F202
Hemodialysis Fistula Maturation Study (HFM/MANVAS Studies)
Demographics, Comorbidities, and Exposures Form (Form # 202)

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1. Identification Number PID 2. Alphacode AC3. Visit Number VIST 4. Date of Visit/Interview: VISIT_DT

Race/Ethnicity

5. Race (self-reported) .... RACE
   1=Native American, Aboriginal Canadian or Alaskan Native, First Nation, Aboriginal Australian
   2=Asian
   3=Native Hawaiian or Other Pacific Islander
   4=Black, African American, African
   5=White/Caucasian
   6=More than one race (multiracial)
   9=Unknown or not reported

6. Hispanic or Latino ethnicity? (0=no, 1=yes, 9=unknown or not reported) ....HISP_LAT

Communication

7. Patient's primary language?
   (1=English, 2=Spanish, 3=Chinese, 4=Russian, 5=Haitian/Creole, 7=Tongan, 99=Other)............. PRIM_LANG
8. Can the patient speak English? (0=no, 1=yes) .... SPEAK_ENG
9. Can the patient read English? (0=no, 1=yes).. READ_ENG
10. Can the patient speak Spanish? (0=no, 1=yes, 8-not asked because patient speaks English)... SPEAK_SPA
11. Can the patient read Spanish? (0=no, 1=yes, 8=not asked because patient speaks English) ...... READ_SPA
12. Can the patient himself/herself communicate by telephone? (0=no, 1=yes, 2=TTY phone) TELEPHONE

Demographic/SES

13. Marital status: .... MARITAL
    1=Never been married
    2=Married
    3=Common law marriage/partnered/ living together unmarried
    4=Separated
    5=Divorced
    6=Widowed
    9=Unknown

14. Household Size: (Code 0=no, 1=yes, 9 = unknown)
    a. Lives with family (e.g., spouse, children, parents):.. HH_FAMILY
    b. Lives alone: ....HH_ALONE
    c. Lives with others (e.g., retirement community, nursing home, rooming house):..HH_OTHERS
    d. Homeless: .... HH_HOMELESS
15. Highest level of formal education achieved?...EDUCATION
    1=8th Grade or less
    2=9th-12th grade, no diploma
    3=High school graduate
    4=Vocational/technical/business degree
    5=Some college, no degree
    6=Associate's degree
    7=Bachelor's degree
    8=Master's/Doctorate/Professional School
    9=Unknown

16. Has the patient ever been employed for pay? (0=no, 1=yes, 9=unknown).......................... EMPLOYED

17. What was the last year the patient was employed? (yyyy)...LAST_EMPLOYED
(Enter current year if currently employed)

18. Current work status:..CURR_WORK

01=Student, not employed	06=Not employed, seeking work, disabled
02=Student, employed	07=Not employed, seeking work, not disabled
03=Homemaker	08=Employed full-time
04=Not employed, not seeking work, disabled	09=Employed part-time
05=Not employed, not seeking work, not disabled	10=Retired
	99=Unknown

19. Current household gross annual income? ....HH_INCOME

1=<$10,000	6=$40,000-$49,999
2=$10,000-$14,999	7=$50,000-$99,999
3=$15,000-$19,999	8=≥$100,000
4=$20,000-$29,999	9=Unknown or refused
5=$30,000-$39,999	

20. a. Zip code of patient's home (for US sites only) .... HOME_ZIP

b. Postcode of patient's home (for MANVAS only) .... ___ ___ ___ ___ ___ ___ ___

Patient Health Insurance

21. Does this patient have any kind of health insurance? (0=no, 1=yes, 8=not applicable, 9=unknown) - INSURANCE

22. If yes, what type of health insurance does the patient have? (For Q22a-f, code 0=no, 1=yes)
   a. Medicare health insurance:... MEDICARE
   b. Medicaid or State Medical Assistance: .... MEDICAID
   c. State or county program other than Medicaid: .... OTH_PROG
   d. Employer-sponsored or retiree health plan:...EMPLOYER
   e. Privately-purchased policy (e.g., Medigap or Medicare supplement): .... PRIVATE
   f. Veterans benefit, TriCare or military health plan: .... VETERAN

23. a. Is Medicare paying for this patient's dialysis? ....DIAL_MEDICARE
   0=no (answer Q23b), 1=yes, 9 = unknown
   b. If "no" to Q23a, why not? ....REASON
   1=Patient has not been on dialysis for 90 days (this includes patients who have never been on dialysis)
   2=Patient is not eligible for Medicare for some other reason but has alternative insurance
   3=Patient is not eligible for Medicare for some other reason and has **no** alternative insurance
   4=Unknown

