Hospitalization Form Instructions
HOS Version B: 04/13/2007
QxQ Date: 04/13/2007

I. GENERAL INSTRUCTIONS

Before completing the Hospitalization Form (HOS), it is essential that you read chapter 10, Endpoints. Chapter 10 provides information regarding how to assign an EPID number, what events will be adjudicated, what source documents are required, how to assign contact occasion and sequence numbers and how and when to complete a physician's narrative.

Prior to completing the HOS, data collectors or abstractors must be familiar with and understand chapter 14: Administrative Procedures, in the Manual of Procedures, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Last Name and Initials) is completed as described in that document.

Since hospitalizations may occur at any time, recording "Sequence Number" for the HOS form is more complex than for most other forms. Record 00 if a participant was hospitalized on the date of a scheduled contact occasion. Record 01 if the hospitalization is the first one occurring after a completed contact occasion; record 02 if it is the second hospitalization occurring after a completed contact occasion, and so on.

For example, if the participant is admitted to the hospital on the day the scheduled six-month telephone contact is completed, the contact occasion should be 02 and sequence number should be 00. If the participant is hospitalized one month after the six-month contact, the HOS form would be completed indicate 02 for contact occasion and 01 for sequence number. A second hospitalization one month later would require a second HOS form with 02 for contact occasion and 02 for sequence number. If the participant is hospitalized one week after the 12-month clinic visit, then the HOS form would have contact occasion 03 and sequence number 01.

This HOS should be completed whenever the participant is admitted to the hospital for any condition. All outpatient angioplasty (coronary, lower extremities and renal arteries) procedures also require completion of an HOS form.

To record times within this form use the 12-hour clock. If the time given in the chart is from the 24-hour clock, it should be converted to the 12-hour clock before it is recorded. For example: 1 AM=01:00 am, 2 AM= 02:00 am, 12 NOON=12:00 pm, 13:00 = 1:00 pm, 12 MIDNIGHT= 12:00 am.

If an exact time is not given in the chart, the best estimate should be recorded using the following guidelines:

middle of the night = 03:00 am
early morning = 08:00 am
morning = 09:00 am
late morning = 10:00 am
midday = 12 Noon = 12:00 pm
early afternoon = 02:00 pm
afternoon or midafternoon = 03:00 pm
late afternoon = 04:00 pm
early evening = 07:00 pm
evening = 09:00 pm
late evening = 10:00 pm
no mention of time = Set to perm. missing

II. SPECIFIC INSTRUCTION

A. Administrative Information

1a. For the hospitalization being recorded, record (F) if the participant was hospitalized in one of the 30 participating FAVORIT hospitals (see the protocol for a list of the 30 FAVORIT affiliated hospitals), skip to item 8. If they were hospitalized in a hospital not participating in the FAVORIT study record (N) and skip to item 8. Record "O" if the participant has an outpatient angioplasty, skip to item 2. If no record of this hospitalization can be found record "H". Then you must enter into a notelog the steps taken to locate this hospitalization. These should include:

- Number of attempts that were made to locate hospitalization
- Contact with participant to re-confirm location, date of hospitalization and hospital medical record number
- Indicate whether this hospitalization was already captured in a previous HOS form, record the contact occasion, sequence number and date of admission
- Indicate if this was actually an ER visit and length of stay was not > 24 hours
- Record any other information that you find imperative

1b. For the hospitalization that was not found, record the contact occasion for the corresponding follow-up form (FUP) where the participant indicated he/she was hospitalized. If the sequence number for the FUP is not 00 please note this in a notelog. Then skip to item 34.

B. Coronary Disease Events - Outpatient

2. For outpatient coronary artery or peripheral angioplasty, record the status of your access to the outpatient chart. It is essential that the study obtain an accurate report of events that occurred during this procedure. Please make every effort to obtain the medical records. If pending (P) or there is no possibility of ever accessing the chart (N), skip to item 34 and record administrative information. Please add a notelog if the chart is unobtainable stating the steps taken in locating the chart. Please be sure to have your PI assist in trying to obtain charts from other hospitals. If this status changes, return to this HOS and revise item 2 and continue completing the form, as

needed. If you are unable to obtain an outpatient chart please explain why in a notelog.

