

**Form 6****Instructions for difficult items on Form 6 --**

AV access section (questions 6 - 18). At Baseline, answer access questions as either no (0) or yes (1) if an event occurred since the patient was enrolled in Baseline. In the Follow-Up period, the answers should reflect the number of times an event happened; i.e., 0 for none, 1 for one time, 2 for two times, etc. Information should be obtained from the hemodialysis chart or the patient.

question 6. Clotted permanent access -- this refers to a clotted permanent vascular access which no longer has blood flow.

question 7. Soft-tissue infection, cellulitis, abscess (access related) -- this refers to documented infections that either involve the skin or the soft tissue in or around the vascular access. There may even be a frank abscess. This would be demonstrable by physical exam and/or culture results.

question 8. Steal syndrome, limb ischemia, access related -- this occurs when the permanent vascular access steals blood to a distal limb site. This would be demonstrated radiographically or by Doppler flow or by clinical exam demonstrating evidence of poor vascular supply to a limb distal to a vascular access.

question 9. Hemorrhage from vascular access requiring visit to ER or hospital -- this refers to bleeding from the vascular access, either at a site of a previous stick or a site of other trauma that requires the patient to seek assistance in the ER or to be hospitalized.

question 10. Subclavian vein or superior vena cava stenosis -- this occurs when there is a stenosis or an occlusion to either superior vena cava or subclavian vein typically as a result of previous temporary access often leading to swelling in the distal arm, or the head and neck. This would be defined after a radiographic procedure demonstrates a stenosis in the subclavian vein or superior vena cava.

question 11. Nerve entrapment, access related -- this refers to a situation where a patient has demonstrable neurologic damage, either on physical exam or by nerve-conduction studies, which is in the nerves of the same limb as the vascular access and is attributed to complications related to the vascular access.

question 13. Surgical access repair -- this is defined as any surgical procedure performed on an existing permanent access which is still functioning at the time of surgery. If the permanent existing access still has blood flow at the time of surgical repair, then it would fall into this category.

question 14. Surgical thrombectomy with or without revision (access clotted at time of OR) -- this is defined as a surgical procedure done on a permanent existing access which is clotted at the time of surgery. Any permanent existing access that has no blood flow in it at the time of surgery would fall into this category.

question 15. Angioplasty or stent placement for vascular access -- this occurs when the patient has dye injected into the existing permanent graft and either a balloon catheter is used to relieve a stenosis or blocked area or a stent is placed to hold open a stenotic area. These procedures are typically done in radiology. A patient may have pharmacologic declotting followed by angioplasty; then both would be entered.

question 16. Pharmacologic and/or radiographic procedures for declotting -- these procedures occur when drugs are injected into a graft or temporary access to declot them. Such drugs include urokinase and streptokinase. Mechanical declotting may include emulsification using the "Clot buster" Amplatz thrombectomy device.

question 17. New access placement of AV fistula (native or graft) -- this describes a surgical procedure in which a permanent vascular access is placed under the skin of the patient. This may be a surgical procedure where the patient's own artery and vein are connected to create a new vascular access, or a piece of foreign material such as Gortex or PTFE is placed under the skin to create a connection between one of the patient's arteries and veins. By new access, this would refer to any procedure in which a completely new site on the patient's body was selected for creation of the vascular access.

question 18. Temporary access placement -- this is defined as the placement of a temporary catheter for the purpose of dialysis. Such a catheter comes in many different brands. It could be in the femoral, internal jugular, or subclavian veins. In general, it is easily recognized since plastic material with ports to connect to the dialysis machine will be easily visible outside the patient's body. This would also include permacaths. All permacath changes within a 6 month period should be scored.

question 19. Mechanical declotting of a permanent AV fistula using the procedure called possis or ultrasound -- at this point, these procedures are mostly experimental but may become more widely used in the future. These procedures would not typically involve thrombolytic agents.

question 20. Other -- this should be used only if the access procedure is not found under questions 13 - 19. An example of "other" is ligation of venous collaterals.

