HOSPITAL DISCHARGE FORM: T3 FORM 10 (Rev 2)

PURPOSE: To identify the procedures or major events that occurred during the patient's initial hospitalization.

PERSONS RESPONSIBLE: Certified Research Coordinator.

SOURCES OF INFORMATION: Medical record, patient, physicians and nurses caring for patient.

TIME OF DATA COLLECTION: To be completed the day of discharge from the hospital if the hospital stay is $\leq$ 21 days. If the hospital stay is greater than 21 days, complete this form to report on the first 21 days in hospital.

GENERAL INSTRUCTIONS: Information collected on this form is used to complete the Hospital Discharge Notification Form (T3 Form 32) which is transmitted to the Data Coordinating Center by fax within 48 hours of hospital discharge or upon completion of 21 days in the hospital, whichever is earlier.

T3 Form 10 should contain data for events occurring during the period from initiation of study drug to the earlier of hospital discharge or 21 days in the hospital. This includes events occurring during the first 24 hours after initial treatment which also may have been reported on T3 Form 04, Admission and Treatment Assignment Form. However, events occurring <u>during or within 24 hours after</u> PTCA or CABG procedure are not reported on T3 Form 10. Such events are reported on T3 Forms 6A or 6B, PTCA Procedures Forms or T3 Forms 25 or 26, CABG Surgery Forms.

PART I: IDENTIFICATION

1. **NAME CODE:** As previously defined for the patient.

2. **DATE OF HOSPITAL DISCHARGE OR REPORT:** If patient has been discharged, record the date of discharge to home or extended care facility. If patient has not been discharged, record the date 21 days after study treatment initiation. Record date of death if patient dies while in the hospital.

3. **STATUS OF PATIENT ON ABOVE DATE:** Self-explanatory.

PART II: PROCEDURES

4. **PROCEDURES PERFORMED DURING HOSPITALIZATION:** Record the total number of each procedure performed during this hospital admission. If the procedure was not performed, record "0". If nine or more of a procedure are performed, record "9". Only those procedures which are required to be reported should be listed. (Report an ECG only if it is a qualifying, baseline, discharge, or treatment failure ECG.) An appropriate form should be completed for each procedure listed.

   For patients who are discharged from the hospital at or before 21 days, the thallium imaging test and exercise treadmill test should be performed at or within the five days following hospital discharge. If these protocol required tests are not performed at or within the five days following hospital discharge, Form 18, Non-Performance of Protocol Procedure Form, should be completed and submitted for each test not performed. The discharge ECG should be obtained within the three days prior to hospital discharge. If not performed during this 3-day period, Form 18 should be completed and submitted.

   For patients who are discharged from the hospital after more than 21 days, the discharge ECG, thallium imaging test, and exercise treadmill test, unless medically contraindicated, should be performed at or before 21 days in hospital. However, if these tests are not performed, it is <u>not</u> necessary to complete and submit Form 18 for each test not performed.

PART III: MAJOR EVENTS

5. **DID THE QUALIFYING EPISODE OF PAIN EVOLVE INTO A NON Q-WAVE MYOCARDIAL INFARCTION:** Self-explanatory.

6. **DID PATIENT REACH A DEFINED STUDY ENDPOINT:** According to protocol definition, check all that apply and submit documentation to relevant Core Labs and to the Data Coordinating Center. It is possible that one event would be counted in multiple categories. For instance, a single episode of ischemic pain at rest lasting at least 20 minutes with ST elevation/depression $\geq$ 2 mm in $\geq$ 2 contiguous leads would be recorded in 6.C.1 and 6.C.2.

   Events reported here such as MI or ischemic pain at rest with ECG changes meeting study criteria should also be reported in Item 7.

7. **DID PATIENT EXPERIENCE RECURRENT ISCHEMIA:** Check "yes" if patient experienced any ischemic pain episodes following the initiation of the study drug infusion. For ischemic pain episodes, check all the following responses that apply. It is possible that one episode of recurrent ischemic pain would be counted in multiple categories. For instance, a single episode of ischemic pain lasting at least 20 minutes with ST elevation/depression $\geq$ 2 mm in $\geq$ 2 contiguous leads would be recorded in 7.A and 7.B.

   Events reported here should also be reported in Item 6, if appropriate.

8. **HEMORRHAGIC EVENT:** Check "yes" if the patient experienced any of the hemorrhagic events listed on the Form 10.

9. **EVENTS DURING HOSPITALIZATION OTHER THAN DURING OR WITHIN 24 HOURS OF PTCA OR CABG:** Events occurring during or within 24 hours after PTCA or CABG are recorded on the Procedures Forms. **THEY SHOULD NOT BE RECORDED HERE.**

   A. **Non-fatal cardiac arrest requiring CPR or countershock:** Self-explanatory.

   B. **Transient abrupt closure:** Obstruction of contrast flow in the dilated segment where there previously had been a patent segment and documented antegrade flow. For an initial subtotal lesion prior to PTCA, transient abrupt closure more than 24 hours post-PTCA describes total obstruction occurring more than 24 hours after PTCA, that is reversed either mechanically or pharmacologically. In a situation where the dilated segment was closed at the beginning of the PTCA procedure (e.g., the PTCA is attempting to open a total occlusion), transient abrupt closure more than 24 hours post-PTCA should only be used to describe the outcome if there was a period of vessel patency during the PTCA procedure documented by normal antegrade contrast flow beyond the vessel with balloon dilatation equipment removed from the vessel followed by closure of the vessel more than 24 hours after PTCA.

C. **Sustained abrupt closure:** Sustained obstruction of contrast flow in the dilated segment where there previously had been a patent segment and documented antegrade flow. For an initial subtotal lesion prior to PTCA, sustained abrupt closure more than 24 hours post-PTCA describes total obstruction that occurs more than 24 hours after the PTCA procedure. In a situation where the dilated segment was closed at the beginning of the PTCA procedure (e.g., the PTCA is attempting to open a total occlusion), sustained abrupt closure more than 24 hours post-PTCA should only be used to describe the outcome if there was a period of vessel patency during the PTCA procedure documented by normal antegrade contrast flow beyond the vessel with balloon dilatation equipment removed from the vessel followed by sustained closure of the vessel more than 24 hours after the PTCA procedure.