Height (Measured height is preferred)

24. a. Most recent measured or estimated height (cm)...HT_CM
   b. Is this an actual (measured) height? (1=actual, 2=based on recall, 3=estimated) ....ACTUAL
   c. Date height measured/estimated (mm/dd/yyyy) .... HT_DT
   (If month is unknown – use "06", if day is unknown – use "15")

25. Leg amputations

a. Left (0=none, 1=toe(s), 2=transmetatarsal, 3=below knee, 4=above knee) .... L_LEG_AMP
b. L Reason (0=not for trauma/accident, 1=due to trauma/accident).................................... L_LEG_RSN
c. Right (0=none, 1=toe(s), 2=transmetatarsal, 3=below knee, 4=above knee) .... R_LEG_AMP
d. R Reason (0 =not for trauma/accident, 1=due to trauma/accident) .... R_LEG_RSN

26. Ask patient: What hand do you usually write or eat with? ....WRITE
1=left, 2=right, 8=not applicable, 9=unknown

Diabetes:

27. Does the patient have a previous history of diabetes? (0=no, 1=yes) .... DIABETES
28. If yes, estimated year of diagnosis (yyyy).. DIABETES_YR
29. If yes, current treatment for diabetes.. DIABETES_TRT
0 = not applicable (the patient is not diabetic)
1 =diet alone
2 = oral hypoglycemic agents
3 = insulin
4 = oral hypoglycemic agents and insulin

Comorbidities:

Is it known that the patient has this condition / noted in the medical chart problem list / noted on a recent discharge summary or self-reported? (Code 0=no, 1=yes)

30. a. History of congestive heart failure .... CHF
b. History of myocardial infarction .... MI
c. History of angina .... ANGINA
d. Prior coronary artery bypass surgery .... BYPASS
e. Prior percutaneous coronary intervention (angioplasty).............................. ANGIOPLASTY
f. Prior carotid endarterectomy .... CEA
g. Prior carotid artery angioplasty ....CA_ANGIO
h. History of cardiac arrhythmias or conduction problems ....CA_ARRHY
i. History of stroke or TIA ....TIA
j. History of hypertension ....HTN
k. History of claudication .... CLAUD
l. Known hypercoagulable state...HYPERCOAG
m. History of lower extremity angioplasty or bypass surgery ....LOW_BYPASS
n History of deep venous thrombosis ....DVT
o. History of pulmonary embolism... PE
p. Peptic ulcer disease diagnosed within the preceding 3 months .... PUD
q. History of inflammatory bowel disease.. IBD
r. History of chronic liver disease .... CLD
s. History of vasculitis...VASCULITIS
t. History of Systemic Lupus Erythmatosus (SLE).. SLE

u. History of scleroderma .... SCLERODERMA
v. History of dyslipidemia .... HYPERLIPIDEMIA
w. HIV positive .... HIV
x. Other major comorbidity 1
____ CONDITION1
(write in words, code with MedDRA code) ....MEDRA_CODE1

y. Other major comorbidity 2
____ CONDITION2
(write in words, code with MedDRA code) ....MEDRA_CODE2

z1. Other major comorbidity 3
____ CONDITION3
(write in words, code with MedDRA code) ....MEDRA_CODE3

z2. Other major comorbidity 4
____ CONDITION4
(write in words, code with MedDRA code) ....MEDRA_CODE4

Smoking/Drugs/Alcohol:

31. Cigarette smoking status (0=never, 1=former, 2=current, 9=unknown)..SMOKE
32. Total number of years smoked.. SMOKE_YRS
33. Number of packs per day .... SMOKE_PACKS
34. For former smokers only: months since last smoked.. SMOKE_LAST
(Note: 12 months = 1 year, 120 months = 10 years, etc)

For 35-37, code 0=no, not in the medical record and per patient report, 1=yes, but more than 5 years ago, 2=yes, in the past 5 years, 9=unknown

35. Is there a history of <u>IV</u> recreational drug use or does the patient currently use IV recreational drugs? ....IV_DRUG
36. Is there a history of <u>other</u> recreational drug use or does the patient currently use other recreational drugs? ....OTH_DRUG
37. Is there a history of alcohol abuse or does the patient currently abuse alcohol? .... ALCOHOL

Compliance:

38. Does this patient generally comply with medical appointments?........................COMPLY_APPT
0=no, often misses appointments; 1=yes, patient generally complies, 9=unknown

200. Date this form completed (mm/dd/yyyy) .... COMP_DT

201. Username of person completing/reviewing completeness of this form...................COMP_USER

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ENTER_DT

Username of person entering this form ENTER_USER