S.Tan May 1, 2009

Dataset Integrity Check (DSIC) for the Boston Area Community Health Survey (BACH) Baseline File Addendum: Additional Analysis using Full Legacy Medication Dataset Reference paper: FitzGerald MP, et.al. The Association of Nocturia With Cardiac Disease,

Diabetes, Body Mass Index, Age and Diuretic Use: Results from the BACH Survey *The Journal of Urology* 177 [Apr 2007]: 1385-89.

The BACH survey is a population based epidemiological survey of a broad range of urological symptoms in randomly selected respondents. The BACH sample of 5506 participants was recruited from April 2002 through June 2005. In 2007, BACH main study survey data was submitted to the NIDDK Data Repository, and a data set integrity check (DSIC) performed on the data with reference to the publication Fitzgerald MP [2007]¹. For the purposes of completing the aforementioned DSIC, a single medication variable was submitted to the Repository by the Data Coordinating Center, as the entire legacy medication dataset was not yet available. The current analysis is performed to verify published results on medication use could be reproduced using the full legacy medication dataset.

Archived Medication Dataset Contents. The DCC submitted a single *PC-SAS v9* analytical data file (*<bachmeds.sas7bdat>*) representing medication intake data collected from data collection forms, along with a documentation file, *<Sloan Medication Data Systems.doc>*. In total, the data file contains 36145 observations and 8 variables, including the participant identification number, *<id>,* drug (medication) number, *<drugnum>*, drug class *<classlbl>*, and drug coalition number, *<coalitionnum>*. The file contains 4867 unique participant ID numbers, 201 unique drug numbers, 116 drug classes, and 69 coalition numbers.

There is no unique record identifier; rather, unique records in the medication dataset are identified by unique combinations of id-drug-class and/or id-drug-coalition. One drug may belong to simultaneous multiple classes and/or multiple coalitions. The total number of unique drugs taken by the participant is designated by the variable *<drugcnt>*, which is constant for each participant ID.

For purposes of confidentiality, drugs or drug classes reported at low frequency are recoded to "Miscellaneous".

Remaining variables in the file are: *<indic>*, item number from the medication questionnaire; *<druglbl>*, character label for drug number; and *<caalitionlbl>*, the character label for coalition number. (Accompanying documentation by the DCC refers to *<caalitionlbl>* as *"<coalitionlbl>"*.)

Analysis

Part I. A single variable, an indicator for diuretic use, <diuretic01>, was previously submitted to the Repository for the purpose of completing the main study data DSIC. Participants taking diuretics were identified by (<diuretic01>=1); those not taking diuretics, as (<diuretic01>=0). For the current analysis, <diuretic01> is set out for replication using the full legacy medication dataset. For simplicity, the new diuretic indicator from the full legacy dataset shall be referred to as " $<diu_legacy01>$ ". The steps for calculating $<diu_legacy01>$ are as follows:

- All participants reporting medications with at least one occurrence of the word "Diuretic" in a medication's class or coalition labels are considered as diuretic users; i.e., (<*diu_legacy01>=1*). Remaining subjects, including those who did not report medication use, are considered as non-users of diuretics, or (<*diu_legacy01>=0*).
- Comparison of <*diuretic01*> to <*diu_legacy01*> is 99.7% concordant. All diuretic users according to the previously submitted variable (<*diuretic01*>=1) are also classified as diuretic users per the full legacy variable (<*diu_legacy01*>=1). However, eighteen additional subjects are classified as diuretic users per the full legacyvariable (<*diu_legacy01*>=1), though not as users according to the previous indicator variable (<*diuretic01*>=0). [Table 1].
- Upon examination of the 18 discordant pairings, it is noted that drug code for all is "miscellaneous", leaving open the possibility these are infrequently reported drugs that have been recoded in the legacy dataset.

In summary, the variable on diuretic use, as previously submitted by the DCC, was reproduced in the full medication legacy dataset with a differential rate of 0.3%. Differences are possibly attributable to low frequency responses being recoded to "miscellaneous" in the legacy dataset.

