

AFRICAN AMERICAN STUDY OF KIDNEY DISEASE AND HYPERTENSION
AASK COHORT STUDY
VISIT/MISSED VISIT FORM # 111

1. Identification Number... [] [] [] [] [] [] [] []

2. Name Code... [] [] [] [] [] [] [] []

3. Visit Number... [] [] []

4. Visit Date: mm/dd/yyyy... [] [] [] [] [] [] [] [] [] [] [] [] [] [] [] []

This form is completed at all AASK Cohort visits. When a protocol visit is missed and the entire visit window has passed, complete question 5a-c, 37a, 37b (if ESRD pt), 38, 39 and 40a then skip to question 200. (Use the last day of the window for "Item 4. Visit Date" if the visit was missed.)

5. a. Visit status: *vis_stat*
- | | | |
|-------------------------------|---|---------------------------------------|
| 1=The visit was held | 6=Too sick to come in | 10=Refused; other reason |
| The visit was missed because: | 7=In the hospital | 11=Refused; reason unknown |
| 2=The patient forgot | 8=Refused; felt appt. for protocol visit was too soon | 12=Scheduling conflict w/clinic staff |
| 3=Could not get off work | after an interim visit | 13=Other |
| 4=Dependent care problem | 9=Refused; unhappy with frequency of protocol visits | 14=In jail or prison |
| 5=Transportation problem | | 15=Moved |

- b. Type of Visit: *vis_type*
- 1=This is a protocol visit
- Type of Interim Visit: 2=Blood pressure measure and blood pressure counseling, 3=Blood pressure measure, no blood pressure counseling, 4=Related to illness, 5=Related to hospitalization, 6=Lab values repeated, 7=Other, patient or team preference, 8=Medication drop-off/pick-up (associated with all medications on Form 140), 9=Finishing Protocol/visit requirements, 10=Miscellaneous drop-off/pick-up, 11=Counseling

Note: If Q05b (type of visit) = 8 (medication drop-off/pick-up) OR 10 (miscellaneous drop-off/pick-up), then Q05a (visit status) must = 1 (The visit was held).

- c. Location of Visit *vis_loc*
- 1=AASK clinical site (or satellite AASK site)
2=Some other outpatient clinical location
3=Institutional clinical setting (hospital, nursing home or rehab unit)
4=A private residence
5=Patient's place of employment
6=Other

- d. Date of the next scheduled visit (leave blank only if unknown) (mm/dd/yyyy) *next_vis_dt*

- e. Change in medications? (0=no, 1=yes) *med_chg*
- Regardless of how this question is coded, please enter a Form 140 for this visit - checking/confirming all medications.

6. a. Who is the primary person responsible for managing your blood pressure (who is adjusting your medications)? *bp_person*
- 1=AASK Study
2=Personal Physician
3=Other: _____
4=Nobody

6. b. For female patients of child-bearing potential: Are you pregnant? pregnant
 (0=no, 1=yes, 8=not applicable, 9=unknown)
Note: ACE inhibitors should generally not be used in pregnant patients. Discuss this with the team physician.

Symptoms:

Ask the participant if he or she has/had any symptoms since last visit. Enter a 1=yes for any the patient reports. Ask explicitly about the symptoms marked with asterisks. For these, enter 0=no or 1=yes.

7. *Shortness of breath/dyspnea* (10013963) Sob
 8. *Loss of consciousness* (10024857) Syncope
 9. *Dizzy* (10013580) dizzy
 10. *Fainting* (10016169) faint
 11. *Rapid heart rate, heart palpitations* (10033557) hrt-palp
 12. *Lightheaded on standing* (10013581) lighthead
 13. *Muscular weakness* (10028372) muscleweak

Ask the patient, "Do you have any other symptoms to report?" Here are some symptoms that AASK patients mentioned during the AASK trial.

14. Angioedema (swelling of the lips and mouth) (10002424) angio
 15. Backache (10003993) backache
 16. Had/have a cold (10009867) cold
 17. Cold hands (10009860) cold hand
 18. Cough (10011224) cough
 19. Depressed (10012378) depress
 20. Drowsy, sleepy, can't stay awake (10041018) drowsy
 21. Dry mouth (10013781) dry-mouth
 22. Edema (10014210) edema
 23. Had/have the flu (10016790) flu
 24. Headache (10019211) headache
 25. Heartburn (10019326) hrtburn
 26. Abnormal hair growth (10000147) ab-hair
 27. Insomnia, can't sleep (10022437) insomnia
 28. Joint pain (10023222) joint-pain
 29. Lack of energy, feeling run down, fatigued (10016256) fatigue
 30. Leg cramps (not from exercising) (10024125) leg-cramp
 31. Nausea (10028816) nausea
 32. Sexual dysfunction (10040477) sex prob

You may enter as many other symptoms and MedDRA Code numbers as you wish.

(Use the back of this page if necessary.)

Symptom:	MedDRA Code:
33. <u>Symp-desc</u>	<u>Symptom</u>
34.	
35.	
36.	

Hospitalizations:

37. a. How many times was the participant hospitalized since the last visit? hosp-no
(0=none, 1=once, 2=twice, etc., 9=unknown)
Note: If the patient has been hospitalized since the last AASK Visit, complete Form 141 or Form 144 for each hospitalization as soon as possible.

b. **For dialysis patients only:** How many cardiovascular hospitalizations has this patient had since the last visit? (0=none, 1=once, 2=twice, etc., 9=unknown) cardio-hosp
Note: If the patient has had a cardiovascular hospitalization since the last AASK Visit, complete Form 141 for each cardiovascular hospitalization as soon as possible.

Edema:

38. Edema location: Highest-spot on leg edema-loc
(0=None, 1=Ankle, 2=Pretibial, 3=Above knee, 4=Presacral, 5=Anasarca, 9=unknown)

39. Ankle Edema Severity Code: edema-cod
(0=No Edema, 1=Trace or 1+, 2=2+, 3=3+, 4=4+, 9=unknown)

Adverse Reactions:

If the patient had any symptoms since the last visit (as listed in question 7 thru 36), then please answer the following:

40. a. In the judgement of the AASK staff, is one of the symptoms reported in question 7 thru 36 an adverse reaction to a drug? (0=no, 1=yes, 8=not applicable)? drug-reac

First Symptom/Drug

b. If yes, which symptom? (enter MedDRA symptom code from question 7 thru 36) which-symp

c. If yes, which drug? (enter the name of the medication from the previous F140 that was entered) which-drug

Second Symptom/Drug

d. If yes, which symptom? (enter MedDRA symptom code from question 7 thru 36) which-symp 1

e. If yes, which drug? (enter the name of the medication from the previous F140 that was entered) which-drug 1

Third Symptom/Drug

f. If yes, which symptom? (enter MedDRA symptom code from question 7 thru 36) which-symp 2

g. If yes, which drug? (Enter the name of the medication from the previous F140 that was entered) which-drug 2

200. Date this form completed (mm/dd/yyyy) / / Compl-dt

201. Certification ID of person completing this form Compl-by

For Clinical Center Use Only:

Certification ID of person entering this form: _____

Date Entered: ____/____/____