Dataset Integrity Check for the FHN Daily Trial Data Files

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Table of Contents

1 Standard Disclaimer

The intent of this DSIC is to provide confidence that the data distributed by the NIDDK repository is a true copy of the study data. Our intent is not to assess the integrity of the statistical analyses reported by study investigators. As with all statistical analyses of complex datasets, complete replication of a set of statistical results should not be expected in secondary analysis. This occurs for a number of reasons including differences in the handling of missing data, restrictions on cases included in samples for a particular analysis, software coding used to define complex variables, etc. Experience suggests that most discrepancies can ordinarily be resolved by consultation with the study data coordinating center (DCC), however this process is labor-intensive for both DCC and Repository staff. It is thus not our policy to resolve every discrepancy that is observed in an integrity check. Specifically, we do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancies that involve complex analyses, unless NIDDK Repository staff suspect that the observed discrepancy suggests that the dataset may have been corrupted in storage, transmission, or processing by repository staff. We do, however, document in footnotes to the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

2 Study Background

In this randomized clinical trial, we aimed to determine whether increasing the frequency of in-center hemodialysis would result in beneficial changes in left ventricular mass, self-reported physical health, and other intermediate outcomes among patients undergoing maintenance hemodialysis.

3 Archived Datasets

All SAS data files, as provided by the Data Coordinating Center (DCC), are located in the "\FHN\private_created_data\" folder in the data package. For this replication, variables were taken from the different form and analysis datasets.

4 Statistical Methods

Analyses were performed to duplicate results for the data published by The FHN Trial Group in The New England Journal of Medicine, 2010 December 9. To verify the integrity of the three datasets, three tables from the paper were checked (Tables B, D, and F)

5 Results

Table 1 in the publication [1], Baseline Characteristics of the Study Participants.* Table A lists the variables that were used in the replication and Table B compares the results calculated from the archived data file to the results published in Table 1. The results of the replication are a close match to the publication with the exception of the duration variable.

The duration categories in the publication were “< 2 year”, “2-5 year”, and “> 5 year”, however the numbers in the publication were based on the categories “< 1 year”, “1-4 year”, and “> 4 year”. A correction will be made in the publication.

6 Conclusions

The NIDDK repository is confident that the FHN Daily Trial data files to be distributed are a copy of the manuscript data.

7 References

[1] Chertow GM[et al] FHN Trial Group: In-center hemodialysis six times per week versus three times per week. N Engl J Med 363: 2287–2300, 2010

Table A: Variables used to replicate Table 1. Baseline Characteristics of the Study Participants.

Characteristic	Variable(s)
Age(yr)	F110_Daily.BIRTH_DT, F110_Daily.VISIT_DT
Female sex (%)	F110_Daily.Gender
Black	F110_Daily.Race
White	F110_Daily.Race
Native American, Aboriginal Canadian, Alaskan Native, or First Nation	F110_Daily.Race
Asian	F110_Daily.Race
Native Hawaiian or other Pacific Islander	F110_Daily.Race
Other or mixed	F110_Daily.Race
Body-mass index‡	F242_Daily.HT_CM, F242_Daily.DRY_WT_KG
Weight after dialysis (kg)	F242_Daily.DRY_WT_KG
Anthropometric volume (liters)§	analysis_monthly_d.V_SA
Cause: Diabetic nephropathy	F104_daily.KD_FAIL
Cause: Glomerulonephritis	F104_daily.KD_FAIL
Cause: Hypertensive nephrosclerosis	F104_daily.KD_FAIL
Cause: Polycystic kidney disease	F104_daily.KD_FAIL
Cause: Other	F104_daily.KD_FAIL
Duration: <2 yr	F110_daily.ESRD_DT, RAND_DAILY.rand_dt
Duration: 2–5 yr	F110_daily.ESRD_DT, RAND_DAILY.rand_dt
Duration: >5 yr	F110_daily.ESRD_DT, RAND_DAILY.rand_dt
Coexisting: Hypertension	analysis_quarterly_d. antihyp and hneph
Coexisting: Myocardial infarction	f104_daily.MI
Coexisting: Heart failure	f104_daily.CHF
Coexisting: Atrial fibrillation	f104_daily.ATRIAL_FIB
Coexisting: Peripheral arterial disease	f104_daily.PVD
Coexisting: Abdominal aortic aneurysm repair or bypass	f104_daily.AAA_REPAIR
Coexisting: Stroke	f104_daily.CVA
Coexisting: Dementia	f104_daily.DEMENTIA
Coexisting: Tumor without metastases	f104_daily.TUMOR
Coexisting: Diabetes and complications of diabetes	f104_daily.DIAB_WO_DAM, DIAB_W_DAM
Coexisting: Hemiplegia	f104_daily.HEMIPLEGIA
Coexisting: Chronic pulmonary disease	f104_daily.CPD
Coexisting: Moderate or severe liver disease	f104_daily.MOD_LIV_DIS
Residual: Anuria	analysis_quarterly_d. rrf
Residual: >0 to 1 ml/min	analysis_quarterly_d. rrf
Residual: >1 to 3 ml/min	analysis_quarterly_d. rrf
Diastolic blood pressure before dialysis (mm Hg)	analysis_monthly_d.pre_dia
Serum creatinine (mg/dl)	analysis_monthly_d.CREAT
Kt/Vurea: Weekly standard	analysis_ quarterly _d.stdktvUDialKOA
Kt/Vurea: Equilibrated	analysis_ quarterly _d. eKtVtatV
Access: Fistula	f271_daily.ACCESS_TYPE
Access: Synthetic graft	f271_daily.ACCESS_TYPE
Access: Catheter	f271_daily.ACCESS_TYPE

