

Dataset Integrity Check for
Baseline Lower Urinary Tract Symptoms
in Patients Enrolled in Lurn: A
Prospective, Observational Cohort Study
(Cameron)

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Contents

1 Standard Disclaimer	2
2 Study Background	2
3 Archived Datasets	2
4 Statistical Methods	3
5 Results	3
6 Conclusions	3
7 References	3
Table A: Variables used to replicate Table 1: Demographics and Medical History of LURN Participants by Gender	4
Table B: Comparison of values computed in integrity check to reference article Table 1 values.....	5
Attachment A: SAS Code.....	9

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

Lower urinary tract dysfunction (LUTD) is common in both men and women, and the incidence and prevalence increases as people age. The effects of LUTD on individuals and the nation are enormous. People with LUTD face a number of social, mental and physical health effects as a result of their symptoms, and treatments for LUTD are not very effective, have significant side-effects, and are costly. The financial burden of this disorder is expected to increase dramatically as the population ages.

In an effort to better understand the nature of the symptoms that characterize LUTD, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has established the Symptoms of Lower Urinary Tract Dysfunction Research Network (*LURN*). The *LURN* is comprised of an interdisciplinary team of researchers, study coordinators, and medical facilities at six US clinical sites and a data coordinating center (DCC). These sites are working together to improve the lives of people with LUTD.

The long term goals of *LURN* are to increase our understanding of lower urinary tract symptoms (LUTS) by (1) identifying and explaining the important subtypes of patients with LUTS, (2) improving the measurement of patient experiences of LUTS by developing new patient questionnaires, and (3) disseminating data, research tools, and biological samples to research and clinical communities. Through these activities, investigators hope that their efforts will inform strategies to prevent and manage LUTS and improve patients' lives.

3 Archived Datasets

All the SAS data files, as provided by the Data Coordinating Center (DCC), are located in the *LURN* folder in the "LURN_Data_Repository_Submission" data package. For this replication, variables were taken from the "descriptive.sas7bdat" dataset (Located in Publications/AnalysisFiles).

4 Statistical Methods

Analyses were performed to duplicate results for the data published by Anne Cameron et al [1] in The Journal of Urology April 2018. To verify the integrity of the dataset, descriptive statistics were computed.

5 Results

For Table 1 in the publication [1], **Demographics and Medical History of LURN Participants by Gender**, Table A lists the variables that were used in the replication and Table B compares the results calculated from the archived data files to the results published in Table 1. The results of the replication are an exact match to the published results.

6 Conclusions

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

7 References

[1] Anne P. Cameron,^{*},[†] Christina Lewicky-Gaupp, Abigail R. Smith, Brian T. Helfand, John L. Gore, J. Quentin Clemens,[‡] Claire C. Yang, Nazema Y. Siddiqui, H. Henry Lai, James W. Griffith, Victor P. Andreev, Gang Liu, Kevin Weinfurt, Cindy L. Amundsen, Catherine S. Bradley, John W. Kusek, Ziya Kirkali and the Symptoms of Lower Urinary Tract Dysfunction Research Network Study Group. The Journal of Urology Vol. 199, 1023-1031, April 2018

Table A: Variables used to replicate Table 1: Demographics and Medical History of LURN Participants by Gender

Table Variable	dataset.variable
Gender	descriptive.gender
Age	descriptive.age
Race	descriptive.race_num
Ethnicity	descriptive.ethnicity
BMI	descriptive.bodymassindex
Current/Former smoker	descriptive.smoker
Diabetes	descriptive.diabetes1
Vaginal Births	descriptive.partvagbirth
Post menopause	descriptive.postmenopause
Post menopausal hormone use	descriptive.pmhormones
Anticholinergic medication use	descriptive.anticholtx
Anti-constipation medication use	descriptive.constipationtx
Alpha blocker medication use	descriptive.alphablockertx
5alpha-reductase medication use	descriptive.fivearitx
Urgency urinary incontinence surgery	descriptive.urgeincontsurg
SUI/prolapse surgery	descriptive.prolapsesuisurg
Hysterectomy	descriptive.parthysterectomy
Prostate surgery	descriptive.prostatesurg
Urethral dilation surgery	descriptive.urdialsurg
Other surgery	descriptive.othersurg
Functional comorbidity index	descriptive.fci_total
Prolapse stage	descriptive.popqfindings
Prostate findings	descriptive.prostatefind
Nitrate pos	descriptive.nitrites
Red blood cells	descriptive.redbloodcells
White blood cells	descriptive.whitebloodcells
Glucose	descriptive.glucose
Urine specific gravity	descriptive.urinespgrav
pH	descriptive.ph
Post-void residual volume	descriptive.postvoidvol
AUA SI	descriptive.aua_si
AUA quality of life	descriptive.feelaboutcond

