

VA COOPERATIVE STUDY #578

Participant ID: _____ - _____

SOURCE DOCUMENT WORKSHEET FOR FORM 15: HOSPITALIZATIONS WITHIN 96 HOURS POST PROCEDURE

To be completed by study personnel via medical record review for participants who remain hospitalized beyond 12 hours following their index angiography or for participants who are discharged after their angiography and then readmitted to a hospital within 96 hours. Once completed, this data should be entered into eDC and this form should be filed in the Participant's Study Binder.

1. Did the participant remain in the hospital (beyond 12 hours) following their index angiography procedure?

Form15_HospPost12 **Blank: -1**

Yes **1**

No **If no, answer Q2** **2**

2. Was the participant readmitted to a hospital within 96 hours of their index angiography procedure?

Readmit **Blank: -1**

Yes (Complete the remaining questions and an Endpoint_SAE Form) **1**

No **2**



If Q1=no and Q2=no, then this form is complete.

REMINDER: All participants are required to have a blood sample collected 96 hours post-angiography to be sent to the Central Laboratory. If the participant remains hospitalized or is readmitted during this time frame, the 96 hour blood sample should be collected at the hospital and sent to the Central Laboratory.

3. Did the participant require the use of any IV inotropes during their hospitalization and within 96 hours following their index angiography? (For example, inamrinone (Inocor), milrinone (Primacor), dobutamine)

InotropeHospPost **Blank: -1**

Yes **1**

No **2**

4. Did the participant require the use of any IV vasodilators during their hospitalization and within 96 hours following their index angiography? (For example, nesiritide (Natreacor) or nitrates/GTN)

VasodilatorHospPost **Blank: -1**

Yes **1**

No **2**

5. Did the participant require the use of any IV vasopressors during their hospitalization and within 96 hours following their index angiography? (For example, dopamine (Intropin), phenylephrine (Neosynephrine),

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norepinephrine/noradrenalin (Levophed), epinephrine/adrenalin, ephredrine, vasopressin, metaraminol bitartrate (Aramine)) **VasopressorHospPost** **Blank: -1**

- Yes **1**
- No **2**

6. Did the participant experience any episodes of hypotension [defined as systolic blood pressure <90 mmHg and/or MAP < 55 mmHg] during their hospitalization and within 96 hours following their index angiography?

HypoHospPost **Blank: -1**

- Yes **1**
- No **2**

7. Did the participant require any additional radiological procedures involving contrast administration, including coronary or non-coronary angiography or computed tomography during their hospitalization and within 96 hours following their index angiography? **AddDyeHospPost** **Blank: -1**

- Yes **If yes, answer Q8.1-Q8.7 for each additional procedure** **1**
- No **2**

8.1 What was the date of the additional procedure? ____/____/____ **AddDyeHospPostDate**

8.2 Was the additional procedure planned? **AddDyeHospPostPlanned** **Blank: -1**

- Yes **1**
- No **2**

8.3 Which of the following contrast dyes was administered during the additional procedure?

AddDyeTypeHospPost **Blank: -1**

- Iodixanol (Visipaque) **1**
- Iopamidol (Isovue) **2**
- Iopromide (Ultravist) **3**
- Ioversol (Optiray) **4**
- Ioxilan (Oxilan) **5**
- Ioxaglate (Hexabrix) **If checked, answer Q8.5** **6**
- Iohexol (Omnipaque) **If checked, answer Q8.5** **7**
- Other contrast dye **8**

(8.4. Specify: _____ **AddDyeHospPostOth** _____)

8.5. The contrast dye you noted as administered during the procedure (ioxaglate (Hexabrix) or iohexol (Omnipaque) has been associated with a higher risk of contrast nephropathy. What

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was the reason for choosing this contrast dye type? **AddDyeHospPostExplain** **Blank: -1**

- Only contrast dye available at my facility **1**
- It is the least expensive with comparable safety **2**
- No specific reason **3**
- Other reason **4**

(8.6. Please specify: _____ **AddDyeHospPostExplainOth** _____)

8.7. What was the total volume of contrast administered during the additional procedure? _____ mls

AddDyeHospPostVol

9. Did the participant need any surgical procedure(s) requiring general or epidural anesthesia during their hospitalization and within 96 hours following their index angiography? **SurgHospPost** **Blank: -1**

- Yes **If yes, answer Q10.1-Q10.3 for each surgical procedure 1**
- No **2**

10.1. What was the date of the surgical procedure? ____/____/____ **SurgHospPostDat**

10.2. What type of surgical procedure was performed? **SurgHospPostType** **Blank: -1**

- coronary artery bypass graft surgery **1**
- other surgical procedure **2**

(10.3 Specify: _____ **SurgHospPostTypeOth** _____)

REMINDER: All participants are required to have a blood sample collected 96 hours post-angiography to be sent to the Central Laboratory. If a participant is discharged from the hospital before 96 hours, determine whether he/she will be able to return to the site for this blood draw or, if unable, if the mobile specimen collection service will be required (US participants only).

11. Date Form Completed: _____ **F15Complete** _____

Signature of person completing the form: _____