Table B: Comparison of values computed in integrity check to reference article Table 1 values

Characteristic	Conventional Hemodialysis (Manuscript N = 120)	Conventional Hemodialysis (DSIC N = 120)	Conventional Hemodialysis (DIFF N = 0)
Age(yr)	52.0±14.1	52.1 ± 14.1	-0.1
Female sex (%)	39.2	39.2	0
Black	44.2	44.2	0
White	38.3	38.3	0
Native American, Aboriginal Canadian, Alaskan Native, or First Nation	3.3	3.3	0
Asian	4.2	4.2	0
Native Hawaiian or other Pacific Islander	2.5	2.5	0
Other or mixed	7.5	7.5	0
Body-mass index‡	27.5±7.1	27.6 ± 6.9	-0.1,0.2
Weight after dialysis (kg)	78.7±20.5	78.6 ± 20.4	0.1,0.1
Anthropometric volume (liters)§	39.5±8.3	39.4 ± 8.2	0.1,0.1
Cause: Diabetic nephropathy	32.5	32.5	0
Cause: Glomerulonephritis	19.2	19.2	0
Cause: Hypertensive nephrosclerosis	20.0	20.0	0
Cause: Polycystic kidney disease	5.0	5.0	0
Cause: Other	23.3	23.3	0
Duration: <2 yr	16.7	26.7	-10*
Duration: 2–5 yr	42.5	35.8	6.7*
Duration: >5 yr	40.8	37.5	3.3*
Hypertension	87.3	88.3	-1
Myocardial infarction	13.3	13.3	0
Coexisting: Heart failure	20.0	20.0	0
Coexisting: Atrial fibrillation	7.5	7.5	0
Coexisting: Peripheral arterial disease	8.3	8.3	0
Coexisting: Abdominal aortic aneurysm repair or bypass	1.7	1.7	0
Coexisting: Stroke	7.5	7.5	0
Coexisting: Dementia	0.8	0.8	0
Coexisting: Tumor without metastases	6.7	6.7	0
Coexisting: Diabetes and complications of diabetes	41.7	41.7	0
Coexisting: Hemiplegia	0.8	0.8	0
Coexisting: Chronic pulmonary disease	4.2	4.2	0
Coexisting: Moderate or severe liver disease	0.8	0.8	0
Residual: Anuria	60.0	60.0	0
Residual: >0 to 1 ml/min	15.8	15.8	0
Residual: >1 to 3 ml/min	24.2	22.5	1.7
Diastolic blood pressure before dialysis (mm Hg)	78.4±11.7	78.5 ± 11.8	0.1, -0.1
Serum creatinine (mg/dl)	10.3±2.5	10.3 ± 2.5	0,0
Kt/V_{urea}: Weekly standard	2.54±0.39	2.53 ± 0.39	.01,0
Kt/V_{urea}: Equilibrated	1.43±0.28	1.43 ± 0.28	0.0
Access: Fistula	62.5	59.0	3.5
Access: Synthetic graft	18.3	22.0	-3.7
Access: Catheter	19.2	19.0	0.2

