

Dataset Integrity Check for the Evaluating Predictors & Interventions in Sphincter of Oddi Dysfunction (EPISOD) Data File

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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

The Evaluating Predictors & Interventions in Sphincter of Oddi Dysfunction(SOD) study (EPISOD) is a randomized sham-controlled study of biliary and pancreatic sphincterotomy as treatment for patients with pain after cholecystectomy fitting the criteria for sphincter of Oddi dysfunction type III.

3 Archived Datasets

All SAS data files, as provided by the Data Coordinating Center (DCC), are located in the “Data” folder in the data package. For this replication, variables were taken from the datasets listed below.

4 Statistical Methods

Analyses were performed to duplicate results for the data published in JAMA May 28, 2014. To verify the integrity of the datasets, tables from the paper were checked (Table 1-4).

5 Results

Table 1 in the publication [1], Sphincter of Oddi Dysfunction After Cholecystectomy: 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 similar.

Table 2 in the publication [1]: Table C lists the variables that were used in the replication and Table D compares the results calculated from the archived data file to the results published in Table 2. The results are the same.

Table 3 in the publication [1]: Table E lists the variables that were used in the replication and Table F compares the results calculated from the archived data file to the results published in Table 3. The results are similar.

Table 4 in the publication [1]: Table G lists the variables that were used in the replication and Table H compares the results calculated from the archived data file to the results published in Table 4. The results are similar.

6 Conclusions

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

7 References

Peter B. Cotton, MD, FRCP, FRCS; Valerie Durkalski, PhD; Joseph Romagnuolo, MD; Qi Pauls, MS; Evan Fogel, MD; Paul Tarnasky, MD; Giuseppe Aliperti, MD; Martin Freeman, MD; Richard Kozarek, MD; Priya Jamidar, MD; Mel Wilcox, MD; Jose Serrano, MD, PhD; Olga Brawman-Mintzer, MD; Grace Elta, MD; Patrick Mauldin, PhD; Andre Thornhill; Robert Hawes, MD; April Wood-Williams; Kyle Orrell; Douglas Drossman, MD; Patricia Robuck, PhD. Effect of Endoscopic Sphincterotomy for Suspected Sphincter of Oddi Dysfunction on Pain-Related Disability Following Cholecystectomy The EPISOD Randomized Clinical Trial. JAMA. 2014 May 28;311(20):2101-9.

Table A: Variables used to replicate Table 1: Baseline Characteristics of Study Population by Assigned Treatment Group.

Table Variable	Variables Used in Replication from the Dataset
No. of Patients, Treatment Group	Derived.ztreatmentnm
Age, y	Form00. f00q05
Women	Form00. f00q06
Race/ethnicity	Form00. f00q08
Employment	Form21. f21q03
Elevated liver enzymes	Form08 – Q11-14
Gallstones at cholecystectomy	Form39. f39q04
Pain relief after cholecystectomy	Form39. f39q09
Daily abdominal discomfort in past 30 d	Form39. f39q18
Abnormal sphincter manometry	Form17. f17q35, f17q38, f17q41, f17q44
Irritable bowel syndrome	Addition.ibs6m
DSM-IV depressive disorders	Form11. f11q01, f11q02, f11q03, f11q26, f11q04
DSM-IV anxiety disorders	Form11. f11q24, f11q08, f11q09n, f11q10, f11q11, f11q13, f11q14
Physical/sexual abuse	Form19.f19q01, f19q02, f19q03, f19q07, f19q08, f19q09, f19q17, f19q13, f19q06, f19q12, f19q16, f19q21
Narcotics use (in last month)	Addition.narco_prior
Antidepressant/anxiolytic use	Addition.antidep_prior
Time from cholecystectomy to randomization, y	Addition.cholecystectomy_year
Pain; Baseline RAPID score	Form12.f12q22
Days of pain episodes in past 90d	Form12.f12q16

Average pain intensity (0-10) in past 90 d	Form12.f12q19
SF-36 Pain Scale	Form 15, calculated variable SFPAIN2
HADS	
--Anxiety (0-21)	Form14.f14q15
--Depression (0-21)	Form14.f14q16
BDI-II (0-63)	Form13.q22
CSQ-CAT score (0-36)	Form20. f20q01+f20q02+f20q03+f20q04+f20q05+f20q06
SF-36-Physical	Form15, calculated variable AGG_PHYS_T
SF-36-Mental	Form15, calculated variable AGG_MENT_T

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

Table 1 Demographic	Table 1 Values		DSIC Calculated	
	Sphincterotomy	Sham	Sphincterotomy	Sham
N	141	73	141	73
Age, mean (SD)[range], y	38 (11) [19-64]	39 (11) [20-59]	38 (11) [19-64]	39 (11) [20-59]
Women	128 (91)	69 (95)	128 (91)	69 (95)
Race/ethnicity				
--Black	5 (4)	3 (4)	5 (4)	3 (4)
--White	132 (94)	70(96)	132 (94)	70(96)
--Other race/unknown	4 (2)	0 (0)	4 (3)	0 (0)
Employment				
--Full-time	81 (57)	43 (59)	81 (57)	43 (59)
--Part-time	20 (14)	12 (16)	20 (14)	12 (16)
--Homemaker	17 (12)	4 (5)	17 (12)	4 (5)
Elevated liver enzymes	11(8)	8(11)	11(8)	8(11)
Gallstones at cholecystectomy	67 (48)	34 (47)	67 (48)	34 (47)
Pain relief after cholecystectomy	100 (71)	47 (64)	100 (71)	47 (64)
Daily abdominal discomfort in past 30 d	74 (52)	36 (49)	74 (52)	36 (49)
Abnormal sphincter manometry	110 (78)	52 (71)	110 (78)	52 (71)
--Pancreatic only	42 (30)	22 (30)	42 (30)	22 (30)
--Biliary only	16 (11)	9 (12)	16 (11)	9 (12)
--Pancreatic and biliary	52 (37)	21 (29)	52 (37)	21 (29)
Irritable bowel syndrome	45 (32)	28 (38)	45 (32)	28 (38)
DSM-IV depressive disorders	10 (7)	7 (10)	10 (7)	7 (10)
DSM-IV anxiety disorders	9 (6)	10(14)	9 (6)	10(14)
Physical/sexual abuse	38 (27)	13 (18)	38 (27)	13 (18)
Narcotics use (in last month)	40 (28)	16 (22)	40 (28)	16 (22)
Antidepressant/anxiolytic use	55 (39)	29 (40)	55 (39)	29 (40)
Time from cholecystectomy to randomization, mean (SD) [range], y	4 (4.57) [0.27-21.08]	5 (6.67) [0.25-41.67]	4 (4.57) [0.27-21.08]	5 (6.67) [0.25-41.67]
Pain; Baseline RAPID score, mean (SD) [range]	82 (52.76) [11-251]	89 (67.28) [11-270]	82 (52.76) [11-251]	89 (67.28) [11-270]
Days of pain episodes in past 90d, mean (SD)[range]	69 (27.08) [0-90]	69 (26.10) [3-90]	69 (27.08) [0-90]	69 (26.10) [3-90]
Average pain intensity (0-10) in past 90 d, mean (SD) [range]	7 (1.83) [3-10]	7 (1.99) [3-10]	7 (1.83) [3-10]	7 (1.99) [3-10]
SD-36 Pain Scale, mean (SD) [range]	35 (15,58) [0-84]	35 (18.26) [0-100]	35 (15,58) [0-84]	35 (18.26) [0-100]
HADS, mean (SD) [range]				
--Anxiety (0-21)	4 (3.56) [0-16]	5 (3.37) [0-13]	4 (3.56) [0-16]	5 (3.37) [0-13]

Table 1 Demographic	Table 1 Values		DSIC Calculated	
	Sphincterotomy	Sham	Sphincterotomy	Sham
--Depression (0-21)	3 (3.12) [0-16]	4 (3.05) [0-11]	3 (3.12) [0-16]	4 (3.05) [0-11]
BDI-II (0-63), mean (SD) [range]	7.5 (5.32) [0-23]	8 (5.54) [0-26]	7.5 (5.32) [0-23]	8 (5.54) [0-26]
CSQ-CAT score (0-36) mean (SD) [range]	7 (6.30) [0-32]	9 (7.26) [0-28]	7 (6.30) [0-32]	9 (7.26) [0-28]
SF-36, mean (SD) [range]				
--Physical	38 (8.19)[19.43-54-69]	40 (7.22) [20.31-56.58]	38 (8.19)[19.43-54-69]	40 (7.22) [20.31-56.58]
--Mental	49 (9.20) [17.86-66.89]	48 (10.36) [16.37-63.32]	49 (9.20) [17.86-66.89]	48 (10.36) [16.37-63.32]

Table C: Variables used to replicate Table 2: Primary Outcome by Treatment Group and Success Rate for the Secondary Comparison of Biliary vs Dual Sphincterotomy for the Pancreatic Sphincter Hypertension Subgroup.