3a-b. Record whether an outpatient coronary artery angioplasty occurred, and if so, the date of the procedure.

Alternative names for PCI (percutaneous coronary artery angioplasty:

- Balloon angioplasty;
- Coronary angioplasty;
- Cardiac angioplasty;
- PTCA;
- Percutaneous transluminal coronary angioplasty;
- Heart artery dilation;
- Rotational atherectomy;
- Directional atherectomy;
- Extraction atherectomy;
- Laser angioplasty;
- Implantation of intracoronary stents.

4a-b. Record whether outpatient angioplasty of the lower extremity arteries occurred, and if so, the date of the procedure, if not skip to item 5a.

5a-b. Record whether outpatient angioplasty of the renal arteries occurred, and if so, the date of the procedure, if not skip to item 6a.

6a-b. Record whether outpatient carotid artery endarterectomy occurred, and if so, the date of the procedure, if not skip to item 7a.

7a-b. Record whether outpatient carotid artery angioplasty occurred, and if so, the date of the procedure. This is the end of the outpatient section of the HOS. Skip to item 34 and record the administrative information

C. Hospital Administrative Information

8. For inpatient hospitalizations, record the status of your access to the hospital chart. If pending (P) or there is no possibility of ever accessing the chart (N), skip to item 34 and record administrative information. If this status changes, return to this HOS and revise item 8 and continue completing the form, as needed. Please add a notelog if the chart is unobtainable stating the steps taken in locating the chart. Please be sure to have your PI assist in trying to obtain charts from other hospitals.

9. The date of arrival at the hospital may be different from the date of admission. For this item we are want to capture the date of Admission. For example, a patient may first be taken to the emergency room (arrival at the hospital) at 11:00 pm, but may not be admitted for several hours (2:00 am). In this case, record date of admission not the

date of arrival. If the exact date of admission is not recorded explicitly in the chart, abstract the earliest date recorded in the chart (such as the date a procedure was ordered or date of the admitting history and physical examination).

10. Discharge date will generally be found on the face sheet. If the participant died, record the date of death. If transferred from acute care to rehabilitation or chronic care in the same hospital, count the date of transfer as the discharge date.

D. Discharge Information

11. Record the disposition of the participant on discharge. If deceased record "D" and complete an Outcomes Documentation Form (OUT) after completing the HOS.

If the participant was transferred to another hospital record "T", not including rehab, nursing home or long-term care, then complete a separate HOS for that hospitalization and go to item 14. In general, the HOS for the transferred hospitalization will have the same Contact Occasion (CO) as the transferring hospitalization, and the Sequence Number (SN) will be incremented by one. If either the originating hospitalization or the transfer hospitalization triggers an EPID number that number should be used for both the originating HOS and the transfer HOS forms.

If the participant was transferred to another medical care facility such as Rehab, nursing home or long-term care center, record "M" or if the participant was discharged to home record "H, then go to item 14.

12. For a deceased participant, record "Y" if any causes of death are given on the discharge summary. If not, skip to item 14.

13a-f. Record the causes of death exactly as they appear on the discharge summary. Record only text descriptions in these items, not diagnosis codes. Record one diagnosis per line; do not use two or more lines for one diagnosis.

14a-z. Record all discharge diagnosis codes exactly as they appear in the order listed on the front sheet of the discharge summary. Do not enter a zero unless it appears in the chart. If digits are absent, leave blank. Be sure to include all primary and secondary diagnoses as designated by the physician. If ICD codes of the discharge diagnosis are not given on hospital charts and are only available from the diagnostic index, leave blank. If none, leave blank.