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

Variable	LURN Manuscript Males (n=519)	LURN Manuscript Females (n=545)	LURN DSIC Males (n=519)	LURN DSIC Females (n=545)	Diff. Males (n=0)	Diff. Females (n=0)
Age (mean & STD)	61.2 ± 13.3	56.4 ± 14.5	61.2 ± 13.3	56.4 ± 14.5	0 ± 0.0	0 ± 0.0
Race						
- American Indian/Alaskan Native	3 (1)	5 (1)	3 (1)	5 (1)	0 (0)	0 (0)
- Asian	20 (4)	14 (3)	20 (4)	14 (3)	0 (0)	0 (0)
- African American	53 (11)	65 (12)	53 (11)	65 (12)	0 (0)	0 (0)
- Native Hawaiian/Pacific Islander	0	1 (0)	0	1 (0)	0 (0)	0 (0)
- Caucasian	418 (84)	448 (83)	418 (84)	448 (83)	0 (0)	0 (0)
- Multiracial/Other	6 (1)	5 (1)	6 (1)	5 (1)	0 (0)	0 (0)
Ethnicity						
- Hispanic	22 (4)	21 (4)	22 (4)	21 (4)	0 (0)	0 (0)
BMI						
- Median (IQR)	28.6 (25.6-32.6)	29.3 (24.7-34.7)	28.6 (25.6-32.6)	29.3 (24.7-34.7)	0 (0-0)	0 (0-0)
- Underweight (<18.5)	4 (1)	12 (2)	4 (1)	12 (2)	0 (0)	0 (0)
- Normal (18.5-24.9)	105 (20)	144 (26)	105 (20)	144 (26)	0 (0)	0 (0)
- Overweight (25-29.9)	204 (39)	142 (26)	204 (39)	142 (26)	0 (0)	0 (0)
- Obese (30+)	206 (40)	247 (45)	206 (40)	247 (45)	0 (0)	0 (0)
Number of current/former smokers (%)	238 (46)	188 (35)	238 (46)	188 (35)	0 (0)	0 (0)
Number diabetes type I or II (%)	96 (19)	78 (14)	96 (19)	78 (14)	0 (0)	0 (0)
Median Number of Vaginal Births (IQR)	--	2.0 (0.0-3.0)	--	2.0 (0.0-3.0)	0 (0-0)	0 (0-0)
Post-menopause (%)	--	347 (65)	--	347 (65)	0 (0)	0 (0)
Post-menopausal hormone use (%)	--	62 (18)	--	62 (18)	0 (0)	0 (0)
Medication (%)						
- Anticholinergic	18 (3)	11 (2)	18 (3)	11 (2)	0 (0)	0 (0)
- Anti-constipation	43 (8)	34 (6)	43 (8)	34 (6)	0 (0)	0 (0)
- Alpha Blocker	202 (39)	9 (2)	202 (39)	9 (2)	0 (0)	0 (0)
- 5Alpha-reductase	78 (15)	--	78 (15)	--	0 (0)	0 (0)