Characteristic	Variable(s)
No. of Patients, Treatment Group	Derived.ztreatmentnm
Primary Outcome	Derived.success
Secondary Outcome	F37q04

Table D: Comparison of values computed for integrity check of reference article Table 2 values

	Treatment	No. of Patients Table 2	No. of Patients DSIC Calculated	No. (%) Table 2	No. (%) DSIC Calculated
Primary outcome	Sham	73	73	27 (37)	27 (37)
	Sphincterotomy (any)	141	141	32 (23)	32 (23)
Secondary outcome	Pancreatic sphincter hypertension with biliary sphincterotomy	51	51	10 (20)	10 (20)
	Pancreatic sphincter hypertension with pancreatic and biliary sphincterotomy	47	47	14 (30)	14 (30)

Table E: Variables used to replicate Table 3: Secondary Outcomes Month-12 Change From Baseline.

Characteristic	Variable(s)
Sphincterotomy vs Sham	Derived. ztreatmentnm
RAPID score, baseline	Form12. f12q22
RAPID score, 12 month	Form36. f36q01+ f36q04+ f36q07+ f36q10+ f36q13 +f36q16
HADS Anxiety, baseline	Form14. f14q15
HADS Anxiety, 12 month	Form14.f14q15
HADS Depression, baseline	Form14.f14q16
HADS Depression, 12 month	Form14.f14q16
SF-36 Physical, baseline and 12 month	Form15, calculated variable AGG_PHYS_T
SF-36 Mental, baseline and 12 month	Form15, calculated variable AGG_MENT_T

Table F: Comparison of values computed for integrity check of reference article Table 3 values.

	Sphincterotomy			Sham		
	No.	Mean	Median	No.	Mean	Median
RAPID score						
Table 3	131	-45	-40	65	-62	-38
DSIC	131	-44	-40	65	-62	-38
HADS Anxiety						
Table 3	131	-1	-1	68	-1	-1
DSIC	131	-1	-1	68	-1	-1
HADS Depression						
Table 3	131	-1	-1	68	-1	-1
DSIC	131	-1	-1	68	-1	-1
SF-36 Physical						
Table 3	130	7	7	68	8	8
DSIC	130	7	7	68	8	8
SF-36 Mental						
Table 3	130	3	3	68	4	4
DSIC	130	3	3	68	4	4

Table G: Variables used to replicate Table 4: Manometry and Outcomes in Patients Assigned to Sphincterotomy and Sham Group.

Characteristic	Variable(s)
Sphincterotomy vs Sham	Derived. Ztreatmentnm
Manometry Sphincter Pressures	Form17. f17q35, f17q38, f17q41,f17q44
Treatment Success	Derived.sucess

Table H: Comparison of values computed for integrity check of reference article Table 4 values.

	Manometry Sphincter Pressures		Sphincterotomy				Sham	
			Biliary		Biliary and Pancreatic			
	Biliary	Pancreatic	No. of Patients	No. (%) of Treatment Success	No. of Patients	No. (%) of Treatment Success	No. of Patients	No. (%) of Treatment Success
Table 4	Abnormal	Abnormal	25	5 (20)	27	9 (33)	21	8 (38)
DSIC			25	5 (20)	27	9 (33)	21	8 (38)
Table 4	Normal or 0	Abnormal	25	5 (20)	17	4 (23)	22	8 (36)
DSIC			25	5 (20)	17	4 (24)	22	8 (36)
Table 4	Abnormal	Normal	14	3 (21)	2	0	9	1 (11)
DSIC			14	3 (21)	2	0	9	1 (11)
Table 4	Normal or 0	Normal	30	5 (17)	1	1 (100)	21	10 (48)
DSIC			30	5 (17)	1	1 (100)	21	10 (48)

Attachment A: SAS Code

```
***Program:/prj/niddk/ims_analysis/EPISOD/prog_initial_analysis/dsic_puds_table1.sas
***Programmer: Patty Griffin
*** Duplicate the Table 1 in the JAMA_primary.pdf article.
***;

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

libname puds '/prj/niddk/ims_analysis/EPISOD/private_orig_data/PUDS/SAS files';
libname addi '/prj/niddk/ims_analysis/EPISOD/private_orig_data/addition/';

data addition;
  set addi.addition;

proc contents data = addition;
proc freq data = addition;
  tables narco_prior antidep_prior cholecystectomy_year/list missing;

proc sort data = puds.form15 (where=(zVisitNm='Baseline'))
  out=form15 nodupkey;
  by zSubjectID;
run;
data form15;
  set form15;
  F15Q21_org = F15Q21;

DATA form15;
SET form15;
/** RENAME ITEMS TO CONFORM TO SURVEY **/
RENAME
f15q01 = I1
f15q02 = I2
f15q03 = I3
f15q04 = I4
f15q05 = I5
f15q06 = I6
f15q07 = I7
f15q08 = I8
f15q09 = I9
f15q10 = I10
f15q11 = I11
f15q12 = I12
f15q13 = I13
f15q14 = I14
f15q15 = I15
f15q16 = I16
f15q17 = I17
f15q18 = I18
f15q19 = I19
f15q20 = I20
f15q21_org = I21
```

```

f15q22 = I22
f15q23 = I23
f15q24 = I24
f15q25 = I25
f15q26 = I26
f15q27 = I27
f15q28 = I28
f15q29 = I29
f15q30 = I30
f15q31 = I31
f15q32 = I32
f15q33 = I33
f15q34 = I34
f15q35 = I35
f15q36 = I36
;
RUN;
*****;
** CODE OUT-OF-RANGE VALUES TO MISSING;
*****;
DATA form15;
  SET form15;
  ARRAY PT3 I3-I12;
  DO OVER PT3;
  IF PT3 NOT IN (1,2,3) THEN PT3=.;
  END;

  ARRAY PT5 I1 I2 I13-I20 I22 I32-I36;
  DO OVER PT5;
  IF PT5 NOT IN (1,2,3,4,5) THEN PT5=.;
  END;

  ARRAY PT6 I21 I23-I31; /*INCLUDE RESPONSE=3 FOR I23-I31*/
  DO OVER PT6;
  IF PT6 NOT IN (1,2,3,4,5,6) THEN PT6=.;
  END;
RUN;
*****;

*****;
DATA form15; SET form15;
* KEEP AS IS: I3-I19, I24, I25, I28, I29, I31, I32, I33, I35;
*****;
* RAND versions of items;
RAND21=I21;
RAND22=I22;
RAND1=I1;
*****;
** WHEN NECESSARY, REVERSE CODE ITEMS SO A HIGHER SCORE MEANS BETTER HEALTH;
*****;
IF I21=1 THEN RI21=6.0; ELSE /*QUESTION 7*/
IF I21=2 THEN RI21=5.4; ELSE
IF I21=3 THEN RI21=4.2; ELSE
IF I21=4 THEN RI21=3.1; ELSE
IF I21=5 THEN RI21=2.2; ELSE
IF I21=6 THEN RI21=1.0;

