

FAVORIT

Folic Acid for Vascular Outcome
Reduction in Transplantation

OUTCOMES DOCUMENTATION FORM

FORM CODE: OUT VERSION: A 12/04/02

ID NUMBER:

CONTACT OCCASION:

SEQUENCE #:

PATIENT LAST NAME:

FIRST/MIDDLE INITIALS:

This form is to be used to document key outcome information for Death and the following non-fatal events: Myocardial Infarction (MI), Unstable Angina (USA), Stroke, Resuscitated Sudden Death (RSD) events and Urgent Revascularization Procedures (when an MI is not suspected).

If more than one non-fatal event of the same type is suspected to have occurred during one hospitalization (i.e. the patient is suspected to have had two strokes during one hospitalization), please complete a second OUT form, incrementing the sequence number. Otherwise, please use this form to capture all applicable events that may have occurred during one hospitalization.

Seq #:	0,1,2...	0,1,2...	0,1,2...	0,1,2...	0,1,2...	0,1,2...	0,1,2...	0,1,2...	0,1,2...	0,1,2...	0,1,2...
Contact #:	1	2	3	4	5	6	7	8	9	10	11
Study Month:	0	6	12	18	24	30	36	42	48	54	60

OUTCOMES DOCUMENTATION FORM (OUTA Screen 1 of 39)

A. ADMINISTRATION INFORMATION

1. An "Event Packet ID" must be assigned/used whenever an Outcomes Documentation form (or forms) are prepared. The same Event Packet ID must be used on the corresponding HOS form (s) supporting this OUT.

Record appropriate FAVORIT Event Packet ID:

Blind_EPID

OUTCOMES DOCUMENTATION FORM (OUTA Screen 2 of 39)

B. DEATH EVENT

2. Is patient's death documented on this form?

Y Yes

N No — Go to Item 18

OUTA2

3. Date of Death:

 / /

Month Day Year

OUTA3

OUTCOMES DOCUMENTATION FORM (OUTA Screen 3 of 39)

4. Investigator's assessment of primary cause of death: **Indicate only one.****OUTA4**

A Atherosclerotic Coronary Heart Disease

B Atherosclerotic Vascular Disease, — C Other Cardiovascular Disease (Non-Atherosclerotic) — D Non-Cardiovascular — E Unknown —

OUTCOMES DOCUMENTATION FORM (OUTA Screen 4 of 39)

5. Which of the following describes the primary Atherosclerotic Coronary Heart Disease cause of death?

OUTA5**Indicate only one.**

A Acute Myocardial Infarction

B Sudden Death

C Non-Sudden Death

D Cardiovascular Unwitnessed Death
(not seen > 24 hrs)

E Procedural (related to coronary artery procedure)

Specify: _____

6. Which of the following describes the primary Atherosclerotic Vascular Disease, (excluding coronary disease) cause of death?

OUTA6**Indicate only one.**A Cerebrovascular disease,
including stroke and hemorrhageB Aortic, mesenteric, renal
vascular or peripheral vascular
diseaseC Procedural (related to vascular
procedures)

Specify: _____

D Other

Specify: _____

OUTCOMES DOCUMENTATION FORM (OUTA Screen 5 of 39)

7. Which of the following describes the primary Other Cardiovascular Disease (Non-Atherosclerotic) cause of death?

OUTA7**Indicate only one.**

A Pulmonary Embolism

B Endocarditis

C Valvular Disease

D Procedural

Specify: _____

E Other

Specify: _____

8. Which of the following describes the primary Non-Cardiovascular cause of death?

OUTA8**Indicate only one.**

A Infection

B Malignancy

C Pulmonary

D Gastrointestinal

E Accidental

F Suicide

G Diabetes

H Renal

Specify: _____

I Other

Specify: _____

OUTCOMES DOCUMENTATION FORM (OUTA Screen 6 of 39)

9. Was the patient hospitalized at the time of death? **OUTA9**

Y Yes

N No —

OUTCOMES DOCUMENTATION FORM (OUTA Screen 7 of 39)

10. Source Documentation is required. Please review the Hospital Death/Discharge Summary to be sure it provides an accurate and complete description of the patient's death. Is a Death/Discharge Summary being sent to the DCC? **OUTA10**

Y Yes, Hospital Death/Discharge Summary gives an accurate and complete description of the patient's death and is being sent to the DCC. —

S Yes, Hospital Death/Discharge Summary is being sent to the DCC and in addition, a Physician Narrative is being completed because the Hospital Death/Discharge Summary does not provide sufficient details of the patient's death.

