
FORM:	17 - CaD MANAGEMENT AND SAFETY INTERVIEW
Version:	5 – November, 15, 2001
Description:	Interviewer-administered; 2-page form; key-entered at Clinical Center (CC).
When used:	For Calcium/Vitamin D (CaD) participants at 4-week call, semi-annual and annual contacts, and non-routine contacts with CaD participants, as needed to document CaD safety or adherence concerns. Complete this form at the next routinely scheduled visit or contact after stopping CaD intervention. (See <i>Form 17A</i> for mail contacts.)
Purpose:	To assess CaD participants for safety issues and to identify needs and strategies to improve adherence.

GENERAL INSTRUCTIONS

1. This form is printed in both English (*Form 17*) and Spanish (*Form 17S*) versions. Use the appropriate form for the participant. The form is also printed in a self-administered version for use at semi-annual contacts – see *Form 17A*.
2. For the semi-annual and annual contacts, include the form in the packet of forms to be completed at the visit.
3. Affix the participant bar-code label to the front of the form.
4. The interview should be conducted on the phone or in person during CC contacts.
5. Complete the contact information in Questions 1-4.
6. At annual visits, assess the participant's adherence to taking her CaD medications by actual weights or, if necessary, estimates of pill count.
7. Complete the remainder of the form as the interview/discussion proceeds.
 - Review the possible symptoms and conditions in Questions 6-8. If the participant marked "yes" to any questions in 6.3 – 7.3, refer to CP. Indicate a summary of the discussion in Question 9 – Resulting Action. At a minimum, reassure the participant about her continuation on the study pills.
 - Review the participant's responses to taking pills in question 10. If she reports missing any pills, discuss ways to help remember pills each day, and indicate a summary of the discussion in questions 10.7 – Strategies.
 - Answer questions 11-12 to indicate follow-up plans.

Note: If the participant is off CaD pills and you are completing the form for the one contact after stopping, you do not need to complete Questions 10 – 12.
8. Review the form for completeness and forward to Data Entry.
9. Data Entry: Review the form for completeness and return to appropriate CC staff for any problems or questions. Key-enter when complete or questions have been resolved.
Initial the first page after key-entry.
10. File the key-entered form in the participant's file.

Item Instructions

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|---------|----------------------------------|--|
| 1. | Contact date | Date you conducted the interview. |
| 2. | Staff person | Standard 3-digit WHI employee ID of staff person performing the interview. (See common data items.) |
| 3. | Contact type | Mark appropriate box. (See common data items.) |
| 4. | Visit type | The contact at which you conducted the interview.

Mark the appropriate box and enter the number. (See common data items.) |
| 5.1-5.3 | Dosage/adherence/
formulation | Review the participant's current dosage status on the latest <i>Form 54 - Change of Medications</i> to determine if the participant is on the standard WHI dosage. If she is, mark "Yes" to Item 5.1 and "No" to Item 5.2. If she is taking an altered dosage as indicated on <i>Form 54</i> , mark "No" to Item 5.1 and "Yes" to Item 5.2. Determine adherence using the procedures in <i>Vol. 2, Section 15.6 - Study Pill Adherence Monitoring</i> .

Write the adherence rate in the appropriate space provided.

Mark appropriate box for CaD formulation participant is currently taking.

Data Entry: Adherence data and current formulation not key-entered. Pill adherence is key-entered in Task 951 - Adherence Collection. |
| 6.1-6.3 | Current medications | Refer any "Yes" responses to Items 6.2 or 6.3 to the Clinic Practitioner for evaluation. |
| 6.1 | Calcium | No/Yes. |
| 6.1 a | Dosage | Mg calcium per day. If participant is taking more than one pill per day containing calcium, total the mg from each pill and record the total. |
| 6.1 b | Name of Calcium | If participant is unsure of name of calcium, leave blank. Examples of calcium carbonate are: Tums, Roloids, OsCal, Centrum Singles Calcium, One A Day Women's, Caltrate 600, Caltrate 600+D. |
| 6.2 | Vitamin D | No/Yes. Refer yes response to CP for evaluation. |
| 6.2 a | Dosage | Data Entry: Dosage not data entered. |
| 6.3 | Calcitriol | No/Yes. Refer yes response to CP for evaluation. |
| 7. | Medical conditions | Refer to Clinic Practitioner if response to any question is "yes" or if participant is unsure. Discontinue study pills if the participant has developed hypercalcemia, urinary or renal calculi (stones), or is undergoing kidney dialysis. |
| 7.1 | Hypercalcemia | No/Yes. |
| 7.2 | Kidney problems | No/Yes. |
| 7.3 | Kidney Dialysis | No/Yes. |
| 8. | Worries or discomforts | Ask this question in an open, interested manner. List the problems that the participant identifies.