```

```

IF I21 ne . THEN DO;
IF I22=1 & I21 =1 THEN RI22=6; ELSE /*QUESTION 8 WHEN QUESTION 7 IS ANSWERED*/
IF I22=1 & I21>=2 THEN RI22=5; ELSE
IF I22=2 & I21>=1 THEN RI22=4; ELSE
IF I22=3 & I21>=1 THEN RI22=3; ELSE
IF I22=4 & I21>=1 THEN RI22=2; ELSE
IF I22=5 & I21>=1 THEN RI22=1;
END;
ELSE IF I21=. THEN DO; /*QUESTION 8 WHEN QUESTION 7 IS MISSING*/
IF I22=1 THEN RI22=6.0 ; ELSE
IF I22=2 THEN RI22=4.75; ELSE
IF I22=3 THEN RI22=3.5 ; ELSE
IF I22=4 THEN RI22=2.25; ELSE
IF I22=5 THEN RI22=1.0 ;
END;

IF I1=1 THEN RI1=5.0; ELSE /*QUESTION 1*/
IF I1=2 THEN RI1=4.4; ELSE
IF I1=3 THEN RI1=3.4; ELSE
IF I1=4 THEN RI1=2.0; ELSE
IF I1=5 THEN RI1=1.0;

ARRAY CAT5 I2 I20 I34 I36 ;
ARRAY RCAT5 RI2 RI20 RI34 RI36;
DO OVER CAT5;
IF CAT5=1 THEN RCAT5=5; ELSE
IF CAT5=2 THEN RCAT5=4; ELSE
IF CAT5=3 THEN RCAT5=3; ELSE
IF CAT5=4 THEN RCAT5=2; ELSE
IF CAT5=5 THEN RCAT5=1;
END;
ARRAY CAT6 I23 I26 I27 I30 ;
ARRAY RCAT6 RI23 RI26 RI27 RI30 ;
DO OVER CAT6;
IF CAT6=1 THEN RCAT6=6; ELSE
IF CAT6=2 THEN RCAT6=5; ELSE
IF CAT6=3 THEN RCAT6=4; ELSE
IF CAT6=4 THEN RCAT6=3; ELSE
IF CAT6=5 THEN RCAT6=2; ELSE
IF CAT6=6 THEN RCAT6=1;
END;

IF RAND21=1 THEN RRAND21=6; ELSE
IF RAND21=2 THEN RRAND21=5; ELSE
IF RAND21=3 THEN RRAND21=4; ELSE
IF RAND21=4 THEN RRAND21=3; ELSE
IF RAND21=5 THEN RRAND21=2; ELSE
IF RAND21=6 THEN RRAND21=1;

IF RAND22=1 THEN RRAND22=5; ELSE
IF RAND22=2 THEN RRAND22=4; ELSE
IF RAND22=3 THEN RRAND22=3; ELSE
IF RAND22=4 THEN RRAND22=2; ELSE
IF RAND22=5 THEN RRAND22=1;

```

```

IF RAND1=1 THEN RRAND1=5; ELSE
IF RAND1=2 THEN RRAND1=4; ELSE
IF RAND1=3 THEN RRAND1=3; ELSE
IF RAND1=4 THEN RRAND1=2; ELSE
IF RAND1=5 THEN RRAND1=1;

*****;
** RE-CODE ITEMS TO 0-100;
*****;
ARRAY FIVEPT RI1 RI2 I13-I16
      I17-I19
      RI20

      I32
      I33 RI34 I35 RI36
      RRAND1 RRAND22;

ARRAY SIXPT RI21 RI22
      RI23 I24 I25 RI26 RI27 I28 I29 RI30 I31
      RRAND21;

ARRAY THREEPT I3-I12;

DO OVER FIVEPT;
FIVEPT=(FIVEPT-1)*25;
END;

DO OVER SIXPT;
SIXPT=(SIXPT-1)*20;
END;

DO OVER THREEPT;
THREEPT=(THREEPT-1)*50;
END;

/** CREATE SCALESFOR MISSING DATA**/
tPHYFUN10=MEAN(I3,I4,I5,I6,I7,I8,I9,I10,I11,I12);
tROLEP4=MEAN(I13,I14,I15,I16);
tSFPAIN2=MEAN(RI21,RI22);/*NEMC*/
tSFGENH5=MEAN(RI1,I33,RI34,I35,RI36);/*NEMC*/
tENFAT4=MEAN(RI23,RI27,I29,I31);
tSOCFUN2=MEAN(RI20,I32);
tROLEE3=MEAN(I17,I18,I19);
tEMOT5=MEAN(I24,I25,RI26,I28,RI30);

tPAIN2=MEAN(RRAND21,RRAND22);/*RAND*/
tGENH5=MEAN(RRAND1,I33,RI34,I35,RI36);/*RAND*/

** APPLY OPTION THAT REQUIRES AT LEAST HALF OF ITEMS IN A SCALE TO BE PRESENT
   IN ORDER THAT THE SCALE BE NON-MISSING;
** NEED AT LEAST HALF (OR HALF + 1 FOR SCALES WITH ODD # OF ITEMS) OF ITEMS PRESENT,
   ELSE SET SCALE TO MISSING;

```



```
/* UNCOMMENT THIS SECTION IF YOU WANT TO USE THE OPTION */
```

```
IF N(OFF I3,I4,I5,I6,I7,I8,I9,I10,I11,I12) <=4 THEN TPHYFUN10=.;  
IF N(OFF I13,I14,I15,I16) <=1 THEN TROLEP4 =.;  
IF N(OFF RI21,RI22) <=0 THEN tSFPAIN2 =.;  
IF N(OFF RI1,I33,RI34,I35,RI36) <=2 THEN tSFGENH5 =.;  
IF N(OFF RI23,RI27,I29,I31) <=1 THEN tENFAT4 =.;  
IF N(OFF RI20,I32) <=0 THEN tSOCFUN2 =.;  
IF N(OFF I17,I18,I19) <=1 THEN tROLEE3 =.;  
IF N(OFF I24,I25,RI26,I28,RI30) <=2 THEN tEMOT5 =.;
```

```
IF N(OFF RRAND21,RRAND22) <=0 THEN PAIN2 =.;  
IF N(OFF RRAND1,I33,RI34,I35,RI36) <=2 THEN tGENH5 =.;
```

```
ARRAY PHY I3 I4 I5 I6 I7 I8 I9 I10 I11 I12;
```

```
DO OVER PHY;  
IF PHY=. AND TPHYFUN10 NE . THEN PHY=TPHYFUN10;  
END;
```

```
ARRAY ROLE4 I13 I14 I15 I16;
```

```
DO OVER ROLE4;  
IF ROLE4=. AND TROLEP4 NE . THEN ROLE4=TROLEP4;  
END;
```

```
ARRAY SFPAIN RI21 RI22;
```

```
DO OVER SFPAIN;  
IF SFPAIN=. AND tSFPAIN2 NE . THEN SFPAIN=tSFPAIN2;  
END;
```

```
ARRAY SFGH RI1 I33 RI34 I35 RI36;
```

```
DO OVER SFGH;  
IF SFGH=. AND tSFGENH5 NE . THEN SFGH=tSFGENH5;  
END;
```

```
ARRAY ENF RI23 RI27 I29 I31;
```

```
DO OVER ENF;  
IF ENF=. AND tENFAT4 NE . THEN ENF=tENFAT4;  
END;
```

```
ARRAY SOC RI20 I32;
```

```
DO OVER SOC;  
IF SOC=. AND tSOCFUN2 NE . THEN SOC=tSOCFUN2;  
END;
```

```
ARRAY ROLE I17 I18 I19;
```

```
DO OVER ROLE;  
IF ROLE=. AND tROLEE3 NE . THEN ROLE=tROLEE3;  
END;
```

```
ARRAY EMOT I24 I25 RI26 I28 RI30;
```

```
DO OVER EMOT;  
IF EMOT=. AND tEMOT5 NE . THEN EMOT=tEMOT5;  
END;
```

```
ARRAY PA2 RRAND21 RRAND22;
```

```
DO OVER PA2;  
IF PA2=. AND PAIN2 NE . THEN PA2=PAIN2;  
END;
```

```
ARRAY GH5 RRAND1 I33 RI34 I35 RI36;
```

```
DO OVER GH5;  
IF GH5=. AND tGENH5 NE . THEN GH5=tGENH5;  
END;
```

```
/*FINAL SCORES*/
```

```

PHYFUN10=MEAN(I3,I4,I5,I6,I7,I8,I9,I10,I11,I12);
ROLEP4=MEAN(I13,I14,I15,I16);
SFPAIN2=MEAN(RI21,RI22);
SFGENH5=MEAN(RI1,I33,RI34,I35,RI36);
ENFAT4=MEAN(RI23,RI27,I29,I31);
SOCFUN2=MEAN(RI20,I32);
ROLEE3=MEAN(I17,I18,I19);
EMOT5=MEAN(I24,I25,RI26,I28,RI30);

PAIN2=MEAN(RRAND21,RRAND22);
GENH5=MEAN(RRAND1,I33,RI34,I35,RI36);

IF N(OF I3,I4,I5,I6,I7,I8,I9,I10,I11,I12) <=4 THEN PHYFUN10=.;
IF N(OF I13,I14,I15,I16) <=1 THEN ROLEP4 =.;
IF N(OF RI21,RI22) <=0 THEN SFPAIN2 =.;
IF N(OF RI1,I33,RI34,I35,RI36) <=2 THEN SFGENH5 =.;
IF N(OF RI23,RI27,I29,I31) <=1 THEN ENFAT4 =.;
IF N(OF RI20,I32) <=0 THEN SOCFUN2 =.;
IF N(OF I17,I18,I19) <=1 THEN ROLEE3 =.;
IF N(OF I24,I25,RI26,I28,RI30) <=2 THEN EMOT5 =.;

IF N(OF RRAND21,RRAND22) <=0 THEN PAIN2 =.;
IF N(OF RRAND1,I33,RI34,I35,RI36) <=2 THEN GENH5 =.;

label phyfun10="Physical functioning scale";
label rolep4="Physical health problems scale";
label sfpain2="SF-36 pain scale";
label sfgenh5="SF-36 general health perceptions scale";
label enfat4="Energy/fatigue scale";
label socfun2="Social functioning scale";
label rolee3="Emotional health problems scale";
label emot5="Emotional well-being scale";

label pain2="Pain scale (RAND)";
label genh5="General health perceptions scale (RAND)";

*****
*** NEMC PHYSICAL AND MENTAL HEALTH COMPOSITE - SF36 *****
*****

*** 1) Transform SF-36 scores (NEMC Scoring) to z-scores; ***** ;
*** 1998 US general population means and SDs are used here ** ;
*** (not age/gender based) ***** ;

PF_Z = (PHYFUN10 - 83.29094) / 23.75883 ;
RP_Z = (ROLEP4 - 82.50964) / 25.52028 ;
BP_Z = (SFPAIN2 - 71.32527) / 23.66224 ;
GH_Z = (SFGENH5 - 70.84570) / 20.97821 ;
EM_Z = (EMOT5 - 74.98685) / 17.75604 ;
RE_Z = (ROLEE3 - 87.39733) / 21.43778 ;
SF_Z = (SOCFUN2 - 84.30250) / 22.91921 ;
EN_Z = (ENFAT4 - 58.31411) / 20.01923 ;

label pf_z="NEMC physical functioning z-score";