N No, Hospital Death/Discharge Summary is unavailable and cannot be obtained by the site. (Please review the next question and complete a Physician Narrative)

OUTCOMES DOCUMENTATION FORM (OUTA Screen 8 of 39)

Physician Narrative should support the reasons for your death classification. This narrative should be complete and concise, and should contain all the relevant information of the patient's status/clinical course before the death.

Examples of what to consider when completing Physician Narrative:

-Did the death occur shortly after an important medical event? If so, did that non-fatal event contribute to, or directly cause the patient's death?

-Was the patient expected to die? Describe the patient's condition in detail, prior to death (i.e. If the patient had been failing or had a poor prognosis prior to death, please explain).

-If the patient had been stable or out of the hospital, support your cause of death and describe the circumstances by which the patient was found to have died.

-Key autopsy findings, if performed, when report cannot be obtained.

11. Is a Physician Narrative being sent to the DCC that describes the circumstances surrounding the death and all other details that may provide support for the investigator's classification of death? **OUTA11**

Y Yes, Physician Narrative being sent to the DCC

N No

If No, specify why it is not available: _____

OUTCOMES DOCUMENTATION FORM (OUTA Screen 9 of 39)

<p>12. Was an autopsy performed? OUTA12</p> <p>Y Yes</p> <p>N No — <input type="text" value="Go to Item 14a"/></p> <p>U Unknown — <input type="text" value="Go to Item 14a"/></p>	<p>13. Autopsy Report: OUTA13</p> <p>A Autopsy report is being sent to the DCC [Required document.]</p> <p>B Autopsy report is unavailable and cannot be obtained by the site. [Send Physician Narrative (as explained in Question 11) of the principal autopsy findings to the DCC.]</p> <p>C Site is unable to obtain the autopsy report findings and the Investigator is unaware of principal findings.</p>
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OUTCOMES DOCUMENTATION FORM (OUTA Screen 10 of 39)

<p>14a. Date of last known creatinine: OUTA14</p> <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">/</td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">/</td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td colspan="3" style="text-align: center;">Month</td> <td colspan="3" style="text-align: center;">Day</td> <td colspan="5" style="text-align: center;">Year</td> </tr> </table> <p>b. Creatinine Value: OUTA14B (note: mg/dL = $\mu\text{mol/L}$ / 88.4)</p> <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> mg/dL			/			/						Month			Day			Year								<p>16. Prior to death, did the patient have a recurrence of renal failure? OUTA16</p> <p>Y Yes</p> <p>N No — <input type="text" value="Go to Item 18"/></p> <p>U Unknown — <input type="text" value="Go to Item 18"/></p>
		/			/																					
Month			Day			Year																				
<p>15. Considering the patient's condition in the days prior to death, was the death clinically expected? OUTA15</p> <p>Y Yes</p> <p>N No</p> <p>U Unknown</p>	<p>17a. Date the patient was found to have renal failure: OUTA17A</p> <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">/</td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">/</td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td colspan="3" style="text-align: center;">Month</td> <td colspan="3" style="text-align: center;">Day</td> <td colspan="5" style="text-align: center;">Year</td> </tr> </table>			/			/						Month			Day			Year							
		/			/																					
Month			Day			Year																				

OUTCOMES DOCUMENTATION FORM (OUTA Screen 11 of 39)

17b. Were complications of acute renal failure present at the time of death?

OUTA17B

- Y Yes
- N No
- U Unknown

If yes, specify complications: _____

17d. Did patient die of complications related to a procedure to treat renal failure?

OUTA17D

- Y Yes
- N No —
- U Unknown —

c. Did patient's refusal to reinitiate dialysis contribute to death?

OUTA17C

- Y Yes
- N No
- U Unknown

OUTCOMES DOCUMENTATION FORM (OUTA Screen 12 of 39)

17e. Type of renal failure procedure with which participant had complications related to death:

OUTA17E

- A Dialysis procedure
- B Dialysis access procedure
- C Renal re-transplantation
- D Other

If other, specify procedure: _____

C. OTHER CARDIOVASCULAR OUTCOMES

18. Are there events (other than death) associated with this EPID to be reported on this OUT?

OUTA18

- Y Yes
- N No —

19. Date of Hospitalization admission for the events captured below:

		/			/				
Month			Day			Year			

OUTA19

f. Date of Procedure

		/			/				
Month			Day			Year			

OUTA17F

OUTCOMES DOCUMENTATION FORM (OUTA Screen 13 of 39)

Event Source Documentation

20. Source Documentation is required. Is the Hospital Discharge Summary being sent to the DCC?

OUTA20

PLEASE REFER TO THE QxQ BEFORE COMPLETING THIS SECTION.