D. **Isolated congestive heart failure:** Isolated episode of congestive heart failure documented by chest x-ray or treatment with diuretics. A history of CHF is a difficult diagnosis. Verification by a physician statement in the medical record is required. In general, CHF is clinically manifest by one or more features including: dyspnea on exertion (DOE--shortness of breath on exertion), bilateral pedal edema, fatigue, orthopnea (sleeping on two or more pillows to facilitate breathing), paroxysmal nocturnal dyspnea (shortness of breath that awakens the patient from sleep). Other findings supporting the clinical manifestations include but are not restricted to: presence of S^3 gallup by auscultation, elevated venous jugular pressure > 8 cm H_2O by physical exam, or radiographic evidence of pulmonary congestion.

E. **Pulmonary edema (cardiac):** Acute profound left sided congestive heart failure resulting in the accumulation of intra-bronchial and alveolar fluid, reflected by pulmonary rales, a characteristic "bat-wing" appearance on the chest radiograph, and almost always associated with marked dyspnea and hypoxia. If hemodynamic measurements are performed, they will invariably show elevation of the pulmonary capillary wedge pressure above 25 mmHg.

F. **Cardiogenic shock:** Shock defined as a systolic blood pressure < 80 mmHg which either persists for more than one hour or requires specific treatment for at least one hour. In general, shock is associated with a low urine output, decreased mental acuity or coma, and compensatory vasoconstriction (decreased blood vessel caliper). Hypotension (very low blood pressure) without these associated manifestations of low cardiac output will not be considered as shock.

G. **Cardiac tamponade:** The appearance of the following three manifestations are typical of cardiac tamponade from intra-pericardial hemorrhage due to penetrating heart wounds, aortic dissections, and intra-pericardial rupture of an aorta, or cardiac aneurysm: decline in systemic arterial pressure, elevation of systemic venous pressure, and a small, quiet heart.

H. **Arterial embolus of extremity or loss of pulse requiring treatment:** Arterial embolus is the acute occlusion of a main or distal arterial trunk supply in a limb, due to formation and distal migration of thrombotic or atherosclerotic material, associated with decreased or loss of limb perfusion, and treated by surgical embolectomy or local thrombolytic therapy. Permanent loss of pulse is the lack of detectable distal arterial pulsations (by pulsation or Doppler examination) which had previously been observable prior to instrumentation of a more proximal arterial branch. Loss of pulse may or may not be associated with ischemia of the affected limb.

I. **Arterial dissection requiring repair:** A tearing of an arterial wall which requires surgical repair.

J. **Pseudoaneurysm requiring repair:** A pulsatile hematoma requiring surgical repair at the site of percutaneous arterial puncture. The aneurysm wall at the site of the dilatation will be composed of hematoma and adventitia only.

K. **Hypotension requiring treatment:** Reduction in systolic blood pressure to < 90 mmHg, or reduction by ≥ 30 mmHg compared to baseline value which persists for more than one minute and requires a fluid bolus > 500 cc, Trendelenburg position, or pressor support (dopamine, leafafed, etc.) to restore baseline blood pressure.

L. **TIA-transient ischemic attack:** A focal neurologic defect (usually corresponding to a singular vascular territory) which resolves spontaneously so that no residual evidence of this neurologic deficit is evident within 24 hours.

M. **Stroke:** A focal neurologic deficit which appears and is still at least partially evident more than 24 hours after its onset. Submit Severe Neurologic Event Form 27 if event has occurred.

N. **Coma:** Profound depression in level of consciousness reflected by loss of contact with the environment and loss of spontaneous movement. Brain stem activity (respiration and response to deep pain) may or may not be preserved. Submit Severe Neurologic Event Form 27 if event has occurred.

O. **Hypersensitivity reaction:** Allergic reaction to iodine containing radiographic contrast media or prodamine, marked by the development of urticaria, wheezing, prolonged hypotension, or laryngospasm.

P. **Respiratory failure:** Inability of the patient to maintain adequate gas exchange during spontaneous ventilation, even with the assistance of supplemental oxygen. This may be reflected either by marked hypoxia (PO_2 < 50 TORR) or respiratory acidosis with PCO_2 > 45 TORR and pH < 7.30. Respiratory failure meeting the above criteria would usually require endotracheal intubation or tracheostomy, and mechanical ventilatory assistance. In the setting where a patient is receiving mechanical ventilatory assistance following surgery, respiratory failure shall be inability to wean the patient from mechanical ventilation within 48 hours of completion of the surgical procedure.

Q. **Pulmonary embolus:** Occlusion (partial or complete) of one or more of the pulmonary artery branches with thrombus dislodged from the systemic venous circulation. Newly occurring acute events are often (but not always) characterized by chest pain and decreases in arterial oxygenation; increased pulmonary artery pressure and even frank hemodynamic collapse may occur. The diagnosis must be supported by a "high probability" (multiple mismatched defects) lung scan and/or a confirmatory (and more definitive) pulmonary angiogram.

R. **Chest tube still in place ≥ 5 days post-surgery:** Chest tubes left in place at least 5 days post surgery. The date listed on the form should be the date the tube is removed.

S. **Renal failure requiring dialysis:** Deteriorating renal function requiring dialysis.

T. **Re-operation for bleeding:** Re-operation to remedy bleeding post-surgery.

U. **Wound dehiscence:** The splitting or bursting open of a procedural wound.

V. **Mediastinitis:** Chart documented inflammation of mediastinum following surgery.

10. **ADDITIONAL ADVERSE EVENTS:** Record any adverse events not already recorded in Items 8 and 9.

PART IV: MEDICATION

11. **MEDICATIONS AT HOSPITAL DISCHARGE:** Record all medications the patient is taking at the time of hospital discharge. Definitions of each item are provided in the instructions for the Admissions Form. If the patient is still in the hospital or has died, check "not applicable."

12. **CONTINUOUS INFUSION OF HEPARIN STOPPED OR INTERRUPTED:** Self-explanatory.

PART V: ADMINISTRATIVE MATTERS

13. **A. PRE-DISCHARGE ECG:** If the patient is still in the hospital or has died, check "not applicable."

    B. NARRATIVE SUMMARY: For patients hospitalized $\geq$ 21 days and/or having adverse events, submit a Narrative Summary $\leq$ one double-spaced page in length, which describes pertinent clinical features and, in particular, adherence to the T3 protocol and effects of T3 therapy. This narrative should be recorded in such a way as to maintain treatment blinding and patient confidentiality.