15. Record coding system used (ICD-9 or ICD-10), for codes in items 14a-z.

16a-z. Record the discharge diagnoses exactly as they appear on the discharge summary. Record only text descriptions in these items, not diagnosis codes. Record one diagnosis per line and do not use two or more lines for one diagnosis.

E. Events Requiring Outcomes Documentation

If a myocardial infarction (MI), unstable angina (USA), stroke, resuscitated sudden death (RSD), urgent coronary artery angioplasty or other percutaneous coronary revascularization procedures, non-urgent coronary artery angioplasty or other percutaneous coronary revascularization procedures with an MI associated, urgent coronary artery bypass graft (CABG) or non-urgent coronary artery bypass graft with an associated MI occurred during this hospitalization then complete an Outcomes Documentation Form. The HOS allows study coordinators to report up to three of the same kind of events (e.g., 1 or 2 or 3 MI's), but the OUT allows for only one of each kind of event. Therefore multiple OUT forms must be used when reporting more than one of the same types of event. For example, if a participant has 2 MI's and an USA you will need to complete two OUT's. Record the first MI and the USA on the first OUT and the second MI on the second OUT.

The same EPID number is used on the HOS and on all of its associated OUT forms.

17a-e. Record whether a myocardial infarction occurred during the hospitalization, if so, how many times, and the date of each occurrence. Check the ER sheet, admit note, and history for reference to when events took place.

Record a maximum of three events, in chronological order. If, after recording the events, you learn the order of events is incorrect, do not revise the order. Also complete an OUT form for each occurrence.

Alternative names for MI's:

- MI extension
- Evolving MI
- Acute MI
- Aborted MI
- Heart attack

18a-e. Record whether unstable angina occurred during the hospitalization, if so, how many times, and the date of each occurrence. Check the ER sheet, admit note, and history for reference to when events took place.

USA is defined as pain due to myocardial ischemia without myocardial infarction. Included in this definition for pain are ischemic pain, angina, cardiac and substernal pain, and acute pain anywhere in the chest, left arm or jaw (and perhaps the back, shoulder, right arm or abdomen on one or both sides) mentioned anywhere in the chart and present within 72 hours of arrival at the hospital. Chronic pain is not included in the definition of USA.

Record a maximum of three occurrences, in chronological order, if possible. If, after recording the events, you learn the order of events is incorrect, do not revise the order. Also complete an OUT form for each occurrence.

Examples of how USA might be recorded in the medical records

Term	Comments
Ischemic pain	
Substernal pain	Only if due to myocardial ischemia
Chest tightness	Only if due to myocardial ischemia

19a-e. Record whether stroke occurred during the hospitalization, if so, how many times, and the date of each occurrence. Check the ER sheet, admit note, and history for reference to when events took place. Stroke is defined as neurological deficit lasting 24 hours or more.

Record a maximum of three occurrences, in chronological order, if possible. If, after recording the events, you learn the order of events is incorrect, do not revise the order. Also complete an OUT form for each occurrence.

Examples of how Stroke might be recorded in the medical records

Term	Comments
Cortical infarction	Only if symptoms persist for 24 hours
Intracranial hemorrhage	Only if symptoms persist for 24 hours
Cerebral thrombosis	Only if symptoms persist for 24 hours
Cerebral artery occlusion	Only if symptoms persist for 24 hours
Cerebral infarction	Only if symptoms persist for 24 hours
Subarachnoid hemorrhage	Only if symptoms persist for 24 hours
Brain attack	Only if symptoms persist for 24 hours
Cerebral vascular incident	Only if symptoms persist for 24 hours
Apoplexy	Only if symptoms persist for 24 hours
Cerebrovascular accident (CVA)	Only if symptoms persist for 24 hours

20a-e. Record whether resuscitated sudden death occurred prior to or during the hospitalization, if so, how many times, and the date of each occurrence. Check the ER sheet, admit note, and history for reference to when events took place. Include RSDs that took place at place of residence, in ambulance, in ER etc. RSD is defined as successful resuscitation after cardiac arrest.