Characteristic	Conventional Hemodialysis (Manuscript N = 120)	Conventional Hemodialysis (DSIC N = 120)	Conventional Hemodialysis (DIFF N = 0)
Age(yr)	48.9±13.6	49.0 ± 13.6	-0.1,0
Female sex (%)	37.6	37.6	0
Black	39.2	39.2	0
White	34.4	34.4	0
Native American, Aboriginal Canadian, Alaskan Native, or First Nation	3.2	3.2	0
Asian	8.8	8.8	0
Native Hawaiian or other Pacific Islander	0.8	0.8	0
Other or mixed	13.6	13.6	0
Body-mass index‡	27.3±6.5	27.4 ± 6.5	-0.1,0
Weight after dialysis (kg)	77.6±20.6	77.3 ± 20.2	0.3,0.4
Anthropometric volume (liters)§	39.3±8.1	38.9 ± 8.2	0.2,-0.1
Cause: Diabetic nephropathy	36.0	36.0	0
Cause: Glomerulonephritis	19.2	19.2	0
Cause: Hypertensive nephrosclerosis	21.6	21.6	0
Cause: Polycystic kidney disease	3.2	3.2	0
Cause: Other	20.0	20.0	0
Duration: <2 yr	16.0	26.4	-10.4*
Duration: 2–5 yr	35.2	30.4	4.8*
Duration: >5 yr	48.8	43.2	5.6*
Hypertension	91.5	90.4	1.1
Myocardial infarction	8.8	8.8	0
Coexisting: Heart failure	20.0	20.0	0
Coexisting: Atrial fibrillation	4.0	4.0	0
Coexisting: Peripheral arterial disease	12.0	12.0	0
Coexisting: Abdominal aortic aneurysm repair or bypass	2.4	2.4	0
Coexisting: Stroke	7.2	7.2	0
Coexisting: Dementia	0.0	0	0
Coexisting: Tumor without metastases	1.6	1.6	0
Coexisting: Diabetes and complications of diabetes	40.0	40.0	0
Coexisting: Hemiplegia	1.6	1.6	0
Coexisting: Chronic pulmonary disease	4.8	4.8	0
Coexisting: Moderate or severe liver disease	0.8	0.8	0
Residual: Anuria	72.0	72.0	0
Residual: >0 to 1 ml/min	14.4	14.4	0
Residual: >1 to 3 ml/min	13.6	12.0	1.6
Diastolic blood pressure before dialysis (mm Hg)	81.0±11.2	81.1 ± 11.3	0.1,-0.1
Serum creatinine (mg/dl)	10.8±3.0	10.8 ± 2.9	0,0.1
Kt/V_{urea}: Weekly standard	2.50±0.31	2.50 ± 0.31	0,0
Kt/V_{urea}: Equilibrated	1.43±0.25	1.43 ± 0.26	0,-0.01
Access: Fistula	65.6	66.7	-1.1
Access: Synthetic graft	16.0	15.2	0.8
Access: Catheter	18.4	18.2	0.2

