Dataset Integrity Check for Treatment Options for Type 2 Diabetes in Adolescents & Youth Echocardiogram Non-Diabetic, Non-Hypertensive, Obese and Lean Controls (TODAY2 ECHO) Study Data

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Contents

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 TODAY (Treatment Options for Type 2 Diabetes in Adolescents and Youth) study was a multi-center randomized clinical trial (2004-2011). Youth aged 10-17 years diagnosed with type 2 diabetes (T2D) for less than 2 years were enrolled. The trial compared the efficacy of three treatment arms: (1) metformin alone, (2) metformin plus rosiglitazone, and (3) metformin plus an intensive lifestyle intervention. The TODAY trial concluded in February 2011 and was followed by TODAY2 (2011-2020), an observational longitudinal study to continue follow-up of the TODAY cohort to document the progression of diabetes and its complications and related comorbidities.

In the last year of the TODAY2 study, the cohort was assessed by echocardiography. A follow-up echocardiogram was completed 5 years later during the TODAY2 study. During TODAY2, the study also collected comparative echocardiogram control data in individuals without diabetes and hypertension, and also performed a one-time collection of data and blood for storage of serum and plasma in these consented control participants.The purpose of the echocardiogram non-diabetic, non-hypertensive, obese and lean control participants (TODAY2 ECHO) study was to collect control sample data to compare with the outcomes from the TODAY/TODAY2 studies.

3 Archived Datasets

All data files, as provided by the Data Coordinating Center (DCC), are located in the TODAY2 ECHO folder in the data package. For this replication, variables were taken from the “ptdatafinal.sas7bdat” dataset.

4 Statistical Methods

Analyses were performed to replicate results for the data in the publication by the TODAY Study Group [1]. To verify the integrity of the data, descriptive statistics were computed.

5 Results

For Table 2 in the publication [1], Sex-Specific Characteristics at 5-y Follow-Up of Participants and Normal-Weight and Obese Controls, 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 in Table 2. The results of the replication are within expected variation of the published results.

6 Conclusions

The NIDDK Central Repository is confident that the TODAY2 ECHO data files to be distributed are a true copy of the study data.

7 References

[1] TODAY Study Group. Longitudinal Changes in Cardiac Structure and Function From Adolescence to Young Adulthood in Participants With Type 2 Diabetes Mellitus: The TODAY Follow-Up Study. Circulation: Heart Failure, 13(6), e006685, June 2020. doi: https://doi.org/10.1161/CIRCHEARTFAILURE.119.006685

Table A: Variables used to replicate Table 2 – Sex-Specific Characteristics at 5-y Follow-Up of Participants and Normal-Weight and Obese Controls

Table Variable	**dataset.variable**
Sex	ptdatafinal.sex
Race/ethnicity	ptdatafinal.race
Age	ptdatafinal.age
Body mass index	ptdatafinal.bmi
HbA1c	ptdatafinal.hba1c
Systolic blood pressure	ptdatafinal.sbp
Diastolic blood pressure	ptdatafinal.dbp
Smoking	ptdatafinal.smoke

Table B: Comparison of values computed in integrity check to reference article Table 2 Normal-Weight Control values

	Normal-Weight Controls					
	Women Publication	**Women DSIC**	**Diff.**	**Men Publication**	**Men DSIC**	**Diff.**
Sex, n	29	29	0	22	21	1
Race/ethnicity, %						
Non-Hispanic white	55.2	55.2	0	45.5	42.9	2.6
Non-Hispanic black	31.0	31.0	0	40.9	42.9	2.0
Hispanic	13.8	13.8	0	4.6	4.8	0.2
Other	0.0	0.0	0	9.1	9.5	0.4
Age, years	23.3 (3.0)	23.3 (3.0)	0 (0.0)	22.2 (2.9)	22.2 (3.0)	0 (0.1)
Body mass index, kg/m^2	21.5 (1.6)	21.6 (1.6)	0.1 (0.0)	22.8 (1.7)	22.7 (1.6)	0.1 (0.1)
HbA1c, %	5.1 (0.3)	5.1 (0.3)	0 (0.0)	4.8 (0.4)	4.8 (0.4)	0 (0.0)
Blood pressure, mmHg						
Systolic	106.3 (6.9)	106.3 (6.9)	0 (0.0)	113.6 (6.4)	113.5 (6.6)	0.1 (0.2)
Diastolic	68.5 (5.8)	68.5 (5.8)	0 (0.0)	68.8 (6.7)	68.7 (6.9)	0.1 (0.2)
Smoking, %	24.1	24.1	0	54.6	57.1	2.5

