

CAUSE OF DEATH FORM: T3 FORM 16 (Rev. 1)

PURPOSE: To record the primary cause of death, the time frame of and circumstances surrounding death.

PERSONS RESPONSIBLE: Certified Nurse/Coordinator, and T3 physician.

SOURCES OF INFORMATION: Family members, physician and primary care nurses caring for the patient, hospital records, in some cases death certificate or coroner's report.

TIME OF DATA COLLECTION: As soon as knowledge of death occurs.

GENERAL INSTRUCTIONS: This form should be completed for any T3 patient who dies. The following should be sent to the Data Coordinating Center:

1. T3 Form 15 and T3 Form 16
2. Death Certificate
3. Autopsy Report (if available)
4. ECGs (if relevant)
5. Final Hospital Summary
6. Physician's Summary
7. FDA Form 1639, if death occurs before six-week follow-up contact.

PART I: IDENTIFICATION

1. **NAME CODE:** As previously defined for the patient.
2. **DATE AND MILITARY TIME OF DEATH:** Record the date and military time of death. This information can be obtained from hospital records, death certificate or coroner's report.

PART II: CAUSE OF DEATH

3. **UNDERLYING CAUSE OF DEATH:** Check only 1 of A-D.
 - A. **Atherosclerotic Cardiovascular Disease:** More than one atherosclerotic cardiovascular disease can be checked as the underlying cause of death, however, each underlying cause of death should be justified in the physician summary.
 - 1) **Recent or acute event:** Death within 1 week of an acute myocardial infarction or sudden unexpected, unobserved death or death following acute myocardial ischemia (insufficiency).
 - 2) **Without recent or acute cardiac event:** Chronic congestive heart failure. Such a patient may die of an acute cardiac arrhythmia. If documented, cardiac arrhythmia should also be checked as an underlying cause of death.
 - 3) **Cardiac arrhythmia:** Documented ventricular tachycardia or fibrillation, complete heart block. If the arrhythmia was agonal, this category should not be checked.
 - 4) **Complication of surgery for coronary artery disease:** The complication is directly attributable to the surgery e.g. perioperative myocardial infarction.
 - 5) **Other:** For example, complication of PTCA.
 - B. **Non-atherosclerotic Cardiovascular Disease:** e.g., cardiomyopathy (non-ischemic), valvular heart disease, infective endocarditis, pulmonary thromboembolism, ruptured aneurysm.
 - C. **Non-cardiovascular Disease:** For example, malignancy, trauma.
 - D. **Unknown:** If primary cause of death cannot be determined check "unknown."
4. **THE IMMEDIATE CAUSE OF DEATH:** More than one of the following items may be checked, but an explanation should be contained in the Physician's Summary.

- A. **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 caliber). Hypotension (very low blood pressure) without these associated manifestations of low cardiac output will not be considered as shock.
- B. **Cardiac dysrhythmia:** Bradycardia or tachycardia, e.g., heart block or ventricular tachycardia or fibrillation.
- C. **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 S³ gallop by auscultation, elevated venous jugular pressure > 8 cm H₂O by physical exam, or radiographic evidence of pulmonary congestion.
- D. **Pulmonary edema:** 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 pulmonary capillary wedge pressure above 25 mmHg.
- E. **Ruptured myocardium with 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 system venous pressure, and a small, quiet heart.
- F. **Stroke:** A focal neurologic deficit which appears and is still at least partially evident more than 24 hours after its onset. The type of stroke should be indicated. Submit Severe Neurologic Event Form 27 if event has occurred. Also submit Hemorrhagic Event Form 24 if a hemorrhagic stroke has occurred.
- G. **Acute pulmonary thromboembolism:** 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.

H. **Hemorrhage:** Other than cerebrovascular, e.g., gastrointestinal hemorrhage. Submit Hemorrhagic Event Form 24 if event has occurred.

I. **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.

J. **Other:** E.g., septicemia, trauma.

I. **Unknown.**

5. **UNDERLYING ILLNESS:** To be completed using the ICD-9 Code, (International Classification of Disease, 9th Edition, available from the US Department of Health and Human Services). The following list represents several common disease categories. Consult the above text for categories not included in this list.