[Table 1.]

Diuretic according to full legacy dataset Diuretic according to previous indicator						
Frequency Percent Row Pct Col Pct	 N	Y	Total			
N	4674 84.89 100.00 99.62	0 0.00 0.00 0.00	4674 84. 89			
Y	18 0. 33 2. 16 0. 38	814 14. 78 97. 84 100. 00	832 15. 11			
Total	++ 4692 85. 22	814 14. 78	5506 100. 00			

Part II. After creating a variable for diuretic use using the full legacy medication dataset, the prevalence of nocturia by diuretic use is calculated and compared to published results.

The method for defining nocturia status is previously described in the main study DSIC¹. The prevalence of nocturia by diuretic use/nonuse is estimated, as well as the effect of diuretic use on the prevalence of nocturia. Prevalences are reported as weighted percents, and Chi-square tests are used to assess differences in two-way breakdowns.

Results of the analysis show weighted distributions of diuretic use, overall and by gender, match published breakdowns in Fitzgerald MP [2007]¹ when rounded to the nearest whole number. Observed numbers of participants using diuretics differ in DSIC versus published results, corresponding with the 18 discordant designations described in Part I. [Table 2].

Table 2.

Diuretic Use in 5,506 BACH respondents							
(published results extracted from Table 1 in Fitzgerald, MP, 2007: p. 1387) No. Overall (weighted							
		preval	ence)				
	Archived		Published		Difference		
Overall (weighted %)	832	(11.2)	814	(10.8)	<mark>-18</mark>	<mark>(-0.4)</mark>	
Men (weighted %)	256	(8.0)	255	(8.0)	<mark>-1</mark>	(0.0)	
Women (weighted %)	576	(14.1)	559	(13.4)	<mark>-17</mark>	<mark>(-0.7)</mark>	
P value	<	0.001	<().001		0	

The prevalence of nocturia in diuretic users/nonusers match published breakdowns when rounded to the nearest whole number [Table 3]. Differences in observed versus published numbers of nocturia may be due to the inclusion of multiply imputed missing data in published results, as described previously¹, and possibly to low frequency responses being recoded to "miscellaneous' in the legacy medication dataset.

Table 3.

Nocturia in BACH survey overall and by diuretic use						
(published results extracted from Table 2 in Fitzgerald, MP, 2007: p. 1388)						
	<u>No</u>	. Overall (weig	hted pr	<u>evalence)</u>		
	<u> </u>	<u>Archived</u>	Published		Difference	
Overall	1865	(28.4)	1872	(28.4)	7	(0.0)
Diuretic use						
Yes (weighted %)	429	(48.1)	422	(48.4)	<mark>-7</mark>	<mark>(0.3)</mark>
No (weighted %)	1436	(25.9)	1451	(26.0)	<mark>15</mark>	<mark>(0.1)</mark>
OR (95% CI)	2.64	(2.09, 3.34)	2.66	(2.13, 3.34)	<mark>0.02</mark>	<mark>(0.04, 0)</mark>
P value		< 0.001		<0.001		0
	Nocturia in BACH (published results extr Overall Diuretic use Yes (weighted %) No (weighted %) OR (95% CI) P value	Nocturia in BACH survey (published results extracted fr No Overall 1865 Diuretic use Yes (weighted %) 429 No (weighted %) 1436 OR (95% CI) 2.64 P value	Nocturia in BACH survey overall and by (published results extracted from Table 2 in Fin No. Overall (weighted from Table 2 in Fin No. Overall (weighted from Table 2 in Fin No. Overall (weighted from Table 2 in Fin No (weighted %)Diuretic use Yes (weighted %)1865(28.4)Diuretic use Yes (weighted %)429(48.1) (48.1)No (weighted %)1436(25.9)OR (95% CI)2.64(2.09, 3.34)P value<0.001	Nocturia in BACH survey overall and by diuret (published results extracted from Table 2 in Fitzgerald, No. Overall (weighted privar)No. Overall (weighted privar)No. Overall (weighted privar)Overall1865(28.4)Diuretic use Yes (weighted %)429(48.1)No (weighted %)1436(25.9)OR (95% CI)2.64(2.09, 3.34)P value<0.001	Nocturia in BACH survey overall and by diuretic use (published results extracted from Table 2 in Fitzgerald, MP, 2007: p. No. Overall (weighted prevalence) ArchivedPublishedOverall1865(28.4)1872(28.4)Diuretic use Yes (weighted %)429(48.1)422(48.4)No (weighted %)1436(25.9)1451(26.0)OR (95% CI)2.64(2.09, 3.34)2.66(2.13, 3.34)P value<0.001	Nocturia in BACH survey overall and by diuretic use (published results extracted from Table 2 in Fitzgerald, MP, 2007: p. 1388) No. Overall (weighted prevalence) No. Overall (weighted prevalence) Archived Published Overall 1865 Overall 1865 Verall 1872 Overall 1865 Ves (weighted %) 429 Yes (weighted %) 1436 OR (95% CI) 2.64 Veslue <0.001