*See the results section above

```
*************************************************************************************************************************
***Program:
***Programmer: Michael Spriggs
***Date Created: 7/12/2015
***Purpose: FHN DSIC
*************************************************************************************************************************;

title1 "%sysfunc(getoption(sysin))";
title2 " ";

options nofmterr mprint source2;

libname fhn '/prj/niddk/ims_analysis/FHN/private_orig_data/FHN_Daily_Trial_SAS_Datasets_10012014/';
libname qa '/prj/niddk/ims_analysis/FHN/private_orig_data/FHN_Daily_Trial_SAS_Qtrly_Analysis_09192014/';

*** File containing macro for examining each dataset ***;
%include '/prj/niddk/ims_analysis/sas_macros/redaction_data_summary.sas';

%macro freqdata1(order=, invar=, level=);

data data0 data1;
  set _null_;

  proc freq data=table1 noprint;
       tables &invar*treatment/out=data0 outpct;
       format _all_;
       run;

data data1;
  set data0;
  length LEVEL $100;
  LEVEL=strip(&invar);

  data data1(keep=LEVEL treatment name CHARALL ORDERER);
    set data1;
    length name $100 CHARALL $100;
    name=upcase("&invar");
    PCT_DISP=round(PCT_COL,.1);
    CHARALL=compress(put(PCT_DISP,8.1));
    /*
    CHARALL=compress(put(COUNT,8.))||" ("||compress(put(PCT_DISP,8.1))||")";
    */
    ORDERER=&order;
    if level in &level then output data1;

data accumfreq1;
  set accumfreq1 data1;

%mend freqdata1;

%macro meandata1(order=, invar=, roundvar=, digit=);
proc means data=table1 mean stddev noprint;
       var &invar;
       class treatment;
       output out=data1 mean=mean stddev=stddev;
       run;
```

```
data data1(drop=_TYPE_ _FREQ_ mean stddev);
  set data1;
  length name CHARALL $100;
  name=upcase("&invar");
  mean=round(mean,&roundvar);
  stddev=round(stddev,&roundvar);
  CHARALL=compress(put(mean,8.&digit))||" ± "||compress(put(stddev,8.&digit));
  ORDERER=&order;

data accummean1;
  set accummean1 data1;

%mend meandata1;

%macro mediandata1(order=, invar=, roundvar=, digit=);
proc means data=table1 median p25 p75 min max noprint;
        var &invar;
        class treatment;
        output out=data1 median=median p25=p25 p75=p75 min=min max=max;
        run;

data data1(drop=_TYPE_ _FREQ_ median p25 p75 min max);
  set data1;
  length name CHARALL $100;
  name=upcase("&invar");
  median=round(median,&roundvar);
  min=round(min,&roundvar);
  max=round(max,&roundvar);
  ORDERER=&order;
  CHARALL=compress(put(median,8.&digit));
  output;
  ORDERER=ORDERER+.01;
  CHARALL=compress(put(min,8.&digit)||"-"||put(max,8.&digit));
  output;

data accummedian1;
  set accummedian1 data1;

%mend mediandata1;

%macro rangedata1(order=, invar=, roundvar=, digit=);
proc means data=table1 median p25 p75 min max noprint;
        var &invar;
        class treatment;
        output out=data1 min=min max=max;
        run;

data data1(drop=_TYPE_ _FREQ_ min max);
  set data1;
  length name CHARALL $100;
  name=upcase("&invar");
  min=round(min,&roundvar);
  max=round(max,&roundvar);
  ORDERER=&order;
  CHARALL=compress(put(min,8.&digit)||"-"||put(max,8.&digit));
```

```
  output;

data accummedian1;
  set accummedian1 data1;

%mend rangedata1;


data accumfreq1 accummean1 accummedian1;
  set _null_;

data rand_daily;
  set fhn.rand_daily;