Y Hospital Discharge Summary is being sent to the DCC.

S Hospital Discharge Summary is being sent to the DCC and in addition, a Physician Narrative is being sent in order to provide additional details of the event (s) being reported.

N Hospital Discharge Summary is not able to be obtained. A Physician Narrative is being sent to the DCC that outlines the following key information in the patient's hospital course:

- dates of admission and discharge,
- all admitting and discharge diagnoses,
- full description of clinical symptoms and physical findings, and
- relevant tests that were performed and principal findings.

[Complete 21a-44b for all outcomes being reported for this hospitalization.]

OUTCOMES DOCUMENTATION FORM (OUTA Screen 14 of 39)

Non-fatal Myocardial Infarction

21a. Is a Non-fatal Myocardial Infarction being documented on this **OUTA21A**

Y Yes

N No

To which Event Number and Event Date as reported on the Hospitalization Form does this correspond? (i.e. the 1st, 2nd, or 3rd MI that may have occurred during this hospitalization)?

b. Event Number:

OUTA21B

c. Event Date:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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OUTA21C

Month Day Year

22. Did this event occur within the setting of a coronary revascularization?

OUTA22

Y Yes

N No

OUTCOMES DOCUMENTATION FORM (OUTA Screen 15 of 39)

Non-fatal Myocardial Infarction

23. Did the patient experience ischemic symptoms: (pain, dyspnea, pressure) at rest or accelerated ischemic symptoms, either of which lasts 10 minutes or more and is determined by the investigator to be secondary to ischemia? [Please be sure to include event source documentation as requested in Item 20.]

OUTA23

Y Yes

N No

24a. Were cardiac markers (CK, CKMB, and/or Troponin I/T) drawn in association with this event?

OUTA24A

Y Yes

N No — Go to Item 25a

OUTCOMES DOCUMENTATION FORM (OUTA Screen 16 of 39)

Non-fatal Myocardial Infarction

24b. Are lab reports of the PEAK values of all cardiac markers (CK, CKMB, Troponin I/T) drawn being sent to the DCC? (Lab report must include ULN and be labeled with a date and time. If CK is the only marker used, please provide all CK values in order to establish serial change. If Troponin was drawn and the results are given in ranges, please be sure and provide all reference range values).

OUTA24B

Y Yes

N No

If No, specify why lab report is not available: _____

OUTCOMES DOCUMENTATION FORM (OUTA Screen 17 of 39)

Non-fatal Myocardial Infarction

25a. Was an ECG performed in association with this event?

OUTA25A

Y Yes

N No —

b. In the opinion of the investigator, are there new ECG changes consistent with infarction documented in association with this event?

OUTA25B

Y Yes

N No —

c. Date of ECG consistent with infarction:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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OUTA25C

Month

Day

Year

OUTCOMES DOCUMENTATION FORM (OUTA Screen 18 of 39)

Non-fatal Myocardial Infarction

In the opinion of the investigator (not using results printed on the ECGs), please complete below to indicate the presence of ECG changes consistent with infarction.

25d. New significant Q waves (or R waves in V1-V2) in two contiguous leads in the absence of previous LVH or conduction abnormalities:

OUTA25D

Y Yes

N No

e. Evolving ST-segment to T-wave changes in two or more contiguous leads:

OUTA25E

Y Yes

N No

f. Development of new left bundle branch block:

OUTA25F

Y Yes

N No

OUTCOMES DOCUMENTATION FORM (OUTA Screen 19 of 39)

Non-fatal Myocardial Infarction

In the opinion of the investigator (not using results printed on the ECGs), please complete below to indicate the presence of ECG changes consistent with infarction.

25g. ST segment elevation requiring thrombolytics or PCI. **OUTA25G**

Y Yes

N No

h. Other **OUTA25H**

Y Yes

N No

Please describe in detail ischemic changes seen in association with this event

_____ **OUTA25I**

_____ **OUTA25J**

OUTCOMES DOCUMENTATION FORM (OUTA Screen 20 of 39)

Unstable Angina

26a. Is an Unstable Angina event being documented on this form? **OUTA26A**

Y Yes

N No

To which Event Number and Event Date as reported on the Hospitalization Form does this correspond? (i.e. the 1st, 2nd, or 3rd USA that may have occurred during this hospitalization)?

b. Event Number: **OUTA26B**

c. Event Date: / / **OUTA26C**
Month Day Year

OUTCOMES DOCUMENTATION FORM (OUTA Screen 21 of 39)

Unstable Angina

27. Did the patient experience ischemic symptoms: (pain, dyspnea, pressure) at rest or accelerated ischemic symptoms, either of which lasts 10 minutes or more and is determined by the investigator to be secondary to ischemia? [Please be sure to include event source documentation as requested in Item 20.]