14. Self-explanatory.

15. Self-explanatory.

Complete this form for the entire period of initial hospitalization, or, for patients with extended stay, complete this form to report on the first 21 days in hospital. This form should contain data for events occurring during the period from initiation of study drug treatment to the earlier of hospital discharge or 21 days in the hospital unless stated otherwise.

Clinic No.			-						
ID No.			-						
Form Type	H	D	0	1					

PART I: IDENTIFICATION

1. Patient's NAME CODE: ---------- ___ ___ ___ ___ ___

fm10dys

2. Date of hospital discharge or report: ---------- ___ ___ - ___ ___ - ___ ___
Month Day Year

hnstatus

3. Status of the patient on above date:
Dead ---------- (1)*
Alive - discharged from hospital ---------- (2)
Alive - remains in hospital ---------- (3)

**Submit Death Notification Form 15 and Cause of Death Form 16 and complete as much of this form as possible.*

PART II: PROCEDURES

4. Procedures performed during hospitalization that are requested by protocol to be submitted: (*Answer each item: use 0 if not performed, record separate entries for Thallium Imaging and ETT.*)

		Number Performed
A.	12-lead ECG(s):	
	1) Qualifying ---------- qualecg	___
	2) Baseline ---------- baseecg	___
	3) Ischemic episode or suspect MI ---------- ischecg	___
	4) Discharge ---------- hdecg	___
B.	Left heart cath for angiography, without PTCA ---------- cathnum	___
C.	Left heart cath for angiography, with PTCA ---------- ptcanum	___
D.	CABG ---------- cabgnum	___
E.	Exercise Treadmill Test** ---------- ettnum	___
F.	Thallium Imaging Test after ETT** ---------- tptnum	___
G.	Persantine/Thallium Imaging Test** ---------- perthlnm	___
H.	Holter Monitoring ---------- holtnum	___

holtrcd

1) Was Holter Core Lab Report (telephone call) received before hospital discharge or report date (Item 2 date)? --- (1) Yes (2) No (3) Not Applicable

***For patients who are discharged from the hospital at or before 21 days, these tests should be performed at or within the five days following hospital discharge. For patients who are discharged from the hospital more than 21 days after study treatment initiation, these tests, unless medically contraindicated, should be performed within the first 21 days.*

PART III: MAJOR EVENTS

	Yes	No
5. Did the qualifying episode of pain evolve into a non Q-wave myocardial infarction? (hdnqmi)	(1)	(2)
6. Did patient reach any of the following defined study end points? (endpt)	(1)	(2)

End point: (*Answer each item.*)

A. Death (death)	(1)*	(2)
B. MI after study drug treatment initiation (mi)	(1)*	(2)
C. Ischemic pain at rest with ECG changes meeting study criteria (ischem)	(1)*	(2)

(*Check all that apply.*)

1) Single episode of pain lasting at least 5 minutes with ST elevation/depression ≥ 2 mm in ≥ 2 contiguous leads (ischt1)	(1)
2) Single episode of pain lasting at least 20 minutes with: a) ST elevation/depression ≥ 1 mm in ≥ 2 contiguous leads; or b) T-wave inversion in ≥ 2 contiguous leads (ischt2)	(1)
3) Two or more episodes of pain lasting at least 5 minutes with: a) ≥ 1 mm ST elevation/depression in ≥ 2 contiguous leads; or b) T-wave inversion in ≥ 2 contiguous leads (ischt3)	(1)

D. Notification from Holter Core Lab of abnormal Holter Test (holtab)	(1)*	(2)
E. Positive Thallium Imaging Test: a) abnormal lung uptake and ≥ 1 region with reversible hypoperfusion; or b) ≥ 2 regions with reversible hypoperfusion (tptab)	(1)*	(2)
F. Positive ETT Test: a) ischemic pain prior to completion of Stage II; or b) ≥ 2 mm ST elevation/depression with or without symptoms; or c) > 10 mm Hg reduction in SBP compared to previous recording (ettab)	(1)*	(2)

**Submit appropriate event, ECGs and test forms to Core Laboratories and the DCC.*

	Yes	No	
7. Did patient experience any recurrent ischemic pain?	(1)	(2)	hdpain

Answer each item:

A. Ischemic pain associated with ≥ 2 mm ST elevation/depression in ≥ 2 contiguous leads	(1)	(2)	hdpaina
1) Number of episodes	___	___*	hdpnanum
B. Ischemic pain ≥ 20 min duration with ECG changes**	(1)	(2)	hdpainb
1) Number of episodes	___	___*	hdpnbnum *
C. ≥ 2 episodes of ischemic pain > 5 min duration with ECG changes**	(1)	(2)	hdpainc
1) Number of episodes	___	___*	hdpncnum
D. Recurrent ischemic pain with insignificant or no ECG changes	(1)	(2)	hdpaind
1) Number of episodes	___	___	hdpndnum
E. Suspect MI	(1)	(2)	hdmisus
1) Number of suspect MI's	___	___	hdminum

Submit Myocardial Infarction Event Form 23 and ECG Form 09 for each MI.

Submit ECG Form 09 for each episode.

**ECG changes:

ST elevation or depression ≥ 1 mm in ≥ 2 contiguous leads or T-wave inversion in ≥ 2 contiguous leads.

* hdpndnum 6=6 or 7, 8=8 or more

ID No.			-					

	Yes	No
8. Did patient experience any of the following hemorrhagic events? (hdbleed)	(1)	(2)

Submit Hemorrhagic Event Form 24 for each episode. In addition, submit Severe Neurologic Event Form 27 for intracranial bleeding.