```

```

label rp_Z="NEMC role limitation physical Z-score";
label bp_Z="NEMC pain Z-score";
label gh_Z="NEMC general health Z-score";
label em_Z="NEMC emotional well-being Z-score";
label re_Z="NEMC role limitation emotional Z-score";
label sf_Z="NEMC social functioning Z-score";
label en_Z="NEMC energy/fatigue Z-score";

*** 2) Create physical and mental health composite scores: *****;
***   Multiply z-scores by varimax-rotated factor scoring *****;
***   coefficients and sum the products *****;

AGG_PHYS = (PF_Z * 0.42402) + (RP_Z * 0.35119) + (BP_Z * 0.31754) +
            (GH_Z * 0.24954) + (EM_Z * -.22069) + (RE_Z * -.19206) +
            (SF_Z * -.00753) + (EN_Z * 0.02877);

AGG_MENT = (PF_Z * -.22999) + (RP_Z * -.12329) + (BP_Z * -.09731) +
            (GH_Z * -.01571) + (EM_Z * 0.48581) + (RE_Z * 0.43407) +
            (SF_Z * 0.26876) + (EN_Z * 0.23534);

label agg_phys="NEMC physical health - SF36 (raw Z-score)";
label agg_ment="NEMC mental health - SF36 (raw Z-score)";

*** 3) Transform composite and scale scores to T-scores: ***** ;

AGG_PHYS_T = 50 + (AGG_PHYS * 10);
AGG_MENT_T = 50 + (AGG_MENT * 10);

label agg_phys_t="NEMC physical health T-score - SF36(PCS)";
label agg_ment_t="NEMC mental health T-score - SF36(MCS)";
PF_T = 50 + (PF_Z * 10) ;
RP_T = 50 + (RP_Z * 10) ;
BP_T = 50 + (BP_Z * 10) ;
GH_T = 50 + (GH_Z * 10) ;
EM_T = 50 + (EM_Z * 10) ;
RE_T = 50 + (RE_Z * 10) ;
SF_T = 50 + (SF_Z * 10) ;
EN_T = 50 + (EN_Z * 10) ;

label pf_t="NEMC physical functioning T-score";
label rp_t="NEMC role limitation physical T-score";
label bp_t="NEMC pain T-score";
label gh_t="NEMC general health T-score";
label em_t="NEMC emotional well-being T-score";
label re_t="NEMC role limitation emotional T-score";
label sf_t="NEMC social functioning T-score";
label en_t="NEMC energy/fatigue T-score";

RUN;

%include 'borrowed_macro.sas';

%let caser=treatment_group;

```

```

/*****
/** Make dataset with relevant variables that are spread across the form files      **/
/** Import the necessary form datasets and merge                                   **/
*****/
proc sort data = puds.derived out=derived(keep=zSubjectID ztreatmentnm f3 zStudy real_trt) nodupkey;
  by zSubjectID;
run;

proc freq data = derived;
  table ztreatmentnm / list missing;
run;

proc sort data = addition;
  by zSubjectID;

proc sort data = puds.form00 out=form00(keep=zSubjectID zVisitNm f00q05 f00q06 f00q07 f00q08) nodupkey;
  by zSubjectID;
run;

proc sort data = puds.form01 out=form01(keep=zSubjectID zVisitNm f01q08 f01q09 f01q22) nodupkey;
  by zSubjectID;
run;

proc sort data = puds.form08 out=form08(keep=zSubjectID zVisitNm f08q12 f08q13 f08q14 f08q15 f08q16 F08Q11) nodupkey;
  by zSubjectID;
run;

proc sort data = puds.form11 out=form11(keep=zSubjectID zVisitNm f11q01 f11q02 f11q03 f11q04 f11q26 f11q24 f11q08 f11q09 f11q10 f11q11 f11q13 f11q14)
nodupkey;
  by zSubjectID;
run;

proc sort data = puds.form12 (where=(zVisitNm='Baseline'))
  out=form12(keep=zSubjectID zVisitNm f12q16 f12q22 f12q19) nodupkey;
  by zSubjectID;
run;

proc sort data = puds.form13 (where=(zVisitNm='Baseline'))
  out=form13(keep=zSubjectID zVisitNm f13q22) nodupkey;
  by zSubjectID;
run;

proc sort data = puds.form14 (where=(zVisitNm='Baseline'))
  out=form14(keep=zSubjectID zVisitNm f14q15 f14q16) nodupkey;
  by zSubjectID;
run;

proc sort data = puds.form16 (where=(zVisitNm='Baseline'))
  out=form16 nodupkey;
  by zSubjectID;
run;

proc sort data = puds.form17 (where=(zVisitNm='Randomization - Treatment'))
  out=form17(keep=zSubjectID zVisitNm f17q35 f17q38 f17q41 f17q44 ) nodupkey;

```

```

    by zSubjectID;
run;

proc sort data = puds.form18 (where=(zVisitNm='Randomization - Treatment'))
    out=form18(keep=zSubjectID zVisitNm formdate_f18 ) nodupkey ;
    by zSubjectID;
run;

proc sort data = puds.form19 out=form19(keep=zSubjectID zVisitNm f19q01 f19q02 f19q03 f19q07 f19q08 f19q09
    f19q06 f19q12 f19q13 f19q16 f19q17 f19q21) nodupkey;
    by zSubjectID;
run;

proc sort data = puds.form20 (where=(zVisitNm='Baseline'))
    out=form20(keep=zSubjectID zVisitNm f20q01 f20q02 f20q03 f20q04 f20q05 f20q06) nodupkey;
    by zSubjectID;
run;

proc sort data = puds.form21 out=form21(keep=zSubjectID zVisitNm f21q03) nodupkey;
    by zSubjectID;
run;

proc sort data = puds.form39 out=form39(keep=zSubjectID zVisitNm f39q01_d f39q04 f39q09 f39q18 formdate_f39) nodupkey;
    by zSubjectID;
run;

proc freq data = form15;
    table f15q21 / list missing;
run;

proc sort data = puds.form41(where=(zVisitNm='Randomization - Treatment'))
    out=form41(keep=zSubjectID zVisitNm f41q01_d) nodupkey;
    by zSubjectID;
run;

data table1;
    merge derived(in=ind) form00(in=in00) form01(in=in01) form08(in=in08) form11(in=in11) form12(in=in12)
        form13(in=in13) form14(in=in14) form15(in=in15) form17(in=in17) form18(in=in18) form19(in=in19)
        form20(in=in20) form21(in=in21) form39(in=in39) form41(in=in41) form16 addition;
    by zSubjectID;
    if ind;
    if ztreatmentnm = '' then delete;                *not included;
    if ztreatmentnm in ('Biliary','Dual') then treatment_group = 'Sphincterotomy';
    else if ztreatmentnm = 'Sham' then treatment_group = 'Sham';

    /**recode f00q08/RACE for the categories in the table**/
    if f00q08 = 3 then f00q08_RACE = 3;
    else if f00q08 = 5 then f00q08_RACE = 5;
    else f00q08_RACE = 99;                          *other, unknown (all other categories);

    /**recode for elevated liver enzymes **/        **NOT DEFINITION WITH TABLE IN PAPER;
    if (f08q13 > 1 or f08q14 > 1) or f08q12 > 1 or f08q11>1 then LIVER_ENZYMES = 1;
    else LIVER_ENZYMES = 0;

