PROTOCOL REVIEW AND MEDICATION AND SCHEDULING DECISION

40 (6/8) SEQUENCE

33 (2) VERSION

(6) 41-46

1. SHEP ID: |22|23| - |24|25|26|27| - |28|29| (5)

2. Acrostic: | | | | | |

3. Date of Clinic Visit: |36|37| |38|39| |34|35| (7)
   Month   Day   Year

4. Sequence number: |47|48| (8)

REVIEW OF PROTOCOL

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5. At the last clinic visit, were SHEP medications prescribed in dosages specified in the protocol?

49 (9) 1 □ Yes   2 □ No
   ↓
   [Skip to 11]

6. What has happened with respect to the problem which caused this deviation from the protocol?
   Comment: _____

   _____

50 (10) 1 □ Resolved
        2 □ Improved
        3 □ Worse
        4 □ Unchanged

7. Have any other potentially serious conditions arisen since the last visit which are probably a result of the use of SHEP medications?

51 (11) 1 □ Yes
        2 □ No
        3 □ Not on SHEP meds

8. At this visit, do you plan to restore the participant to the SHEP drugs and doses specified in the protocol?

52 (12) 1 □ Yes   2 □ No
        ↓
        [Skip to 11]

9. Reason: (Check all that apply.)

53 (13) 1 □ Side effects judged to be severe enough to deviate from protocol

54 (14) 1 □ Participant has reached escape blood pressure and requires deviation from protocol

55 (15) 1 □ Other (Specify): _____

10. Has this decision already been reported on a Deviation from Protocol form, SH48?

(16) 56

1 □ Yes   2 □ No
          ↓
          [Initiate SH48 for this decision.]

_____
Clinic Physician Initial

11. In the judgment of the SHEP clinician, are any of the positive or abnormal responses in the General Well-Being or Side Effects sections related to the current use of SHEP medications?

(17) 57

1 □ Yes
2 □ Possibly
3 □ No
4 □ No positive or abnormal responses

[Skip to 14] ◄─

12. In the judgment of the SHEP clinician and physician, do any of these responses require deviation from protocol in prescribing SHEP medication?

(18) 58

1 □ Yes   2 □ No
          ↓
          [Skip to 14]

13. Are any of these conditions possibly harmful
to the participant?   (19) 59   1 □ Yes   2 □ No

   ┌───┐
   │ Initiate SH48 for Deviation from Protocol. │
   └───┘

                                                          ‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾
                                                          Clinic Physician Initial

14. Are there reasons other than those in Questions 5-13
    that require a deviation from protocol in prescribing   60
    SHEP medications (e.g., interference from other   (20)
    medicine, etc.)?   1 □ Yes   2 □ No
    (Specify): _____   ↓

   ┌───┐   ┌──────────────────────┐
   │ Initiate SH48 for Deviation from Protocol. │   │ Skip to next section │
   └───┘   └──────────────────────┘

                                                          ‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾‾
                                                          Clinic Physician Initial

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SHEP MEDICATION AND SCHEDULING DECISION

SBP today: _____   Goal SBP: _____
DBP today: _____

15. Blood pressure review:

   a. 1 □ SBP above 110 ──────► b. At least second consecutive visit at these
   61 (21) and at or below goal,   levels on same dose and Step?
          with DBP <90 mm Hg   1 □ Yes   Remain on same Step and dose.
                                62 (22)   Schedule next quarterly visit.
   61 (21)   2 □ No   Remain on same Step and dose.
                                                 Schedule next visit in one month.

   a. 2 □ SBP above goal ──────► b. At least second consecutive visit at these
            and <220,   levels on same Step and dose?
            with DBP <90 mm Hg   1 □ Yes   Move to next dose or Step.
                                                  If already on Step II Dose 2,
                                63 (23)   continue current regimen.
                                                  Schedule next visit in one month.
   61 (21)   2 □ No   Continue same dose and Step.
                                                 Schedule next visit in one month.

   a. 3 □ SBP ≧240 ──────────► b. Initiate open-label antihypertensive therapy
            or DBP ≧115 mm Hg   at this visit. (Initiate Deviation from
                                        Protocol, SH48.) If already on open-label
                                        therapy, step up according to clinician
                                        judgment. Schedule next visit according
                                        to clinician judgment. (Visits must be at
   61 (21)   least quarterly.)

