

# ACTG 5031

## Adherence Support Call Script

### PART 1: CLARIFYING THE REGIMEN

**This is** (your name) **with the** (identify clinic or study). **I'm calling because I'd like to**

- **Follow up on your recent visit**
- **Ask you a few questions about how you have been doing with your medications**
- **See if you have any questions**
- **Try to do all we can to help make participating in ACTG 5031 go well for you.**

**We know you have been given quite a few pills to take. For many people it can be difficult to take medications correctly. The best way to make sure that WE have done a good job in telling you about which pills to take when is to have people TELL US what they are taking and when.**

**Don't worry if you aren't sure. That's why I'm calling. And if you have any questions, this is a great time to ask.**

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**Have you started taking your study medications?**

The material between the lines is for the FIRST CALL ONLY.

**IF YES**, continue by asking the questions below.

**IF NO**, ask, **Do you plan to start taking the study drugs? Are there any problems we can help with?** And then continue by asking the questions below. Please note that patient must start taking study medications within 72 hours of receiving the medications.

The material between the lines is for the FIRST CALL ONLY.

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**Let's take this time to review what you were told about your medications. If you don't know the names of the pills, feel free to use their size, shape, or color to explain which pill you mean.**

- **Can you describe what medications you are supposed to be taking?**
- **How many pills of each medication are you supposed to be taking?**
- **When are you supposed to take each of these medications?**
- **Do you know about the special instructions involved with these medications (i.e. timing your medications with your meals)?**

Compare what the patient told you against the ACTG 5031 treatment assignment. Does patient understand any special instructions? NOTE: ddl should be taken on an empty stomach and should not be taken at the same time as Nelfinavir. Nelfinavir should be taken with food. If patient does not understand these instructions, explain and troubleshoot. If patient is not taking

the right medications and dosages, check the patient's randomization and troubleshoot.

If you have any questions about the adherence telephone intervention, please feel free to contact XXX (XXX@XXX.XXX) at XXX-XXX-XXXX or XXX (XXX@XXX.XXX) at XXX-XXX-XXXX.

## **PART 2: ASSESSING ADHERENCE**

**Sometimes people have difficulties taking their pills, especially in the beginning.**

- **Some people get busy**
- **Some forget to carry their pills with them**
- **Some find it hard to follow all the detailed instructions**
- **Still other people have side effects**

Remind patients: Missing pills will NOT affect their participation in the study.

**Since you were given your pills at the clinic, how has it been going?**

**Thinking about TODAY, how many doses of your medication did you miss?  
Thinking about YESTERDAY, how many doses of your medication did you miss?**

- If patient reports taking all the medications, say:

**Everyone finds some times for medicine more difficult to remember. Which time of day have you found to be the most difficult time to remember to take your medication?**

Go to Part 3 and modify questions to fit "difficult dose."

- If patient reports no difficulties whatsoever, say:

**Some of the other participants are having difficulties. Since you are doing well, it would be helpful if you could tell us how you remember to take all your pills. We can then share some of your ideas and "tricks" with others who are having trouble. Fax new ideas to XXX at XXX-XXX-XXXX and we will send these out to the team.**

Then go to Part 4 on the last page.

- If patient reports missing one or more doses, go to Part 3.

### PART 3: ADHERENCE COUNSELING

**What do you think may have been the reason that you missed or had difficulty with taking your medication on time?**

The patient's response to this question will determine how you proceed. Please use the following table to assist you with the next section.