Answer each item:

A. Absolute decrease in hematocrit ≥ 10% or decrease in hemoglobin > 3 gm not associated with CABG* (hdanemia)	(1)	(2)
B. Intracranial bleeding (hdicb)	(1)	(2)
C. GI bleeding (hdgib)	(1)	(2)
D. Retroperitoneal bleeding (hdrpb)	(1)	(2)
E. Bleeding, requiring surgery, not associated with CABG (hdsurgb)	(1)	(2)
F. Bleeding, requiring transfusion, not associated with CABG (hdtransb)	(1)	(2)

**Treat each unit transfused as equivalent to an absolute decrease in hematocrit of 3% or a decrease in hemoglobin of 1 gm/dl.*

9. Did patient experience any events listed below at times other than during or within 24 hours after PTCA or CABG procedure? -------- hdevent (1) Yes (2) No (3) Unknown

Answer each item and record date of first of each event:	YES	NO	DATE OF EVENT Month Day Year
CARDIOVASCULAR EVENTS			
A. Non-fatal cardiac arrest requiring CPR or countershock	hdcpr (1)	(2)	cpdays ___ ___-___ ___-___ ___
B. Transient abrupt coronary closure occurring > 24 hours post-PTCA	hdtrcl (1)	(2)	trdays ___ ___-___ ___-___ ___
C. Sustained abrupt coronary closure occurring > 24 hours post-PTCA	hdsrcl (1)	(2)	srdays ___ ___-___ ___-___ ___
D. Isolated congestive heart failure	hdchf (1)	(2)	chdays ___ ___-___ ___-___ ___
E. Pulmonary edema (cardiac)	hdedema (1)	(2)	eddays ___ ___-___ ___-___ ___
F. Cardiogenic shock	hdshock (1)	(2)	shdays ___ ___-___ ___-___ ___
G. Cardiac tamponade	hdtamp (1)	(2)	tadays ___ ___-___ ___-___ ___
H. Arterial embolus of extremity or loss of pulse requiring treatment	hdembol (1)	(2)	emdays ___ ___-___ ___-___ ___
I. Arterial dissection requiring repair	hddissct (1)	(2)	disdays ___ ___-___ ___-___ ___
J. Pseudoaneurysm requiring repair	hdaneur (1)	(2)	andays ___ ___-___ ___-___ ___
K. Hypotension requiring treatment	hdlbp (1)	(2)	lbdays ___ ___-___ ___-___ ___
NEUROLOGIC EVENTS			
L. TIA	hdtia (1)	(2)	tiadays ___ ___-___ ___-___ ___
M. Stroke	hdstroke (1)*	(2)	stdays ___ ___-___ ___-___ ___
N. Coma	hdcoma (1)*	(2)	codays ___ ___-___ ___-___ ___
ALLERGIC EVENT			
O. Hypersensitivity reaction	hdallerg (1)	(2)	aldays ___ ___-___ ___-___ ___
PULMONARY EVENTS			
P. Respiratory failure including non-cardiac pulmonary edema and ARDS	hdards (1)	(2)	ardays ___ ___-___ ___-___ ___
Q. Pulmonary embolus	hdpulemb (1)	(2)	pudays ___ ___-___ ___-___ ___
R. Chest tube still in place ≥ 5 days post-CABG	hdtube (1)	(2)	tudays ___ ___-___ ___-___ ___
RENAL EVENT			
S. Renal failure requiring dialysis	hddialys (1)	(2)	diadays ___ ___-___ ___-___ ___
PROCEDURAL EVENTS			
T. Re-operation for bleeding	hdreop (1)	(2)	redays ___ ___-___ ___-___ ___
U. Wound dehiscence	hdwound (1)	(2)	wodays ___ ___-___ ___-___ ___
V. Mediastinitis or wound infection	hdinfect (1)	(2)	indays ___ ___-___ ___-___ ___

Submit Severe Neurologic Event Form 27.

ID No. | | | - | | | | | |

10. Were there additional adverse events not listed in Questions 8 or 9? ---- (1) Yes (2) No — hdadvev

Specify: _____

_____

PART IV: MEDICATION

11. Were any of the listed medications prescribed at hospital discharge? (*Answer each item.*)

		Yes	No	Not Applicable* or Unknown
A.	Heparin — hdhep	(1)	(2)	(3)
B.	Nitrates — hdnitra	(1)	(2)	(3)
C.	Beta-blocker therapy — hdbeta	(1)	(2)	(3)
D.	Calcium channel blockers — hdccb	(1)	(2)	(3)
E.	Persantine/sulfinpyrazone — hdpers	(1)	(2)	(3)
F.	Antiplatelet agent other than ASA or persantine — hdplate	(1)	(2)	(3)
G.	Aspirin — hdasa	(1)	(2)	(3)
H.	Anticoagulant other than heparin — hdcoag	(1)	(2)	(3)
I.	Lipid-lowering agent — hdliplo	(1)	(2)	(3)
J.	Diuretics — hddiur	(1)	(2)	(3)
K.	ACE inhibitors — hdacein	(1)	(2)	(3)
L.	Vasodilator other than ACE inhibitor/nitrates/ calcium channel blockers — hddilat	(1)	(2)	(3)
M.	Digitalis or derivative — hddigit	(1)	(2)	(3)
N.	Inotropic agent — hdinotr	(1)	(2)	(3)
O.	Antiarrhythmic agent — hdrhyth	(1)	(2)	(3)

**Patient has not been discharged from the hospital or patient died during the hospitalization.*

12. Was the continuous infusion of heparin stopped or interrupted for > 4 hours prior to catheterization or prior to 3 days after initial treatment/revascularization? ---------- (1) Yes (2) No — hepstop

A. How many hours of continuous heparin infusion were administered before it was discontinued? ---------- ___ ___ ___ ___ — hephours

B. Reason for heparin discontinuation: _____

_____

ID No.			-					

PART V: ADMINISTRATIVE MATTERS

13. The following required items are being submitted:

	Yes	No	Not Applicable
A. Pre-discharge ECG labelled and sent to Core Lab and copy of ECG Form 09 to DCC deleted	(1)	(2)	(3)
B. Narrative Summary* (only if patient hospitalized ≥ 21 days and/or had adverse events) deleted	(1)	(2)	

**For patients hospitalized ≥ 21 days and/or having adverse events, submit a Narrative Summary ≤ 1 double-spaced page in length, which describes pertinent clinical features and, in particular, adherence to the T3 protocol and effects of T3 therapy. This narrative should be recorded in such a way as to maintain treatment blinding and patient confidentiality.*

14. Research Coordinator:

Signature: _____ T3 Staff No.: ___ ___ - ___ ___ ___

15. Date form completed: ---------- ___ ___ - ___ ___ - ___ ___
Month Day Year

FOR DATA COORDINATING CENTER USE ONLY

16. Documents received:

	Yes
A. Narrative Summary	(1)
B. Pre-discharge ECG	(1)

ID No.			-					

T3 Form 10: Variables from earlier revisions

HDSTATUS Revision 0, Item 3
Current status of the patient
1=Alive 2=Dead

FAILECG Revision 0, Item 4A3
Number of Treatment failure 12-lead ECG(s)