```

```

/*recode for abnormal sphincter manometry*/
if (f17q35 =1 and f17q38 = 1) or (f17q41 = 1 and f17q44 = 1) then ABNORMAL_SPHINC_MANO = 1;
else ABNORMAL_SPHINC_MANO = 0;

if (f17q35 =1 and f17q38 = 1) and (f17q41 = 1 and f17q44 = 1) then ABNORMAL_SPHINC_CAT = 3;
else if (f17q35 =1 and f17q38 = 1) then ABNORMAL_SPHINC_CAT = 1;
else if (f17q41 = 1 and f17q44 = 1) then ABNORMAL_SPHINC_CAT = 2;

/**recode for DSM_IV_DEPRESSIVE disorders**/
DSM_IV_DEPRESSIVE = 0;
if f11q01 ne 0 or f11q02 = 1 or f11q03 = 1 or f11q26 = 1 or f11q04 = 1 then DSM_IV_DEPRESSIVE = 1;

/**recode for DSM_IV_ANXIETY disorders**/
DSM_IV_ANXIETY = 0;
if f11q24 = 1 or f11q08 = 1 or f11q09 = 1 or f11q10 = 1 or f11q11 = 1 or f11q13 = 1 or f11q14 = 1 then DSM_IV_ANXIETY = 1;

/*sexual abuse */
sexual_abuse = 0;
if f19q01 = 1 or f19q02 = 1 or f19q03 = 1 or f19q07 = 1 or f19q08 = 1 or f19q09 = 1 then sexual_abuse = 1;

physical_abuse = 0;
if f19q17 = 1 or f19q13 = 1 or f19q06 > 1 or f19q12 > 1 or f19q16 > 1 or f19q21 > 1 then physical_abuse = 1;

if sexual_abuse or physical_abuse then PHYSICAL_SEXUAL_ABUSE = 1;
else PHYSICAL_SEXUAL_ABUSE = 0;

/**Time from cholecystectomy **/      **STILL NOT RIGHT;
TIME_CHOLECYSTECTOMY = (-1*f39q01_d)/365;      **make years & make positive number;

/**CSQ-CAT score **/
CSQ_CAT = f20q01+f20q02+f20q03+f20q04+f20q05+f20q06;

/**SF-36 Physical score **/      **STILL NOT RIGHT;
SF36_PHYSICAL = sum(of f15q03-f15q16);
SF36_MENTAL = sum(of f15q23-f15q32);

rename f00q05=f00q05_AGE
       f00q06=f00q06_GENDER
       f21q03=f21q03_EMPLOYMENT
       f39q04=f39q04_GALLSTONES_AT
       f39q09=f39q09_PAIN_RELIEF_AFTER
       f39q18=f39q18_AB_DISCOMFORT
       f12q22=f12q22_PAIN_BASE_RAPID
       f12q16=f12q16_DAYS_PAIN
       f12q19=f12q19_PAIN_INTENSITY
       f14q15=f14q15_HADS_ANXIETY
       f14q16=f14q16_HADS_DEPRESSION
       f13q22=f13q22_BDI_II
       ;

if F16Q46>0 then IBS1=1; else IBS1=0;
if F16Q47>0 or F16Q48>0 then IBS2=1; else IBS2=0;

```

```

if F16Q49>0 or F16Q50>0 then IBS3=1; else IBS3=0;

    IBS3a=sum(of IBS1-IBS3);

if F16Q41>2 and F16Q43 ne 1 and IBS3a>1 then IBS=1; else IBS=0;
    ** 'Q43 ne 1' so that women who felt such pain only during menses are excluded from being diagnosed IBS;

if IBS=1 and F16Q45=1 then IBS6m=1; else IBS6m=0;
/*
    label IBS1 = 'IBS1: 1st var to define IBS';
    label IBS2 = 'IBS2: 2nd var to define IBS';
    label IBS3 = 'IBS3: 3rd var to define IBS';
    label IBS3a = 'IBS3a: sum of 3 vars to define IBS: IBS possible if IBS3a ge 2';
    label IBS = 'C1 Irritable bowel syndrome or IBS';
    label IBS6m = 'C1 Irritable bowel syndrome or IBS for at least 6 months';

run;

    format IBS1 yn.;
    format IBS2 yn.;
    format IBS3 yn.;
    format IBS yn.;
    format IBS6m yn.;

*/

data accumfreq1 accummean1 ;
    set _null_;
run;

proc freq data = table1;
    table treatment_group / list missing;
run;

proc sort data = table1;
    by treatment_group;
run;

proc freq data = table1;
    by treatment_group;
    table F16Q41 * F16Q43 * F16Q45* F16Q46* F16Q47 *F16Q48 *F16Q49 * F16Q50
    F16Q41 F16Q43 F16Q45 F16Q46 F16Q47 F16Q48 F16Q49 F16Q50
/ list missing;
run;

%macro datachunk();

%meandatal(order=1, invar=f00q05_AGE, roundvar=1, digit=0);
%freqdatal(order=2, invar=f00q06_GENDER, level=("2"), levelname="Women"); *females;
%freqdatal(order=3, invar=f00q08_RACE, level=(3), levelname="Black"); *black;
%freqdatal(order=4, invar=f00q08_RACE, level=(5), levelname="White"); *white;
%freqdatal(order=5, invar=f00q08_RACE, level=(99), levelname="Other race/Unknown"); *other/unknown;
%freqdatal(order=6, invar=f21q03_EMPLOYMENT, level=(1), levelname="Full-time"); *full-time;
%freqdatal(order=7, invar=f21q03_EMPLOYMENT, level=(2), levelname="Part-time"); *part-time;
%freqdatal(order=8, invar=f21q03_EMPLOYMENT, level=(7), levelname="Homemaker"); *homemaker;
%freqdatal(order=10, invar=f39q04_GALLSTONES_AT, level=(1), levelname="Yes");

```

```

%freqdata1(order=11, invar=f39q09_PAIN_RELIEF_AFTER, level=(1), levelname="Yes");
%freqdata1(order=12, invar=f39q18_AB_DISCOMFORT, level=(1), levelname="Yes");
%freqdata1(order=13, invar=ABNORMAL_SPHINC_MANO, level=(1), levelname="Yes");
%freqdata1(order=14, invar=ABNORMAL_SPHINC_CAT, level=(1), levelname="Pancreatic only");
%freqdata1(order=15, invar=ABNORMAL_SPHINC_CAT, level=(2), levelname="Biliary only");
%freqdata1(order=16, invar=ABNORMAL_SPHINC_CAT, level=(3), levelname="Pancreatic and biliary");
%freqdata1(order=18, invar=DSM_IV_DEPRESSIVE, level=(1), levelname="Yes");
%freqdata1(order=19, invar=DSM_IV_ANXIETY, level=(1), levelname="Yes");
%freqdata1(order=20, invar=PHYSICAL_SEXUAL_ABUSE, level=(1), levelname="Yes");
%meandatal(order=23, invar=TIME_CHOLECYSTECTOMY, roundvar=.01, digit=2);
%meandatal(order=24, invar=f12q22_PAIN_BASE_RAPID, roundvar=.01, digit=2);
%meandatal(order=25, invar=f12q16_DAYS_PAIN, roundvar=.01, digit=2);
%meandatal(order=26, invar=f12q19_PAIN_INTENSITY, roundvar=.01, digit=2);
%meandatal(order=28, invar=f14q15_HADS_ANXIETY, roundvar=.01, digit=2);
%meandatal(order=29, invar=f14q16_HADS_DEPRESSION, roundvar=.01, digit=2);
%meandatal(order=30, invar=f13q22_BDI_II, roundvar=.01, digit=2);
%meandatal(order=31, invar=CSQ_CAT, roundvar=.01, digit=2);
%meandatal(order=32, invar=SF36_PHYSICAL, roundvar=.01, digit=2);
%meandatal(order=33, invar=SF36_MENTAL, roundvar=.01, digit=2);

%freqdata1(order=34, invar=LIVER_ENZYMES, level=(1), levelname="Yes");

%freqdata1(order=35, invar=IBS6m, level=(1), levelname="Yes");
%freqdata1(order=36, invar=narco_prior, level=(1), levelname="Yes");
%freqdata1(order=37, invar=antidep_prior, level=(1), levelname="Yes");
%meandatal(order=38, invar=cholecystectomy_year, roundvar=.01, digit=2);
%meandatal(order=39, invar=SPAIN2, roundvar=.01, digit=2);
%meandatal(order=40, invar=AGG_PHYS_T, roundvar=.01, digit=2);
%meandatal(order=41, invar=AGG_MENT_T, roundvar=.01, digit=2);

%mend datachunk;

%datachunk();

data accumtabl;
  set accumfreq1 accummean1 ;
  if &caser='' then delete;
run;

proc sort data=accumtabl;
  by &caser orderer;

proc print data=accumtabl noobs;
  by &caser;
  pageby &caser;
  var name level levelname charall;
  title3 'Table 1 stats (list)';

/*****
/** Make dataset with relevant variables that are spread across the form files      **/
/** Import the necessary form datasets and merge                                  **/
*****/
proc sort data = puds.derived out=derived nodupkey;
  by zSubjectID;
run;

