

African American Study of Kidney Disease and Hypertension
AASK Study - VISIT/MISSED VISIT FORM # 11

Grid for identification number, name code, visit number, and visit date.

This form is completed at all AASK visits after SV-2. When a protocol visit is missed and the entire visit window has passed, complete 5a and 5b and skip to 201. Use the appointment schedule target date for "Item 4. Visit Date" if the visit was missed.

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

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).

- b. Type of Visit: 1=This is a Protocol visit. Type of Interim Visit: 2=Blood pressure measure and blood pressure counselling, 3=Blood pressure measure, no blood pressure counselling, 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 antihypertensive meds which are documented on Form 5/Form 40), 9=Finishing Protocol/visit requirements, 10=Miscellaneous drop-off/pick-up, 11=Counselling

- b1. Location of Visit: 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

c. Date of the next scheduled visit (leave blank only if unknown) (mm/dd/yyyy)

d. Change in NON-RANDOMIZED medication? (1=yes, 2=No change, 3=Minor intermediate change for which you do not intend to file a Form 40.) If the response is "1 = yes," please be sure to complete Form 40.

6. a. Were new bottles of RANDOMIZED drug dispensed at this visit? (0=no, 1=yes)

b. Dose (1=low, 2=medium, 3=high)

c. If yes, number of "bottle pairs" dispensed (1,2)

VISIT

Ask the participant if he or she has any symptoms. 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.

Required fields

- | | | |
|-----|---|-------------|
| 7. | *Shortness of breath/dyspnea* | Sob |
| 8. | *Loss of consciousness* | syncope |
| 9. | *Dizzy or feeling faint* | dizzy |
| 10. | *Rapid heart rate, heart palpitations* | hrt-palp |
| 11. | *Lightheaded on standing* | lighthead |
| 12. | *Muscular weakness* | muscle |
| 13. | Change in weight, gain or loss | wt-chn |
| 14. | Chest Pain | chest pa |
| 15. | Edema (swelling) of the extremities | edema |
| 16. | Heart skipping beats | hrt-sk |
| 17. | Wheezing | wheeze |
| 18. | Cough | cough |
| 19. | Fever | fever |
| 20. | Headache | headach |
| 21. | Backache, sore neck, sciatica | backach |
| 22. | Sore feet, heel spur, shin splints, athlete's foot, ingrown toenail | feet |
| 23. | Cold, flu, misc. body aches, sinus, allergic rhinitis, sore throat | cold flu |
| 24. | Nosebleeds | noseblee |
| 25. | Burning on urination, vaginitis | u-pain |
| 26. | Increased hair growth | hair |
| 27. | Angioedema (swelling of the lips and mouth) | angioed |
| 28. | Cold Hands | hands |
| 29. | Dry mouth | mouth |
| 30. | Changes in vision | vision |
| 31. | Depression | depress |
| 32. | Sexual dysfunction | sexprob |
| 33. | Trouble sleeping/insomnia | insomni |
| 34. | Sleepy, drowsy | drowsy |
| 35. | Fatigue/lack of pep and energy | fatigue |
| 36. | Slow heart rate | slow h |
| 37. | Nausea/vomiting | nausea |
| 38. | Heartburn/gas/GI reflux | hrt burr |
| 39. | Constipation, hemorrhoids | constipati |
| 40. | Diarrhea | diarrhea |
| 41. | Skin rash | skin ras |
| 42. | Hives | hives |
| 43. | Joint pain | joint pain |
| 44. | Muscle cramps at rest, muscle aches, musculoskeletal pain | clamps rest |
| 45. | Muscle cramps with exercise, claudication | clamps exe |
| 46. | Other (specify but do not key enter: _____) | oth sym |

Symptom

Hospitalization and Edema: Complete at all Protocol Visits.

Physical Exam

- | | | |
|-----|---|-----------|
| 47. | Was the participant hospitalized since the last visit? (0=no, 1=yes) | hospital |
| | If yes, complete Form 45. | |
| 48. | Edema location: Highest spot on leg
(0=None, 1=Ankle, 2=Pretibial, 3=Above knee, 4=Presacra, 5=Anasarca) | edema loc |
| 49. | Ankle Edema Severity Code:
(0=No Edema, 1=Trace or 1+, 2=2+, 3=3+, 4=4+) | edema s |

Physical - Exam

Lung and Heart Exam: Perform if the patient has occurrences of the symptoms marked with an asterisk or in the presence of edema, and perform at all annual visits. Otherwise leave blank.

- 50. Lung: (0=normal, 1=rales, 2=rhonchi or wheezes, 3=decreased breath sounds) Lung
- 51. Heart: Rhythm (1=Regular, 2=Irregular) Rhythm
- 52. Heart: Cardiomegaly (0=Absent, 1=Present) Cardiomegaly
- 53. Heart: Jugular venous distension (0=no, 1=yes) Jugular
- 54. Heart: Heart code (0=normal, 1=3rd heart sound, 2=4th heart sound, 3=rub, 4=other) hrt-c

Certification

- 201. Certification ID of person completing this form Compl-
- 202. Certification ID of person entering this form Enter-

For Clinical Center Use Only

Date Entered ___/___/___

Verified? _____