- #410 acute myocardial infarction:
 - #410.0 anterolateral wall infarction
 - #410.1 other anterior wall infarction
 - #410.2 inferolateral wall infarction
 - #410.3 inferoposterior wall infarction
 - #410.4 other inferior wall infarction
 - #410.5 other lateral wall infarction
 - #410.6 true posterior wall infarction
 - #410.7 subendocardial infarction
 - #410.9 unspecified site
- #411.1 unstable angina
- #414.8 chronic ischemic heart disease
- #415.1 pulmonary embolism and infarction
- #421.0 acute and subacute bacterial endocarditis
- #423.0 hemopericardium
- #424.0 mitral valve disorder
 - #424.1 aortic valve disorder
- #427.31 atrial fibrillation
- #427.32 atrial flutter

#427.41 ventricular fibrillation
#427.42 ventricular flutter
#428.0 congestive heart failure
#428.1 left heart failure
#430 subarachnoid hemorrhage
#431 intracerebral hemorrhage
#432.9 unspecified intracranial hemorrhage
#434.0 cerebral thrombosis
#434.1 cerebral embolism
#434.9 cerebral artery occlusion
#581.81 respiratory failure

PART III: HOSPITALIZATION

6. **REHOSPITALIZATION:** Check "Yes" and complete and submit T3 Form 14, Subsequent Hospitalization Form if the patient has been hospitalized for any cardiac reason associated with the terminal event.

PART IV: CIRCUMSTANCES OF DEATH

7. **CHRONOLOGY OF DEATH:** Indicate which of the descriptions best describes the chronology of death.
8. **DEATH WITNESSED:** Self-explanatory, this information is particularly useful for out-of-hospital deaths.
9. **LOCATION OF PATIENT AT TIME OF DEATH:** Self-explanatory.

PART V: RESOURCE MATERIAL

10. **AUTOPSY PERFORMED:** Self-explanatory.
11. **RESOURCE MATERIALS AVAILABLE AND SUBMITTED:** Indicate the availability of each resource document. For each available document, indicate if it is being submitted.

PART VI: ADMINISTRATIVE MATTERS

12. **RESEARCH COORDINATOR SIGNATURE AND T3 STAFF NUMBER:** Self-explanatory.
13. **DATE OF FORM COMPLETION:** This form should be completed and forwarded to the Data Coordinating Center as soon as possible.

CAUSE OF DEATH FORM

Complete this form as soon as possible after assembling required documentation.

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

PART I: IDENTIFICATION

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

2. Date of death: ----- fm16day
Month Day Year

A. Military time of death: ----- deathhr deathmin
Hours Minutes
deathunk
(1)
Unknown

PART II: CAUSE OF DEATH

3. Underlying cause of death? (Check only one.) acvddth

A. Atherosclerotic cardiovascular disease ----- (1)
↓

Which atherosclerotic cardiovascular disease was the underlying cause of death?

More than one item may be checked, but an explanation should be contained in the Physician's Summary.

- 1) Atherosclerotic coronary heart disease with recent or acute cardiac event (e.g., myocardial infarction, acute coronary insufficiency, sudden unexpected or unobserved death) ----- acutedth (1)
- 2) Atherosclerotic coronary heart disease without recent or acute cardiac event (e.g., chronic congestive heart failure) ----- ashddth (1)
- 3) Cardiac arrhythmia, without new infarct ----- rhythdth (1)
- 4) Atherosclerotic coronary heart disease resulting in surgery for heart disease ----- csurgdth (1)
- 5) Other ----- othcddtg (1)

Specify: _____

B. Non-atherosclerotic cardiovascular disease ----- (2)
 C. Non-cardiovascular disease ----- (3)
 D. Unknown ----- (4)

ID No.			-				
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PART IV: CIRCUMSTANCES OF DEATH

A patient dying in the emergency room should be reported as dying in the hospital, however, if the patient was "dead on arrival" the patient should be reported as dying outside the hospital.