In summary, analyses of a diuretic use indicator, created using the BACH full legacy medication dataset, replicated published prevalences with rounding to the nearest whole number.

References.

[1] Dataset Integrity Check (DSIC) for the Boston Area Community Health Survey (BACH) Baseline File, with reference to: FitzGerald MP, et.al. The Association of Nocturia With Cardiac Disease, Diabetes, Body Mass Index, Age and Diuretic Use: Results from the BACH Survey *The Journal of Urology* 177 [Apr 2007]: 1385-89.

BACH Baseline DSIC may be downloaded from: https://www.niddkrepository.org/niddk/jsp/public/dataset.jsp#BACH.

Attachment 1

SAS 9.1 and SAS-Callable SUDAAN 9.0.1 Log for programming code submitted for the replication of results in Tables 1 and 2 of Fitzgerald MP, et.al. [Apr 2007]

```
1
                   The SAS System
                                                 17:03 Friday, May 1, 2009
NOTE: Copyright (c) 2002-2003 by SAS Institute Inc., Cary, NC, USA.
NOTE: SAS (r) 9.1 (TS1M3)
     Licensed to RTI INTERNATIONAL, Site 0047670001.
NOTE: This session is executing on the XP PRO platform.
NOTE: SAS 9.1.3 Service Pack 4
NOTE: SAS initialization used:
                  7.28 seconds
     real time
                       0.62 seconds
     cpu time
          1
2
          * BACH DSIC diuretic full legacy.sas
3
          * Purpose: to complete Data Set Integrity Analyses
4
          * on BACH study legacy dataset
5
          * using data from BACH medication legacy dataset
6
          * comparison study paper: Fitzgerald, 2007 Apr (J.Urology)*
7
          * Programmed by: S. Tan
          8
          options ps=60 ls=78 nonumber formchar='|----|+\---+=|-^<>*' mprint
9
orientation=portrait
9
       !;
10
11
          libname bach 'Z:\05_Users\Sylvia\BACH\data';
NOTE: Libref BACH was successfully assigned as follows:
     Engine:
                   V9
     Physical Name: Z:\05_Users\Sylvia\BACH\data
12
          libname library 'Z:\05_Users\Sylvia\BACH\data';
NOTE: Libname LIBRARY refers to the same physical library as BACH.
NOTE: Libref LIBRARY was successfully assigned as follows:
     Engine:
                   V9
     Physical Name: Z:\05_Users\Sylvia\BACH\data
          libname mednutr 'Z:\05_Users\Sylvia\BACH\data\MEDNUTR';
13
NOTE: Libref MEDNUTR was successfully assigned as follows:
     Engine:
                   V9
     Physical Name: Z:\05_Users\Sylvia\BACH\data\MEDNUTR
14
15
            * Medication info:
16
            * Notes. 1. There are no formats assigned to the variables (even
though formats are
16 ! implied in the
17
                    README.TXT
18
                    2. There is no unique record ID #, or unique patient-
drug #.
19
                    Unique records appear to be identified by Drug-Class or
Drug-Coalition.
20
                    A drug may belong to multiple classes or to
21
                    multiple coalitions (class/coalition do not completely
match up).
                    Variable DrugCnt verifies unique # of drugs being
22
taken.
23
                    3. Variable CoalitionLbl is mispelled as CaalitionLbl .
*;
24
25
          * BACH Full Legacy Medication Dataset, submitted 12/08 *;
26
          data bachmeds; set mednutr.bachmeds;
27
            recordid+1; * to create unique ID for records, it is not in the
dataset *;
28
```

