

Dataset Integrity Check for the Value of Urodynamic Evaluation (ValUE) Data Files

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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 Value of Urodynamic Evaluation (VALUE) study was an 11-center, randomized, non-inferiority trial. The primary aim of this clinical trial was to determine whether women with symptomatic, uncomplicated SUI who undergo only a basic office evaluation (BOE) prior to SUI surgery (No UDS arm) have non-inferior treatment outcomes compared to women who have BOE and UDS (UDS arm).

Secondary aims were: 1) to determine how often physicians use preoperative UDS results to alter clinical and surgical decision-making, 2) to compare the amount of improvement in incontinence outcomes, and 3) to determine the incremental cost and utility of performing UDS compared with not performing UDS.

3 Archived Datasets

All SAS data files, as provided by the Data Coordinating Center (DCC), are located in the VALUE “datasets” folder in the data package. For this replication, variables were taken from the “table1”, “table 2”, and “table 3”, datasets. These datasets were analysis datasets created by the DCC .

4 Statistical Methods

Analyses were performed to duplicate results for the data published by Nager et al [1] in the New England Journal of Medicine in May 2012.

To verify the integrity of the three datasets, descriptive statistics of baseline characteristics were computed, by treatment group (Table B and Table D).

5 Results

Table 1 in the publication [1], Baseline Demographic and Clinical Characteristics of the Patients with Primary Outcome Data in the Per-Protocol Analysis.* 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 identical to the published results.

Table 2 in the publication [1]: Outcomes.*. 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 of the replication are very similar to the published results.

6 Conclusions

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

7 References

1. Nager CW, Brubaker L, Litman HJ, et al. A randomized trial of urodynamic testing before stress-incontinence surgery. N Engl J Med 2012;366:1987-1997

Table A: Variables used to replicate Table 1: Baseline Demographic and Clinical Characteristics of the Patients with Primary Outcome Data in the Per-Protocol Analysis.

Table Variable	Variables Used in Replication from the Analysis Dataset
Urodynamic Testing/Office Evaluation Only	assignment
Age — yr	AGE
Body-mass index [†]	BMI
Race or ethnic group — no. (%) [‡]	hispanic
Parous — no. (%)	n_pregcat
Duration of incontinence — mo	dur_of_incont
Postmenopausal — no./total no. (%) [§]	Menop
Current estrogen-replacement therapy — no./total no. (%)	Any_hrt
Current smoking — no. (%)	smok
History of nonsurgical treatment for urinary incontinence — no. (%)	nosurgtx
History of pelvic surgery — no. (%) [?]	PEL_SURG
Urethral mobility — no. (%) ^{**}	URETHRAL_MOB
Postvoiding residual urine volume — ml	PVR
Urogenital Distress Inventory score ^{††}	udi_tot
Incontinence Severity Index score ^{‡‡}	isi_scale
Stress incontinence	STRESS_INDEX
Urgency incontinence	urge_index
Incontinence Impact Questionnaire score	iiq_tot
SF-12 score ^{??}	sf12
Score of moderate or severe on the Patient Global Impression of Severity — no./total no. (%) ^{***}	pgi_s_ind
Score of 0 on the Charlson comorbidity index — no. (%)	comorb_score