```



```

/*
data table2;
  set derived(in=ind) ;

  if ztreatmentnm in ('Biliary','Dual') then treatment_group = 'Sphincterotomy';
  else if ztreatmentnm = 'Sham' then treatment_group = 'Sham';
  else if ztreatmentnm = '' then treatment_group='';          *not included;
run;
*/
proc sort data = puds.form37 out=form37 nodupkey;
  by zSubjectID;
run;

data table2;
  merge derived(in=ind) form37(in=in37) ;
  by zSubjectID;
  if ind;
  if ztreatmentnm = '' then delete;          *not included;
  if ztreatmentnm in ('Biliary','Dual') then treatment_group = 'Sphincterotomy';
  else if ztreatmentnm = 'Sham' then treatment_group = 'Sham';

proc sort data = table2;
  by treatment_group;
run;

proc freq data = table2 ;
  table treatment_group*success ztreatmentnm * F37Q04 ztreatmentnm * F37Q04 * success/;
run;

proc freq data = table2(where=(treatment_group='Sphincterotomy'));
  table ztreatmentnm*success ;
run;

***Program:/prj/niddk/ims_analysis/PUDS/prog_initial_analysis/dsic_puds_table3.sas
***Programmer: Patty Griffin
***Date Created: 03/10/15
*** Duplicate the Table 3 in the JAMA_primary.pdf article.
***;

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

libname puds '/prj/niddk/ims_analysis/EPISOD/private_orig_data/PUDS/SAS files';
%include 'borrowed_macro.sas';

%let caser=treatment_group;

***Program:/prj/niddk/ims_analysis/PUDS/prog_initial_analysis/dsic_puds_table3.sas
***Programmer: Patty Griffin
***Date Created: 03/10/15

```

```
*** Duplicate the Table 3 in the JAMA_primary.pdf article.
```

```
***;
```

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

```
title2 " ";
```

```
libname puds '/prj/niddk/ims_analysis/EPISOD/private_orig_data/PUDS/SAS files';
```

```
libname addi '/prj/niddk/ims_analysis/EPISOD/private_orig_data/addition/';
```

```
data addition;
```

```
  set addi.addition;
```

```
proc contents data = addition;
```

```
proc freq data = addition;
```

```
  tables narco_prior antidep_prior cholecystectomy_year/list missing;
```

```
data form15 ;
```

```
  set puds.form15 ;
```

```
data form15;
```

```
  set form15;
```

```
  F15Q21_org = F15Q21;
```

```
DATA form15;
```

```
SET form15;
```

```
/** RENAME ITEMS TO CONFORM TO SURVEY **/
```

```
RENAME
```

```
f15q01 = I1
```

```
f15q02 = I2
```

```
f15q03 = I3
```

```
f15q04 = I4
```

```
f15q05 = I5
```

```
f15q06 = I6
```

```
f15q07 = I7
```

```
f15q08 = I8
```

```
f15q09 = I9
```

```
f15q10 = I10
```

```
f15q11 = I11
```

```
f15q12 = I12
```

```
f15q13 = I13
```

```
f15q14 = I14
```

```
f15q15 = I15
```

```
f15q16 = I16
```

```
f15q17 = I17
```

```
f15q18 = I18
```

```
f15q19 = I19
```

```
f15q20 = I20
```

```
f15q21_org = I21
```

```
f15q22 = I22
```

```
f15q23 = I23
```

```
f15q24 = I24
```

```
f15q25 = I25
```

```
f15q26 = I26
```

```
f15q27 = I27
```

```
f15q28 = I28
```

```

f15q29 = I29
f15q30 = I30
f15q31 = I31
f15q32 = I32
f15q33 = I33
f15q34 = I34
f15q35 = I35
f15q36 = I36
;
RUN;
*****;
** CODE OUT-OF-RANGE VALUES TO MISSING;
*****;
DATA form15;
  SET form15;
  ARRAY PT3 I3-I12;
  DO OVER PT3;
  IF PT3 NOT IN (1,2,3) THEN PT3=.;
END;

ARRAY PT5 I1 I2 I13-I20 I22 I32-I36;
DO OVER PT5;
IF PT5 NOT IN (1,2,3,4,5) THEN PT5=.;
END;

ARRAY PT6 I21 I23-I31; /*INCLUDE RESPONSE=3 FOR I23-I31*/
DO OVER PT6;
IF PT6 NOT IN (1,2,3,4,5,6) THEN PT6=.;
END;
RUN;
*****;
*****;
DATA form15; SET form15;
* KEEP AS IS: I3-I19, I24, I25, I28, I29, I31, I32, I33, I35;
*****;
* RAND versions of items;
RAND21=I21;
RAND22=I22;
RAND1=I1;
*****;
** WHEN NECESSARY, REVERSE CODE ITEMS SO A HIGHER SCORE MEANS BETTER HEALTH;
*****;
IF I21=1 THEN RI21=6.0; ELSE /*QUESTION 7*/
IF I21=2 THEN RI21=5.4; ELSE
IF I21=3 THEN RI21=4.2; ELSE
IF I21=4 THEN RI21=3.1; ELSE
IF I21=5 THEN RI21=2.2; ELSE
IF I21=6 THEN RI21=1.0;

IF I21 ne . THEN DO;
IF I22=1 & I21 =1 THEN RI22=6; ELSE /*QUESTION 8 WHEN QUESTION 7 IS ANSWERED*/
IF I22=1 & I21>=2 THEN RI22=5; ELSE
IF I22=2 & I21>=1 THEN RI22=4; ELSE
IF I22=3 & I21>=1 THEN RI22=3; ELSE
IF I22=4 & I21>=1 THEN RI22=2; ELSE

```

```

IF I22=5 & I21>=1 THEN RI22=1;
END;
ELSE IF I21=. THEN DO; /*QUESTION 8 WHEN QUESTION 7 IS MISSING*/
IF I22=1 THEN RI22=6.0 ; ELSE
IF I22=2 THEN RI22=4.75; ELSE
IF I22=3 THEN RI22=3.5 ; ELSE
IF I22=4 THEN RI22=2.25; ELSE
IF I22=5 THEN RI22=1.0 ;
END;

IF I1=1 THEN RI1=5.0; ELSE /*QUESTION 1*/
IF I1=2 THEN RI1=4.4; ELSE
IF I1=3 THEN RI1=3.4; ELSE
IF I1=4 THEN RI1=2.0; ELSE
IF I1=5 THEN RI1=1.0;

ARRAY CAT5 I2 I20 I34 I36 ;
ARRAY RCAT5 RI2 RI20 RI34 RI36;
DO OVER CAT5;
IF CAT5=1 THEN RCAT5=5; ELSE
IF CAT5=2 THEN RCAT5=4; ELSE
IF CAT5=3 THEN RCAT5=3; ELSE
IF CAT5=4 THEN RCAT5=2; ELSE
IF CAT5=5 THEN RCAT5=1;
END;
ARRAY CAT6 I23 I26 I27 I30 ;
ARRAY RCAT6 RI23 RI26 RI27 RI30 ;
DO OVER CAT6;
IF CAT6=1 THEN RCAT6=6; ELSE
IF CAT6=2 THEN RCAT6=5; ELSE
IF CAT6=3 THEN RCAT6=4; ELSE
IF CAT6=4 THEN RCAT6=3; ELSE
IF CAT6=5 THEN RCAT6=2; ELSE
IF CAT6=6 THEN RCAT6=1;
END;

IF RAND21=1 THEN RRAND21=6; ELSE
IF RAND21=2 THEN RRAND21=5; ELSE
IF RAND21=3 THEN RRAND21=4; ELSE
IF RAND21=4 THEN RRAND21=3; ELSE
IF RAND21=5 THEN RRAND21=2; ELSE
IF RAND21=6 THEN RRAND21=1;

IF RAND22=1 THEN RRAND22=5; ELSE
IF RAND22=2 THEN RRAND22=4; ELSE
IF RAND22=3 THEN RRAND22=3; ELSE
IF RAND22=4 THEN RRAND22=2; ELSE
IF RAND22=5 THEN RRAND22=1;

IF RAND1=1 THEN RRAND1=5; ELSE
IF RAND1=2 THEN RRAND1=4; ELSE
IF RAND1=3 THEN RRAND1=3; ELSE
IF RAND1=4 THEN RRAND1=2; ELSE
IF RAND1=5 THEN RRAND1=1;