The SAS System 17:03 Friday, May 1, 2009 * attempt to recreate DIURETIC variable from BACH DSIC analysis *; 29 NOTE: There were 36145 observations read from the data set MEDNUTR.BACHMEDS. NOTE: The data set WORK.BACHMEDS has 36145 observations and 9 variables. NOTE: DATA statement used (Total process time): real time 32.23 seconds cpu time 0.29 seconds 30 proc freq data=bachmeds noprint; where classlbl contains "DIURETIC" or caalitionlbl 30 ! contains "DIURETIC"; 31 tables recordid/out=a; run; NOTE: There were 998 observations read from the data set WORK.BACHMEDS. WHERE classlbl contains 'DIURETIC' or caalitionlbl contains 'DIURETIC'; NOTE: The data set WORK.A has 998 observations and 3 variables. NOTE: PROCEDURE FREQ used (Total process time): 0.07 seconds real time 0.07 seconds cpu time 32 data bachmeds; merge bachmeds a(in=in2); 33 by recordid; if in2 then diu01=1; else diu01=0; 34 35 NOTE: There were 36145 observations read from the data set WORK.BACHMEDS. NOTE: There were 998 observations read from the data set WORK.A. NOTE: The data set WORK.BACHMEDS has 36145 observations and 12 variables. NOTE: DATA statement used (Total process time): real time 2.50 seconds 0.21 seconds cpu time 36 proc freq data=bachmeds noprint; where diu01=1; tables id/out=b; 37 38 * previously sent in conjunction with BACH DSIC *; NOTE: There were 998 observations read from the data set WORK.BACHMEDS. WHERE diu01=1; NOTE: The data set WORK.B has 832 observations and 3 variables. NOTE: PROCEDURE FREQ used (Total process time): real time 0.04 seconds 0.04 seconds cpu time 39 data diuretic; set bach.diuretic; 40 NOTE: There were 5506 observations read from the data set BACH.DIURETIC. NOTE: The data set WORK.DIURETIC has 5506 observations and 2 variables. NOTE: DATA statement used (Total process time): real time 0.78 seconds

The SAS System 17:03 Friday, May 1, 2009 cpu time 0.01 seconds 41 proc sort data=diuretic; by id; NOTE: There were 5506 observations read from the data set WORK.DIURETIC. NOTE: The data set WORK.DIURETIC has 5506 observations and 2 variables. NOTE: PROCEDURE SORT used (Total process time): real time 0.03 seconds cpu time 0.01 seconds 42 data diuretic; merge diuretic b(in=in2); by id; 43 if in2 then diu01=1; else diu01=0; 44 label diuretic01=Diuretic acc to DCC 45 diu01=Diuretic acc to Full Legacy; 46 NOTE: There were 5506 observations read from the data set WORK.DIURETIC. NOTE: There were 832 observations read from the data set WORK.B. NOTE: The data set WORK.DIURETIC has 5506 observations and 5 variables. NOTE: DATA statement used (Total process time): real time 0.01 seconds cpu time 0.01 seconds proc freq; tables diu01*diuretic01/ missing; run; 47 NOTE: There were 5506 observations read from the data set WORK.DIURETIC. NOTE: The PROCEDURE FREQ printed page 1. NOTE: PROCEDURE FREQ used (Total process time): real time 0.18 seconds cpu time 0.03 seconds 48 * 18 cases too many (compared to previously received dataset) 49 MAY BE due to infrequently reported class or coalition being recoded to MISCELLANEOUS *; 50 51 data mednutr.dsic_diu; set diuretic; keep id diu01; run; NOTE: There were 5506 observations read from the data set WORK.DIURETIC. NOTE: The data set MEDNUTR.DSIC_DIU has 5506 observations and 2 variables. NOTE: DATA statement used (Total process time): real time 1.96 seconds cpu time 0.03 seconds 52 53 * BACH baseline survey legacy dataset *; 54 data bachdata; set bach.repositmain2; 55 if 4<=nghtufrq<=6 then nightfreq=1; else if 1<=nghtufrq<=3 then nightfreq=0; 56 if urinnt>=2 then twiceurin=1; else if urinnt in (0,1) then twiceurin=0; 57 if nightfreq=1 or twiceurin=1 then nocturia=100;