   a. 4 □ SBP ≦110 mm Hg ──────► b. SHEP medications may be stepped down
                                        to the next lower dose or step, at the
                                        discretion of the SHEP clinician. Schedule
                                        next visit according to clinician judgment
                                        (visits must be at least quarterly). If
                                        drugs are stepped down, initiate SH48,
                                        Deviation from Protocol. Are drugs being
                                        stepped down this visit?
                                64 (24) 1 □ Yes
                                        2 □ No

SH43/2

a.　5 □　SBP 220-239 ──────▶ b.　Monitor for escape BP according
　　　　　　or DBP 90-114 mm Hg　　　　　to following table; has escape BP criteria
61 ㉑　　　　　　　　　　　　　　　　　been reached?
　　　　　　　　　　　　　　　　　　　1 □ Yes　Move to next Step or dose;
　　　　　　　　　　　　　　　　　　　　　　　　if on maximum Step and Dose,
RECORD TYPE ㊺ 96　　　　　65 ㉕　　　　initiate open-label therapy.
　　　　　　　　　　　　　　　　　　　　　　　　Initiate Deviation from Protocol,
DATE RECEIVED ㊻ 97-102　　　　　　　　SH48. If already on open-label
　　　　　　　　　　　　　　　　　　　　　　　　therapy, adjust treatment
UPDATE NUMBER ㊼ 103-105　　　　　　　and schedule next visit according
　　　　　　　　　　　　　　　　　　　　　　　　to clinician judgment.
DATE LAST PROCESSED ㊽ 106-111　　　2 □ No　　Remain on same Step and dose.

PAPER COPY ㊾ 112　　　　　　　　c.　Schedule next visit at earliest interval:
　　　　　　　　　　　　　　　　　　　1 □ DBP 95-114　→　1-2 weeks
Cross-Forms Edit ㊿ 113　　66 ㉖　2 □ SBP 220-239　→　2 weeks
　　　　　　　　　　　　　　　　　　　3 □ DBP 90-94　→　1 month
　　　　　　　　　　　　　　　　　　　4 □ Other schedule → Specify: _____

Escape Criteria for SBP 220-239 or DBP 90-114 mm Hg (visits on same Step and Dose)

	1st Visit	2nd Visit	3rd Visit	Comment
SBP:	220-239	220-239		
DBP:	95-114	95-114		
	95-114	90-94	≥90	
	90-94	≥90		Not on maximum study meds
	90-94	90-114	≥90	On maximum study meds

16.　SHEP medication prescription last visit:　　　　　㉘

67 ㉗ a.　Step I:　3 □ C1, dose ½　1 □ C1　　2 □ C2　　4 □ None　b.　Bottle #: | 68 | 69 | 70 |

71 ㉙ c.　Step II:　1 □ A1　　3 □ R, Dose 1　　5 □ None　　d.　Bottle #: | 72 | 73 | 74 |
　　　　　　　　　　2 □ A2　　4 □ R, Dose 2　　　　　　　　　　　　　　　㉚

75 ㉛ e.　1 □ Open-label antihypertensives　→　Specify: _____

76 ㉜ f.　1 □ Potassium supplement　→　g.　| 77 | 78 | meq/day ㉝

79 ㉞ h.　1 □ Uric acid agent　→　Specify drug and dose: _____

　　　　　　　　　　　　　　　　　　　　　80
17.　SHEP medication prescription this visit:　㉟ 1 □ No change ──────▶ | Go to 18. |

81 ㊱ a.　Step I:　3 □ C1, dose ½　1 □ C1　　2 □ C2　　4 □ None　㊲ b. Bottle #: | 82 | 83 | 84 |

85 ㊳ c.　Step II:　1 □ A1　　3 □ R, Dose 1　　5 □ None　　d.　Bottle #: | 86 | 87 | 88 | ㊴
　　　　　　　　　　2 □ A2　　4 □ R, Dose 2

89 ㊵ e.　1 □ Open-label antihypertensives　→　Specify: _____

90 ㊶ f.　1 □ Potassium supplement　→　㊷ g. | 91 | 92 | meq/day

93 ㊸ h.　1 □ Uric acid agent　→　Specify drug and dose: _____

　　　　　　　　　　　　　　　　　　　　　　　　　　　㊹ | 94 | 95 |
18.　Clinician: _____
　　　　　　　Signature　　　　　　　　　　　　　　　　　　　Code

(514) 3-8 BATCH DATE　　(515) 11-16 DATE MODIFIED　　(516) 17-20 TIME MODIFIED　　(517) 21 EDIT STATUS　　Keypuncher's code 1-2
　　Verifyier's code 9-10
　　SH43/3