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Data Integrity Check for the Diabetes Prevention Project (DPP) 2008 Full Scale Release (continued)

As a continued check of the integrity of the 2008 Full Scale Release of the Diabetes Prevention Program (DPP) data archived in the NIDDK data repository, a series of additional tabulations was performed to verify that published results from the DPP study can be reproduced using the archived datasets. Analyses on the following publications have been previously conducted:

> The Diabetes Prevention Program: Baseline characteristics of the randomized cohort (2000) *Diabetes Care* 23:1619-1629
>
> Impact of Intensive Lifestyle and Metformin Therapy on Cardiovascular Disease Risk Factors in the Diabetes Prevention Program (2005) *Diabetes Care* 28:888-894
>
> Role of Insulin Secretion and Sensitivity in the Evolution of Type 2 Diabetes in the Diabetes Prevention Program: Effects of lifestyle intervention and metformin (2005) *Diabetes* 54: 2404-14

Additional analyses were performed to duplicate results published by the DPP Research Group in the following publication:

> Prevention of Type 2 Diabetes with Troglitazone in the Diabetes Prevention Program (2005) *Diabetes* 54:1150-1156

The full text of the selected article can be found in Attachment 1. STATA (v10) code for our data integrity checks is included in Attachment 2.

Sample sizes from our analyses varied from those in the published article. Some discrepancies arose since only study clinic sites whose IRBs approved the distribution of their data to the NIDDK repository are included in the archived data; other discrepancies were related to the omission of dates in the repository data. Dates were removed during de-identification of the data to protect the identity of the DPP participants. Consequently, it was not possible to replicate exactly several of the results presented in the *Diabetes* (2005) article.

<u>The 2008 Full-Scale Data Release: Baseline and Follow-up Data</u>
The DPP Research Group reports results for 3,665 participants in the 2008 Full Scale Data Release who were randomly assigned to one of four treatment arms aimed at preventing type 2 diabetes in high-risk adults: metformin (N=1,027), troglitazone (N=584), intensive lifestyle (N=1,024), or placebo (N=1030). Eligibility criteria for the study included: age 25 years and older, BMI of 24 kg/m^2 or higher (22+ if Asian

American), a fasting plasma glucose (FPG) level of 95-125 mg/dl (<=125 for American Indians), and a 2-hour plasma glucose concentration of 140-199 mg/dl (see 2008 Data Release Documentation for full details). Enrollment began in 1996 and participants were followed through 2001. Follow-up assessments (quarterly, semi-annual, annual, etc) included various physical measurements, medical history updates, questionnaire administration, medication adherence, and medical testing according to a standard protocol.

In de-identifying the data, all personal identifiers including all dates were removed from the DPP archive. Variables that could possibly identify a particular individual were grouped, e.g., race/ethnicity was recoded into 4 groups (Caucasian, African American, Hispanic and Other), age at baseline was recoded in 5-year groupings with truncation of those <40 and 65+, fasting glucose levels less than 100 at baseline appear as 99, and baseline BMI is provided in two alternative groupings (2 kg/m^2 with truncation of those $\leq$ 26 kg/m^2 and those $\geq$ 42 kg/m^2 and tertiles of <30, 30 to <35, and $\geq$ 35 kg/m^2. Only research data are included in the released dataset (screening and post-randomization visits, clinic visits, lifestyle visits, laboratory data). Non-research data and adverse event data are not included.

Data Forms

The NIDDK data repository includes 37 data files – 31 files of data collected on standard forms ('form' files) and 6 files of data not collected on forms ('nonform' files) that include laboratory data, nutrition, quality of well-being, CT-scan, a summary of event variables for diabetes, and a baseline file (treatment assignment, baseline age and BMI group, sex, and race/ethnicity). Several variables are common to all datasets and can be used to link multiple files or to match specific visits across multiple forms. These include RELEASE_ID (unique subject ID), VISIT (baseline, screening, annual visits, interim unscheduled visit, etc), and DAYSRAND (number of days between a visit and randomization). For this verification exercise, data from 7 of the 37 files were accessed.

All form files are named with the prefix DPP_REL and either a S (screening form), F (follow-up form), TR (form for participants randomized to troglitazone), Q (questionnaires), L (lifestyle form), E (events form, e.g. pregnancy), or R (report, e.g. CHD risk status) suffix. One dataset exists for each DPP form and corresponding SAS dataset. Variables and measurement times for all non-form files, eg., LAB, Nutrient Data, CT Scan Data, Quality of Well Being Data, Baseline Data, and Events Data, are provided in the Data Release Documentation (pages 16-26).

The Diabetes Prevention Program Research Group (2005). Prevention of Type 2 Diabetes with Troglitazone in the Diabetes Prevention Program *Diabetes* 54:1150-1156.