data f104_daily;
  set fhn.f104_daily;

data f110_daily;
  set fhn.f110_daily;

  length RENAL_DUR_CHAR $50;
  RENAL_DUR=(VISIT_DT-ESRD_DT)/365.25;
  IF RENAL_DUR<2 and RENAL_DUR ne . then RENAL_DUR_CHAR="<2 yr";
  else IF 2<=RENAL_DUR<=5 then RENAL_DUR_CHAR="2-5 yr";
  else IF RENAL_DUR>5 then RENAL_DUR_CHAR=">5 yr";



  length RENAL_DUR2_CHAR $50;
  RENAL_DUR2=(consent_dt-ESRD_DT)/365.25;
  IF RENAL_DUR2<1 and RENAL_DUR2 ne . then RENAL_DUR2_CHAR="<2 yr";
  else IF 1<=RENAL_DUR2<=4 then RENAL_DUR2_CHAR="2-5 yr";
  else IF RENAL_DUR2>4 then RENAL_DUR2_CHAR=">5 yr";

data f206_daily;
  set fhn.f206_daily;

data f208_daily;
  set fhn.f208_daily;

data f242_daily;
  set fhn.f242_daily;

data f256_daily;
  set fhn.f256_daily;

data f271_daily;
  set fhn.f271_daily;


data f274_daily;
  set fhn.f274_daily;

data analysis_monthly_d;
  set qa.analysis_monthly_d;
```

```
data analysis_quarterly_d;
  set qa.analysis_quarterly_d;


proc sort data=rand_daily;
  by PID;

proc sort data=f104_daily;
  by PID;

proc sort data=f110_daily;
  by PID;

proc sort data=f206_daily;
  by PID VISN;

proc sort data=f208_daily;
  by PID;

proc sort data=f242_daily;
  by PID VISN;

proc sort data=f256_daily;
  by PID VISN;

proc sort data=f271_daily;
  by PID VISN;


proc sort data=f274_daily;
  by PID VISN;

data f206_daily;
  set f206_daily;
  by PID;
  length VISN_CHECK 8.;
  retain VISN_CHECK;
  if first.PID then VISN_CHECK=VISN;
  if VISN=VISN_CHECK and VIST="B" then output;

data f208_visit_ct(keep=PID SESSION_CT_FINAL SESSION_CT_ACCUM SESSION_CT RECORD_CT);
  set f208_daily;
  by PID;
  length SESSION_CT_ACCUM RECORD_CT 8.;
  retain SESSION_CT_ACCUM RECORD_CT;
  if first.PID then do;
    SESSION_CT_ACCUM=0;
    RECORD_CT=0;
  end;
  SESSION_CT_ACCUM=sum(SESSION_CT_ACCUM,SESSION_CT);
  RECORD_CT=RECORD_CT+1;
  if last.PID then do;
    SESSION_CT_FINAL=SESSION_CT_ACCUM/RECORD_CT;
  end;
  output;
```

```
/*
proc print data=f208_visit_ct noobs;
  by PID;
  title3 '?';
*/

data f208_visit_ct;
  set f208_visit_ct;
  by PID;
  if last.PID then output;

data f242_daily;
  set f242_daily;
  by PID;
  length VISN_CHECK 8.;
  retain VISN_CHECK;
  if first.PID then VISN_CHECK=VISN;
  if VISN=VISN_CHECK and VIST="B" then output;

data f256_daily;
  set f256_daily;
  by PID;
  length VISN_CHECK 8.;
  retain VISN_CHECK;
  if first.PID then VISN_CHECK=VISN;
  if VISN=VISN_CHECK and VIST="B" then output;

data f271_daily;
  set f271_daily;
  by PID;
  length VISN_CHECK 8.;
  retain VISN_CHECK;
  if first.PID then VISN_CHECK=VISN;
  if VISN=VISN_CHECK and VIST="B" then output;
data f274_daily;
  set f274_daily;
  by PID;
  length VISN_CHECK 8.;
  retain VISN_CHECK;
  if first.PID then VISN_CHECK=VISN;
  if VISN=VISN_CHECK and VIST="B" then output;

data analysis_monthly_d;
  set analysis_monthly_d;
  by PID;
  length VISN_CHECK 8.;
  retain VISN_CHECK;
  if first.PID then VISN_CHECK=VISN;
  if VISN=VISN_CHECK then output;

data analysis_quarterly_d(rename = (stdktvUDialKOA = stdktvUDialKOA_q stdktvUKOA = stdktvUKOA_q hypertn = hypertn_q));
  set analysis_quarterly_d;
  by PID;
  length VISN_CHECK 8.;
  retain VISN_CHECK;
  if first.PID then VISN_CHECK=VISN;
```

```
  if VISN=VISN_CHECK then output;

data analysis_quarterly_d;
  set analysis_quarterly_d;
  length  URN_CHAR_2  $50.;
  if krcr_ml<0 then URN_CHAR_1=" ";

