxes of lozenges with pink instructions sheet, Clearing the Air, Mediator survey with return envelope. Let study coordinator know of change in QD so that breath sample can be collected.)

IF QUIT DATE IS \leq 3 DAYS FROM NOW:

“Since your quit date will be soon, I need to go over a few things to help you prepare to quit. Our rationale for having you cut down gradually prior to your quit date was based on several things. For one, smoking less cigarettes each day should reduce your addiction to cigarettes. Do you feel less addicted to cigarettes?”

“Secondly, as smokers cut down, they usually gain a sense of control over their smoking habit. Do you feel more in control of your smoking? (if yes) What makes you feel that way?”

“Cutting down should also increase confidence in quitting. Do you feel more confident in quitting? (if yes) Why? Finally, with cutting down most smokers find they can be in situations that they would normally smoke in without smoking. Has that happened for you?”

“Now I’d like to go over the use of the nicotine lozenges to quit rather than reduce. How much lozenge do you have left? (Assess how many bags or sheets they have) We will be sending you a new shipment of lozenge with new instructions, but it will take 2-4 days for these to get to you. In the package we will be sending, there will also be a booklet with some tips on quitting.”

“In the past week you have been smoking and using lozenges on the same day, but as of your quit date, we recommend you completely stop smoking altogether, no matter whether you reached your reduction goal or not. Once you receive the new instructions in the package we’ll be sending, you should throw away your old instructions for using the lozenge to reduce and read the new instructions for using the lozenge to quit.”

“Once you quit, you should be using a nicotine lozenge every one to two hours. You should use the lozenge whenever you have a craving or a withdrawal symptom such as mood changes, irritability, difficulty concentrating, hunger or insomnia. We recommend you use it for 12 wks after your quit date. Most smokers do not use enough lozenge each day and do not use it for long enough. We recommend that you use at least 9 lozenges a day, but you can use up to 20.”

“Once you quit it’s important that you not use any other nicotine products, like cigarettes, while you are using the lozenges. 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 information sheet we will send with the lozenges. Do you have any questions about the use of the lozenges?”

“Now I would like to spend some time thinking about how you can get through the first few days of not smoking at all. What plans or strategies do you have for this time? (Reinforce whatever they bring up). What have you learned during reduction that you think might be helpful for quitting altogether?” (reinforce anything they say-Do not suggest specific techniques)

- **End call**

“I’d like to set up another call for 2 days after your quit date. Since you’ve decided to quit early the next call will be my last to you. Can I call you on _____ at _____?”

(If that won’t work, arrange another.)

(Record information on counselor log, noting that the **next call will skip to session 5**. Send 2 boxes of lozenges with pink instructions sheet, Clearing the Air. Let study coordinator know about change of QD.)

Gradual Cessation Telephone Counseling Manual Session 3 (14 days)

Be sure you know baseline CPD, reduction goal in CPD, gradual reduction method chosen and number of lozenges/day recommended before calling. Also, look at Adverse Events form to identify any reported symptoms or problems with the lozenges that need follow-up.

- **Begin call**

“Hello, may I please speak to _____. Hi, this is _____. I’m with the Nicotine Lozenge Study and am calling to check in with you to see how you’re doing with cutting down on your smoking. Is this a good time to talk for about 15 minutes?”
(If it’s not, schedule another time.)

- **Do TLFB for CPD and lozenges per day for every empty day on calendar since last call**

“The first thing I need to do is get a clear idea of the number of cigarettes you’ve smoked and lozenges you’ve used each day since we last spoke.”
(Quickly estimate average CPD and lozenge and categorize into one of the following 4 groups)

IF THE PERSON DID NOT CUT DOWN AT ALL, skip to page 15.

IF THE PERSON CUT DOWN SOME, BUT DID NOT REACH THEIR GOAL, skip to page 15.

IF THE PERSON ALREADY QUIT, skip to page 15.

IF THE PERSON MET OR EXCEEDED THEIR REDUCTION GOAL, continue here:

“I see that you have made (or exceeded) your goal of _____ cigs/day. That’s great! Did you use the _____ method of reducing? Was it helpful? (if yes) How so? Did you have any problems in reaching your goal?”

“I see that you used about _____ lozenges/day.”

(If \geq recommended amount) “That’s great.”