Table C: Comparison of values computed in integrity check to reference article Table 2 Obese Control values

	Obese Controls					
	Women Publication	**Women DSIC**	**Diff.**	**Men Publication**	**Men DSIC**	**Diff.**
Sex, n	147	146	1	47	46	1
Race/ethnicity, %						
Non-Hispanic white	21.1	21.2	0.1	23.4	21.7	1.7
Non-Hispanic black	68.7	68.5	0.2	59.6	60.9	1.3
Hispanic	7.5	7.5	0.0	14.9	15.2	0.3
Other	2.7	2.7	0.0	2.1	2.2	0.1
Age, years	24.4 (3.6)	24.5 (3.6)	0.1 (0.0)	24.9 (3.8)	24.8 (3.8)	0.1 (0.0)
Body mass index, kg/m^2	38.1 (7.0)	38.0 (6.9)	0.1 (0.1)	38.5 (7.1)	38.2 (6.9)	0.3 (0.2)
HbA1c, %	5.1 (0.5)	5.1 (0.4)	0 (0.1)	5.2 (0.5)	5.1 (0.5)	0.1 (0.0)
Blood pressure, mmHg						
Systolic	111.2 (9.0)	111.2 (9.1)	0 (0.1)	118.4 (8.1)	118.5 (8.2)	0.1 (0.1)
Diastolic	67.9 (6.2)	67.9 (6.3)	0 (0.1)	69.3 (7.5)	69.0 (7.4)	0.3 (0.1)
Smoking, %	44.2	43.8	0.4	57.5	58.7	1.2

Attachment A: SAS Code

```
libname echo "X:\NIDDK\niddk-dr_studies6\TODAY2-ECHO\private_orig_data\TODAY2 ECHO SAS datasets extracted from xpt files";

proc contents data=echo.echodatafinal;
run;

proc contents data=echo.ptdatafinal;
run;

proc freq data=echo.ptdatafinal;
tables bmi;
run;

*seperating the Obese vs. Lean controls;
data pt; set echo.ptdatafinal;
run;

data lean; set pt;
if bmi < 25;
run;

data obese; set pt;
if bmi > 30;
run;

*N by sex;
proc freq data=lean;
tables sex;
run;

proc freq data=obese;
tables sex;
run;

*race ethniciy by sex;
proc freq data=lean;
tables race*sex/norow nopercent;
run;

proc freq data=obese;
tables race*sex/norow nopercent;
run;

*Age by sex;
proc sort data=lean;
by sex;
run;

proc sort data=obese;
by sex;
run;

proc means data=lean n mean std;
```

```
var age;
by sex;
run;

proc means data=obese n mean std;
var age;
by sex;
run;

*BMI by sex;
proc means data=lean n mean std;
var bmi;
by sex;
run;

proc means data=obese n mean std;
var bmi;
by sex;
run;

*HbA1c by sex;
proc means data=lean n mean std;
var hba1c;
by sex;
run;

proc means data=obese n mean std;
var hba1c;
by sex;
run;

*Systolic BP by sex;
proc means data=lean n mean std;
var sbp;
by sex;
run;

proc means data=obese n mean std;
var sbp;
by sex;
run;

*diastolic BP by sex;
proc means data=lean n mean std;
var dbp;
by sex;
run;

proc means data=obese n mean std;
var dbp;
by sex;
run;
```

```
*Smoking by sex;
proc freq data=lean;
tables smoke*sex/norow nopercent;
run;

proc freq data=obese;
tables smoke*sex/norow nopercent;
run;
```