The following may help you enter the medication questions:

questions 23 - 35. (Medications) Record medications for which there is a current prescription. Here are examples of some of the antihypertensives we are tracking. If a patient is on a combination drug, answer yes to each class of drug in the combination.

ACE inhibitors.....Answer yes to item 23 for any of these

- Accupril (quinapril)
- Aceon (perindopril)
- Altace (ramipril)
- Capoten (captopril)
- Lotensin (benazepril)
- Mavik (trandolapril)
- Monopril (fosinopril)
- Univasc (moexipril)
- Vasotec (enalapril)
- Zestril, Prinivil (lisinopril)

Combination of ACE inhibitors and diuretics .....Answer yes to item 23 for any of these

- Capozide (captopril + HCTZ)
- Lotensin (benazepril + HCTZ)
- Prinzide (lisinopril + HCTZ)
- Unirectic (moexipril + HCTZ)
- Vasoretic (enalapril + HCTZ)
- Zestoretic (lisinopril + HCTZ)

Combination of ACE inhibitors and Ca channel blockers.....Answer yes to 23 & 25 for these

- Lexxel (enalopril + felodipine)
- Lotrel (amlodipine + benazepril)
- Tarka (trandopril + verapamil)

Beta blockers.....Answer yes to item 24 for any of these

- Betapace (sotalol)
- Blocardren (timolol)
- Brevibloc (esmoiol)
- Corgard (nadolol)
- Inderal (propranolol)
- Kerlone (betaxolol)
- Levitol (penbutolol)
- Lopressor (metoprolol)
- Sectral (acebutolol)
- Tenormin (atenolol)
- Toprol XL (metoprolol)
- Trandate, Normodine (labetalol)
- Visken (pindolol)
- Zebeta (bisoprolol)

Beta blocker with diuretic.....Answer yes to item 24 for any of these

- Inderide LA (propranolol + HCTZ)
- Lopressor HCT (metoprolol + HCTZ)
- Tenoretic (atenolol + chlorthalidone)
- Timolide (timolol + HCTZ)
- Ziac (bisoprolol + HCTZ)

Calcium channel blockers.....Answer yes to item 25 for any of these

- Adalat (nifedipine)
- Calen (verapamil)
- Cardene (nicardipine)
- Cardizem (diltiazem)
- Covera (verapamil)
- Dilacor (diltiazem)
- Dynacirc (isradipine)
- Isoptin (verapamil)
- Nimotop (nimodipine)
- Norvasc (amlodipine)
- Plendil (felodipine)
- Posicor (mibefradil)
- Procardia, Adalat (nifedipine)
- Sular (nisoldipine)
- Tiazac (diltiazem)
- Vascor (bepridil)
- Verelan (verapamil)

Alpha 1 antagonists .....Answer yes to item 26 for any of these

- Cardura (doxazosin)
- Prasozin (Minipres)
- Terazocin (Hytrin)

Angiotensin II Receptor Antagonists.....Answer yes to item 27 for any of these

- Cozaar (losartan)
- Diovan (valsartan)
- Hyzaar (losartan + HCTZ)

Minoxidil.....Answer yes to item 28 if patient is on minoxidil

Adrenergic stimulants .....Answer yes to item 29 for any of these

- Aldomet (methyldopa)
- Aldoril (methyldopa + HCTZ)
- Catapres (clonidine)
- Combipres (clonidine + chlorthalidone)
- Tenex (guanfacine)

Nitrates.....Answer yes to item 34 for any of these

- Cardilate (erythryl tetranitrate)
- Isordil, Sorbitate, or Dilatrate (isosorbide dinitrate)
- Nitropaste
- Nipride (nitroprusside)
- Nitrospray

**HEMO Study Form 6. Access-Related Conditions and Other Semi-Annual Data**

Complete this form at week 4 of Baseline and at month 4 of Follow-Up at the time of the month 4 kinetic-modelling session. Then, from months 12 to 72, it should be done semi-annually.