Variable	LURN Manuscript Males (n=519)	LURN Manuscript Females (n=545)	LURN DSIC Males (n=519)	LURN DSIC Females (n=545)	Diff. Males (n=0)	Diff. Females (n=0)
Previous Surgery (%)						
- Urgency Urinary Incontinence	1 (0)	6 (1)	1 (0)	6 (1)	0 (0)	0 (0)
- SUI/prolapse	--	67 (12)	--	67 (12)	0 (0)	0 (0)
- Hysterectomy	--	164 (30)	--	164 (30)	0 (0)	0 (0)
- Prostate	23 (4)	--	23 (4)	--	0 (0)	0 (0)
- Urethral dilation	5 (1)	4 (1)	5 (1)	4 (1)	0 (0)	0 (0)
- Other	0	2 (0)	0	2 (0)	0 (0)	0 (0)
Median Functional Comorbidity Index (IQR)	2.0 (1.0-3.0)	2.0 (1.0-4.0)	2.0 (1.0-3.0)	2.0 (1.0-4.0)	0 (0-0)	0 (0-0)
Prolapse Stage (%)						
- 0	--	143 (31)	--	143 (31)	0 (0)	0 (0)
- 1	--	147 (32)	--	147 (32)	0 (0)	0 (0)
- 2	--	139 (30)	--	139 (30)	0 (0)	0 (0)
- 3	--	28 (6)	--	28 (6)	0 (0)	0 (0)
- 4	--	1 (0)	--	1 (0)	0 (0)	0 (0)
Prostate Findings (%)						
- Nodule or anomaly	8 (2)	--	8 (2)	--	0 (0)	0 (0)
- Normal or enlarged prostate	442 (98)	--	442 (98)	--	0 (0)	0 (0)
- Nitrate pos (%)	4 (1)	10 (2)	4 (1)	10 (2)	0 (0)	0 (0)
- Red blood cell pos (%)	19 (5)	34 (10)	19 (5)	34 (10)	0 (0)	0 (0)
- White blood cell pos (%)	17 (4)	54 (11)	17 (4)	54 (11)	0 (0)	0 (0)
- Glucose pos (%)	30 (7)	16 (3)	30 (7)	16 (3)	0 (0)	0 (0)
- Median urine specific gravity (IQR)	1.0 (1.0-1.0)	1.0 (1.0-1.0)	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0 (0-0)	0 (0-0)
- Median pH (IQR)	6.0 (5.0-6.5)	6.0 (5.0-7.0)	6.0 (5.0-6.5)	6.0 (5.0-7.0)	0 (0-0)	0 (0-0)
Median ml post-void residual volume (IQR)	27.0 (0.0-78.5)	25.0 (10.0-60.0)	27.0 (0.0-78.5)	25.0 (10.0-60.0)	0 (0-0)	0 (0-0)
Median AUA SI (IQR)	13.0 (8.0-18.5)	12.0 (8.0-16.0)	13.0 (8.0-18.5)	12.0 (8.0-16.0)	0 (0-0)	0 (0-0)
Median AUA quality of life (IQR)	4.0 (3.0-5.0)	5.0 (4.0-5.0)	4.0 (3.0-5.0)	5.0 (4.0-5.0)	0 (0-0)	0 (0-0)

Variable	LURN Manuscript Overall (n=1,064)	LURN DSIC Overall (n=1064)	Diff. Overall (n=0)	LURN Manuscript p-value (Chi-square/Wilcoxon)	LURN DSIC p-value (Chi-square/Wilcoxon)	Diff. p-value (n=0)
Age (mean & STD)	58.8 ± 14.1	58.8 ± 14.1	0 ± 0.0	<0.001	<0.001	0
Race				0.620	0.620	0
- American Indian/Alaskan Native	8 (1)	8 (1)	0 (0)			
- Asian	34 (3)	34 (3)	0 (0)			
- African American	118 (11)	118 (11)	0 (0)			
- Native Hawaiian/Pacific Islander	1 (0)	1 (0)	0 (0)			
- Caucasian	866 (83)	866 (83)	0 (0)			
- Multiracial/Other	11 (1)	11 (1)	0 (0)			
Ethnicity				0.907	0.907	0
- Hispanic	43 (4)	43 (4)	0 (0)			
BMI				0.448	0.448	0
- Median (IQR)	28.9 (25.1-33.4)	28.9 (25.1-33.4)	0 (0-0)			
- Underweight (<18.5)	16 (2)	16 (2)	0 (0)	<0.001	<0.001	0
- Normal (18.5-24.9)	249 (23)	249 (23)	0 (0)			
- Overweight (25-29.9)	346 (33)	346 (33)	0 (0)			
- Obese (30+)	453 (43)	453 (43)	0 (0)			
Number of current/former smokers (%)	426 (40)	426 (40)	0 (0)	<0.001	<0.001	0
Number diabetes type I or II (%)	174 (16)	174 (16)	0 (0)	0.073	0.073	0
Median Number of Vaginal Births (IQR)	--	--	0 (0-0)	--	--	--
Post-menopause (%)	--	--	0 (0)	--	--	--
Post-menopausal hormone use (%)	--	--	0 (0)	--	--	--
Medication (%)				0.147	0.147	0
- Anticholinergic	29 (3)	29 (3)	0 (0)			
- Anti-constipation	77 (7)	77 (7)	0 (0)	0.198	0.198	0
- Alpha Blocker	211 (20)	211 (20)	0 (0)	<0.001	<0.001	0
- 5Alpha-reductase	--	--	0 (0)	<0.001	<0.001	0