```

```
*****;
```

```

** RE-CODE ITEMS TO 0-100;
*****;
ARRAY FIVEPT RI1 RI2 I13-I16
      I17-I19
      RI20

      I32
      I33 RI34 I35 RI36
      RRAND1 RRAND22;

ARRAY SIXPT RI21 RI22
      RI23 I24 I25 RI26 RI27 I28 I29 RI30 I31
      RRAND21;

ARRAY THREEPT I3-I12;

DO OVER FIVEPT;
FIVEPT=(FIVEPT-1)*25;
END;

DO OVER SIXPT;
SIXPT=(SIXPT-1)*20;
END;

DO OVER THREEPT;
THREEPT=(THREEPT-1)*50;
END;

/** CREATE SCALESFOR MISSING DATA**/
tPHYFUN10=MEAN(I3,I4,I5,I6,I7,I8,I9,I10,I11,I12);
tROLEP4=MEAN(I13,I14,I15,I16);
tSFPAI2=MEAN(RI21,RI22);/*NEMC*/
tSFGENH5=MEAN(RI1,I33,RI34,I35,RI36);/*NEMC*/
tENFAT4=MEAN(RI23,RI27,I29,I31);
tSOCFUN2=MEAN(RI20,I32);
tROLEE3=MEAN(I17,I18,I19);
tEMOT5=MEAN(I24,I25,RI26,I28,RI30);

tPAIN2=MEAN(RRAND21,RRAND22);/*RAND*/
tGENH5=MEAN(RRAND1,I33,RI34,I35,RI36);/*RAND*/

** APPLY OPTION THAT REQUIRES AT LEAST HALF OF ITEMS IN A SCALE TO BE PRESENT
   IN ORDER THAT THE SCALE BE NON-MISSING;
** NEED AT LEAST HALF (OR HALF + 1 FOR SCALES WITH ODD # OF ITEMS) OF ITEMS PRESENT,
   ELSE SET SCALE TO MISSING;

/* UNCOMMENT THIS SECTION IF YOU WANT TO USE THE OPTION */

IF N(OF I3,I4,I5,I6,I7,I8,I9,I10,I11,I12) <=4 THEN tPHYFUN10=.;
IF N(OF I13,I14,I15,I16) <=1 THEN tROLEP4 =.;
IF N(OF RI21,RI22) <=0 THEN tSFPAI2 =.;
IF N(OF RI1,I33,RI34,I35,RI36) <=2 THEN tSFGENH5 =.;
IF N(OF RI23,RI27,I29,I31) <=1 THEN tENFAT4 =.;

```

```

IF N(OF RI20,I32)                <=0 THEN tSOCFUN2 =.;
IF N(OF I17,I18,I19)            <=1 THEN tROLEE3 =.;
IF N(OF I24,I25,RI26,I28,RI30)  <=2 THEN tEMOT5 =.;

IF N(OF RRAND21,RRAND22)        <=0 THEN PAIN2 =.;
IF N(OF RRAND1,I33,RI34,I35,RI36) <=2 THEN tGENH5 =.;

ARRAY PHY I3 I4 I5 I6 I7 I8 I9 I10 I11 I12;
DO OVER PHY;
  IF PHY=. AND TPHYFUN10 NE . THEN PHY=TPHYFUN10;
END;
ARRAY ROLE4 I13 I14 I15 I16;
DO OVER ROLE4;
  IF ROLE4=. AND TROLEP4 NE . THEN ROLE4=TROLEP4;
END;
ARRAY SFPAIN RI21 RI22;
DO OVER SFPAIN;
  IF SFPAIN=. AND tSFPAIN2 NE . THEN SFPAIN=tSFPAIN2;
END;
ARRAY SFGH RI1 I33 RI34 I35 RI36;
DO OVER SFGH;
  IF SFGH=. AND tSFGENH5 NE . THEN SFGH=tSFGENH5;
END;
ARRAY ENF RI23 RI27 I29 I31;
DO OVER ENF;
  IF ENF=. AND tENFAT4 NE . THEN ENF=tENFAT4;
END;
ARRAY SOC RI20 I32;
DO OVER SOC;
  IF SOC=. AND tSOCFUN2 NE . THEN SOC=tSOCFUN2;
END;
ARRAY ROLE I17 I18 I19;
DO OVER ROLE;
  IF ROLE=. AND tROLEE3 NE . THEN ROLE=tROLEE3;
END;
ARRAY EMOT I24 I25 RI26 I28 RI30;
DO OVER EMOT;
  IF EMOT=. AND tEMOT5 NE . THEN EMOT=tEMOT5;
END;
ARRAY PA2 RRAND21 RRAND22;
DO OVER PA2;
  IF PA2=. AND PAIN2 NE . THEN PA2=PAIN2;
END;
ARRAY GH5 RRAND1 I33 RI34 I35 RI36;
DO OVER GH5;
  IF GH5=. AND tGENH5 NE . THEN GH5=tGENH5;
END;

/*FINAL SCORES*/
PHYFUN10=MEAN(I3,I4,I5,I6,I7,I8,I9,I10,I11,I12);
ROLEP4=MEAN(I13,I14,I15,I16);
SFPAIN2=MEAN(RI21,RI22);
SFGENH5=MEAN(RI1,I33,RI34,I35,RI36);
ENFAT4=MEAN(RI23,RI27,I29,I31);
SOCFUN2=MEAN(RI20,I32);
ROLEE3=MEAN(I17,I18,I19);

```

```

EMOT5=MEAN(I24,I25,RI26,I28,RI30);

PAIN2=MEAN(RRAND21,RRAND22);
GENH5=MEAN(RRAND1,I33,RI34,I35,RI36);

IF N(OF I3,I4,I5,I6,I7,I8,I9,I10,I11,I12) <=4 THEN PHYFUN10=. ;
IF N(OF I13,I14,I15,I16) <=1 THEN ROLEP4 =. ;
IF N(OF RI21,RI22) <=0 THEN SFPAIN2 =. ;
IF N(OF RI1,I33,RI34,I35,RI36) <=2 THEN SFGENH5 =. ;
IF N(OF RI23,RI27,I29,I31) <=1 THEN ENFAT4 =. ;
IF N(OF RI20,I32) <=0 THEN SOCFUN2 =. ;
IF N(OF I17,I18,I19) <=1 THEN ROLEE3 =. ;
IF N(OF I24,I25,RI26,I28,RI30) <=2 THEN EMOT5 =. ;

IF N(OF RRAND21,RRAND22) <=0 THEN PAIN2 =. ;
IF N(OF RRAND1,I33,RI34,I35,RI36) <=2 THEN GENH5 =. ;

label phyfun10="Physical functioning scale";
label rolep4="Physical health problems scale";
label sfpain2="SF-36 pain scale";
label sfgenh5="SF-36 general health perceptions scale";
label enfat4="Energy/fatigue scale";
label socfun2="Social functioning scale";
label rolee3="Emotional health problems scale";
label emot5="Emotional well-being scale";

label pain2="Pain scale (RAND)";
label genh5="General health perceptions scale (RAND)";

*****;
*** NEMC PHYSICAL AND MENTAL HEALTH COMPOSITE - SF36 *****;
*****;

*** 1) Transform SF-36 scores (NEMC Scoring) to z-scores; ***** ;
*** 1998 US general population means and SDs are used here ** ;
*** (not age/gender based) ***** ;

PF_Z = (PHYFUN10 - 83.29094) / 23.75883 ;
RP_Z = (ROLEP4 - 82.50964) / 25.52028 ;
BP_Z = (SFPAIN2 - 71.32527) / 23.66224 ;
GH_Z = (SFGENH5 - 70.84570) / 20.97821 ;
EM_Z = (EMOT5 - 74.98685) / 17.75604 ;
RE_Z = (ROLEE3 - 87.39733) / 21.43778 ;
SF_Z = (SOCFUN2 - 84.30250) / 22.91921 ;
EN_Z = (ENFAT4 - 58.31411) / 20.01923 ;

label pf_Z="NEMC physical functioning Z-score";
label rp_Z="NEMC role limitation physical Z-score";
label bp_Z="NEMC pain Z-score";
label gh_Z="NEMC general health Z-score";
label em_Z="NEMC emotional well-being Z-score";
label re_Z="NEMC role limitation emotional Z-score";
label sf_Z="NEMC social functioning Z-score";
label en_Z="NEMC energy/fatigue Z-score";