The SAS System 17:03 Friday, May 1, 2009 58 else if nightfreq=0 and twiceurin=0 then nocturia=0; nocturia1=nocturia; if nocturia=100 then nocturia1=1; 59 NOTE: There were 5506 observations read from the data set BACH.REPOSITMAIN2. NOTE: The data set WORK.BACHDATA has 5506 observations and 587 variables. NOTE: DATA statement used (Total process time): real time 1:15.07 cpu time 0.82 seconds 60 proc sort data=bachdata; by id; 61 NOTE: There were 5506 observations read from the data set WORK.BACHDATA. NOTE: The data set WORK.BACHDATA has 5506 observations and 587 variables. NOTE: PROCEDURE SORT used (Total process time): real time 5.50 seconds 0.40 seconds cpu time 62 data dsic diu; set mednutr.dsic diu; NOTE: There were 5506 observations read from the data set MEDNUTR.DSIC_DIU. NOTE: The data set WORK.DSIC DIU has 5506 observations and 2 variables. NOTE: DATA statement used (Total process time): real time 0.67 seconds 0.01 seconds cpu time 63 proc sort; by id; NOTE: There were 5506 observations read from the data set WORK.DSIC_DIU. NOTE: The data set WORK.DSIC DIU has 5506 observations and 2 variables. NOTE: PROCEDURE SORT used (Total process time): real time 0.18 seconds 0.01 seconds cpu time 64 data bachdata; merge bachdata dsic_diu; by id; 65 66 * prevalences using SAS-callable SUDAAN *; 67 * compare to BACH study publication by Fitzgerald MP [2007] *; NOTE: There were 5506 observations read from the data set WORK.BACHDATA. NOTE: There were 5506 observations read from the data set WORK.DSIC DIU. NOTE: The data set WORK.BACHDATA has 5506 observations and 588 variables. NOTE: DATA statement used (Total process time): 37.03 seconds real time 0.68 seconds cpu time 68 proc sort data=bachdata; by strata psunit;

69 * for table 1 *;

The SAS System 17:03 Friday, May 1, 2009 70 %macro crosstabs(classvar,tablevar); 71 proc crosstab data=bachdata atlevel1=1 atlevel2=2 deft2; 72 nest strata psunit; 73 weight wtr; 74 class &classvar / nofreq; 75 tables &tablevar; 76 print nsum rowper serow colper secol atlev1 atlev2 chisqp llchisqp/style=nchs 77 rowperfmt=f7.1 serowfmt=f7.1 colperfmt=f7.1 secolfmt=f7.1; 78 test chisq llchisq; 79 run; 80 %mend; %crosstabs(diu01 gender,gender*diu01); 81 NOTE: There were 5506 observations read from the data set WORK.BACHDATA. NOTE: The data set WORK.BACHDATA has 5506 observations and 588 variables. NOTE: PROCEDURE SORT used (Total process time): real time 3.54 seconds 0.34 seconds cpu time MPRINT(CROSSTABS): proc crosstab data=bachdata atlevel1=1 atlevel2=2 deft2; MPRINT(CROSSTABS): nest strata psunit; MPRINT(CROSSTABS): weight wtr; MPRINT(CROSSTABS): class diu01 gender / nofreq; MPRINT(CROSSTABS): tables gender*diu01; MPRINT(CROSSTABS): print nsum rowper serow colper secol atlev1 atlev2 chisqp llchisqp/style=nchs rowperfmt=f7.1 serowfmt=f7.1 colperfmt=f7.1 secolfmt=f7.1; MPRINT(CROSSTABS): test chisq llchisq; MPRINT(CROSSTABS): run; SUDAAN Release 10.0.0 (Windows Individual User SAS-Callable version) Serial Number A0003686, for 150 user(s) is licensed to RTI International (RTI Staff). It expires on October 01, 2009. Opened SAS data file BACHDATA for reading. NOTE: There were 5506 observations read from the data set WORK.BACHDATA. NOTE: The PROCEDURE CROSSTAB printed pages 2-4. NOTE: PROCEDURE CROSSTAB used (Total process time): real time 31.04 seconds 0.70 seconds cpu time 82 83 * for table 2 *;