Record a maximum of three occurrences, in chronological order, if possible. If, after recording the events, you learn the order of events is incorrect, do not revise the order. Also complete an OUT form for each occurrence.

Examples of how RSD might be recorded in the medical records.

Term	Comments
Cardiopulmonary resuscitation	
Closed chest massage	
Cardioversion/Defibrillation	But **not** as part of CABG or EP studies

F. Coronary Disease Events - Hospitalization

21a-d. Record whether coronary artery angioplasty or any other percutaneous coronary revascularization procedure (PCI, laser rotational/directional/extraction atherectomy, stent implants, Vineberg) was performed during this hospitalization, if so, the date and time of the procedure. If more than one procedure, record the first one only. If none, skip to item 22a. **Exclude Coronary Artery Bypass Surgery (CABG).**

e. Record whether an MI is being reported in association with this procedure. If an MI is being reported, complete an OUT for the MI.

f. Record whether the procedure was performed urgently, i.e., not electively. It does not qualify as urgent if it is being performed quickly due to the availability of surgeon or operating room. If yes, complete the applicable sections of the OUT for this "Urgent Revascularization".

22a-d. Record whether coronary artery bypass graft surgery (CABG) was performed during this hospitalization and the date and time of the procedure. If more than one procedure occurred, record the first one only. If none, skip to item 23.

e. Record whether an MI is being reported in association with this procedure. If an MI is being reported, complete an OUT for the MI.

f. Record whether the procedure was performed urgently (not electively). It does not qualify as urgent if it is being performed quickly due to the availability of surgeon or operating room. If it was urgent, complete the applicable sections of the OUT for this "Urgent Revascularization".

23. Record whether congestive heart failure (CHF) occurred during the hospitalization. CHF is an inability to adequately maintain cardiac output, but not as severe as cardiogenic shock (pump failure).

Alternative names for CHF:

- Pulmonary edema due to poor coronary output

24. Record whether cardiac arrhythmia occurred during the hospitalization.

Alternative names for cardiac arrhythmia:

- Cardiac dysrhythmia
- Atrial fibrillation
- Ventricular fibrillation

G. Peripheral Vascular Disease

25a-29b. Record whether any of the following occurred during the hospitalization: carotid artery endarterectomy or carotid artery angioplasty, thoraco-abdominal aortic aneurysm repair, lower extremity arterial bypass graft surgery, renal arterial bypass graft surgery, angioplasty for lower extremity arterial disease and the date of the procedure. If more than one of the same kinds of procedure occurred during this hospitalization, record the first one only.

30a-c. Record whether lower extremity amputation above the ankle occurred during the hospitalization and the date and the reason for the amputation. If more than one lower extremity amputation occurred during this hospitalization, record the first one only.

31-b. Record whether angioplasty for renal arterial disease occurred during the hospitalization and the date of the procedure. If more than one occurred, record the first one only.

H. Other Conditions of Interest

32a-h. Record whether any of the following procedures occurred during the hospitalization: renal graft dysfunction/rejection, abnormal renal biopsy, infection/sepsis, gastrointestinal complications, diabetic complications, and organ transplant. If an organ transplant was performed, also record the type of transplant and the date of the procedure.

I. Administrative Information

33a. Record whether an OUT form needs to be completed. If the participant was not transferred to another hospital and an OUT was triggered then record "Y". If the participant was transferred to another hospital and at the transfer hospital an OUT was triggered but no OUT was triggered at the original hospital then record "T". If an OUT was triggered at both the originating hospital and the transfer hospital then record "B". If the OUT was not triggered at either the originating hospital or transfer hospital then record "N". If you do not have information regarding the transfer hospitalization at the time you are completing the originating HOS, then record the response that is appropriate for the originating hospitalization and once you obtain information from the transfer hospitalization you need to update your response.

b. If an Outcomes Documentation Form was triggered by this HOS or from a transfer HOS then you will need to assign an EPID number. This EPID will be used on all documents related to this hospitalization as well as any transfer hospitalizations.