HDCLOSE Revision 0, Item 8B
Abrupt coronary closure occurring > 24 hours post-PTCA
1=Yes 2=No

T3 Form 10: Data Set Revisions

The following items were deleted – no relevant information

Item 13A: Pre-discharge ECT submitted
Item 13B: Narrative summary submitted

The following variable was recoded

HDPNDNUM	Item 7D1: Nr Ischemic pain w/o ECG chg 6=6 or 7, 8=8 or more

T3B form10

The CONTENTS Procedure

Data Set Name:	WORK.FORM10	**Observations:**	1473
Member Type:	DATA	**Variables:**	111
Engine:	V8	**Indexes:**	0
Created:	13:31 Wednesday, February 11, 2004	**Observation Length:**	552
Last Modified:	13:31 Wednesday, February 11, 2004	**Deleted Observations:**	0
Protection:		**Compressed:**	NO
Data Set Type:		**Sorted:**	NO
Label:			

-----Alphabetic List of Variables and Attributes-----

#	Variable	Type	Len	Pos	Format	Label
103	ALDAYS	Num	8	136		f10q9O: Hypersensitivity days
98	ANDAYS	Num	8	96		f10q9J: Pseudoaneurysm days
104	ARDAYS	Num	8	144		f10q9P: Resp failure days
5	BASEECG	Num	4	220		f10q4A2: Nr baseline ECG
11	CABGNUM	Num	4	244		f10q4D: Nr CABG
9	CATHNUM	Num	4	236		f10q4B: Nr Lt Heart Cath
92	CHDAYS	Num	8	48		f10q9D: Isolated CHF days
102	CODAYS	Num	8	128		f10q9N: Coma days
89	CPDAYS	Num	8	24		f10q9A: NF cardiac arrest days
19	DEATH	Num	4	276		f10q6A: Death
107	DIADAYS	Num	8	168		f10q9S: Renal failure days
97	DISDAYS	Num	8	88		f10q9I: Arterial dissection days
93	EDDAYS	Num	8	56		f10q9E: Pulmonary edema days
96	EMDAYS	Num	8	80		f10q9H: Arterial embolus days
18	ENDPT	Num	4	272		f10q6: Any endpoints
27	ETTAB	Num	4	308		f10q6F: Positive ETT
13	ETTNUM	Num	4	252		f10q4E: Nr ETT
7	FAILECG	Num	4	228		f10q4A3: Nr treatment failure ECG
88	FM10DYS	Num	8	16		f10q2: Days to discharge
81	HDACEIN	Num	4	524		f10q11K: ACE inhibitors prescribed
70	HDADVEV	Num	4	480		f10q10: Additional adverse events
62	HDALLERG	Num	4	448		f10q9O: Hypersensitivity

(11FEB04--13:31)

T3B form10

The CONTENTS Procedure

-----Alphabetic List of Variables and Attributes-----						
#	Variable	Type	Len	Pos	Format	Label
40	HDANEMIA	Num	4	360		f10q8A: Decrease hematocrit
57	HDANEUR	Num	4	428		f10q9J: Pseudoaneurysm
63	HDARDS	Num	4	452		f10q9P: Resp failure
77	HDASA	Num	4	508		f10q11G: Aspirin prescribed
73	HDBETA	Num	4	492		f10q11C: Beta-blocker prescribed
39	HDBLEED	Num	4	356		f10q8: Hemorrhagic events
74	HDCCB	Num	4	496		f10q11D: Ca Chan Blocker prescribed
51	HDCHF	Num	4	404		f10q9D: Isolated CHF
50	HDCLOSE	Num	4	400		f10q8B: Coronary closure
78	HDCOAG	Num	4	512		f10q11H: Anticoagulant prescribed
61	HDCOMA	Num	4	444		f10q9N: Coma
47	HDCPR	Num	4	388		f10q9A: NF cardiac arrest
66	HDDIALYS	Num	4	464		f10q9S: Renal failure
83	HDDIGIT	Num	4	532		f10q11M: Digitalis prescribed
82	HDDILAT	Num	4	528		f10q11L: Vasodilator prescribed
56	HDDISSCT	Num	4	424		f10q9I: Arterial dissection
80	HDDIUR	Num	4	520		f10q11J: Diuretics prescribed
8	HDECG	Num	4	232		f10q4A4: Nr discharge ECG
52	HDEDEMA	Num	4	408		f10q9E: Pulmonary edema
55	HDEMBOL	Num	4	420		f10q9H: Arterial embolus
46	HDEVENT	Num	4	384		f10q9: Events
42	HDGIB	Num	4	368		f10q8C: GI bleeding
71	HDHEP	Num	4	484		f10q11A: Heparin prescribed
41	HDICB	Num	4	364		f10q8B: Intracranial bleeding
69	HDINFECT	Num	4	476		f10q9V: Mediastinitis
84	HDINOTR	Num	4	536		f10q11N: Inotropic agent prescribed
58	HDLBP	Num	4	432		f10q9K: Hypotension
79	HDLIPLO	Num	4	516		f10q11I: Lipid-lowering prescribed
38	HDMINUM	Num	4	352		f10q7E1: Nr Suspect MI
37	HDMISUS	Num	4	348		f10q7E: Suspect MI
72	HDNITRA	Num	4	488		f10q11B: Nitrates prescribed

(11FEB04--13:31)