  if rrf<0 then URN_CHAR_2=" ";
  else if rrf=0 then URN_CHAR_2="Anuria";
  else if 0<rrf<=1 then URN_CHAR_2=">0 to 1";
  else if 1<rrf<=3 then URN_CHAR_2=">1 to 3";
  else if rrf>3 then URN_CHAR_2="HIGH";
  else abort;


  if antihyp<0 then HB_CHAR=" ";
  else if antihyp=0 and hneph = 0 then HB_CHAR="0";
  else if antihyp>=1 or hneph = 1 then HB_CHAR="1";

proc freq data = analysis_quarterly_d;
  tables HB_CHAR *antihyp HB_CHAR* hneph *hypertn_q         /list missing;

data table1;
  merge RAND_DAILY
        f104_daily
        f110_daily
        f206_daily
        f208_visit_ct
        f242_daily
        f256_daily
        f271_daily
        f274_daily
        analysis_monthly_d
        analysis_quarterly_d

        ;
  by PID;
  AGE=(VISIT_DT-BIRTH_DT)/365.25;
  length RACE_CHAR GENDER_CHAR KD_FAIL_CHAR URN_CHAR ACCESS_CHAR $50;
  if GENDER=1 then GENDER_CHAR="Male";
  else if GENDER=2 then GENDER_CHAR="Female";
  if RACE=1 then RACE_CHAR="Native";
  else if RACE=2 then RACE_CHAR="Asian";
  else if RACE=3 then RACE_CHAR="Island";
  else if RACE=4 then RACE_CHAR="Black";
  else if RACE=5 then RACE_CHAR="White";
  else if RACE in (6 9) then RACE_CHAR="Other or Mixed";
  else abort;
  BMI=10000*DRY_WT_KG/(HT_CM*HT_CM);
  if KD_FAIL=1 then KD_FAIL_CHAR="Diabetic Neph";
  else if KD_FAIL=2 then KD_FAIL_CHAR="Hypertensive Neph";
  else if KD_FAIL=3 then KD_FAIL_CHAR="Glomerulonephritis";
  else if KD_FAIL=4 then KD_FAIL_CHAR="Polycystic K";
  else KD_FAIL_CHAR="Other";

  if DIAB_WO_DAM=1 or DIAB_W_DAM=1 then DIAB=1;
```

```
  else DIAB=0;

  u_convert=urate*1000/(24*60);

  if u_convert<0 then URN_CHAR=" ";
  else if u_convert=0 then URN_CHAR="Anuria";
  else if 0<u_convert<=1 then URN_CHAR=">0 to 1";
  else if 1<u_convert<=3 then URN_CHAR=">1 to 3";
  else if u_convert>3 then URN_CHAR="HIGH";
  else abort;

  if ACCESS_TYPE=1 then ACCESS_CHAR="FISTULA";
  else if ACCESS_TYPE=2 then ACCESS_CHAR="SYNTHETIC GRAFT";
  else if ACCESS_TYPE=3 then ACCESS_CHAR="CATHETER";

  length RENAL_DUR_CHAR_1 $50;
  RENAL_DUR1=(rand_dt-ESRD_DT)/365.25;
  IF RENAL_DUR1<2 and RENAL_DUR1 ne . then RENAL_DUR_CHAR_1="<2 yr";
  else IF 2<=RENAL_DUR1<=5 then RENAL_DUR_CHAR_1="2-5 yr";
  else IF RENAL_DUR1>2 then RENAL_DUR_CHAR_1=">5 yr";

  if treatment=. then delete;

proc freq data=table1;
  tables treatment /* RENAL_DUR1 rand_dt ESRD_DT *//missing list;
  title3 'Table 1, 2 and 4 N';

*** Table 1 ***;

%meandata1(order=1, invar=age, roundvar=.1, digit=1);
%freqdata1(order=2, invar=GENDER_CHAR, level=("Female"));
%freqdata1(order=3,  invar=RACE_CHAR, level=("Black"));
%freqdata1(order=4,  invar=RACE_CHAR, level=("White"));
%freqdata1(order=5,  invar=RACE_CHAR, level=("Native"));
%freqdata1(order=6,  invar=RACE_CHAR, level=("Asian"));
%freqdata1(order=7,  invar=RACE_CHAR, level=("Island"));
%freqdata1(order=8,  invar=RACE_CHAR, level=("Other or Mixed"));
%meandata1(order=9, invar=BMI, roundvar=.1, digit=1);
%meandata1(order=10, invar=DRY_WT_KG, roundvar=.1, digit=1);
%meandata1(order=11, invar=v_sa, roundvar=.1, digit=1);
%freqdata1(order=12,  invar=KD_FAIL_CHAR, level=("Diabetic Neph"));
%freqdata1(order=13,  invar=KD_FAIL_CHAR, level=("Glomerulonephritis"));
%freqdata1(order=14,  invar=KD_FAIL_CHAR, level=("Hypertensive Neph"));
%freqdata1(order=15,  invar=KD_FAIL_CHAR, level=("Polycystic K"));