(If $<$ recommended amount) “Why did you use less than the recommended _____ lozenges/day?” (encourage to use more)

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?”

“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)

Go to page 17- “GOALS FOR TIME UNTIL QUIT DATE”

IF PERSON DID NOT CUT DOWN AT ALL:

“I see you have not cut down. Did you try to cut down?”

(If yes) “Did you try to use the _____ method? Why do you think that didn't work? What do you think you could do to help it work better for you?”

(If no) “Why didn't you try to cut down?”

“I see that you used about _____ lozenges/day.”

(If \geq recommended amount) “That's great”

(If $<$ recommended amount) “Why did you use less than the recommended _____ lozenges/day?” (encourage to use more)

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?”

“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)

Go to page 17- “GOALS FOR TIME UNTIL QUIT DATE”

IF THE PERSON CUT DOWN SOME, BUT DID NOT REACH THEIR GOAL

“I see you have cut down some and that's great, but I also see you did not make your goal. Did you use the _____ method of reducing? What seemed to be most helpful in cutting down? What kind of problems did you have in reaching your goal?”

“I see that you used about _____ lozenges/day.”

(If \geq recommended amount) “That's great”

(If $<$ recommended amount) “Why did you use less than the recommended _____ lozenges/day?” (encourage to use more)

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?”

“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)

Go to page 17- “GOALS FOR TIME UNTIL QUIT DATE”

IF THE PERSON ALREADY QUIT:

“It appears you have already quit. That's great!”

“What made you decide to go ahead and quit rather than waiting and doing it more slowly?”

“I see that you used about _____ lozenges/day.”

(If \geq recommended amount) “That’s great”

(If $<$ recommended amount) “Why did you use less than the recommended _____ lozenges/day?” (encourage to use more)

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?”

“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)

- **Review rationale for reducing before quitting**

“Our rationale for having you cut down gradually prior to your quit date was based on several things. For one, smoking less cigarettes each day probably cuts your dependence on them. **(if person has reduced)** Do you feel less addicted to cigarettes?”

“Secondly, we believe that as smokers cut down, they gain a sense of control over their smoking habit. Do you feel more in control of your smoking or more confident than you did a month ago? What makes you feel that way?”

“Finally, we believe it is better to take small steps and succeed rather than a large step and fail. Did you feel a strong momentum, as you got ready to quit?”

- **Discuss using lozenges to quit**

“Since you’ve already quit, I’d like to go over the use of the nicotine lozenges to quit rather than reduce. How much lozenge do you have left?” (Assess how many bags or sheets they have)

“We will be sending you a new shipment of lozenge with new instructions, but it will take 2-4 days for these to get to you. In the package we will be sending, there will also be a booklet with some tips on quitting.”

“Once you receive the new instructions in the package we’ll be sending, you should throw away your old instructions for using the lozenge to reduce and read the new instructions for using the lozenge to quit. Now that you’ve quit, you should be substituting a nicotine lozenge every one to two hours. You should use the lozenge whenever you have a craving or a withdrawal symptom such as mood changes, irritability, difficulty concentrating, hunger or insomnia. We recommend you use it for 12 wks after your quit date. Most smokers do not use enough lozenge each day and do not use it for long enough. We recommend that you use at least 9 lozenges a day, but you can use up to 20.”

“Now that you’ve quit it’s important that you not use any other nicotine products, like cigarettes, while you are using the lozenges. 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 information sheet we will send with the lozenges. Do you have any questions about the use of the lozenges?"

- **End call**

"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. Since you quit early, this next call will be our last one. Could we schedule a call for _____ at _____?"

(If that won't work, arrange another.)

(Record information on counselor log, noting that the **next call will skip to session 5**. Send 2 boxes of lozenges with pink instructions sheet, Clearing the Air. Let study coordinator know about change of QD.)

GOALS FOR TIME UNTIL QUIT DATE

- **Review quit date and discuss mailing**

"You have chosen _____ as your quit date. We recommend you continue to reduce as much as possible before you quit. Our next call will occur 3 days prior to your quit date so we can talk about preparing for your quit date."

"Prior to your quit date we will be sending you a booklet with some helpful tips on quitting and a new shipment of nicotine lozenge to use for quitting with new instructions. When your quit date comes, you should throw away your old instructions and use only these new ones. As we will discuss later, using the lozenges for quitting is somewhat different than using them for reducing. Finally, in the package we will be sending there will also be a questionnaire to complete and send back in the stamped envelope. We would appreciate it if you could complete this questionnaire and mail it back to us as soon as possible. Do you have any questions about this?"