T3B form10

The CONTENTS Procedure

-----Alphabetic List of Variables and Attributes-----						
#	Variable	Type	Len	Pos	Format	Label
17	HDNQMI	Num	4	268		f10q5: Non Q-wave MI
28	HDPAIN	Num	4	312		f10q7: Recurrent pain
29	HDPAINA	Num	4	316		f10q7A: ST elevation
31	HDPAINB	Num	4	324		f10q7B: 20 min w ECG changes
33	HDPAINC	Num	4	332		f10q7C: 5 min w ECG changes
35	HDPAIND	Num	4	340		f10q7D: Ischemic pain w/o ECG chg
75	HDPERS	Num	4	500		f10q11E: Persantine prescribed
76	HDPLATE	Num	4	504		f10q11F: Antiplatelet agent prescribed
30	HDPNANUM	Num	4	320		f10q7A1: Nr ST elevation
32	HDPNBNUM	Num	4	328		f10q7B1: Nr 20 min w ECG changes
34	HDPNCNUM	Num	4	336		f10q7C1: Nr 5 min w ECG changes
36	HDPNDNUM	Num	4	344		f10q7D1: Nr Ischemic pain w/o ECG chg
64	HDPULEMB	Num	4	456		f10q9Q: Pulmonary embolus
67	HDREOP	Num	4	468		f10q9T: Reoperation bleeding
85	HDRHYTH	Num	4	540		f10q11O: Antiarrhythmic agent prescribed
43	HDRPB	Num	4	372		f10q8D: Retroperitoneal bleeding
53	HDSHOCK	Num	4	412		f10q9F: Cardiogenic shock
49	HDSRCL	Num	4	396		f10q9C: Sus coronary closure
2	HDSTATUS	Num	4	208		f10q3: Status at discharge
60	HDSTROKE	Num	4	440		f10q9M: Stroke
44	HDSURGB	Num	4	376		f10q8E: Bleeding req surgery
54	HDTAMP	Num	4	416		f10q9G: Cardiac tamponade
59	HDTIA	Num	4	436		f10q9L: TIA
45	HDTRANSB	Num	4	380		f10q8F: Bleeding req transfusion
48	HDTRCL	Num	4	392		f10q9B: Trans coronary closure
65	HDTUBE	Num	4	460		f10q9R: Chest tube
68	HDWOUND	Num	4	472		f10q9U: Wound dehiscence
111	HEPHOURS	Num	8	200	4.	f10q12A: Hours of heparin infusion
86	HEPSTOP	Num	4	544		f10q12: Heparin stopped
3	HNSTATUS	Num	4	212		f10q3: Status at discharge
25	HOLTAB	Num	4	300		f10q6D: Abnormal Holter

(11FEB04--13:31)

T3B form10

The CONTENTS Procedure

-----Alphabetic List of Variables and Attributes-----						
#	Variable	Type	Len	Pos	Format	Label
14	HOLTNUM	Num	4	256		f10q4H: Nr Holter Monitoring
16	HOLTRCD	Num	4	264		f10q4H1: Holter report received
110	INDAYS	Num	8	192		f10q9V: Mediastinitis days
6	ISCHECG	Num	4	224		f10q4A3: Nr ischemic episode ECG
21	ISCHEM	Num	4	284		f10q6C: Ischemic pain
22	ISCHT1	Num	4	288		f10q6C1: Single episode 5 min
23	ISCHT2	Num	4	292		f10q6C2: Single episode 20 min
24	ISCHT3	Num	4	296		f10q6C3: Multiple episodes
99	LBDAYS	Num	8	104		f10q9K: Hypotension days
20	MI	Num	4	280		f10q6B: MI after treatment
87	NEWID	Num	8	8		Patient Identification
15	PERTHLNM	Num	4	260		f10q4G: Nr Persantine tests
10	PTCANUM	Num	4	240		f10q4C: Nr PTCA
105	PUDAYS	Num	8	152		f10q9Q: Pulmonary embolus days
4	QUALECG	Num	4	216		f10q4A1: Nr qualifying ECG
108	REDAYS	Num	8	176		f10q9T: Reoperation bleeding days
1	REV	Num	8	0		Revision
94	SHDAYS	Num	8	64		f10q9F: Cardiogenic shock days
91	SRDAYS	Num	8	40		f10q9C: Sus coronary closure days
101	STDAYS	Num	8	120		f10q9M: Stroke days
95	TADAYS	Num	8	72		f10q9G: Cardiac tamponade days
100	TIDAYS	Num	8	112		f10q9L: TIA days
26	TPTAB	Num	4	304		f10q6E: Positive Thallium
12	TPTNUM	Num	4	248		f10q4F: Nr Thallium tests
90	TRDAYS	Num	8	32		f10q9B: Trans coronary closure days
106	TUDAYS	Num	8	160		f10q9R: Chest tube days
109	WODAYS	Num	8	184		f10q9U: Wound dehiscence days

T3B form10

Variable	Label	Value	N	%	<= 20
REV	Revision	0	208	14.1	
		1	154	10.5	
		2	1111	75.4	
HNSTATUS	f10q3: Status at discharge	.	208	14.1	
		1	26	1.8	
		2	1151	78.1	
		3	88	6.0	
HDSTATUS	f10q3: Status at discharge	.	1265	85.9	
		1	204	13.8	
		2	4	0.3	*
QUALECG	f10q4A1: Nr qualifying ECG	0	35	2.4	
		1	1253	85.1	
		2	159	10.8	
		3	21	1.4	
		4	5	0.3	*
BASEECG	f10q4A2: Nr baseline ECG	0	173	11.7	
		1	1295	87.9	
		2	5	0.3	*
ISCHECG	f10q4A3: Nr ischemic episode ECG	.	362	24.6	
		0	848	57.6	
		1	100	6.8	
		2	72	4.9	
		3	37	2.5	
		4	29	2.0	
		5	9	0.6	*
		6	4	0.3	*
		7	12	0.8	*

T3B form10

Variable	Label	Value	N	%	<= 20
FAILECG	f10q4A3: Nr treatment failure ECG	.	1111	75.4	
		0	279	18.9	
		1	34	2.3	
		2	24	1.6	
		3	10	0.7	*
		4	7	0.5	*
		5	3	0.2	*
		6	1	0.1	*
		7	4	0.3	*
HDECG	f10q4A4: Nr discharge ECG	0	64	4.3	
		1	1408	95.6	
		6	1	0.1	*
CATHNUM	f10q4B: Nr Lt Heart Cath	0	584	39.6	
		1	871	59.1	
		2	18	1.2	*
PTCANUM	f10q4C: Nr PTCA	0	1036	70.3	
		1	420	28.5	
		2	17	1.2	*
CABGNUM	f10q4D: Nr CABG	0	1168	79.3	
		1	302	20.5	
		2	2	0.1	*
		3	1	0.1	*
ETTNUM	f10q4E: Nr ETT	0	330	22.4	
		1	1141	77.5	
		2	2	0.1	*