%freqdata1(order=16,  invar=KD_FAIL_CHAR, level=("Other"));
%freqdata1(order=17,  invar=RENAL_DUR_CHAR_1, level=("<2 yr"));
%freqdata1(order=18,  invar=RENAL_DUR_CHAR_1, level=("2-5 yr"));
%freqdata1(order=19,  invar=RENAL_DUR_CHAR_1, level=(">5 yr"));
%freqdata1(order=20,  invar=HB_CHAR, level=("1"));
%freqdata1(order=21,  invar=MI, level=("1"));
%freqdata1(order=22,  invar=CHF, level=("1"));
%freqdata1(order=23,  invar=ATRIAL_FIB, level=("1"));
%freqdata1(order=24,  invar=PVD, level=("1"));
%freqdata1(order=25,  invar=AAA_REPAIR, level=("1"));
%freqdata1(order=26,  invar=CVA, level=("1"));
%freqdata1(order=27,  invar=DEMENTIA, level=("1"));
```

```
%freqdata1(order=28,  invar=TUMOR, level=("1"));
%freqdata1(order=29,  invar=DIAB, level=("1"));
%freqdata1(order=30,  invar=HEMIPLEGIA, level=("1"));
%freqdata1(order=31,  invar=CPD, level=("1"));
%freqdata1(order=32,  invar=MOD_LIV_DIS, level=("1"));
%freqdata1(order=33,  invar=URN_CHAR_2, level=("Anuria"));
%freqdata1(order=34,  invar=URN_CHAR_2, level=(">0 to 1"));
%freqdata1(order=35,  invar=URN_CHAR_2, level=(">1 to 3"));
%meandata1(order=36,  invar=pre_dia, roundvar=.1, digit=1);
%meandata1(order=37,  invar=creat, roundvar=.1, digit=1);
%meandata1(order=38,  invar=stdktvUDialKOA_q, roundvar=.01, digit=2);
%meandata1(order=39,  invar=eKtVtatV, roundvar=.01, digit=2);
%freqdata1(order=40,  invar=ACCESS_CHAR, level=("FISTULA"));
%freqdata1(order=41,  invar=ACCESS_CHAR, level=("SYNTHETIC GRAFT"));
%freqdata1(order=42,  invar=ACCESS_CHAR, level=("CATHETER"));

%freqdata1(order=43,  invar=RENAL_DUR2_CHAR, level=("<2 yr"));
%freqdata1(order=44,  invar=RENAL_DUR2_CHAR, level=("2-5 yr"));
%freqdata1(order=45,  invar=RENAL_DUR2_CHAR, level=(">5 yr"));
%freqdata1(order=46,  invar=RENAL_DUR_CHAR, level=("<2 yr"));
%freqdata1(order=47,  invar=RENAL_DUR_CHAR, level=("2-5 yr"));
%freqdata1(order=48,  invar=RENAL_DUR_CHAR, level=(">5 yr"));


data accumtab1;
  set accumfreq1 accummean1 accummedian1;
  if treatment=" " then delete;

proc sort data=accumtab1;
  by treatment orderer;

proc print data=accumtab1 noobs;
  by treatment;
  pageby treatment;
  title3 'Table 1 stats (list)';

*** Table 2 ***;

data accumtab1 accumfreq1 accummean1 accummedian1;
  set _null_;

%meandata1(order=1, invar=SESSION_CT_FINAL, roundvar=.01, digit=2);

data accumtab1;
  set accumfreq1 accummean1 accummedian1;
  if treatment=" " then delete;

proc sort data=accumtab1;
  by treatment orderer;

proc print data=accumtab1 noobs;
  by treatment;
  pageby treatment;
  title3 'Table 2 stats (list)';

*** Table 4 ***;
```

```
data f307_daily;
  set fhn.f307_daily;

data f308_daily;
  set fhn.f308_daily;

data ae_combo(keep=PID FHN_ID MEDDRA_CODE CONDITION DEATH HOSP);
  set f307_daily(in=in_ae) f308_daily(in=in_sae);
  length FHN_ID 8.;
  if in_ae then FHN_ID=FHN_AE_ID;
  else if in_sae then FHN_ID=FHN_SAE_ID+10000;
  else abort;

proc sort data=ae_combo;
  by PID;

proc freq data=ae_combo;
  tables MEDDRA_CODE*CONDITION/missing list;
  title3 'AE file information';

data table1;
  merge table1 ae_combo;
  by PID;
  if treatment=. then delete;

proc freq data=table1;
  tables TREATMENT*PID*DEATH/missing list;
  title3 'Multiple Death records per PID check';
  where DEATH=1;

proc freq data=table1;
  tables TREATMENT*PID*HOSP/missing list;
  title3 'Multiple Hosp records per PID check';
  where HOSP=1;
```