"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. Do you have any questions about this?"

- **Setting goal**

(determine what 75% of baseline CPD is)

"So now we need to think of a goal for the time between now and your quit date. We recommend that you reduce a total of 75%, or get down to 25% of your previous number of

cigarettes, before you quit; so for you that would be to _____ cigs/day. Does that seem reasonable to you? **(if not)** What do you think should be your goal to reduce to before you try to quit?" (negotiate goal and record on counselor log)

"OK, this would mean that, by the end of next week, you reduce to _____ cigs/day. Do you want to stick with the current _____ method of reducing?"

(If yes: Review reduction method and re-set parameters using smoking table or timed reduction chart)

(If no: Go back to session 1 page 2 and describe other methods and set parameters accordingly)

If goal is to quit early, skip to "If person wants to quit early" on this page.

- **NRT Needs**

"Finally, 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. Send more if needed, and inform participant that you will do so.)

- **Summarize and end call**

"So let's review. Your QD is set at _____ and between now and then you plan reduce from _____ to _____ cigarettes each day and you will be using the _____ method plus _____ lozenges/day."

"I'd like to call you again three days before your quit date to help prepare you for that day. Could we schedule a call for _____ at _____?"
(If that won't work, arrange another.)

(record information on counselor log)

If QD >10 days from now, send out more lozenge to use while reducing, if needed, and make a note of when to send lozenge to quit, Clearing the Air and mediator survey (at QD -7 days).

If QD <10 days from now, send out lozenge to use for quitting with pink instructions sheet, Clearing the Air, and mediator survey with return envelope now.

IF PERSON WANTS TO QUIT EARLY:

"That's great you want to quit. We recommend you continue to reduce as much as possible before you quit. After you quit you will be using more lozenge than now. So that we can get more lozenges to you for quitting and a booklet on quitting tips, it would be best to set a quit day for sometime after 7 days from now but if you want to quit before then, that's okay. What do you think would be a good quit date for you? OK, so _____ will be your new quit day." (Do not change QD TLFB, make note of it only in counselor notes).

IF QUIT DATE IS \geq 3 DAYS FROM NOW:

“I’d like to call you again 3 days before your quit date so I can help you prepare for quitting and teach you how to use the lozenge for quitting. I will be sending you a new shipment of nicotine lozenges that will have new instructions for how to use the lozenge for quitting rather than reducing plus a questionnaire to complete and send back in a stamped envelope. This is important information for us, so we would appreciate it if you can return the questionnaire as soon as possible. We will compensate you for completing and returning the questionnaire.”

If new QD is at least 7 days from now: “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. Do you have any questions about this?”

- **End call**

“I’d like to set up another call for 3 days before your quit date. Can I call you on _____ at _____?”

(If that won’t work, arrange another.)

(Record information on counselor log, send 2 boxes of lozenges with pink instructions sheet, Clearing the Air, Mediator survey with return envelope. Let study coordinator know of change in QD so that breath sample can be collected.)

IF QUIT DATE IS \leq 3 DAYS FROM NOW:

“Since your quit date will be soon, I need to go over a few things to help you prepare to quit. Our rationale for having you cut down gradually prior to your quit date was based on several things. For one, smoking less cigarettes each day should reduce your addiction to cigarettes. Do you feel less addicted to cigarettes?”

“Secondly, as smokers cut down, they usually gain a sense of control over their smoking habit. Do you feel more in control of your smoking? (if yes) What makes you feel that way?”

“Cutting down should also increase confidence in quitting. Do you feel more confident in quitting? (if yes) Why? Finally, with cutting down most smokers find they can be in situations that they would normally smoke in without smoking. Has that happened for you?”

“Now I’d like to go over the use of the nicotine lozenges to quit rather than reduce. How much lozenge do you have left? (Assess how many bags or sheets they have) We will be sending you a new shipment of lozenge with new instructions, but it will take 2-4 days for

these to get to you. In the package we will be sending, there will also be a booklet with some tips on quitting.”

