Dataset Integrity Check for the Look Ahead Follow-up Data Files

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June 9, 2014

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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 Look AHEAD study is a multicenter randomized clinical trial in overweight and obese individuals with type 2 diabetes to evaluate the long-term effects of an intensive weight loss intervention on major cardiovascular events. Eligibility requirements are diagnosis of type 2 diabetes (determined by self-report and verification) in individuals age 45–76 years, BMI >25 kg/m2 (>27 kg/m2 if currently taking insulin). A total of 5,145 participants from 16 clinical centers were randomized between 2001 and 2004. The published manuscript by the Look AHEAD Research Group provides baseline and follow-up characteristics of this randomized cohort.

Users of the Look AHEAD Baseline data should note that data on 239 participants from American Indian clinical sites were not included in the data transferred to the NIDDK repository.

3 Archived Datasets

All SAS data files, as provided by the Data Coordinating Center (DCC), are located in the Look AHEAD data package. For this replication, variables were taken from the "baseline_combined" and "year4_combined" datasets.

4 Statistical Methods

Analyses were performed to duplicate results for the data published by Wadden et al [1] in Obesity in October 2011.

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

5 Results

Table 1 in the publication [1], Table 1 Baseline characteristics of participants in the ILI and DSE groups. 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 within expected results considering the removal of Native American records.

Table 2 in the publication [1] Table 2 Mean (±s.e.) weight losses in the ILI participants at years 1–4 according to gender, age, race/ethnicity for ILI. 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 within expected results considering the removal of Native American records.

The data for Table 3 in the publication [1] In the ILI participants, mean (±s.e.) number of treatment sessions attended in year 1, and treatment contacts in years 2–4, as well as self-reported calorie expenditure/week from physical activity and calorie intake/day at year 4 were not included in the data package and could not be verified.

6 Conclusions

The NIDDK repository is confident that the Look AHEAD data files to be distributed are within expected results considering the removal of Native American records.

7 References

1. Wadden TA, Neiberg RH, Wing RR, Clark JM, Delahanty LM, Hill JO, Krakoff J, Otto A, Ryan DH, Vitolins MZ. Four-year weight losses in the Look AHEAD study: factors associated with long-term success. Obesity. 2011; 19: 1987– 1998.

Table A: Variables used to replicate Table 1: <u>Table 1 Baseline characteristics of participants in the ILI and DSE groups</u>

Table Variable	Variables Used in Replication from the "Table 1" Dataset
Treatment Arm	TREATMENTARM
Sex	PSGENDER
Ethnicity	RACEVAR
Use of Insulin	INSULINS
Age (years)	AGE
BMI (kg/m^2)	BMI
Weight(kg)	BASELINEWGT_KG

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

Characteristic	ILI [Manuscript] (N = 2,570)	ILI [DSIC] (N = 2,451)	ILI [Diff] (N = 129)	DSE [Manuscript] (N = 2,575)	DSE [DSIC] (N = 2,455)	DSE [Diff] (N = 120)
Sex (no. of subjects)						
Female	1,526 (59.3)	1,436 (58.9)	-90	1,537 (59.6)	1,438 (58.6)	-89
Male	1,044 (40.7)	1,015 (41.4)	-29	1,038 (40.4)	1,017 (41.4)	-21
Ethnicity						
African American	399 (15.5)	400 (16.3)	1	404 (15.7)	404 (16.5)	0
American Indian/ Alaskan Native	130 (5.1)	N/A	N/A	128 (5.0)	N/A	N/A
Asian/ Pacific Islander	29 (1.1)	N/A	N/A	21 (0.8)	N/A	N/A
Hispanic/Latino	339 (13.2)	338 (13.8)	-1	338 (13.2)	338 (13.8)	0
Non-Hispanic white	1,618 (63.1)	1,621 (66.1)	3	1,628 (63.3)	1,631 (66.4)	3
Other/multiple ethnicity	48 (1.9)	92(3.8)	44	50 (1.9)	82(3.3)	32
Use of insulin	381 (14.8)	362(14.8)	19	408 (15.8)	385(15.7)	23
Age (years)	58.6 ± 6.8	58.7 ± 6.7	.1	58.9 ± 6.9	59.1 ± 6.8	.2
BMI (kg/m2)						
Females	36.3 ± 6.2	36.3 ± 6.2	.0	36.6 ± 6.0	36.6 ± 6.0	.0
Males	35.3 ± 5.7	35.3 ± 5.7	.0	35.1 ± 5.2	35.1 ± 5.2	.0
Weight (kg)						
Females	94.8 ± 17.9	95.1 ± 17.8	.3	95.4 ± 17.3	95.5 ± 17.3	.1
Males	108.9 ± 19.0	109.2 ± 19.1	.3	109.0 ± 18.0	109.2 ± 17.9	.2