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

Characteristic	Urodynamic Testing (N = 264) [Manuscript]	Urodynamic Testing (N = 264) [DSIC]	Urodynamic Testing (N = 264) [Diff]	Office Evaluation Only (N = 259) [Manuscript]	Office Evaluation Only (N = 259) [DSIC]	Office Evaluation Only (N = 259) [Diff]
Age — yr	51.9±10.4	51.9 ± 10.4	0	51.6±10.0	51.6 ± 10.0	0
Body-mass index†	29.1±5.7	29.1 ± 5.7	0	28.9±6.1	28.9 ± 6.1	0
Race or ethnic group — no. (%)‡						
Non-Hispanic white	209 (79.2)	209 (79.2)	0	191 (73.7)	191 (73.7)	0
Other	55 (20.8)	55 (20.8)	0	68 (26.3)	68 (26.3)	0
Parous — no. (%)	252 (95.5)	252 (95.5)	0	246 (95.0)	246 (95.0)	0
Duration of incontinence — mo	107.4±100.3	107.4 ± 100.3	0	90.7±79.9	90.7 ± 79.9	0
Postmenopausal — no./total no. (%)§	119/264 (45.1)	119/264 (45.1)	0	120/257 (46.7)	120/257 (46.7)	0
Current estrogen-replacement therapy — no./total no. (%)	44/166 (26.5)	44/166 (26.5)	0	57/152 (37.5)	57/152 (37.5)	0
Current smoking — no. (%)	35 (13.3)	35 (13.3)	0	18 (6.9)	18 (6.9)	0
History of nonsurgical treatment for urinary incontinence — no. (%)	174 (65.9)	174 (65.9)	0	148 (57.1)	148 (57.1)	0
History of pelvic surgery — no. (%)	179 (67.8)	179 (67.8)	0	192 (74.1)	192 (74.1)	0
Urethral mobility — no. (%)**	248 (93.9)	248 (93.9)	0	228 (88.0)	228 (88.0)	0
Postvoiding residual urine volume — ml						
Median	10	10	0	18	18	0
Interquartile range	5–30	5-30	0	5–35	5-35	0
Urogenital Distress Inventory score††	125.8±44.3	125.8 ± 44.3	0	121.6±43.5	121.6 ± 43.5	0
Incontinence Severity Index score‡‡	7.9±2.6	7.9 ± 2.6	0	7.4±2.8	7.4 ± 2.8	0
MESA score§§						
Stress incontinence	73.6±16.3	73.6 ± 16.3	0	71.4±19.0	71.4 ± 19.0	0
Urgency incontinence	31.7±21.0	31.7 ± 21.0	0	32.4±22.3	32.4 ± 22.3	0
Incontinence Impact Questionnaire score	42.1±22.6	42.1 ± 22.6	0	42.2±22.4	42.2 ± 22.4	0

Characteristic	Urodynamic Testing (N = 264) [Manuscript]	Urodynamic Testing (N = 264) [DSIC]	Urodynamic Testing (N = 264) [Diff]	Office Evaluation Only (N = 259) [Manuscript]	Office Evaluation Only (N = 259) [DSIC]	Office Evaluation Only (N = 259) [Diff]
SF-12 score	98.0±14.5	98.0 ± 14.5	0	96.4±13.7	96.4 ± 13.7	0
Score of moderate or severe on the Patient Global Impression of Severity — no./total no. (%)***	225/262 (85.9)	225/262 (85.9)	0	227/259 (87.6)	227/259 (87.6)	0
Score of 0 on the Charlson comorbidity index — no. (%)†††	183 (69.3)	183 (69.3)	0	189 (73.0)	189 (73.0)	0

Table C: Variables used to replicate Table 2: Outcomes.*

Table Variable	Variables Used in Replication from the "Table 2" Dataset
Urodynamic Testing/Office Evaluation Only	assignment
70% reduction in Urogenital Distress Inventory score — no. (%)	PCT_UDI_70IND
“Very much better” or “much better” on Patient Global Impression of Improvement — no./total no. (%)†	PGI_I_12MO
Change in Urogenital Distress Inventory score	UDI_TOT_DIFF
Change in Incontinence Severity Index score‡	ISI_SCALE_DIFF
Change in MESA score Stress incontinence	STRESS_INDEX_DIFF
Change in MESA score Urgency incontinence	URGE_INDEX_DIFF
Change in Incontinence Impact Questionnaire score	IIQ_TOT_DIFF
Change in SF-12 score§	SF12_DIFF
Change in Patient Global Impression of Severity score	PGI_S_DIFF
Score of moderate or severe on the Patient Global Impression of Severity at 12 mo — no./total no. (%)	PGI_S_IND_12MO
Overall patient satisfaction score at 12 mo**	SATIS_12MO
Positive provocative stress test at 12 mo — no./total no. (%)††	STRESSTEST