The SAS System 17:03 Friday, May 1, 2009 84 proc freq; tables nocturia*diu01/missing; run; NOTE: There were 5506 observations read from the data set WORK.BACHDATA. NOTE: The PROCEDURE FREQ printed page 5. NOTE: PROCEDURE FREQ used (Total process time): 0.07 seconds real time cpu time 0.03 seconds 85 %macro prevs(classvar, tablevar); 86 proc descript data=bachdata atlevel1=1 atlevel2=2 deft2; 87 nest strata psunit; weight wtr; 88 89 class &classvar / nofreq; 90 var nocturia; 91 tables &tablevar; 92 print nsum mean semean atlev1 deffmean /style=nchs meanfmt=f7.1 semeanfmt=f7.1; 93 run; 94 %mend; 95 %prevs(diu01,diu01); MPRINT(PREVS): proc descript data=bachdata atlevel1=1 atlevel2=2 deft2; MPRINT(PREVS): nest strata psunit; MPRINT(PREVS): weight wtr; MPRINT(PREVS): class diu01 / nofreq; MPRINT(PREVS): var nocturia; MPRINT(PREVS): tables diu01; print nsum mean semean atlev1 deffmean /style=nchs MPRINT(PREVS): meanfmt=f7.1 semeanfmt=f7.1; MPRINT(PREVS): run; SUDAAN Release 10.0.0 (Windows Individual User SAS-Callable version) Serial Number A0003686, for 150 user(s) is licensed to RTI International (RTI Staff). It expires on October 01, 2009. Opened SAS data file BACHDATA for reading. NOTE: There were 5506 observations read from the data set WORK.BACHDATA. NOTE: The PROCEDURE DESCRIPT printed pages 6-7. NOTE: PROCEDURE DESCRIPT used (Total process time): real time 29.71 seconds cpu time 0.59 seconds 96 97 %macro ors(classvar, predvar, reflev); 98 proc rlogist data=bachdata deft2;

```
The SAS System
17:03 Friday, May 1, 2009
99
            nest strata psunit;
100
           weight wtr;
101
           class &classvar / nofreq;
102
           reflevel &predvar = &reflev;
103
           model nocturia1=&predvar;
104
            print/betas=default risk=default tests=default;
105
            run;
106
        %mend;
107
        %ors(diu01,diu01,0);
MPRINT(ORS): proc rlogist data=bachdata deft2;
MPRINT(ORS): nest strata psunit;
MPRINT(ORS): weight wtr;
MPRINT(ORS): class diu01 / nofreq;
MPRINT(ORS):
            reflevel diu01 = 0;
MPRINT(ORS): model nocturial=diu01;
MPRINT(ORS): print/betas=default risk=default tests=default;
MPRINT(ORS): run;
SUDAAN Release 10.0.0 (Windows Individual User SAS-Callable version)
Serial Number A0003686, for 150 user(s) is licensed to
RTI International (RTI Staff).
It expires on October 01, 2009.
```

Opened SAS data file BACHDATA for reading.