EPID labels are provided to the clinics along with a log sheet by the DCC. The participants FAVORIT ID and all forms and their corresponding contact occasions and sequence numbers should be recorded on the EPID log sheet.

34. Record whether the data was collected directly into the data entry system on the computer or whether it was recorded on a paper form.

35. Record the date that the randomization information was collected in the order month, day, year using 2 digits each for the month and day, and 4 digits for the year.

36. Enter the data collector's initials using the 3 initials of the person completing this form. If he/she only has two initials, then record the 1st name initial in the first box, the last name initial in the 2nd box and leave the third box blank.

Hospitalization Form Instructions
HOS Version A: 12/03/2002
QxQ Date: 2/02/2004

I. GENERAL INSTRUCTIONS

Before completing the Hospitalization Form (HOS), it is essential that you read chapter 10, Endpoints. Chapter 10 provides information regarding how to assign an EPID number, what events will be adjudicated, what source documents are required, how to assign contact occasion and sequence numbers and how and when to complete a physician's narrative.

Prior to completing the HOS, data collectors or abstractors must be familiar with and understand chapter 14: Administrative Procedures, in the Manual of Procedures, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Last Name and Initials) is completed as described in that document.

Since hospitalizations may occur at any time, recording "Sequence Number" for the HOS form is more complex than for most other forms. Record 00 if a participant was hospitalized on the date of a scheduled contact occasion. Record 01 if the hospitalization is the first one occurring after a completed contact occasion; record 02 if it is the second hospitalization occurring after a completed contact occasion, and so on.

For example, if the participant is admitted to the hospital on the day the scheduled six-month telephone contact is completed, the contact occasion should be 02 and sequence number should be 00. If the participant is hospitalized one month after the six-month contact, the HOS form would be completed indicate 02 for contact occasion and 01 for sequence number. A second hospitalization one month later would require a second HOS form with 02 for contact occasion and 02 for sequence number. If the participant is hospitalized one week after the 12-month clinic visit, then the HOS form would have contact occasion 03 and sequence number 01.

This HOS should be completed whenever the participant is admitted to the hospital for any condition. All outpatient peripheral angioplasty (coronary, lower extremities and renal arteries) procedures also require completion of an HOS form.

To record times within this form use the 12-hour clock. If the time given in the chart is from the 24-hour clock, it should be converted to the 12-hour clock before it is recorded. For example: 1 AM=01:00 am, 2 AM= 02:00 am, 12 NOON=12:00 pm, 13:00 = 1:00 pm, 12 MIDNIGHT= 12:00 am.

If an exact time is not given in the chart, the best estimate should be recorded using the following guidelines:

middle of the night = 03:00 am
early morning = 08:00 am
morning = 09:00 am
late morning = 10:00 am
midday = 12 Noon = 12:00 pm
early afternoon = 02:00 pm
afternoon or midafternoon = 03:00 pm
late afternoon = 04:00 pm
early evening = 07:00 pm
evening = 09:00 pm
late evening = 10:00 pm
no mention of time = Set to perm. missing

II. SPECIFIC INSTRUCTION

A. Administrative Information

1. For the hospitalization being recorded, record if the participant was hospitalized in one of the 20 participating FAVORIT hospital (see the protocol for a list of the 20 FAVORIT affiliated hospitals), a hospital not participating in the FAVORIT study, or record "O" if the participant has an outpatient coronary artery peripheral angioplasty.

B. Coronary Disease Events - Outpatient

2. For outpatient coronary artery peripheral angioplasty, record the status of your access to the outpatient chart. It is essential that the study obtain an accurate report of events that occurred during this procedure. Please make every effort to obtain the medical records. If pending (P) or there is no possibility of ever accessing the chart (N), skip to item 32 and record administrative information. If this status changes, return to this HOS and revise item 2 and continue completing the form, as needed. If you are unable to obtain an outpatient chart please explain why in a notlog.