7. What was the chronology of death? (Check one.)

Sudden unexpected death does not usually apply to hospitalized patients.

chronodth

Not a sudden unexpected or unobserved death (1)

Sudden unexpected death within 60 minutes of onset of symptoms or unobserved death within 60 minutes of being seen alive without symptoms (2)

Sudden unexpected death between one and 24 hours of onset of symptoms (3)

Unobserved death between one and 24 hours of being seen alive without symptoms (4)

Unobserved death more than 24 hours of being seen alive without symptoms ---- (5)

Was the death witnessed?

witnsdth

Yes (1)

No (2)

Unknown (3)

9. At the time of the onset of the fatal event, the patient was:
(Answer only one.)

placedth

At home (1)

At work, other than home (2)

At a public place, other than work (3)

Hospitalized (4)

Unknown (5)

Other (6)

Specify: _____

PART V: RESOURCE MATERIALS

10. Was an autopsy performed? (1) (2) (3)
Yes No Unknown

autopsy

ID No.				-					
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T3 Form 16: Variables from earlier revisions

- CERTDTH Revision 0 Item 11A1
Were the following resource materials available and are the being submitted with this form?
Death certificate
1=Not Available 2=Available
- AUTORPT Revision 0 Item 11B1
Were the following resource materials available and are the being submitted with this form?
Autopsy report
1=Not Available 2=Available
- ECGDTH Revision 0 Item 11C1
Were the following resource materials available and are the being submitted with this form?
ECG(s)
1=Not Available 2=Available
- HSUMDTH Revision 0 Item 11D1
Were the following resource materials available and are the being submitted with this form?
Final hospital summary
1=Not Available 2=Available
- MDSUMDTH Revision 0 Item 11E1
Were the following resource materials available and are the being submitted with this form?
Physician's summary
1=Not Available 2=Available
- OTHRPT Revision 0 Item 11F1
Were the following resource materials available and are the being submitted with this form?
Other
1=Not Available 2=Available

T3 Form 16: Data Set Revisions

The following items were deleted due to privacy concerns:

- Item 5B1 Primary ICD-9 code
- Item 5B2 Secondary ICD-9 code
- Item 5B3 Other ICD-9 code
- Item 5B4 Other ICD-9 code

The following item was recoded:

- Item 9 Place of death
- 4=Hospitalized
- 6=At home / At work / At a public place / Other

T3B form16**The CONTENTS Procedure**

Data Set Name:	WORK.FORM16	Observations:	73
Member Type:	DATA	Variables:	47
Engine:	V8	Indexes:	0
Created:	9:27 Monday, March 22, 2004	Observation Length:	200
Last Modified:	9:27 Monday, March 22, 2004	Deleted Observations:	0
Protection:		Compressed:	NO
Data Set Type:		Sorted:	NO
Label:			

----Alphabetic List of Variables and Attributes----					
#	Variable	Type	Len	Pos	Label
6	ACUTEDTH	Num	4	40	f16q3A1: ACHD with acute cardiac event
5	ACVDDTH	Num	4	36	f16q3A: Cause of death
7	ASHDDTH	Num	4	44	f16q3A2: ACHD without acute cardiac even
27	AUTOPSY	Num	4	124	f16q10: Autopsy performed
31	AUTORPT	Num	4	140	f16q11B1: Autopsy report not available
32	AUTORPT2	Num	4	144	f16q11B1: Autopsy report available
33	AUTORPTS	Num	4	148	f16q11B2: Autopsy report submitted
19	BLEEDDTH	Num	4	92	f16q4H: Hemorrhage
28	CERTDTH	Num	4	128	f16q11A1: Death certificate not availabl
29	CERTDTH2	Num	4	132	f16q11A1: Death certificate available
30	CERTDTHS	Num	4	136	f16q11A2: Death certificate submitted
13	CHFDTH	Num	4	68	f16q4C: Congestive heart failure
24	CHRONDTH	Num	4	112	f16q7: Chronology of death
9	CSURGDTH	Num	4	52	f16q3A4: Surgery for heart disease
2	DEATHHR	Num	4	24	f16q2AHR: Hour of death
3	DEATHMIN	Num	4	28	f16q2AMN: Minute of death
4	DEATHUNK	Num	4	32	f16q2AUNK: Time of death unknown
34	ECGDTH	Num	4	152	f16q11C1: ECG not available
35	ECGDTH2	Num	4	156	f16q11C1: ECG available
36	ECGDTHS	Num	4	160	f16q11C2: ECG submitted
14	EDEMADTH	Num	4	72	f16q4D: Pulmonary edema
47	FM16DAY	Num	8	16	f16q2: Days to death