T3B form10

Variable	Label	Value	N	%	<= 20
TPTNUM	f10q4F: Nr Thallium tests	0	294	20.0	
		1	1179	80.0	
PERTHLNM	f10q4G: Nr Persantine tests	.	362	24.6	
		0	1030	69.9	
		1	81	5.5	
HOLTNUM	f10q4H: Nr Holter Monitoring	0	56	3.8	
		1	1406	95.5	
		2	11	0.7	*
HOLTRCD	f10q4H1: Holter report received	.	210	14.3	
		1	642	43.6	
		2	538	36.5	
		3	83	5.6	
HDNQMI	f10q5: Non Q-wave MI	.	209	14.2	
		1	320	21.7	
		2	944	64.1	
ENDPT	f10q6: Any endpoints	.	1	0.1	*
		1	618	42.0	
		2	854	58.0	
DEATH	f10q6A: Death	.	935	63.5	
		1	30	2.0	
		2	508	34.5	
MI	f10q6B: MI after treatment	.	931	63.2	
		1	95	6.4	
		2	447	30.3	

T3B form10

Variable	Label	Value	N	%	<= 20
ISCHEM	f10q6C: Ischemic pain	.	899	61.0	
		1	268	18.2	
		2	306	20.8	
ISCHT1	f10q6C1: Single episode 5 min	.	1421	96.5	
		1	52	3.5	
ISCHT2	f10q6C2: Single episode 20 min	.	1352	91.8	
		1	120	8.1	
		2	1	0.1	*
ISCHT3	f10q6C3: Multiple episodes	.	1349	91.6	
		1	124	8.4	
HOLTAB	f10q6D: Abnormal Holter	.	939	63.7	
		1	40	2.7	
		2	494	33.5	
TPTAB	f10q6E: Positive Thallium	.	910	61.8	
		1	237	16.1	
		2	326	22.1	
ETTAB	f10q6F: Positive ETT	.	913	62.0	
		1	208	14.1	
		2	352	23.9	
HDPAIN	f10q7: Recurrent pain	1	732	49.7	
		2	741	50.3	
HDPAINA	f10q7A: ST elevation	.	741	50.3	
		1	95	6.4	
		2	637	43.2	

T3B form10

Variable	Label	Value	N	%	<= 20
HDPNANUM	f10q7A1: Nr ST elevation	.	1378	93.6	
		1	66	4.5	
		2	21	1.4	
		3	4	0.3	*
		4	2	0.1	*
		5	1	0.1	*
		9	1	0.1	*
HDPAINB	f10q7B: 20 min w ECG changes	.	741	50.3	
		1	174	11.8	
		2	558	37.9	
HDPNBNUM	f10q7B1: Nr 20 min w ECG changes	.	1300	88.3	
		1	128	8.7	
		2	33	2.2	
		3	5	0.3	*
		4	5	0.3	*
		5	1	0.1	*
		7	1	0.1	*
HDPAINC	f10q7C: 5 min w ECG changes	.	742	50.4	
		1	121	8.2	
		2	610	41.4	

T3B form10

Variable	Label	Value	N	%	<= 20
HDPNCNUM	f10q7C1: Nr 5 min w ECG changes	.	1352	91.8	
		1	10	0.7	*
		2	67	4.5	
		3	20	1.4	*
		4	15	1.0	*
		5	4	0.3	*
		7	1	0.1	*
		8	1	0.1	*
		9	1	0.1	*
		10	1	0.1	*
		16	1	0.1	*
HDPAIND	f10q7D: Ischemic pain w/o ECG chg	.	742	50.4	
		1	585	39.7	
		2	146	9.9	
HDPNDNUM	f10q7D1: Nr Ischemic pain w/o ECG chg	.	890	60.4	
		1	232	15.8	
		2	132	9.0	
		3	80	5.4	
		4	49	3.3	
		5	20	1.4	*
		6	31	2.1	
		8	39	2.6	
HDMISUS	f10q7E: Suspect MI	.	741	50.3	
		1	88	6.0	
		2	644	43.7	
HDMINUM	f10q7E1: Nr Suspect MI	.	1386	94.1	
		1	82	5.6	
		2	5	0.3	*

T3B form10

Variable	Label	Value	N	%	<= 20
HDBLEED	f10q8: Hemorrhagic events	1	115	7.8	
		2	1358	92.2	
HDANEMIA	f10q8A: Decrease hematocrit	.	1359	92.3	
		1	103	7.0	
		2	11	0.7	*
HDCLOSE	f10q8B: Coronary closure	.	1453	98.6	
		2	20	1.4	*
HDICB	f10q8B: Intracranial bleeding	.	1358	92.2	
		1	4	0.3	*
		2	111	7.5	
HDGIB	f10q8C: GI bleeding	.	1358	92.2	
		1	22	1.5	
		2	93	6.3	
HDRPB	f10q8D: Retroperitoneal bleeding	.	1358	92.2	
		1	3	0.2	*
		2	112	7.6	
HDSURGB	f10q8E: Bleeding req surgery	.	1358	92.2	
		1	7	0.5	*
		2	108	7.3	
HDTRANSB	f10q8F: Bleeding req transfusion	.	1358	92.2	
		1	32	2.2	
		2	83	5.6	
HDEVENT	f10q9: Events	1	106	7.2	
		2	1367	92.8	

T3B form10

Variable	Label	Value	N	%	<= 20
HDCPR	f10q9A: NF cardiac arrest	.	1367	92.8	
		1	16	1.1	*
		2	90	6.1	
HDTRCL	f10q9B: Trans coronary closure	.	1387	94.2	
		1	2	0.1	*
		2	84	5.7	
HDSRCL	f10q9C: Sus coronary closure	.	1387	94.2	
		2	86	5.8	
HDCHF	f10q9D: Isolated CHF	.	1367	92.8	
		1	26	1.8	
		2	80	5.4	
HDEDEMA	f10q9E: Pulmonary edema	.	1367	92.8	
		1	11	0.7	*
		2	95	6.4	
HDSHOCK	f10q9F: Cardiogenic shock	.	1367	92.8	
		1	15	1.0	*
		2	91	6.2	
HDTAMP	f10q9G: Cardiac tamponade	.	1367	92.8	
		1	4	0.3	*
		2	102	6.9	
HDEMBOL	f10q9H: Arterial embolus	.	1367	92.8	
		1	5	0.3	*
		2	101	6.9	