“In the past few weeks you have been smoking and using lozenges on the same day, but as of your quit date, we recommend you completely stop smoking altogether, no matter whether you reached your reduction goal or not. Once you receive the new instructions in the package we’ll be sending, you should throw away your old instructions for using the lozenge to reduce and read the new instructions for using the lozenge to quit.”

“Once you quit, you should be using a nicotine lozenge every one to two hours. You should use the lozenge whenever you have a craving or a withdrawal symptom such as mood changes, irritability, difficulty concentrating, hunger or insomnia. We recommend you use it for 12 wks after your quit date. Most smokers do not use enough lozenge each day and do not use it for long enough. We recommend that you use at least 9 lozenges a day, but you can use up to 20.”

“Once you quit it’s important that you not use any other nicotine products, like cigarettes, while you are using the lozenges. 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 information sheet we will send with the lozenges. Do you have any questions about the use of the lozenges?”

“Now I would like to spend some time thinking about how you can get through the first few days of not smoking at all. What plans or strategies do you have for this time? (Reinforce whatever they bring up). What have you learned during reduction that you think might be helpful for quitting altogether?” (reinforce anything they say-Do not suggest specific techniques)

- **End call**

“I’d like to set up another call for 2 days after your quit date. Since you’ve decided to quit early the next call will be my last to you. Can I call you on _____ at _____?”

(If that won’t work, arrange another.)

(Record information on counselor log, noting that the **next call will skip to session 5**. Send 2 boxes of lozenges with pink instructions sheet, Clearing the Air. Let study coordinator know about change of QD.)

Gradual Cessation Telephone Counseling Manual
Session 4 (QD -3 days)

Before call, be sure and know quit date, baseline CPD, reduction goal in CPD, gradual reduction method chosen, number of lozenges/day recommended. Also, look at Adverse Events form to identify any reported symptoms or problems with the lozenges that need follow-up.

- **Begin call**

“Hello, may I please speak to _____. Hi, this is _____. I’m with the Nicotine Lozenge Study and I am calling to check in to see how you’re doing with cutting down on your smoking and to help you get ready to quit smoking. Is this a good time to talk for about 15 minutes?

(If it’s not, schedule another time.)

- **Check on receipt of lozenge and booklet**

“Before we go any farther, I just want to make sure you received a new shipment of lozenges to use for quitting and a booklet on quitting. Did you get those?” (If not resend.)

“Did you send in the questionnaire that came with that shipment? (If not) Please send this in as soon as possible as this is valuable information for us.”

- **Do TLFB for number of CPD and lozenges per day for the past 7 days, and yes/no to cigs and lozenges on every empty day on calendar since last call**

“The first thing I need to do is get a clear idea of the number of cigarettes you’ve smoked and lozenges you’ve used each day since we last spoke.”

(Quickly estimate average CPD and lozenge)

“I see that you used about ____ lozenges/day.”

(If \geq recommended amount) “That’s great”

(If $<$ recommended amount) “Why did you use less than the recommended ____ lozenges/day?” (encourage to use more)

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?”

“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)

IF THE PERSON ALREADY QUIT, skip to page 23.

IF THE PERSON CUT DOWN SOME AND/OR REACHED THEIR GOAL: “I see you have reduced since we last spoke. That’s great!” **Continue below**

IF THE PERSON DID NOT CUT DOWN AT ALL: “I see you did not cut down. That’s okay. What problems did you have in trying to cut down?” **skip to “Review use of the lozenge and preparing to quit” below.**

- **Review rationale for gradual reduction**

“Our rationale for having you cut down gradually prior to your quit date was based on several things. For one, smoking less cigarettes each day has probably cut your dependence on them. Do you feel less addicted to cigarettes?”

“Secondly, we believe that as smokers cut down, they gain a sense of control over their smoking habit. Do you feel more in control of your smoking or more confident than you did a month ago? What makes you feel this way?”

“Finally, we believe it helps to take small steps and have some successes as you move toward your quit day. Did this help you to feel motivated as you got ready to quit? Finally, you may have noticed that you can be around situations that you normally smoke in without smoking. Have you noticed this?”

- **Review use of the lozenge and preparing to quit**

“Now I’d like to help you prepare for your upcoming quit date, which is on _____. I’d like to explain how you’ll use the lozenge once you have quit. In the past weeks you have been smoking and using lozenges on the same day, but as of your quit date, we recommend you completely stop smoking altogether, no matter whether you reached your reduction goal or not. Now I’d like to go over the use of the nicotine lozenges to quit. You should first throw away your old instructions for using the lozenge to reduce and after this call read the new instructions for using the lozenge to quit.”