NOTE: There were 5506 observations read from the data set WORK.BACHDATA. NOTE: The PROCEDURE RLOGIST printed pages 8-12. NOTE: PROCEDURE RLOGIST used (Total process time): real time 35.92 seconds cpu time 0.57 seconds

NOTE: SAS Institute Inc., SAS Campus Drive, Cary, NC USA 27513-2414 NOTE: The SAS System used: real time 4:26.18 cpu time 5.82 seconds

Attachment 2

SAS 9.1 and SAS-Callable SUDAAN 9.0.1 Output for programming code submitted for the replication of results in Tables 1 and 2 of Fitzgerald MP, et.al. [Apr 2007]

The FREQ Procedure

Table of diu01 by diuretic01

diu01(Diuretic acc to Full Legacy) diuretic01(Diuretic acc to DCC)

Frequency Percent Row Pct Col Pct	0	1	Total
0	4674 84.89 100.00 99.62	0 0.00 0.00 0.00	4674 84.89
1	18 0.33 2.16 0.38	814 14.78 97.84 100.00	832 15.11
Total	4692 85.22	814 14.78	5506 100.00

2009

S U D A A N Software for the Statistical Analysis of Correlated Data Copyright Research Triangle Institute August 2008 Release 10.0

DESIGN SUMMARY: Variances will be computed using the Taylor Linearization Method, Assuming a With Replacement (WR) Design Sample Weight: WTR Stratification Variables(s): STRATA Primary Sampling Unit: PSUNIT

Number of observations read : 5506 Weighted count : 262878 Denominator degrees of freedom : 729

2009

Date: 05-01-2009 Time: 17:06:31

SUDAAN

Variance Estimation Method: Taylor Series (WR) by: FOIA: A5. Sex of respondent, Diuretic acc to Full Legacy.

FOIA: A5. Sex of respondent Diuretic acc to Full Legacy	Sample Size	Row Percent	SE Row Percent	Col Percent	SE Col Percent	Count at Level 1	Count at Level 2
Total							
Total	5506	100.0	0.0	100.0	0.0	12	741
0	4674	88.8	0.6	100.0	0.0	12	725
1	832	11.2	0.6	100.0	0.0	12	378
1: Male							
Total	2301	100.0	0.0	47.6	1.1	12	636
0	2045	91.9	0.7	49.3	1.2	12	612
1	256	8.1	0.7	34.1	2.3	12	182
2: Female							
Total	3205	100.0	0.0	52.4	1.1	11	677
0	2629	85.9	0.9	50.7	1.2	11	650
1	576	14.1	0.9	65.9	2.3	11	303

Time: 17:06:31 Table: 1 Variance Estimation Method: Taylor Series (WR) Chi Square Test of Independence for FOIA: A5. Sex of respondent and Diuretic acc to Full Legacy _____ P-value P-value

I VALAC	r varac
ChiSq	LLChiSq
0.0000	0.0000

Page: 2

SUDAAN

Date: 05-01-2009

The FREQ Procedure

Table of nocturia by diu01

nocturia diu01(Diuretic acc to Full Legacy)

Frequency Percent Row Pct Col Pct	0	1	Total
· 	15 0.27 7 5.00 0.32	5 0.09 25.00 0.60	20 0.36
0	3223 58.54 89.01 68.96	398 7.23 10.99 47.84	3621 65.76
100	1436 26.08 77.00 30.72	429 7.79 23.00 51.56	1865 33.87
Total	4674 84.89	+ 832 15.11	5506 100.00

S U D A A N Software for the Statistical Analysis of Correlated Data Copyright Research Triangle Institute August 2008 Release 10.0

DESIGN SUMMARY: Variances will be computed using the Taylor Linearization Method, Assuming a With Replacement (WR) Design Sample Weight: WTR Stratification Variables(s): STRATA Primary Sampling Unit: PSUNIT

Number of observations read : 5506 Weighted count : 262878 Denominator degrees of freedom : 729

2009

Date: 05-01-2009 Time: 17:07:03 SUDAAN

Page: 1 Table: 1

Variance Estimation Method: Taylor Series (WR) by: Variable, Diuretic acc to Full Legacy.

