

Patient number

Date of visit
month day year

BPH FORM F01.1

October, 1993

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FORM NUMBER = (FORM)
FORM VERSION = (VERS)

NIH - BPH CLINICAL TRIAL: PILOT STUDY

STANDARD FOLLOW-UP VISIT INVENTORY

This form should be completed at all standard follow-up visits (Weeks 1, 2, 3, 4, Months 3, 6, 9, and 12). At this visit, also complete AUA Symptom Questionnaire (Form Q01).

Part I / IDENTIFICATION

A. Patient Identification

1. Patient number (PATID)

clinic patient

2. Patient's initials (INITS)

first last

3. Patient's date of birth (DOB)

month day year

B. Visit Information

1. Date of visit (FVSTDT)

month day year

2. Week of visit (FVIWK)

Part II / COMPLIANCE AND ADVERSE EVENTS

C. Number of days since last visit (FCDAYS)

D. Doxazosin Compliance

YES NO

1. Is the patient taking coded medication? (FCDCODE)

1 2

If NO, SKIP to Section E.

2. Dose of doxazosin (FCDDOSE)

1 mg 2 mg 4 mg 8 mg

1 2 3 4

3. Number of doxazosin tablets dispensed at the last visit (FCDDISL)

4. Number of doxazosin tablets returned today (FCDRET)

5. Compliance (FCDCOMP)

$$\frac{\text{tabs dispensed (\#3) - tabs returned (\#4)}}{\text{days since last visit (question C)}}$$

X 100

%

NOTE: Counsel patient if less than 80% compliant with doxazosin.

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6. Number of doxazosin tablets dispensed today (FCDDIST)

DOXAZOSIN LABELS

Remove labels from coded medication before dispensing.

Affix labels here.

E. Finasteride Compliance

1. Is the patient taking the coded medication? (FCFCODE)

YES	NO
<input type="text"/> ¹	<input type="text"/> ²

If NO, SKIP to Section F.

2. Number of finasteride tablets dispensed at the last visit (FCFDISL)

3. Number of finasteride tablets returned today (FCFRET)

4. Compliance (FCFCOMP)

$$\frac{\text{tabs dispensed (\#2) - tabs returned (\#3)}}{\text{days since last visit (question C)}}$$

X 100

 %

NOTE: Counsel patient if less than 80% compliant with finasteride.

5. Number of finasteride tablets dispensed today (FCFDIST)

FINASTERIDE LABEL

Remove label from coded medication before dispensing.

Affix label here.

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F. Concomitant Medications

YES NO

1. Is the patient taking any medication other than the coded medications? (FCMCON)

 1

 2

If YES, list below:

a.	(FCMCONA)	f.	(FCMCONF)
b.	(FCMCONB)	g.	(FCMCONG)
c.	(FCMCONC)	h.	(FCMCONH)
d.	(FCMCOND)	i.	(FCMCONI)
e.	(FCMCONJ)	j.	(FCMCONJ)

G. Adverse Events

YES NO

1. Since the last scheduled follow-up visit, has the patient had any adverse experiences, drug reactions, side effects, abnormal laboratory values, hospitalizations, other complications or pre-existing conditions that worsened? (FAELVST)

 1

 2

If YES, an Adverse Event Form (Form E04) MUST be completed.

Part III / VITAL SIGNS AND UROFLOW MEASUREMENTS

H. Blood Pressure Readings

1. Supine Blood Pressure (After lying 5 minutes)

a. Heart Rate (FBPLHR)

 bpm

b. Blood Pressure Reading (FBPLS)/(FBPLD)

 / mmHg

2. Standing Blood Pressure (Immediately)

a. Heart Rate 1 (FBPSHR1)

 bpm

b. Blood Pressure Reading 1 (FBPSS1)/(FBPSD1)

 / mmHg

Wait 2 minutes

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c. Heart Rate 2 (FBPSHR2) bpm

d. Blood Pressure Reading 2 (FBPSS2)/(FBPSD2) / mmHg

I. Orthostatic Hypotension

1. Did the patient have orthostatic hypotension? (FORTHYP) YES NO
 1 2

Orthostatic hypotension is defined as a decrease of 20mmHg or more in supine to standing systolic blood pressure or a decrease of 10mmHg or more in supine to standing diastolic blood pressure or the development of significant postural hypotension.

J. Uroflow Measurements

1. Voiding Time (FUMVT) sec

2. Flow Time (FUMFT) sec

3. Time to Maximum Flow (FUMTMF) sec

4. Maximum Flow Rate (FUMMXFR) . ml/sec

5. Mean Flow Rate (FUMMNFR) . ml/sec

6. Voided Volume (FUMVV) ml

7. Post Void Residual (FUMPVR) ml

Mark the date and patient number (either screening or study number) on each printout. Make two copies of the uroflow printout. One copy is filed with the source documents; the other along with the original printout is placed in the envelope in the patient's binder.

Initials of person completing form (FORMIN) first last

Date form completed (FORMDT) month day year

Signature _____