Table C: Variables used to replicate Table 2: <u>Table 2 Mean (±s.e.) weight losses in the ILI participants at years 1–4 according to gender, age, race/ethnicity for ILI</u>.

Table Variable	Variables Used in Replication from the "Table 2" Dataset
Weight Loss	BASELINEWGT_KG,WEIGHT_MEAN_KG
Treatment Arm	TREATMENTARM
Sex	PSGENDER
Ethnicity	RACEVAR
Age (years)	AGE_T2
Year 1-4	MONTHS

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

Characteristic	Year 1 [Manuscript]	Year 1 [DSIC]	Year 1 [Diff]	Year 2 [Manuscript]	Year 2 [DSIC]	Year 2 [Diff]
Entire sample	−8.6 ± 0.1	−9.0 ± 0.2	-.4	−6.4 ± 0.2	−6.7 ± 0.2	-.3
Gender						
Male	−9.3 ± 0.2	−10.3 ± 0.3	-1.0	−7.1 ± 0.2	−7.8 ± 0.3	-.7
Female	−8.1 ± 0.2	−8.0 ± 0.2	.1	−5.9 ± 0.2	−5.9 ± 0.2	0
Age						
45–54 years	−7.9 ± 0.3	−8.9 ± 0.3	-1.0	−5.3 ± 0.3	−6.0 ± 0.3	-.7
55–64 years	−8.6 ± 0.2	−8.9 ± 0.2	-.3	−6.4 ± 0.2	−6.8 ± 0.2	-.4
65–74 years	−9.4 ± 0.3	−9.2 ± 0.3	.2	−7.6 ± 0.3	−7.5 ± 0.3	.1
Ethnicity						
Non-Hispanic white	−9.6 ± 0.2	−10.0 ± 0.2	-.4	−7.0 ± 0.2	−7.3 ± 0.2	-.3
Hispanic	−8.0 ± 0.4	−7.2 ± 0.3	.8	−6.0 ± 0.4	−5.4 ± 0.4	.6
African American	−6.8 ± 0.3	−7.0 ± 0.3	-.2	−5.6 ± 0.3	−5.7 ± 0.3	-.1
American Indian/Other	−5.4 ± 0.4	−6.4 ± 0.7	-1.0	−4.1 ± 0.5	−4.7 ± 0.8	-.6