- 1. Patient Identification Number. . . . . \_\_\_\_\_
- 2. Name Code . . . . . \_\_\_\_\_
- 3. Visit Date . . . . . \_\_\_\_/\_\_\_\_/\_\_\_\_
- 4. Visit Type . . . . . \_\_\_\_\_
- 5. Week/Month Number . . . . . \_\_\_\_\_

**Access-Related Conditions**

Respond to each item with the number of times that the event has occurred since the previous Form 6 was completed; or, for Baseline, since the patient enrolled in Baseline. Use 0 = none, 1 = once, 2 = twice, etc. Information should be obtained from the hemodialysis chart or the patient.

**ACCESS COMPLICATIONS**

- 6. Clotted access . . . . . \_\_\_\_\_
- 7. Soft tissue infection, cellulitis, abscess (access related). . . . . \_\_\_\_\_
- 8. Steal syndrome, limb ischemia, access related . . . . . \_\_\_\_\_
- 9. Hemorrhage from vascular access requiring ER or hospital . . . . . \_\_\_\_\_
- 10. Subclavian vein stenosis (if this has been reported previously, do not include again) . . . . . \_\_\_\_\_
- 11. Nerve entrapment, access related . . . . . \_\_\_\_\_
- 12. Other . . . . . \_\_\_\_\_

**ACCESS PROCEDURES**

- 13. Surgical revision of AV access (no thrombosis). . . . . \_\_\_\_\_
- 14. Surgical thrombectomy with or without revision . . . . . \_\_\_\_\_
- 15. Angioplasty or stent placement for vascular access . . . . . \_\_\_\_\_
- 16. Pharmacologic, radiologic, and/or mechanical declotting of permanent AV access with thrombolytic procedures . . . . . \_\_\_\_\_

- 17. New AV access placement (native or graft) . . . . . \_\_ \_\_
- 18. Temporary access placement (catheter) . . . . . \_\_ \_\_
- 19. Mechanical declotting of AV fistula by possis or ultrasound . . . . . \_\_ \_\_
- 20. Other . . . . . \_\_ \_\_

**Other Semi-Annual Data**

**Weight Reduction Plan**

**Both the study coordinator and the Dietitian must agree on this question.**

- 21. Is the patient taking part in a planned weight-reduction program?  
(0=no, 1=yes) . . . . . \_\_

**Residual Renal Function (Complete this section during Baseline and Annually thereafter, collecting urine if indicated)**

- 22. a. Is the patient producing over 200 ml urine/day? (0=no, ≤ 200; 1=yes, > 200) . . \_\_
- b. Visit urine code . . . . . \_\_
- 0=not a Baseline or an annual visit
- 1=patient produces no urine
- 2=patient produces urine, brought in urine, and there was less then 50 ml
- 3=patient produces urine, brought in urine, and there was 50 ml or more
- 9=unknown. Patient reports producing urine but did not bring urine in

**Medications**

**For questions 23 - 35, code 0=no, 1=yes, 9=unknown.**

- 23. Is the patient on ACE inhibitors? . . . . . \_\_
- 24. Is the patient on beta-blockers? . . . . . \_\_
- 25. Is the patient on calcium-channel blockers? . . . . . \_\_
- 26. Is the patient on alpha-1 antagonists? . . . . . \_\_

- 27. Is the patient on Angiotensin II receptor antagonists? .....
- 28. Is the patient on minoxidil? .....
- 29. Is the patient on Adrenergic stimulants? .....
- 30. Is patient on any other antihypertensives? .....
- 31. Is the patient on EPO? .....
- 32. Is the patient on aspirin? .....
- 33. Is the patient on Coumadin? .....
- 34. Is the patient on nitrates? .....
- 35. Is the patient on vitamin D replacement, either oral or intravenous? .....
- 201. Date this form completed ..... / /
- 202. Certification number of person completing this form .....

Clinical Center Use Only	
Data Form Entered	____/____/____
Verified?	_____
Person Entering this Form	_____