Data Entry: Text not key-entered. |

9. Action Resulting action based on participant responses to Items 6-8. Mark all that apply. Clinic Practitioner can refer to *Vol. 2, Section 7 - Calcium and Vitamin D Intervention*. Local actions and referrals should be based on sound clinical judgment and local guidelines.
- Data Entry: Text for date/time of appointment, physician name and contact information, and other specific text is not key-entered.
10. Adherence to CaD study pills Ask these questions regardless of participants' calculated or estimated adherence.
- 10.1 How often did you take study pills Ask this question as written and read the responses in order until the participant indicates her agreement with the response. If the participant indicates that she doesn't know or can't remember, ask her to provide her best estimate. If the participant responds with some version of "it varies", ask her to choose the response that is most frequently true.
- 10.2 How do you take your pills? Ask this question as written and read the responses in order until the participant indicates her agreement with the response. If the participant indicates that she doesn't know or can't remember, ask her to provide her best estimate. If the participant responds with some version of "it varies", ask her to choose the response that is most frequently true.
- 10.3 Days missed Ask the questions in non-accusing manner. If a participant is unsure, ask her to give her best estimate. You could ask her how many days a week she might miss her pills and record the appropriate monthly amount.
- 10.4 What helped you remember Ask this question to remind participants of their success. Write notes about her successful strategies. Use these responses, if possible, to guide adherence strategies in Item 10.7 and the Intensive Adherence Program, as needed.
- Data Entry: Text not key-entered.
- 10.5 Reasons missed Ask this question in a non-accusing manner. Probe to identify reasons for non- or low-adherence. List and probe for physical, psychological, and social issues.
- Data Entry: Text in "Other Reasons" not key-entered.
- 10.6 CaD Formulation Preference Chewable/Swallowable. Ask this question in a neutral way. Participant has the option to change formulation each time study pills are dispensed.
- Data Entry: Preference is not key-entered in *Form 17* data entry screen.
- 10.7 Strategies to improve adherence Discuss appropriate strategies and options for improving participant adherence. Note that even good adherers should be reassured (and congratulated) on their efforts (see second option below). Use information in *Section 17.2.3 - Reasons for Poor Retention and/or Adherence* as a guide. To apply these strategies, use the following situation as an example:
- Reason (from 10.5): Forgot Pills
- Participant response to request for description: "I seem to forget to take my pills on Thursday mornings when I go to my garden club meetings. I leave earlier that day and don't have a chance to take it with my morning coffee."
- Reassurance: "It sounds like you are busier than usual that day and your schedule is disrupted." or "It sounds like you're doing pretty well with remembering to take your pills."

Palliative Measures: “What helps you remember the pills on your usual days? What do you think might help you remember on Thursdays?”

Steps to improve: “Could a fellow club member remind you? Could your husband remind you at home before you leave?”

Putting concerns in perspective: “Thanks for devoting all this time and effort to taking the pills. We urge taking the pills consistently so much because this study hopes to answer some very important questions about women’s health.”

Data Entry: Strategies not key-entered.

11.1 IAP Referral

No/Yes.

If adherence is < 80%, or if you think the participant could benefit from an intensive adherence program, refer to CP or retention specialist for evaluation.

If participant needs to have more intensive contact, each CC should establish criteria about who should follow-up, when referral to CP or other specialist is required, and which adherence problems could be addressed by the interviewer.

11.2 Recontact date

The date the participant needs to be recontacted.

12.1 Clinical recontact

No/Yes.

If the participant is to be recontacted for clinical and/or safety issues, each CC should establish criteria about who should follow-up, when referral to CP or other CC clinician is required, and which symptoms could be addressed by the interviewer.

12.2 Recontact date

The date the participant needs to be recontacted.

13. Notes

Use this section to record observations or document actions not noted above.

Data Entry: Comments not key-entered.