“Once you quit, you should be using a nicotine lozenge every one to two hours. You should use the lozenge whenever you have a craving or a withdrawal symptom such as mood changes, irritability, difficulty concentrating, hunger or insomnia. Most smokers do not use enough lozenge each day and do not use it for long enough. We recommend that you use at least 9 lozenges a day, but you can use up to 20.”

“Once you quit it’s important that you not use any other nicotine products, like cigarettes, while you are using the lozenges. 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 information sheet we sent with the lozenges. Do you have any questions about the use of the lozenges?”

“Now I would like to spend some time thinking about how you can get through the first few days of not smoking at all. What plans or strategies do you have for this time? (Reinforce whatever they bring up). What have you learned during reduction that you think might be helpful for quitting altogether?” (reinforce anything they say-Do not suggest specific techniques)

- **End call**

“So you plan to quit on _____ and you know how to use the lozenges once you have quit.”

I’d like to set up another call for 2 days after your quit date. The next call will be my last to you and I’d like to talk with you no matter what happens. Can I call you on _____ at _____?”
(if no, arrange another time.)

Record information on Telephone Counseling Log.

IF THE PERSON ALREADY QUIT:

“It appears you have already quit. That’s great!”

“What made you decide to go ahead and quit rather than waiting and doing it more slowly?”

- **Review rationale for reducing before quitting**

“Our rationale for having you cut down gradually prior to your quit date was based on several things. For one, smoking less cigarettes each day probably cuts your dependence on them. **(if person has reduced)** Do you feel less addicted to cigarettes?”

“Secondly, we believe that as smokers cut down, they gain a sense of control over their smoking habit. Do you feel more in control of your smoking or more confident than you did a month ago? What makes you feel that way?”

“Finally, we believe it helps to take small steps and have some successes as you move toward your quit day. Did this help you to feel motivated as you got ready to quit?”

- **Discuss using lozenges to quit**

“Since you’ve already quit, I’d like to go over the use of the nicotine lozenges to quit rather than reduce. At this point you should throw away your old instructions for using the lozenge to reduce and read the new instructions for using the lozenge to quit. Now that you’ve quit, you should be substituting a nicotine lozenge every one to two hours. You should use the lozenge whenever you have a craving or a withdrawal symptom such as mood changes, irritability, difficulty concentrating, hunger or insomnia. Most smokers do not use enough lozenge each day and do not use it for long enough. We recommend that you use at least 9 lozenges a day, but you can use up to 20.”

“Now that you’ve quit it’s important that you not use any other nicotine products, like cigarettes, while you are using the lozenges. 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 information sheet we will send with the lozenges. Do you have any questions about the use of the lozenges?"

- **End call**

"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.)

(record information on counselor log)

Gradual Cessation Telephone Counseling Manual Session 5 (QD +2 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 _____ from the nicotine lozenge study. 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.)

- **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. 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 27.

IF PERSON SAYS DID NOT QUIT AT ALL OR THEY ARE SMOKING 3 OR MORE CPD, skip to Page 29.

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.

(If using less than 9/day) Ask why they're using fewer than 9/day and encourage to use more.

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?"

"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.

"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.)

- 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 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'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'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 weeks 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 TRIED TO QUIT BUT HAS SMOKED 1 or 2 CPD SINCE QUITTING:

- 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.

(If using less than 9/day) Ask why they're using fewer than 9/day and encourage to use more.

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?”

“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.)

“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.)

- 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 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’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’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 weeks 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 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 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?"

If they don't want to set a new quit date now: "Okay, that's fine. This is my last call to you, so I want to wish you much success in your efforts. Someone else from our program will be calling you in a couple of weeks to ask you some questions about your smoking. Please note that we will not be able to send you more lozenges if you are still smoking. However 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." End call.

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?”

(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, I’m wondering if you’ve got any ideas about what might help you get through your quit day?”

- 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 and end conversation

“It sounds to me like you’re ready to give this another try, and that’s excellent. You’re better prepared for your quit day than you were before because you know more. 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.)

“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 weeks 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.