3a-b. Record whether an outpatient coronary artery angioplasty occurred, and if so, the date of the procedure.

Alternative names for PCI (percutaneous coronary artery angioplasty:

- Balloon angioplasty;
- Coronary angioplasty;
- Cardiac angioplasty;
- PTCA;
- Percutaneous transluminal coronary angioplasty;
- Heart artery dilation;
- Rotational Atherectomy;
- Directional Atherectomy;
- Extraction Atherectomy;
- Laser Angioplasty;
- Implantation of Intracoronary Stents.

4a-b. Record whether outpatient angioplasty of the lower extremity arteries occurred, and if so, the date of the procedure.

5a-b. Record whether outpatient angioplasty of the renal arteries occurred, and if so, the date of the procedure. This is the end of the outpatient section of the HOS. Skip to item 32 and record the administrative information

C. Hospital Administrative Information

6. For inpatient hospitalizations, record the status of your access to the hospital chart. If pending (P) or there is no possibility of ever accessing the chart (N), skip to item 32 and record administrative information. If this status changes, return to this HOS and revise item 6 and continue completing the form, as needed. . If you are unable to obtain the hospital chart please explain why in a notlog.

7. The date of arrival at the hospital may be different from the date of admission. For this item we are want to capture the date of Admission. For example, a patient may first be taken to the emergency room (arrival at the hospital) at 11:00 pm, but may not be admitted for several hours (2:00 am). In this case, record date of admission not the date of arrival. If the exact date of admission is not recorded explicitly in the chart, abstract the earliest date recorded in the chart (such as the date a procedure was ordered or date of the admitting history and physical examination).

8. Discharge date will generally be found on the face sheet. If the participant died, record the date of death. If transferred from acute care to rehabilitation or chronic care in the same hospital, count the date of transfer as the discharge date.

D. Discharge Information

9. Record the disposition of the participant on discharge. If deceased record “D” and complete an Outcomes Documentation Form (OUT) after completing the HOS.

   If the participant was transferred to another hospital record “T”, not including rehab, nursing home or long-term care, then complete a separate HOS for that hospitalization and go to item 12. In general, the HOS for the transferred hospitalization will have the same Contact Occasion (CO) as the transferring hospitalization, and the Sequence Number (SN) will be incremented by one. If either the originating hospitalization or the transfer hospitalization triggers an EPID number that number should be used for both the originating HOS and the transfer HOS forms.

   If the participant was transferred to another medical care facility such as Rehab, nursing home or long-term care center, record “M” or if the participant was discharged to home record “H, then go to item 12.

10. For a deceased participant, record “Y” if any causes of death are given on the discharge summary. If not, skip to item 12.

11a-f. Record the causes of death exactly as they appear on the discharge summary. Record only text descriptions in these items, not diagnosis codes. Record one diagnosis per line; do not use two or more lines for one diagnosis.

12a-n. Record all discharge diagnosis codes exactly as they appear in the order listed on the front sheet of the discharge summary. Do not enter a zero unless it appears in the chart. If digits are absent, leave blank. Be sure to include all primary and secondary diagnoses as designated by the physician. If ICD codes of the discharge diagnosis are not given on hospital charts and are only available from the diagnostic index, leave blank. If none, leave blank.

13. Record coding system used (ICD-9 or ICD-10), for codes in items 12a-n.

14a-n. Record the discharge diagnoses exactly as they appear on the discharge summary. Record only text descriptions in these items, not diagnosis codes. Record one diagnosis per line and do not use two or more lines for one diagnosis.