| <b>Reason for missing or having difficulty remembering</b>  | <b>What you should do . . .</b>  |
|---|--|
| <p>Patient did not remember.<br/>Simply forgot.</p> <p><b>THIS WILL PROBABLY BE THE MOST COMMON RESPONSE.</b></p> | <p><b>Tailor the regimen to the patient's lifestyle. THIS IS PROBABLY THE SINGLE MOST EFFECTIVE WAY TO IMPROVE ADHERENCE.</b></p> <p>A detailed account of how to do this appears on page 6. Please turn there now.</p> <p style="text-align: center;">—————→</p>  |
| <p>Felt ill. Wanted to avoid side effects.</p>  | <p>A detailed account of how to help patients deal with managing side effects appears on page 4. Please turn there now.</p> <p style="text-align: center;">—————→</p>  |
| <p>Patient did not understand the drug regimen.</p>   | <ul style="list-style-type: none"> <li>• Review the drug regimen again.</li> <li>• Make sure they received a Drug Card that clearly describes drugs that are to be taken. If not, mail them one.</li> <li>• Ask patient to repeat their regimen back to you.</li> <li>• Check to make sure they have the regimen correct. Make sure they understand any special instructions.</li> <li>• Review with patient will be taking TODAY and TOMORROW.</li> </ul> |
| <p>Felt down, depressed or overwhelmed</p>  | <ul style="list-style-type: none"> <li>• We do not expect you to take on the role of therapist. If a patient's problems are beyond what you feel comfortable dealing with, you should provide the patient with a referral (i.e. mental health counselor).</li> <li>• Explore the patient's interest in counseling or support networks.</li> <li>• Offer to schedule a follow up call.</li> </ul>   |
| <p>Was drunk or high</p>  | <ul style="list-style-type: none"> <li>• We do not expect you to take on the role of substance abuse counselor. If a patient's problems are beyond what you feel comfortable dealing with, you should provide the patient with a referral.</li> <li>• Explore the patient's interest in counseling or support networks.</li> <li>• Emphasize the importance of taking their medications even though they may be drinking or doing drugs.</li> </ul>        |

## Managing Side Effects

**Can you tell me about any new feelings or symptoms you have experienced since you began taking your study medications (or since our last call) that you think may be side effects of these drugs?**

Listed below are some side effects that have been associated with the study medications in this trial. Also listed are suggestions on how to manage these side effects. Please use the table below to assist the patient.

| Side Effects        | What you should do ...  |
|---------------------|---|
| Diarrhea            | <p>A very common side effect, especially in the first few weeks of a regimen and often goes away on its own!</p> <ul style="list-style-type: none"> <li>• increase fiber (vegetables), increase fluids (water).</li> <li>• adjust diet to include more rice, and other starches.</li> <li>• avoid dairy products (milk, ice cream, cheese).</li> <li>• consider switching to a low fat diet.</li> <li>• consider adding: Lomotil, Immodium, or tincture of opium.</li> <li>• <b>Call your PCP or the study investigator.</b></li> </ul> |
| Fatigue             | <p>A very common side effect, especially in the first few weeks of a regimen and often goes away on its own!</p> <ul style="list-style-type: none"> <li>• schedule frequent short naps, increase sleep time.</li> <li>• limit caffeine and sugar.</li> <li>• try to limit work hours, try relaxation techniques.*</li> <li>• gentle exercise (i.e. 15 to 30 minutes of brisk walking).</li> <li>• <b>Call your PCP or the study investigator.</b></li> </ul>  |
| "Feeling different" | <p>Many patients feel different, altered sensorium. A very common side effect, especially in the first few weeks of a regimen and often goes away on its own!</p> <ul style="list-style-type: none"> <li>• try relaxation techniques.*</li> <li>• increase sleep time, try short naps.</li> <li>• avoid alcohol or other drugs.</li> <li>• light exercise (i.e. 15 to 30 minutes of brisk walking).</li> <li>• <b>Call your PCP or the study investigator.</b></li> </ul>   |
| Headache            | <p>A very common side effect, especially in the first few weeks of a regimen and often goes away on its own!</p> <ul style="list-style-type: none"> <li>• Tylenol, aspirin, Advil.</li> <li>• relaxation techniques*, herbal teas, soft music.</li> <li>• <b>Call your PCP or the study investigator.</b></li> </ul>  |

\* Relaxation techniques can include resting and focusing on relaxing muscle groups one by one (arms, neck, shoulders, etc.). Many larger bookstores have books or cassette tapes to assist you with these and other relaxation techniques.