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T3B form16**The CONTENTS Procedure**

-----Alphabetic List of Variables and Attributes-----					
#	Variable	Type	Len	Pos	Label
12	HBDTH	Num	4	64	f16q4B: Cardiac dysrhythmia
23	HOSPCARD	Num	4	108	f16q6: Hospitalized for cardiac reason
37	HSUMDTH	Num	4	164	f16q11D1: Final hospital summary not ava
38	HSUMDTH2	Num	4	168	f16q11D1: Final hospital summary availab
39	HSUMDTHS	Num	4	172	f16q11D2: Final hospital summary submitt
42	MDSUDTHS	Num	4	184	f16q11E2: Physician summary submitted
41	MDSUMDT2	Num	4	180	f16q11E1: Physician summary available
40	MDSUMDTH	Num	4	176	f16q11E1: Physician summary not availabl
46	NEWID	Num	8	8	Patient Identification
10	OTHCDDTH	Num	4	56	f16q3A5: Other atherosclerotic
21	OTHDTH	Num	4	100	f16q4J: Other immediate cause of death
43	OTHRPT	Num	4	188	f16q11F1: Other report not available
44	OTHRPT2	Num	4	192	f16q11F1: Other report available
45	OTHRPTS	Num	4	196	f16q11F2: Other report submitted
26	PLACEDTH	Num	4	120	f16q9: Place of death
18	PLEMBDTH	Num	4	88	f16q4G: Acute pulmonary thromboembolism
20	RESPDTH	Num	4	96	f16q4I: Respiratory failure
1	REV	Num	8	0	Revision
8	RHYTHDTH	Num	4	48	f16q3A3: Cardiac arrhythmia
11	SHOCKDTH	Num	4	60	f16q4A: Cardiogenic shock
17	STRKTYP	Num	4	84	f16q4F1: Type of stroke
16	STROKDTH	Num	4	80	f16q4F: Stroke
15	TAMPDTH	Num	4	76	f16q4E: Ruptured myocardium
22	UNIMDTH	Num	4	104	f16q4K: Unknown cause
25	WITNSDTH	Num	4	116	f16q8: Death witnessed

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Variable	Label	Value	N	%	<= 20
REV	Revision	0	18	24.7	*
		1	55	75.3	
DEATHUNK	f16q2AUNK: Time of death unknown	.	61	83.6	
		1	12	16.4	*
ACVDDTH	f16q3A: Cause of death	1	53	72.6	
		2	4	5.5	*
		3	12	16.4	*
		4	4	5.5	*
ACUTEDTH	f16q3A1: ACHD with acute cardiac event	.	34	46.6	
		1	39	53.4	
ASHDDTH	f16q3A2: ACHD without acute cardiac even	.	67	91.8	
		1	6	8.2	*
RHYTHDTH	f16q3A3: Cardiac arrhythmia	.	71	97.3	
		1	2	2.7	*
CSURGDTH	f16q3A4: Surgery for heart disease	.	60	82.2	
		1	13	17.8	*
OTHCDTH	f16q3A5: Other atherosclerotic	.	70	95.9	
		1	3	4.1	*
SHOCKDTH	f16q4A: Cardiogenic shock	.	50	68.5	
		1	23	31.5	
HBDTH	f16q4B: Cardiac dysrhythmia	.	63	86.3	
		1	10	13.7	*

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Variable	Label	Value	N	%	<= 20
CHFDTH	f16q4C: Congestive heart failure	.	67	91.8	
		1	6	8.2	*
EDEMADTH	f16q4D: Pulmonary edema	.	70	95.9	
		1	3	4.1	*
TAMPDTH	f16q4E: Ruptured myocardium	.	69	94.5	
		1	4	5.5	*
STROKDTH	f16q4F: Stroke	.	70	95.9	
		1	3	4.1	*
STRKTYP	f16q4F1: Type of stroke	.	70	95.9	
		1	1	1.4	*
		2	2	2.7	*
PLEMBDTH	f16q4G: Acute pulmonary thromboembolism	.	70	95.9	
		1	3	4.1	*
BLEEDDTH	f16q4H: Hemorrhage	.	70	95.9	
		1	3	4.1	*
RESPDTH	f16q4I: Respiratory failure	.	65	89.0	
		1	8	11.0	*
OTHDTH	f16q4J: Other immediate cause of death	.	52	71.2	
		1	21	28.8	
UNIMDTH	f16q4K: Unknown cause	.	67	91.8	
		1	6	8.2	*