Characteristic	Year 3 [Manuscript]	Year 3 [DSIC]	Year 3 [Diff]	Year 4 [Manuscript]	Year 4 [DSIC]	Year 4 [Diff]
Entire sample	−5.1 ± 0.2	−5.3 ± 0.2	-.2	−4.7 ± 0.2	−5.0 ± 0.2	-.3
Gender						
Male	−5.9 ± 0.2	−6.5 ± 0.3	-.6	−5.2 ± 0.2	−5.8 ± 0.3	-.6
Female	−4.6 ± 0.2	−4.5 ± 0.2	.1	−4.4 ± 0.2	−4.4 ± 0.2	0
Age						
45–54 years	−4.3 ± 0.3	−4.7 ± 0.3	-.4	−3.9 ± 0.3	−4.3 ± 0.4	-.4
55–64 years	−4.9 ± 0.2	−5.3 ± 0.2	-.4	−4.6 ± 0.2	−4.9 ± 0.2	-.3
65–74 years	−6.7 ± 0.3	−6.7 ± 0.4	0	−6.3 ± 0.3	−6.3 ± 0.4	0
Ethnicity						
Non-Hispanic white	−5.5 ± 0.2	−5.8 ± 0.2	-.3	−5.1 ± 0.2	−5.4 ± 0.2	-.3
Hispanic	−5.0 ± 0.5	−4.1 ± 0.6	.9	−4.8 ± 0.5	−4.2 ± 0.4	.6
African American	−4.5 ± 0.4	−4.6 ± 0.4	-.1	−4.1 ± 0.4	−4.1 ± 0.4	0
American Indian/Other	−3.9 ± 0.5	−4.1 ± 0.8	-.2	−3.4 ± 0.6	−3.3 ± 0.7	-.1

```
/*********************************************************************************************************
***Program: /prj/niddk/ims_analysis/Look_AHEAD/prog_initial_analysis/Look_AHEAD_dsic.sas;
***Programmer: Michael Spriggs
***Date Created: 03/13/2014
*** Must be run with the option -V93
*********************************************************************************************************/;

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

options nofmterr;

libname sasdataa '/prj/niddk/ims_analysis/Look_AHEAD/private_orig_data/LookAHEAD/Baseline/Analysis Data Sets';
libname sasdatac '/prj/niddk/ims_analysis/Look_AHEAD/private_orig_data/LookAHEAD/Year4/Analysis Data Sets';

data baseline_combined   ; set sasdataa.baseline_combined;
data year4_combined   ; set sasdatac.year4_combined;

data baseyear;
  merge baseline_combined year4_combined;
  by P_ID;
  delta_kg=weight_mean_kg-BASELINEWGT_KG;

proc freq data=baseline_combined;
  tables (PSGENDER RACEVAR INSULINS)*treatmentarm
         /missing nopercent norow;
  title3 'Integrity Check for Look AHEAD (Action for Health in Diabetes):  Table 1 Baseline characteristics of participants in the ILI and DSE groups';

proc means data=baseline_combined mean stddev;
  var AGE;
  class treatmentarm;
  title3 'Integrity Check for Look AHEAD (Action for Health in Diabetes):  Table 1 Baseline characteristics of participants in the ILI and DSE groups';

proc means data=baseline_combined mean stddev;
  var BMI BASELINEWGT_KG;
  class PSGENDER treatmentarm;
  title3 'Integrity Check for Look AHEAD (Action for Health in Diabetes):  Table 1 Baseline characteristics of participants in the ILI and DSE groups';

%macro table2(months=);
proc means data=baseyear mean stderr;
  var delta_kg;
  where treatmentarm="Weight Loss Intervention" and months=&months;
  title3 'Integrity Check for Look AHEAD (Action for Health in Diabetes):  Table 2 Mean (±s.e.) weight losses in the ILI participants at years 1-4 according
to gender, age, race/ethnicity for ILI.';
  title4 "Months=&months";

proc means data=baseyear mean stderr;
  var delta_kg;
  class PSGENDER;
  where treatmentarm="Weight Loss Intervention" and months=&months;
  title3 'Integrity Check for Look AHEAD (Action for Health in Diabetes):  Table 2 Mean (±s.e.) weight losses in the ILI participants at years 1-4 according
to gender, age, race/ethnicity for ILI.';
  title4 "Months=&months";

proc means data=baseyear mean stderr;
  var delta_kg;
```

```
   class Age_t2;
   where treatmentarm="Weight Loss Intervention" and months=&months;
   title3 'Integrity Check for Look AHEAD (Action for Health in Diabetes):  Table 2 Mean (±s.e.) weight losses in the ILI participants at years 1-4 according
to gender, age, race/ethnicity for ILI.';
   title4 "Months=&months";

proc means data=baseyear mean stderr;
   var delta_kg;
   class racevar;
   where treatmentarm="Weight Loss Intervention" and months=&months;
   title3 'Integrity Check for Look AHEAD (Action for Health in Diabetes):  Table 2 Mean (±s.e.) weight losses in the ILI participants at years 1-4 according
to gender, age, race/ethnicity for ILI.';
   title4 "Months=&months";
%mend;

%table2(months=12);
%table2(months=24);
%table2(months=36);
%table2(months=48);
```