OUTA27

Y Yes

N No

28a. Were cardiac markers (CK, CKMB, and/or Troponin I/T) drawn in association with this event?

OUTA28A

Y Yes

N No — Go to Item 30a

OUTCOMES DOCUMENTATION FORM (OUTA Screen 22 of 39)

Unstable Angina

28b. Are lab reports of the PEAK values of all cardiac markers drawn being sent to the DCC? (Lab report must include ULN and be labeled with a date and time. If CK is the only marker used, please provide all CK values in order to establish serial change. If Troponin was drawn and the results are given in ranges, please be sure and provide all reference range values).

OUTA28B

Y Yes

N No

Specify why lab report is not available: _____

OUTCOMES DOCUMENTATION FORM (OUTA Screen 23 of 39)

Unstable Angina

29a. Was an ECG performed in association with this event?

OUTA29A

Y Yes

N No — Go to Item 30a

b. In the opinion of the investigator, is there evidence of new ECG changes consistent with ischemia documented in association with this event?

OUTA29B

Y Yes

N No — Go to Item 30a

c. Date of ECG consistent with ischemic changes:

		/			/				
Month			Day			Year			

OUTA29C

OUTCOMES DOCUMENTATION FORM (OUTA Screen 24 of 39)

Unstable Angina

In the opinion of the investigator (not using results printed on the ECGs), please complete below to indicate the presence of ECG changes.

29d. New significant Q waves (or R waves in V1-V2) in two contiguous leads in the absence of previous LVH or conduction abnormalities.

OUTA29D

Y Yes

N No

e. Evolving ST-segment to T-wave changes in two or more contiguous leads.

OUTA29E

Y Yes

N No

f. Development of new left bundle branch block.

OUTA29F

Y Yes

N No

OUTCOMES DOCUMENTATION FORM (OUTA Screen 25 of 39)

Unstable Angina

In the opinion of the investigator (not using results printed on the ECGs), please complete below to indicate the presence of ECG changes.

29g. ST segment elevation requiring thrombolytics or PCI.

OUTA29G

Y Yes

N No

h. Other

OUTA29H

Y Yes

N No — Go to Item 30a

Please describe in detail ischemic changes seen in association with this event

OUTA29I

OUTA29J

OUTCOMES DOCUMENTATION FORM (OUTA Screen 26 of 39)

Non-Fatal Stroke

30a. Is a Non-fatal Stroke being documented on this form?

OUTA30A

Y Yes

N No — Go to Item 35a

To what Event Number and Event Date as reported on the Hospitalization Form does this correspond? (i.e. the 1st, 2nd, or 3rd Stroke that may have occurred during this hospitalization)?

b. Event Number:

OUTA30B

c. Event Date:

		/			/				
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OUTA30C

Month Day Year

OUTCOMES DOCUMENTATION FORM (OUTA Screen 27 of 39)

Non-Fatal Stroke

31. Did the patient suffer a neurological deficit of sudden onset (not attributed to a readily identifiable cause such as brain tumor or trauma)? [Please be sure to include event source documentation as requested above in Item 20.]

OUTA31

Y Yes

N No — Go to Item 35a

U Unknown — Go to Item 35a

32. Was neurological deficit reversible within 24 hours?

OUTA32

Y Yes

N No

U Unknown

OUTCOMES DOCUMENTATION FORM (OUTA Screen 28 of 39)

Non-Fatal Stroke33a. Was a Neurology consult performed in association with this event? **OUTA33A**

Y Yes

N No — Go to Item 34a

U Unknown — Go to Item 34a

b. Is the Neurology Report being sent to the DCC? **OUTA33B**

Y Yes, report is being sent to the DCC

N No, site is unable to obtain a copy of this report but a Physician Narrative of the principal findings is being sent to the DCC

F No, site is unable to report on any findings of the neurology consult

OUTCOMES DOCUMENTATION FORM (OUTA Screen 29 of 39)

Non-Fatal Stroke34a. Were imaging studies performed in association with this event? **OUTA34A**

Y Yes

N No — Go to Item 35a

U Unknown — Go to Item 35a

b. Is the Imaging Studies Report being sent to the DCC? **OUTA34B**

Y Yes, report is being sent to the DCC

N No, site is unable to obtain a copy of this report but a Physician Narrative of the principal findings is being sent to the DCC

F No, site is unable to obtain a copy of this report and is unable to report on any findings of the imaging studies

OUTCOMES DOCUMENTATION FORM (OUTA Screen 30 of 39)

Resuscitated Sudden Death

35a. Is a Resuscitated Sudden Death event being documented on this form?