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

Characteristic	Urodynamic Testing (N = 272) [Manuscript]	Urodynamic Testing (N = 272) [DSIC]	Urodynamic Testing (N = 272) [Diff]	Office Evaluation Only (N = 266) [Manuscript]	Office Evaluation Only (N = 266) [DSIC]	Office Evaluation Only (N = 266) [Diff]
70% reduction in Urogenital Distress Inventory score — no. (%)	210 (77.2)	210 (77.2)	0	210 (78.9)	210 (78.9)	0
“Very much better” or “much better” on Patient Global Impression of Improvement — no./total no. (%)†	248/270 (91.9)	248/270 (91.9)	0	238/262 (90.8)	238/262 (90.8)	0
Change in Urogenital Distress Inventory score	-100.2±50.1	-100.2 ± 50.1	0	-98.4±51.4	-98.4 ± 51.4	0
Change in Incontinence Severity Index score‡	-6.0±3.3	-6.0 ± 3.3	0	-5.7±3.4	-5.7 ± 3.4	0
Change in MESA score Stress incontinence	-61.5±22.0	-61.5 ± 22.0	0	-60.2±24.7	-60.2 ± 24.7	0
Change in MESA score Urgency incontinence	-19.7±21.4	-19.7 ± 21.4	0	-22.2±22.4	-22.2 ± 22.4	0
Change in Incontinence Impact Questionnaire score	-35.9±23.2	-35.9 ± 23.2	0	-37.3±23.7	-37.3 ± 23.7	0
Change in SF-12 score§	5.0±10.8	5.0 ± 10.8	0	7.3±12.0	7.3 ± 12.0	0
Change in Patient Global Impression of Severity score	-1.8±0.9	-1.8 ± 0.9	0	-1.8±0.9	-1.8 ± 0.9	0
Score of moderate or severe on the Patient Global Impression of Severity at 12 mo — no./total no. (%)	19/271 (7.0)	19/271 (7.0)	0	15/266 (5.6)	15/266 (5.6)	0
Overall patient satisfaction score at 12 mo**	79.5±30.4	79.5 ± 30.4	0	82.2±28.6	82.2 ± 28.6	0
Positive provocative stress test at 12 mo — no./total no. (%)††	36/225 (16.0)	36/224 (16.1)	0/1 (0.1)	26/222 (11.7)	26/222 (11.7)	0

```

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

options nofmterr source2 mprint symbolgen spool;
libname sas_data "/prj/niddk/ims_analysis/Value/private_orig_data/Value NIDDK Repository/datasets/";

proc format;
  value yesnof
    1="Yes"
    2="No"
  ;
  value casef
    1="UDS"
    2="No UDS"
  ;

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

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

%if &totalvl.=null %then %do;
  proc freq data=table1 noprint;
    tables &invar*assignment/out=data1 outpct;
    format _all_;
  run;

  data data1(keep=LEVEL ASSIGNMENT name CHARALL ORDERER);
    set data1(rename=(&invar=LEVEL));
    length name $100 CHARALL $100;
    name=upcase("&invar");
    PCT_DISP=round(PCT_COL,.1);
    CHARALL=compress(put(COUNT,8.))||" ("||compress(put(PCT_DISP,8.1))||")";
    ORDERER=&order;
    if level in &level then output;
%end;
%else %do;
  proc freq data=table1 noprint;
    tables &invar*assignment/out=data1 outpct;
    format _all_;
    where &popvar. in &totalvl.;
  run;

  data data1(keep=LEVEL ASSIGNMENT name COUNT PCT_DISP ORDERER) total1(keep=accumer1 accumer2);
    set data1(rename=(&invar=LEVEL)) end=end1;
    length name $100;
    retain accumer1 accumer2;
    if _n_=1 then do;
      accumer1=0;
      accumer2=0;
    end;
    if assignment=1 then accumer1=accumer1+count;
    else if assignment=2 then accumer2=accumer2+count;
    name=upcase("&invar");
    PCT_DISP=round(PCT_COL,.1);

```

```

ORDERER=&order;
if level in &level then output datal;
if endl then output total1;

data total1(drop=accumer:);
  set total1;
  length assignment total 8.;
  assignment=1;
  total=accumer1;
  output;
  assignment=2;
  total=accumer2;
  output;

data datal(drop=COUNT PCT_DISP total);
merge datal total1;
by assignment;
length CHARALL $100;
CHARALL=compress(put(COUNT,8.))||"/"||compress(put(total,8.))||" ("||compress(put(PCT_DISP,8.1))||")";

%end;
data accumfreq1;
  set accumfreq1 datal;

%mend freqdatal;

%macro meandatal(order=, invar=, roundvar=, digit=);
proc means data=table1 mean stddev noprint;
  var &invar;
  class ASSIGNMENT;
  output out=datal mean=mean stddev=stddev;
run;

data datal(drop=_TYPE_ _FREQ_ mean stddev);
  set datal;
  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 datal;

%mend meandatal;

%macro mediandatal(order=, invar=, roundvar=, digit=);
proc means data=table1 median p25 p75 noprint;
  var &invar;
  class ASSIGNMENT;
  output out=datal median=median p25=p25 p75=p75;
run;

data datal(drop=_TYPE_ _FREQ_ median p25 p75);