E. Events Requiring Outcomes Documentation

If a myocardial infarction (MI), unstable angina (USA), stroke, resuscitated sudden death (RSD), urgent coronary artery angioplasty or other percutaneous coronary revascularization procedures, non-urgent coronary artery angioplasty or other percutaneous coronary revascularization procedures with an MI associated, urgent coronary artery bypass graft (CABG) or non-urgent coronary artery bypass graft with an associated MI occurred during this hospitalization then complete an Outcomes Documentation Form. The HOS allows study coordinators to report up to three of the same kind of events (e.g., 1 or 2 or 3 MI's), but the OUT allows for only one of each kind of event. Therefore multiple OUT forms must be used when reporting more than one of the same types of event. For example, if a participant has 2 MI's and an USA you will need to complete two OUT's. Record the first MI and the USA on the first OUT and the second MI on the second OUT.

The same EPID number is used on the HOS and on all of its associated OUT forms.

15a-e. Record whether a myocardial infarction occurred during the hospitalization, if so, how many times, and the date of each occurrence. Check the ER sheet, admit note, and history for reference to when events took place.

Record a maximum of three events, in chronological order. If, after recording the events, you learn the order of events is incorrect, do not revise the order. Also complete an OUT form for each occurrence.

Alternative names for MI's:

- MI extension
- Evolving MI
- Acute MI
- Aborted MI
- Heart attack

16a-e. Record whether unstable angina occurred during the hospitalization, if so, how many times, and the date of each occurrence. Check the ER sheet, admit note, and history for reference to when events took place.

USA is defined as pain due to myocardial ischemia without myocardial infarction. Included in this definition for pain are ischemic pain, angina, cardiac and substernal pain, and acute pain anywhere in the chest, left arm or jaw (and perhaps the back, shoulder, right arm or abdomen on one or both sides) mentioned anywhere in the chart and present within 72 hours of arrival at the hospital. Chronic pain is not included in the definition of USA.

Record a maximum of three occurrences, in chronological order, if possible. If, after recording the events, you learn the order of events is incorrect, do not revise the order. Also complete an OUT form for each occurrence.

Examples of how USA might be recorded in the medical records

Term	Comments
Ischemic pain	
Substernal pain	Only if due to myocardial ischemia
Chest tightness	Only if due to myocardial ischemia

17a-e. Record whether stroke occurred during the hospitalization, if so, how many times, and the date of each occurrence. Check the ER sheet, admit note, and history for reference to when events took place. Stroke is defined as neurological deficit lasting 24 hours or more.

Record a maximum of three occurrences, in chronological order, if possible. If, after recording the events, you learn the order of events is incorrect, do not revise the order. Also complete an OUT form for each occurrence.

Examples of how Stroke might be recorded in the medical records

Term	Comments
Cortical infarction	Only if symptoms persist for 24 hours
Intracranial hemorrhage	Only if symptoms persist for 24 hours
Cerebral thrombosis	Only if symptoms persist for 24 hours
Cerebral artery occlusion	Only if symptoms persist for 24 hours
Cerebral infarction	Only if symptoms persist for 24 hours
Subarachnoid hemorrhage	Only if symptoms persist for 24 hours
Brain attack	Only if symptoms persist for 24 hours
Cerebral vascular incident	Only if symptoms persist for 24 hours
Apoplexy	Only if symptoms persist for 24 hours
Cerebrovascular accident (CVA)	Only if symptoms persist for 24 hours

18a-e. Record whether resuscitated sudden death occurred during the hospitalization, if so, how many times, and the date of each occurrence. Check the ER sheet, admit note, and history for reference to when events took place. RSD is defined as successful resuscitation after cardiac arrest.

Record a maximum of three occurrences, in chronological order, if possible. If, after recording the events, you learn the order of events is incorrect, do not revise the order. Also complete an OUT form for each occurrence.

Examples of how RSD might be recorded in the medical records.