Variable	LURN Manuscript Overall (n=1,064)	LURN DSIC Overall (n=1064)	Diff. Overall (n=0)	LURN Manuscript p-value (Chi-square/Wilcoxon)	LURN DSIC p-value (Chi-square/Wilcoxon)	Diff. p-value (n=0)
Previous Surgery (%)						
- Urgency Urinary Incontinence	7 (1)	7 (1)	0 (0)	0.067	0.067	0
- SUI/prolapse	--	--	0 (0)	--	--	--
- Hysterectomy	--	--	0 (0)	--	--	--
- Prostate	--	--	0 (0)	--	--	--
- Urethral dilation	9 (1)	9 (1)	0 (0)	0.683	0.683	0
- Other	2 (0)	2 (0)	0 (0)	0.167	0.167	0
Median Functional Comorbidity Index (IQR)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	0 (0-0)	0.330	0.330	0
Prolapse Stage (%)				--	--	--
- 0	--	--	0 (0)			
- 1	--	--	0 (0)			
- 2	--	--	0 (0)			
- 3	--	--	0 (0)			
- 4	--	--	0 (0)			
Prostate Findings (%)				--	--	--
- Nodule or anomaly	--	--	0 (0)			
- Normal or enlarged prostate	--	--	0 (0)			
- Nitrate pos (%)	14 (2)	14 (2)	0 (0)	0.149	0.149	0
- Red blood cell pos (%)	53 (7)	53 (7)	0 (0)	0.006	0.006	0
- White blood cell pos (%)	71 (8)	71 (8)	0 (0)	<0.001	<0.001	0
- Glucose pos (%)	46 (5)	46 (5)	0 (0)	0.015	0.015	0
- Median urine specific gravity (IQR)	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0 (0-0)	<0.001	<0.001	0
- Median pH (IQR)	6.0 (5.0-6.5)	6.0 (5.0-6.5)	0 (0-0)	<0.001	<0.001	0
Median ml post-void residual volume (IQR)	26.0 (6.0-67.0)	26.0 (6.0-67.0)	0 (0-0)	0.254	0.254	0
Median AUA SI (IQR)	12.0 (8.0-17.0)	12.0 (8.0-17.0)	0 (0-0)	0.004	0.004	0
Median AUA quality of life (IQR)	4.0 (3.0-5.0)	4.0 (3.0-5.0)	0 (0-0)	<0.001	<0.001	0