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T3B form16

Variable	Label	Value	N	%	<= 20
HOSPCARD	f16q6: Hospitalized for cardiac reason	.	2	2.7	*
		1	14	19.2	*
		2	53	72.6	
		3	4	5.5	*
CHRONDTH	f16q7: Chronology of death	.	1	1.4	*
		1	38	52.1	
		2	17	23.3	*
		3	11	15.1	*
		4	5	6.8	*
		5	1	1.4	*
WITNSDTH	f16q8: Death witnessed	.	1	1.4	*
		1	61	83.6	
		2	8	11.0	*
		3	3	4.1	*
PLACEDTH	f16q9: Place of death	4	52	71.2	
		6	21	28.8	
AUTOPSY	f16q10: Autopsy performed	.	1	1.4	*
		1	20	27.4	*
		2	47	64.4	
		3	5	6.8	*
CERTDTHS	f16q11A2: Death certificate submitted	.	25	34.2	
		1	48	65.8	
CERTDTH	f16q11A1: Death certificate not availabl	.	55	75.3	
		1	2	2.7	*
		2	16	21.9	*

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T3B form16

Variable	Label	Value	N	%	<= 20
CERTDTH2	f16q11A1: Death certificate available	.	19	26.0	*
		1	33	45.2	
		2	21	28.8	
AUTORPT	f16q11B1: Autopsy report not available	.	55	75.3	
		1	14	19.2	*
		2	4	5.5	*
AUTORPT2	f16q11B1: Autopsy report available	.	19	26.0	*
		1	16	21.9	*
		2	38	52.1	
AUTORPTS	f16q11B2: Autopsy report submitted	.	54	74.0	
		1	19	26.0	*
ECGDTH	f16q11C1: ECG not available	.	55	75.3	
		1	8	11.0	*
		2	10	13.7	*
ECGDTH2	f16q11C1: ECG available	.	19	26.0	*
		1	18	24.7	*
		2	36	49.3	
ECGDTHS	f16q11C2: ECG submitted	.	47	64.4	
		1	26	35.6	
HSUMDTH	f16q11D1: Final hospital summary not ava	.	55	75.3	
		1	12	16.4	*
		2	6	8.2	*

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T3B form16

Variable	Label	Value	N	%	<= 20
HSUMDTH2	f16q11D1: Final hospital summary availab	.	19	26.0	*
		1	26	35.6	
		2	28	38.4	
HSUMDTHS	f16q11D2: Final hospital summary submitt	.	44	60.3	
		1	29	39.7	
MDSUMDT2	f16q11E1: Physician summary available	.	19	26.0	*
		1	33	45.2	
		2	21	28.8	
MDSUMDTH	f16q11E1: Physician summary not availabl	.	55	75.3	
		1	3	4.1	*
		2	15	20.5	*
MDSUDTHS	f16q11E2: Physician summary submitted	.	28	38.4	
		1	45	61.6	
OTHRPT	f16q11F1: Other report not available	.	55	75.3	
		1	12	16.4	*
		2	6	8.2	*
OTHRPT2	f16q11F1: Other report available	.	19	26.0	*
		1	11	15.1	*
		2	43	58.9	
OTHRPTS	f16q11F2: Other report submitted	.	57	78.1	
		1	16	21.9	*

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Variable	Label	N	Mean	Std Dev	Minimum	Maximum
FM16DAY	f16q2: Days to death	73	178.8	243.5	1.0	961.0
DEATHHR	f16q2AHR: Hour of death	61	11.6	6.6	0.0	23.0
DEATHMIN	f16q2AMN: Minute of death	61	25.6	18.9	0.0	58.0