T3B form10

Variable	Label	Value	N	%	<= 20
HDDISSCT	f10q9I: Arterial dissection	.	1367	92.8	
		1	1	0.1	*
		2	105	7.1	
HDANEUR	f10q9J: Pseudoaneurysm	.	1400	95.0	
		1	3	0.2	*
		2	70	4.8	
HDLBP	f10q9K: Hypotension	.	1367	92.8	
		1	47	3.2	
		2	59	4.0	
HDTIA	f10q9L: TIA	.	1367	92.8	
		1	3	0.2	*
		2	103	7.0	
HDSTROKE	f10q9M: Stroke	.	1367	92.8	
		1	11	0.7	*
		2	95	6.4	
HDCOMA	f10q9N: Coma	.	1367	92.8	
		1	3	0.2	*
		2	103	7.0	
HDALLERG	f10q9O: Hypersensitivity	.	1367	92.8	
		1	5	0.3	*
		2	101	6.9	
HDARDS	f10q9P: Resp failure	.	1367	92.8	
		1	16	1.1	*
		2	90	6.1	

T3B form10

Variable	Label	Value	N	%	<= 20
HDPULEMB	f10q9Q: Pulmonary embolus	.	1367	92.8	
		1	2	0.1	*
		2	104	7.1	
HDTUBE	f10q9R: Chest tube	.	1367	92.8	
		1	3	0.2	*
		2	103	7.0	
HDDIALYS	f10q9S: Renal failure	.	1367	92.8	
		1	4	0.3	*
		2	102	6.9	
HDREOP	f10q9T: Reoperation bleeding	.	1367	92.8	
		1	2	0.1	*
		2	104	7.1	
HDWOUND	f10q9U: Wound dehiscence	.	1367	92.8	
		1	1	0.1	*
		2	105	7.1	
HDINFECT	f10q9V: Mediastinitis	.	1367	92.8	
		1	5	0.3	*
		2	101	6.9	
HDADVEV	f10q10: Additional adverse events	1	74	5.0	
		2	1399	95.0	
HDHEP	f10q11A: Heparin prescribed	1	7	0.5	*
		2	1345	91.3	
		3	121	8.2	

T3B form10

Variable	Label	Value	N	%	<= 20
HDNITRA	f10q11B: Nitrates prescribed	1	671	45.6	
		2	681	46.2	
		3	121	8.2	
HDBETA	f10q11C: Beta-blocker prescribed	1	838	56.9	
		2	513	34.8	
		3	122	8.3	
HDCCB	f10q11D: Ca Chan Blocker prescribed	1	806	54.7	
		2	545	37.0	
		3	122	8.3	
HDPERS	f10q11E: Persantine prescribed	1	79	5.4	
		2	1272	86.4	
		3	122	8.3	
HDPLATE	f10q11F: Antiplatelet agent prescribed	1	3	0.2	*
		2	1348	91.5	
		3	122	8.3	
HDASA	f10q11G: Aspirin prescribed	1	1227	83.3	
		2	124	8.4	
		3	122	8.3	
HDCOAG	f10q11H: Anticoagulant prescribed	.	1	0.1	*
		1	33	2.2	
		2	1318	89.5	
		3	121	8.2	
HDLIPLO	f10q11I: Lipid-lowering prescribed	1	137	9.3	
		2	1215	82.5	
		3	121	8.2	

T3B form10

Variable	Label	Value	N	%	<= 20
HDDIUR	f10q11J: Diuretics prescribed	1	116	7.9	
		2	1235	83.8	
		3	122	8.3	
HDACEIN	f10q11K: ACE inhibitors prescribed	1	102	6.9	
		2	1249	84.8	
		3	122	8.3	
HDDILAT	f10q11L: Vasodilator prescribed	1	9	0.6	*
		2	1342	91.1	
		3	122	8.3	
HDDIGIT	f10q11M: Digitalis prescribed	1	106	7.2	
		2	1245	84.5	
		3	122	8.3	
HDINOTR	f10q11N: Inotropic agent prescribed	1	5	0.3	*
		2	1347	91.4	
		3	121	8.2	
HDRHYTH	f10q11O: Antiarrhythmic agent prescribed	1	37	2.5	
		2	1315	89.3	
		3	121	8.2	
HEPSTOP	f10q12: Heparin stopped	.	1	0.1	*
		1	259	17.6	
		2	1213	82.3	

T3B form10

Variable	Label	N	Percentile	Value	n	<= 20
HEPHOURS	f10q12A: Hours of heparin infusion	260	5	8	13	*
			25	27	54	
			50	41	68	
			75	55	61	
			95	70	54	
			100	248	10	*

T3B form10

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
FM10DYS	f10q2: Days to discharge	1473	10.5	5.5	1.0	42.0
CPDAYS	f10q9A: NF cardiac arrest days	16	6.7	5.4	1.0	19.0
TRDAYS	f10q9B: Trans coronary closure days	2	5.0	1.4	4.0	6.0
SRDAYS	f10q9C: Sus coronary closure days	0				
CHDAYS	f10q9D: Isolated CHF days	26	5.4	4.3	1.0	20.0
EDDAYS	f10q9E: Pulmonary edema days	11	6.7	5.9	1.0	19.0
SHDAYS	f10q9F: Cardiogenic shock days	15	5.3	6.3	1.0	21.0
TADAYS	f10q9G: Cardiac tamponade days	4	4.0	4.1	1.0	10.0
EMDAYS	f10q9H: Arterial embolus days	5	7.6	7.6	2.0	21.0
DISDAYS	f10q9I: Arterial dissection days	1	4.0		4.0	4.0
ANDAYS	f10q9J: Pseudoaneurysm days	3	7.3	2.1	5.0	9.0
LBDAYS	f10q9K: Hypotension days	47	4.4	4.5	1.0	21.0
TIDAYS	f10q9L: TIA days	3	12.3	5.1	8.0	18.0
STDAYS	f10q9M: Stroke days	11	5.3	4.8	1.0	14.0
CODAYS	f10q9N: Coma days	3	6.7	9.0	1.0	17.0
ALDAYS	f10q9O: Hypersensitivity days	5	2.0	0.7	1.0	3.0
ARDAYS	f10q9P: Resp failure days	16	6.8	6.1	1.0	21.0
PUDAYS	f10q9Q: Pulmonary embolus days	2	16.5	2.1	15.0	18.0
TUDAYS	f10q9R: Chest tube days	3	14.0	7.5	6.0	21.0
DIADAYS	f10q9S: Renal failure days	4	7.5	5.1	3.0	14.0
REDAYS	f10q9T: Reoperation bleeding days	2	5.0	2.8	3.0	7.0
WODAYS	f10q9U: Wound dehiscence days	1	19.0		19.0	19.0
INDAYS	f10q9V: Mediastinitis days	5	15.0	1.9	12.0	17.0