Attachment A: SAS Code

```
*****/  
* Formats */  
*****/  
PROC FORMAT;  
  VALUE BMI  
    LOW-<18.5 = '<18.5'  
    18.5-25  = '18.5-<25'  
    25-<30   = '25-<30'  
    30-HIGH  = '30+';  
  VALUE RBC  
    2,3     = '0'  
    4,5,6   = '1';  
RUN;  
  
*****/  
* Import datasets */  
*****/  
LIBNAME SASDATA '/prj/niddk/ims_analysis/LURN/private_orig_data/LURN_Data_Repository_Submission/Publications/AnalysisFiles/';  
  
DATA DESCRIPTIVE;  
  SET SASDATA.DESRIPTIVE;  
RUN;  
  
*****/  
* Frequencies, Means, and Wilcoxon's for Table 1 */  
*****/  
TITLE2 'Table 1 statistics';  
PROC FREQ DATA=DESCRIPTIVE;  
  TABLE GENDER;  
RUN;  
  
PROC MEANS DATA=DESCRIPTIVE;  
  VAR AGE;  
  CLASS GENDER;  
RUN;  
  
PROC MEANS DATA=DESCRIPTIVE;  
  VAR AGE;  
RUN;  
  
PROC NPAR1WAY WILCOXON;  
  VAR AGE;  
  CLASS GENDER;  
RUN;  
  
PROC FREQ DATA=DESCRIPTIVE;  
  TABLE (RACE_NUM Ethnicity) * GENDER /CHISQ;
```

```

RUN;

PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;
  VAR BodyMassIndex;
  CLASS GENDER;
RUN;

PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;
  VAR BodyMassIndex;
RUN;

PROC NPAR1WAY WILCOXON;
  VAR BodyMassIndex;
  CLASS GENDER;
RUN;

PROC FREQ DATA=DESCRIPTIVE;
  TABLE BODYMASSINDEX * GENDER /MISSING CHISQ;
  TABLE (SMOKER Diabetes1) * GENDER /CHISQ;
  FORMAT BODYMASSINDEX BMI. SMOKER MISS.;
RUN;

PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;
  VAR PartVagBirth;
  CLASS GENDER;
RUN;

PROC FREQ DATA=DESCRIPTIVE;
  TABLE (POSTMENOPAUSE
    PMHormones) * GENDER;
  TABLE (AntiCholTx
    ConstipationTx
    AlphaBlockerTx
    FiveARITx
    UrgeIncontSurg
    ProlapseSUISurg
    PartHysterectomy
    ProstateSurg
    UrDialSurg
    OtherSurg) * GENDER /CHISQ;
RUN;

PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;
  VAR FCI_total;
  CLASS GENDER;
RUN;

PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;
  VAR FCI_total;
RUN;

```

```

PROC NPAR1WAY WILCOXON;
  VAR FCI_total;
  CLASS GENDER;
RUN;

PROC FREQ DATA=DESCRIPTIVE;
  TABLE POPQFindings * GENDER;
  WHERE POPQFindings IN(1,2,3,4,5);
RUN;

PROC FREQ DATA=DESCRIPTIVE;
  TABLE ProstateFind * GENDER;
  WHERE PROSTATEFIND IN(1,2);
RUN;

PROC FREQ DATA=DESCRIPTIVE;
  TABLE (Nitrites
          RedBloodCells
          WhiteBloodCells
          Glucose) * GENDER /CHISQ;
  FORMAT REDBLOODCELLS RBC.;
RUN;

PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;
  VAR UrineSpGrav;
  CLASS GENDER;
RUN;

PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;
  VAR UrineSpGrav;
RUN;

PROC NPAR1WAY WILCOXON;
  VAR UrineSpGrav;
  CLASS GENDER;
RUN;

PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;
  VAR PH;
  CLASS GENDER;
RUN;

PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;
  VAR PH;
RUN;

PROC NPAR1WAY WILCOXON;
  VAR pH;
  CLASS GENDER;
RUN;

```

```
PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;  
  VAR POSTVOIDVOL;  
  CLASS GENDER;  
RUN;
```

```
PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;  
  VAR POSTVOIDVOL;  
RUN;
```

```
PROC NPAR1WAY WILCOXON;  
  VAR POSTVOIDVOL;  
  CLASS GENDER;  
RUN;
```

```
PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;  
  VAR AUA_SI;  
  CLASS GENDER;  
RUN;
```

```
PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;  
  VAR AUA_SI;  
RUN;
```

```
PROC NPAR1WAY WILCOXON;  
  VAR AUA_SI;  
  CLASS GENDER;  
RUN;
```

```
PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;  
  VAR FEELABOUTCOND;  
  CLASS GENDER;  
RUN;
```

```
PROC MEANS DATA=DESCRIPTIVE MEDIAN P25 P75;  
  VAR FEELABOUTCOND;  
RUN;
```

```
PROC NPAR1WAY WILCOXON;  
  VAR FEELABOUTCOND;  
  CLASS GENDER;  
RUN;
```