Variable Diuretic acc to Full Legacy	Sample Size	Mean	SE Mean	Count at Level 1	DEFF Mean #2
NOCTURIA Total 0 1	5486 4659 827	28.4 25.9 48.1	1.1 1.1 2.5	12 12 12	2.99 3.14 2.01

SUDAAN Software for the Statistical Analysis of Correlated Data Copyright Research Triangle Institute August 2008 Release 10.0 DESIGN SUMMARY: Variances will be computed using the Taylor Linearization Method, Assuming a With Replacement (WR) Design Sample Weight: WTR Stratification Variables(s): STRATA Primary Sampling Unit: PSUNIT Number of zero responses : 3621 Number of non-zero responses : 1865 Independence parameters have converged in 5 iterations Number of observations read 5506 : Weighted count: 262878 Observations used in the analysis : 5486 Weighted count: 262108 Denominator degrees of freedom : 729 Maximum number of estimable parameters for the model is 2 File BACHDATA contains 741 Clusters 740 clusters were used to fit the model Maximum cluster size is 59 records Minimum cluster size is 1 records Sample and Population Counts for Response Variable NOCTURIA1 Based on observations used in the analysis 0: Sample Count 3621 Population Count 187617 1: Sample Count 1865 Population Count 74491 R-Square for dependent variable NOCTURIA1 (Cox & Snell, 1989): 0.021826 -2 * Normalized Log-Likelihood with Intercepts Only : 6548.92 -2 * Normalized Log-Likelihood Full Model : 6427.86 Approximate Chi-Square (-2 * Log-L Ratio) : 121.06 Degrees of Freedom • 1 Note: The approximate Chi-Square is not adjusted for clustering. Refer to hypothesis test table for adjusted test.

Date: 05-01-2009 Time: 17:07:32		:	SUDAAN			Page: 1 Table: 1	
Variance Estimation Method: Taylor Series (WR) SE Method: Robust (Binder, 1983) Working Correlations: Independent Link Function: Logit Response variable NOCTURIA1: NOCTURIA1 by: Independent Variables and Effects.							
Independent Variables and Effects B=0	Beta Coeff.	DEFF Beta #2	SE Beta	Lower 95% Limit Beta	Upper 95% Limit Beta	T-Test	
Intercept Diuretic acc to Full Legacy	-1.05	3.28	0.06	-1.17	-0.93	-17.72	
0	0.00 0.97	1.87	0.00 0.12	0.00 0.74	0.00 1.21	8.18	

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Variance Estimation Method: Taylor Series (WR) SE Method: Robust (Binder, 1983) Working Correlations: Independent Link Function: Logit Response variable NOCTURIA1: NOCTURIA1 by: Independent Variables and Effects.

Independent Variables and Effects	P-value T-Test B=0
Intercept Diuretic acc to Full	0.0000
Degacy	
0	•
1	0.0000

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Variance Estimation Method: Taylor Series (WR) SE Method: Robust (Binder, 1983) Working Correlations: Independent Link Function: Logit Response variable NOCTURIA1: NOCTURIA1 by: Contrast.

Contrast	Degrees of Freedom	Wald F	P -value Wald F
OVERALL MODEL	2	159.16	0.0000
MODEL MINUS INTERCEPT	1	66.90	0.000
INTERCEPT			
DIU01	1	66.90	0.0000

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Variance Estimation Method: Taylor Series (WR) SE Method: Robust (Binder, 1983) Working Correlations: Independent Link Function: Logit Response variable NOCTURIA1: NOCTURIA1 by: Independent Variables and Effects.					
Independent Variables and Effects	Odds Ratio	Lower Limit	95% OR	Upper Limit	95% OR
Intercept Diuretic acc to Full Legacy	0.35		0.31		0.39
0 1	1.00 2.64		1.00 2.09		1.00 3.34

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