```

```

set data1;
length name CHARALL $100;
name=upcase("&invar");
median=round(median,&roundvar);
p25=round(p25,&roundvar);
p75=round(p75,&roundvar);
ORDERER=&order;
CHARALL=compress(put(median,8.));
output;
ORDERER=ORDERER+1;
CHARALL=compress(put(p25,8.)||"-"||put(p75,8.));
output;

data accummedian1;
  set accummedian1 data1;

%mend mediandata1;

%macro freqdata2(order=, invar=, level=, popvar=, totalvl=);

%if &totalvl.=null %then %do;
  proc freq data=table2 noprint;
    tables &invar*assignment/out=data2 outpct;
    format _all_;
  run;

  data data2(keep=LEVEL ASSIGNMENT name CHARALL ORDERER);
    set data2(rename=(&invar=LEVEL));
    length name $100 CHARALL $100;
    name=upcase("&invar");
    PCT_DISP=round(PCT_COL,.1);
    CHARALL=compress(put(COUNT,8.)||" ("||compress(put(PCT_DISP,8.1))||")");
    ORDERER=&order;
    if level in &level then output;
  %end;
%else %do;
  proc freq data=table2 noprint;
    tables &invar*assignment/out=data2 outpct;
    format _all_;
    where &popvar. in &totalvl.;
  run;

  data data2(keep=LEVEL ASSIGNMENT name COUNT PCT_DISP ORDERER) total2(keep=accumer1 accumer2);
    set data2(rename=(&invar=LEVEL)) end=end1;
    length name $100;
    retain accumer1 accumer2;
    if _n_=1 then do;
      accumer1=0;
      accumer2=0;
    end;
    if assignment=1 then accumer1=accumer1+count;
    else if assignment=2 then accumer2=accumer2+count;
    name=upcase("&invar");
    PCT_DISP=round(PCT_COL,.1);
    ORDERER=&order;
    if level in &level then output data2;

```

```

    if endl then output total2;

data total2(drop=accumer:);
  set total2;
  length assignment total 8.;
  assignment=1;
  total=accumer1;
  output;
  assignment=2;
  total=accumer2;
  output;

data data2(drop=COUNT PCT_DISP total);
  merge data2 total2;
  by assignment;
  length CHARALL $100;
  CHARALL=compress (put (COUNT,8.)) || "/" || compress (put (total,8.)) || " (" || compress (put (PCT_DISP,8.1)) || ")";

%end;
data accumfreq2;
  set accumfreq2 data2;

%mend freqdata2;

%macro meandata2(order=, invar=, roundvar=, digit=);
proc means data=table2 mean stddev noprint;
  var &invar;
  class ASSIGNMENT;
  output out=data2 mean=mean stddev=stddev;
run;

data data2(drop=_TYPE_ _FREQ_ mean stddev);
  set data2;
  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 accummean2;
  set accummean2 data2;

%mend meandata2;

%macro mediandata2(order=, invar=, roundvar=, digit=);
proc means data=table2 median p25 p75 noprint;
  var &invar;
  class ASSIGNMENT;
  output out=data2 median=median p25=p25 p75=p75;
run;

data data2(drop=_TYPE_ _FREQ_ median p25 p75);
  set data2;
  length name CHARALL $100;