|                   |  |
|-------------------|--|
| Nausea            | <p>A very common side effect, especially in the first few weeks of a regimen and often goes away on its own!</p> <ul style="list-style-type: none"> <li>• eat crackers, sip ginger ale or other soda.</li> <li>• eat cold or room temperature food or liquids.</li> <li>• try Mylanta or Maalox (not with medications).</li> <li>• avoid spicy foods, or foods w/lots of acid.</li> <li>• <b>Call your PCP or the study investigator.</b></li> <li>• additional therapies for nausea include: Zofran, Compazine, benzodiazepines.</li> </ul> <p><b><u>for subjects on ddl:</u></b></p> <ul style="list-style-type: none"> <li>• try crushing and dissolving pills in ice cold water or juice.</li> <li>• try taking pills at a different time (i.e. at bedtime).</li> <li>• remind subjects that ddl must be taken on an empty stomach.</li> </ul> |
| Numbness/Tingling | <p>A very common side effect, and often goes away on its own</p> <ul style="list-style-type: none"> <li>• balanced diet, daily multi-vitamin.</li> <li>• continue study medications.</li> <li>• tell study investigator or PCP if there is an increase in numbness or expanding areas of numbness.</li> </ul>  |
| Rash              | <p>A very common side effect, especially in the first few weeks of a regimen and often goes away on its own, <b>but</b> it is <u>very</u> important that you are evaluated.</p> <ul style="list-style-type: none"> <li>• <b>schedule “urgent” ACTU follow-up.</b></li> <li>• report increasing rash, fever, headache, flu-like symptoms, or any lesions in mouth (or mucosa).</li> <li>• Benadryl (advice should be given <b>only</b> with study MD approval).</li> </ul>  |

**Note: Changes in medications should be discussed with study physician (and PCP).**

## Tailoring the Regimen

If the patient missed medications or dosing times because of forgetting, help the patient integrate medication into his or her daily life.

Consider timing of the doses. Could this be changed?

**Many people have found that by linking daily activities with the times they are supposed to take their medications, they are better able to remember to take their medications. Together we can try to identify some daily activities or “cues” that you may find useful in helping you to remember to take your medications.**

Establish cues for medication

- Identify regular activities that can serve as cues
- Look for activities that fit medication intervals. Emphasize routine activities (e.g. going to the bathroom in the morning, TV shows, walking the dog, meal times).
- Encourage the patient to take the pills BEFORE doing the “cue” activity. (E.g. before going to the bathroom in the morning, before TV show starts, before walking the dog).

Problem solve by having pills nearby. For example:

- Have some extra pills at work
- Consider pill boxes (medisets) or other ways to carry pills

Consider aids that the patient might find helpful. For example:

- Alarm watch or timers that can be preset for difficult time(s)
- Someone who can help the patient remember

Alert: Plan ahead for weekends and changes in routine. Most people have different routines on weekends, around holidays or during vacations. Notice if cues are based on weekday activities (often the case with TV shows) and develop a plan for weekends.



Stay on the phone with patient until you and they have developed a plan for the next day. Before hanging up, ask patient to tell you their plan for remembering to take their medications just to be sure that you understand.

## **PART 4: CLOSING**

- Summarize briefly what, if anything, the patient has agreed to do. Summarize what, if anything, you have agreed to do.
- If earlier in the phone call the patient was not easily able to identify what drugs he or she is supposed to take, you could take this time to ask the patient once again to repeat their study regimen back to you.
- Ask the patient if he or she has any questions. Remind the patient that either you or another staff person will call again. Set up a time and note it on the appropriate calendar.
- Thank the patient for participating in the study.
- If time permits, ask . . .
  1. **How are you feeling about the study?**
  2. **Do you have any questions or concerns?**
  3. **Is there anyway I might be helpful?**

If the patient mentions a problem, so some problem solving and provide support as appropriate.

**BE SURE TO COMPLETE A TELEPHONE INTERVENTION LOG  
FOR THIS PHONE CALL.**