Term	Comments
Cardiopulmonary resuscitation	
Closed chest massage	
Cardioversion/Defibrillation	But **not** as part of CABG or EP studies

F. Coronary Disease Events - Hospitalization

19a-d. Record whether coronary artery angioplasty or any other percutaneous coronary revascularization procedure (PCI, laser rotational/directional/extraction atherectomy, stent implants, Vineberg) was performed during this hospitalization, if so, the date and time of the procedure. If more than one procedure, record the first one only. If none, skip to item 20a. **Exclude Coronary Artery Bypass Surgery (CABG).**

e. Record whether an MI is being reported in association with this procedure. If an MI is being reported, complete an OUT for the MI and skip to item 20a.

f. Record whether the procedure was performed urgently, i.e., not electively. It does not qualify as urgent if it is being performed quickly due to the availability of surgeon or operating room. If yes, complete the applicable sections of the OUT for this "Urgent Revascularization".

20a-d. Record whether coronary artery bypass graft surgery (CABG) was performed during this hospitalization and the date and time of the procedure. If more than one procedure occurred, record the first one only. If none, skip to item 21.

e. Record whether an MI is being reported in association with this procedure. If an MI is being reported, complete an OUT for the MI, and skip to item 21

f. Record whether the procedure was performed urgently (not electively). It does not qualify as urgent if it is being performed quickly due to the availability of surgeon or operating room. If it was urgent, complete the applicable sections of the OUT for this "Urgent Revascularization".

21. Record whether congestive heart failure (CHF) occurred during the hospitalization. CHF is an inability to adequately maintain cardiac output, but not as severe as cardiogenic shock (pump failure).

Alternative names for CHF:

- Pulmonary edema due to poor coronary output

22. Record whether cardiac arrhythmia occurred during the hospitalization.

Alternative names for cardiac arrhythmia:

- Cardiac dysrhythmia
- Atrial fibrillation
- Ventricular fibrillation

G. Peripheral Vascular Disease

23a-27b. Record whether any of the following occurred during the hospitalization: carotid artery endarterectomy or carotid artery angioplasty, thoraco-abdominal aortic aneurysm repair, lower extremity arterial bypass graft surgery, renal arterial bypass graft surgery, angioplasty for lower extremity arterial disease and the date of the procedure. If more than one of the same kind of procedure occurred during this hospitalization, record the first one only.

28a-c. Record whether lower extremity amputation above the ankle occurred during the hospitalization and the date and the reason for the amputation. If more than one lower extremity amputation occurred during this hospitalization, record the first one only.

29a-b. Record whether angioplasty for renal arterial disease occurred during the hospitalization and the date of the procedure. If more than one occurred, record the first one only.

H. Other Conditions of Interest

30a-h. Record whether any of the following procedures occurred during the hospitalization: renal graft dysfunction/rejection, abnormal renal biopsy, infection/sepsis, gastrointestinal complications, diabetic complications, and organ transplant. If an organ transplant was performed, also record the type of transplant and the date of the procedure.

I. Administrative Information

31 a. Record whether an OUT form needs to be completed. If the participant was not transferred to another hospital and an OUT was triggered then record "Y". If the participant was transferred to another hospital and at the transfer hospital an OUT was triggered but no OUT was triggered at the original hospital then record "T". If an OUT was triggered at both the originating hospital and the transfer hospital then record "B". If the OUT was not triggered at either the originating hospital or transfer hospital then record "N". If you do not have information regarding the transfer hospitalization at the time you are completing the originating HOS, then record the response that is appropriate for the originating hospitalization and once you obtain information from the transfer hospitalization you need to update your response.

b. If an Outcomes Documentation Form was triggered by this HOS or from a transfer HOS then you will need to assign an EPID number. This EPID will be used on all documents related to this hospitalization as well as any transfer hospitalizations.

EPID labels are provided to the clinics along with a log sheet by the DCC. The participants FAVORIT ID and all forms and their corresponding contact occasions and sequence numbers should be recorded on the EPID log sheet.

32. Record the date that the randomization information was collected in the order month, day, year using 2 digits each for the month and day, and 4 digits for the year.

33. Enter the data collector's initials using the 3 initials of the person completing this form. If he/she only has two initials, then record the 1st name initial in the first box, the last name initial in the 2nd box and leave the third box blank.