```

```

*** 2) Create physical and mental health composite scores: *****;
***   Multiply z-scores by varimax-rotated factor scoring *****;
***   coefficients and sum the products *****;

```

```

AGG_PHYS = (PF_Z * 0.42402) + (RP_Z * 0.35119) + (BP_Z * 0.31754) +
            (GH_Z * 0.24954) + (EM_Z * -.22069) + (RE_Z * -.19206) +
            (SF_Z * -.00753) + (EN_Z * 0.02877);

```

```

AGG_MENT = (PF_Z * -.22999) + (RP_Z * -.12329) + (BP_Z * -.09731) +
            (GH_Z * -.01571) + (EM_Z * 0.48581) + (RE_Z * 0.43407) +
            (SF_Z * 0.26876) + (EN_Z * 0.23534);

```

```

label agg_phys="NEMC physical health - SF36 (raw Z-score)";
label agg_ment="NEMC mental health - SF36 (raw Z-score)";

```

```

*** 3) Transform composite and scale scores to T-scores: ***** ;

```

```

AGG_PHYS_T = 50 + (AGG_PHYS * 10);
AGG_MENT_T = 50 + (AGG_MENT * 10);

```

```

label agg_phys_t="NEMC physical health T-score - SF36(PCS)";
label agg_ment_t="NEMC mental health T-score - SF36(MCS)";
PF_T = 50 + (PF_Z * 10) ;
RP_T = 50 + (RP_Z * 10) ;
BP_T = 50 + (BP_Z * 10) ;
GH_T = 50 + (GH_Z * 10) ;
EM_T = 50 + (EM_Z * 10) ;
RE_T = 50 + (RE_Z * 10) ;
SF_T = 50 + (SF_Z * 10) ;
EN_T = 50 + (EN_Z * 10) ;

```

```

label pf_t="NEMC physical functioning T-score";
label rp_t="NEMC role limitation physical T-score";
label bp_t="NEMC pain T-score";
label gh_t="NEMC general health T-score";
label em_t="NEMC emotional well-being T-score";
label re_t="NEMC role limitation emotional T-score";
label sf_t="NEMC social functioning T-score";
label en_t="NEMC energy/fatigue T-score";

```

```

RUN;

```

```

%include 'borrowed_macro.sas';

```

```

%let caser=treatment_group;

```

```

/*****/
/** Make dataset with relevant variables that are spread across the form files      **/
/** Import the necessary form datasets and merge                                    **/
/*****/
proc sort data = puds.derived out=derived(keep=zSubjectID ztreatmentnm ) nodupkey;
  by zSubjectID;

```



```

run;

proc sort data = puds.form12 (where=(zVisitNm='Baseline'))
    out=form12(keep=zSubjectID f12q22) nodupkey;
    by zSubjectID;
run;
/*
proc freq data = form12;
    table zVisitNm / list missing;
    title3 'Baseline Form12';
run;
*/

/**HADS**/
proc sort data = puds.form14 (where=(zVisitNm = 'Baseline'))
    out=form14_base(keep=zSubjectID f14q15 f14q16) nodupkey;
    by zSubjectID;
run;

proc sort data = puds.form14 (where=(zVisitNm = '12 Month Follow Up'))
    out=form14_12month(keep=zSubjectID f14q15 f14q16) nodupkey;
    by zSubjectID;
run;

/**RAPID**/
proc sort data = puds.form36(where=(zVisitNm = '12 Month Follow Up'))
    out=form36(keep=zSubjectID f36q01 f36q04 f36q07 f36q10 f36q13 f36q16) nodupkey;
    by zSubjectID;
run;

/**SF-36**/ * ;
proc sort data = form15(where=(zVisitNm='Baseline'))
    out=form15_base (keep=zSubjectID AGG_PHYS_T AGG_MENT_T);
    by zSubjectID;
run;

proc sort data = form15(where=(zVisitNm='12 Month Follow Up'))
    out=form15_12month (keep=zSubjectID AGG_PHYS_T AGG_MENT_T );
    by zSubjectID;
run;

data table3;
    merge derived(in=ind)
          form12(in=in12)
          form14_base(rename=(f14q15=f14q15_base f14q16=f14q16_base))
          form14_12month(rename=(f14q15=f14q15_12m f14q16=f14q16_12m))
          form36(in=in36)
          form15_base
          form15_12month(rename = (AGG_MENT_T = AGG_MENT_T_12 AGG_PHYS_T = AGG_PHYS_T_12));
    ;
    by zSubjectID;
    if ind;
    if ztreatmentnm = '' then delete;          *not included;
    if ztreatmentnm in ('Biliary','Dual') then treatment_group = 'Sphincterotomy';

```

```

else if ztreatmentnm = 'Sham' then treatment_group = 'Sham';

/**RAPID CHANGE **/
RAPID_12month = sum(f36q01, f36q04, f36q07, f36q10, f36q13);

RAPID_CHANGE = RAPID_12month - f12q22;

/**HADS **/
ANXIETY_CHANGE = f14q15_12m - f14q15_base;
DEPRESS_CHANGE = f14q16_12m - f14q16_base;
AGG_MENT_change = AGG_MENT_T_12 - AGG_MENT_T;
AGG_PHYS_T_change = AGG_PHYS_T_12 - AGG_PHYS_T;

run;

proc sort data = table3;
  by treatment_group;
run;
/*
proc freq data = table3;
  by treatment_group;
  table RAPID_12month RAPID_CHANGE / list missing;
run;
*/

proc means data=table3(where=(RAPID_CHANGE ne .)) mean median ;
  var RAPID_CHANGE ;
  class treatment_group;
run;

proc means data=table3(where=(ANXIETY_CHANGE ne .)) mean median ;
  var ANXIETY_CHANGE ;
  class treatment_group;
run;

proc means data=table3(where=(DEPRESS_CHANGE ne .)) mean median ;
  var DEPRESS_CHANGE ;
  class treatment_group;
run;

proc means data=table3(where=(AGG_PHYS_T_change ne .)) mean median ;
  var AGG_PHYS_T_change ;
  class treatment_group;
run;

proc means data=table3(where=(AGG_MENT_change ne .)) mean median ;
  var AGG_MENT_change ;
  class treatment_group;
run;

***Program:/prj/niddk/ims_analysis/PUDS/prog_initial_analysis/dsic_puds_table4.sas
***Programmer: Patty Griffin
***Date Created: 05/01/15
*** Duplicate the Table 4 in the JAMA_primary.pdf article.

```

```

***;

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

libname puds '/prj/niddk/ims_analysis/EPISOD/private_orig_data/PUDS/SAS files';
%include 'borrowed_macro.sas';

%let caser=treatment_group;

/*****
/** Make dataset with relevant variables that are spread across the form files      **/
/** Import the necessary form datasets and merge                                  **/
*****/
proc sort data = puds.derived out=derived(keep=zSubjectID ztreatmentnm success ) nodupkey;
  by zSubjectID;
run;

proc freq data = derived;
  table success;
run;

proc sort data = puds.form17 (where=(zVisitNm='Randomization - Treatment'))
  out=form17(keep=zSubjectID zVisitNm f17q35 f17q38 f17q41 f17q44 ) nodupkey;
  by zSubjectID;
run;

data table4;
  merge derived(in=ind) form17;
  by zSubjectID;
  if ind;
  if ztreatmentnm = '' then delete;           *not included;
  if ztreatmentnm in ('Biliary','Dual') then treatment_group = 'Sphincterotomy';
  else if ztreatmentnm = 'Sham' then treatment_group = 'Sham';

  abnormal_biliary_pressure = 0;
  abnormal_pancreatic_pressure = 0;

  if (f17q35 =1 and f17q38 = 1) then abnormal_pancreatic_pressure = 1;
  if (f17q41 = 1 and f17q44 = 1) then abnormal_biliary_pressure = 1;
run;

proc sort data = table4;
  by treatment_group;
run;

proc freq data = table4;
  by treatment_group;
  table ztreatmentnm*abnormal_biliary_pressure*abnormal_pancreatic_pressure / list missing;
  title3 'Table 4 Number of Patients in each group';
run;

proc freq data = table4;
  by treatment_group;
  table ztreatmentnm*abnormal_biliary_pressure*abnormal_pancreatic_pressure*success ;

```

```
title3 'Table 4 Number of Treatment Success in each group';  
run;
```