Patient number	Date of visit	month day year	BPH FORM E03.2 April, 1995 Page 1 of 4 FORM NUMBER = (FORM) FORM VERSION = (VERS)
NII	H - BPH TRIAL		
URINA	ARY EVENT REPOR	Т	
This form should be completed if the pati	ent experiences a	urinary event listed in S	ection C.
Part I / IDENTIFICATION			

<u>Pa</u> A. Patient Identification 1. Patient number (PATID) 2. Patient's initials (INITS) last 3. Patient's date of birth (DOB) month day year B. Initial Visit Information 1. Date of initial event visit (NVSTDT) month day year 2. Week of initial event visit (NVIWK) 3. Type of visit (NVITYP) Follow-up Visit Interim Visit C. <u>Urinary Event Identification</u>

1. Type of event **(NSCEI)** 1

Initials of person completing form (FORMIN)	first last	Form entered in computer?
Signature of P.I.		Date

Incontinence event (Complete Part IV)

Acute urinary retention event (Complete Part II)

Recurrent urinary tract infection event (Complete Part III)

Patient number Date of visit
Part II / ACUTE URINARY RETENTION EVENT
A. Acute Retention Event
Complete this section if the patient is unable to urinate and requires a catheter.
1. Date of catheterization (NARDTC) month day year
2. Is there an obvious cause of urinary retention other than BPH (e.g. alpha sympathomimetic medications or anesthesia)? (NAROBV) YES NO 2
If YES, CONTINUE. If NO, SKIP to Question 3.
The catheter should be removed and the patient should try to void.
a. Is the patient able to void with the catheter removed? (NARVOID) YES NO 2
If Question A.2.a is YES, this event should be recorded as an adverse event, but is <u>not</u> an acute urinary retention event. DO NOT STOP CODED MEDICATION.
If Question A.2 is NO or question A.2.a is NO, consultation with the Clinical Review Committee is required to declare an acute urinary retention event (i.e. discontinuation of coded medications)
3. Acute urinary retention event declared? (NARDEC) YES NO 2
If YES, CONTINUE.
4. Date of confirmation by Clinical Review Committee (NARCONF) I I I I I I I I I I I I I I I I I I I
This documents an acute urinary retention event. If the patient is on coded medication, STOP ALL CODED MEDICATION.
5. Is the patient on coded medications? (NARMED) YES NO 1 2
If YES, STOP ALL CODED MEDICATIONS AND CONTINUE.
6. Date coded medication discontinued (NARDISC) month day year

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Pat	ient number Date of vis	it mor	nth	day	year	BPH FORM E03.2 April, 1995 Page 3 of 4
Part I	II / RECURRENT URINARY TRACT INFECTION EVENT	-				
А. <u>Г</u>	ocumentation of Urinalysis Cultures					
Com	plete this section if the patient has had 2 positive ur	inalysis	cult	ures w	ithin 1	year.
1.	Has the patient had two positive cultures within 1 year? (NUT2CUL)			YES	NO 2	
	If YES, CONTINUE.					
	a. Date of first positive culture (NUT1PC)	mont	:h	l day	l year	
	b. Date of negative culture (NUTNC)	mont	h	l day	year	
	c. Date of second positive culture (NUT2PC)	mont	:h	l day	year	
	sultation with the Clinical Review Committee is require t (i.e. discontinuation of coded medications).	ed to d	ecla	re a ui	inary tr	ract infection
2.	Recurrent urinary tract infection event declared? (N	UTDEC)	ı	YES	NO 2	
	If YES, CONTINUE.					
3.	Date of confirmation by Clinical Review Committee (NUTCONF)	mont	:h	day	l year	
	documents a recurrent urinary tract infection event. P ALL CODED MEDICATION.	If the p	oatie	ent is c	n code	d medication,
4.	Is the patient on coded medications? (NUTMED)			YES	NO 2	
	If YES, STOP ALL CODED MEDICATIONS AND CONT	INUE.				
5.	Date coded medication discontinued (NUTDISC)	mont	:h	l day	year	

	nt number			Date of visit				April, 1995 Page 4 of 4
					month	day	year	. age . e
Part IV	/ INCONTINE	NCE EVE	<u>VT</u>					
A. <u>Do</u>	cumentation	of Event						
	lete this secti nically unacce		atient has I	nad an involuntary	loss of ur	ine that	is soci	ally or
	las the patien ocially or hygi			oss of urine that is e? (NINLU)	5	YES	NO 2	
lf	YES, CONTIN	IUE.						
	ultation with the iscontinuation			mmittee is require ns).	d to decla	ıre an ir	contine	ence event
						YES	NO	
						123		
2. Ir	ncontinence e	vent decla	red? (NINE	DEC)		1	2	
	ncontinence e		red? (NINE	DEC)		1	2	
If 3. D		IUE. nation by (·		month	day	year	
If 3. D C	TYES, CONTIN Date of confirm Committee (N	IUE. nation by (INCONF)	Clinical Rev				year	P ALL CODED
If 3. D C	TYES, CONTING Date of confirm Committee (N	IUE. nation by (INCONF)	Clinical Rev	iew		edicatio	year n, STOI	P ALL CODED
3. D C This d MEDIC	TYES, CONTING Date of confirm Committee (N	NUE. nation by (INCONF) incontiner	Clinical Rev	iew If the patient is on			year	P ALL CODED
This d MEDIO	TYES, CONTINGENT OF YES, CONTINGENT OF CONTINGENT OF CONTINGENT OF CONTINGENT OF THE PARTICULAR OF THE	nation by (INCONF) incontiner on coded r	Clinical Rev nce event.	iew If the patient is on	coded m	edicatio	year n, STOI	P ALL CODED

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