```

```

name=upcase("&invar");
median=round(median,&roundvar);
p25=round(p25,&roundvar);
p75=round(p75,&roundvar);
ORDERER=&order;
CHARALL=compress(put(median,8.));
output;
ORDERER=ORDERER+1;
CHARALL=compress(put(p25,8.)||"-"||put(p75,8.));
output;

data accummedian2;
  set accummedian2 data2;

%mend mediandata2;

data accumfreq1 accummean1 accummedian1
  accumfreq2 accummean2 accummedian2;
  set _null_;

data table1;
  set SAS_DATA.analysis ;
  if hispanic=2 then NHW=1; *** Non Hispanic White ***;
  else if hispanic>.z then NHW=0; *** Other (NOT a Non Hispanic White) ***;
  else abort;
  if n_pregcat=0 then parity=0; *** Nulliparous ***;
  else if n_pregcat>0 then parity=1; *** Parous ***;
  else abort;

data table1 table2;
  set table1;
  if primary_outcome=. then delete;
  else output table2;
  if pp ne 1 then delete;
  else output table1;

%meandatal(order=1, invar=age , roundvar=.1, digit=1);
%meandatal(order=2, invar=bmi , roundvar=.1, digit=1);
%freqdatal(order=3, invar=NHW , level=(1),popvar=, totalvl=null);
%freqdatal(order=4, invar=NHW , level=(0),popvar=, totalvl=null);
%freqdatal(order=5, invar=parity , level=(1),popvar=, totalvl=null);
%meandatal(order=6, invar=dur_of_incont, roundvar=.1, digit=1);
%freqdatal(order=7, invar=MENOP , level=(2),popvar=MENOP, totalvl=(1 2 3));
%freqdatal(order=8, invar=any_hrt , level=(1),popvar=MENOP, totalvl=(2 3));
%freqdatal(order=9, invar=smok , level=(1),popvar=, totalvl=null);
%freqdatal(order=10, invar=nosurgtx , level=(1),popvar=, totalvl=null);
%freqdatal(order=11, invar=PEL_SURG , level=(1),popvar=, totalvl=null);
%freqdatal(order=12, invar=URETHRAL_MOB, level=(1),popvar=, totalvl=null);
%mediandatal(order=14, invar=PVR, roundvar=1, digit=0);
%meandatal(order=16, invar=udi_tot, roundvar=.1, digit=1);
%meandatal(order=17, invar=isi_scale, roundvar=.1, digit=1);
%meandatal(order=18, invar=STRESS_INDEX, roundvar=.1, digit=1);
%meandatal(order=19, invar=urge_index, roundvar=.1, digit=1);
%meandatal(order=20, invar=iiq_tot, roundvar=.1, digit=1);
%meandatal(order=21, invar=sf12, roundvar=.1, digit=1);

```

```

%freqdata1(order=23, invar=pgi_s_ind , level=(1),popvar=pgi_s, totalvl=(1 2 3 4));
%freqdata1(order=24, invar=comorb_score, level=(1),popvar=, totalvl=null);

data accumtab1;
  set accumfreq1 accummean1 accummedian1;
  if assignment=. then delete;

proc sort data=accumtab1;
  by assignment orderer;

proc print data=accumtab1 noobs;
  by assignment;
  format assignment casef.;
  title3 'Table 1 stats (list)';

%freqdata2(order=1, invar=pct_udi_70ind, level=(1),popvar=, totalvl=null);
%freqdata2(order=2, invar=pgi_i_12mo, level=(1),popvar=pgi_i_12mo, totalvl=(0 1));
%meandata2(order=3, invar=udi_tot_diff, roundvar=.1, digit=1);
%meandata2(order=4, invar=isi_scale_diff, roundvar=.1, digit=1);
%meandata2(order=5, invar=stress_index_diff, roundvar=.1, digit=1);
%meandata2(order=6, invar=urge_index_diff, roundvar=.1, digit=1);
%meandata2(order=7, invar=iiq_tot_diff, roundvar=.1, digit=1);
%meandata2(order=8, invar=sf12_diff , roundvar=.1, digit=1);
%meandata2(order=9, invar=pgi_s_diff , roundvar=.1, digit=1);
%freqdata2(order=10, invar=pgi_s_ind_12mo, level=(1),popvar=pgi_s_ind_12mo, totalvl=(0 1));
%meandata2(order=11, invar=satis_12mo , roundvar=.1, digit=1);
%freqdata2(order=12, invar=stresstest, level=(1),popvar=stresstest, totalvl=(1 2));

data accumtab2;
  set accumfreq2 accummean2 accummedian2;
  if assignment=. then delete;

proc sort data=accumtab2;
  by assignment orderer;

proc print data=accumtab2 noobs;
  by assignment;
  format assignment casef.;
  title3 'Table 2 stats (list)';

```