OUTA35A

Y Yes

N No — Go to Item 39

To what Event Number and Event Date as reported on the Hospitalization Form does this correspond? (i.e. the 1st, 2nd, or 3rd Resuscitated Sudden Death that may have occurred during this hospitalization)?

b. Event Number:

OUTA35B

c. Event Date:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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OUTA35C

Month

Day

Year

OUTCOMES DOCUMENTATION FORM (OUTA Screen 31 of 39)

Resuscitated Sudden Death

36. Did the patient suffer a loss of consciousness due to cardiac arrest (this excludes transient losses of consciousness due to seizure or vasovagal episodes)?

OUTA36

Y Yes

N No

U Unknown

37. Were the following resuscitative means used in association with this event:

YESNOUNKNOWN

a. CPR

Y

N

U

OUTA37A

b. Cardiac defibrillation

Y

N

U

OUTA37B

c. Cardioversion

Y

N

U

OUTA37C

d. Other

Y

N —

Go to Item 38

OUTA37D

Specify _____

OUTCOMES DOCUMENTATION FORM (OUTA Screen 32 of 39)

Resuscitated Sudden Death

38. Please check ONE of the following that best describes the patient's status after the patient was resuscitated:

OUTA38

- A The patient was resuscitated but then later died in the setting of this acute event.
- B The patient was resuscitated (i.e. circulation restored) but did not regain consciousness (i.e. patient was intubated as a result of the event).
- C The patient was resuscitated and was able to regain consciousness after the event (i.e. patient survived the event and may have later been discharged after suffering cardiac arrest).
- D Unknown

OUTCOMES DOCUMENTATION FORM (OUTA Screen 33 of 39)

URGENT Non-CABG CORONARY REVASCULARIZATION

39. Is an urgent coronary revascularization procedure (non-CABG) being reported (i.e., PCI)?

OUTA39

Y Yes

N No — Go to Item 42

40a. Were there new pathologic Q waves or other wall-motion abnormalities identified peri-operatively?

OUTA40A

Y Yes — Provide documentation of this (i.e., two comparative ECGs documenting new Q waves or echo report documenting wall-motion abnormality)

N No — Go to Item 41a

OUTCOMES DOCUMENTATION FORM (OUTA Screen 34 of 39)

URGENT Non-CABG CORONARY REVASCULARIZATION

40b. Is the ECG or the echo report being sent to the DCC?

OUTA40B

Y Yes, report is being sent to the DCC

N No, site is unable to obtain a copy of this report but a Physician Narrative of the principal findings is being sent to the DCC

F No, site is unable to report on any findings of the ECG or echo

41a. Were there cardiac marker elevations $\geq 3x$ ULN and $\geq 50\%$ above last measurement, if last measure was \geq ULN?

OUTA41A

Y Yes — Provide cardiac marker documentation of all markers drawn before and within 24 hours of procedure

N No — Go to Item 42

OUTCOME DOCUMENTATION FORM (OUTA Screen 35 of 39)

URGENT Non-CABG CORONARY REVASCULARIZATION

41b. Is the Lab Report documenting all cardiac markers drawn being sent to the DCC? **OUTA41B**

Y Yes, report is being sent to the DCC

N No, site is unable to obtain a copy of this report but a Physician Narrative of the principal findings is being sent to the DCC

F No, site is unable to report on any findings of the cardiac markers

OUTCOMES DOCUMENTATION FORM (OUTA Screen 36 of 39)

URGENT CABG REVASCULARIZATION

42. Is an urgent Coronary Artery Bypass Graft (CABG) surgery being reported? **OUTA42**

Y Yes

N No —

43a. Were there new pathologic Q waves or other wall-motion abnormalities identified peri-operatively? **OUTA43A**

Y Yes —

N No —

OUTCOMES DOCUMENTATION FORM (OUTA Screen 37 of 39)

URGENT CABG REVASCULARIZATION

43b. Is the ECG or the echo report being sent to the DCC? **OUTA43B**

Y Yes, report is being sent to the DCC

N No, site is unable to obtain a copy of this report but a Physician Narrative of the principal findings is being sent to the DCC

F No, site is unable to report on any findings of the ECG or echo

44a. Were there cardiac marker elevations $\geq 5x$ ULN and $\geq 50\%$ above last measurement, if last measure was \geq ULN? **OUTA44A**

Y Yes —

N No —