This manuscript describes the effects of troglitazone treatment on diabetes incidence before and after the discontinuation of the troglitazone arm from the DPP study on 4 June 1998. Of the 3,665 participants included in the DPP Full Scale Release, this article reports on 2,343 of whom 587 were assigned to the placebo, 587 to metformin, 585 to

troglitazone, and 589 to the intensive lifestyle intervention prior to 4 June 1998. The published article notes that three of four participating Native-American communities declined to include the troglitazone arm and results from all participants in all intervention arms from these centers are excluded from the published data. A copy of the manuscript is included in Attachment 1. STATA programming code for the replication of Table 2 and Figure 1 from the published manuscript is included in Attachment 2.

Baseline randomization to one of the four treatment arms is assessed as of 4 June 1998. Follow-up experience reported in the manuscript is divided into the periods before and after the 4 June 1998 date when troglitazone was discontinued, and data are presented for study participants who were randomized to one of the four treatment groups by this date. It is impossible to replicate exactly the results reported in the published manuscript for several reasons: 1) no dates are provided in the NIDDK repository datasets, so it is not possible to select the exact date of randomization or to select follow-up events before and after the 4 June 1998 date, rather date of randomization is provided in 3-month groupings beginning with July-September 1996 and continuing through May 1999 [DPP.EVENTS, rand_per], 2) adverse events are not included in the NIDDK repository, and 3) baseline body weight was removed during de-identification of the data and is not included in the repository dataset.

Baseline and follow-up values of body size and glucose measurements are shown in Table 2 and Figure 1 of the manuscript. Table 2 of the published manuscript provides the sample N and mean body weight (kg), waist circumference (cm), fasting plasma glucose (mmol/l), and 2-hour plasma glucose (mmol/l) for participants assigned to one of the four treatment groups at baseline and various time periods (up to 1.5 years) following randomization. The mean body size and glucose measurements also are presented in Figure 1.

The variables used from the NIDDK repository to retabulate published Table 2 and Figure 1 are shown below. Body weight was measured twice and repeated a third time only if the first 2 measurements were not within 0.2 kg. Mean body weight was calculated as the average of the first and second measurements if only 2 measurements were taken, and the average of 3 measurements if a third weight measurement was recorded. Similar calculations were performed for waist circumference in which a third measurement was completed if the first 2 measurements were not within 0.5 cm.

NIDDK variables used in replication of Table 2 and Figure 1.

Table2/Figure 1 Variable	**NIDDK variable used in replication**
Treatment assignment	DPP.REL.Basedata, assign
Randomization period	DPP.EVENTS, rand_per
Body weight, 0.5 and 1.5 yr	DPP_REL.F01, qpwght1-3
Body weight, 1 yr	DPP_REL.F02, apwght1-3
Waist circumference, baseline	DPP_REL.S05, siwstc1-3
Waist circumference, 1 yr	DPP_REL.F02, apwstc1-3
FPG	DPP_REL.LAB, g000
2-h plasma glucose	DPP_REL.LAB, g120

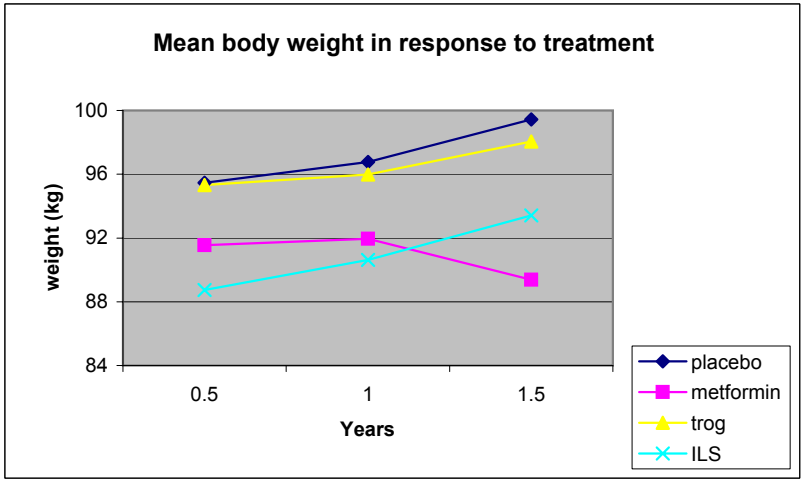
Visit	DPP_REL.F01, F02, S05, Basedata

The number of observations at baseline and follow-up presented in the published table differ from the tabulations using the NIDDK repository data, as do the mean values (**TABLE H**). In general, the number of observations in the recalculations using the repository data exceeds the number of observations in the published table. The published manuscript notes that the "numbers of observations declined with increasing follow-up because of the variable randomization date together with a common closing date for the analysis" (p 1151). To roughly approximate the published randomization date and common closing date, we relied upon the variable rand_per (DPP_REL.EVENTS) as a proxy measure of the date participants entered the trial. This variable groups the date of randomization into 3-month groupings beginning with July-September 1996 and ending with the 2-month group April-May 1999. Selecting participants that were randomized up to (and including) the period April-June 1998 decreased the sample to 2,465 participants (compared to 2,343 in the published article). In addition, the published analyses include follow-up prior to the 4 June 1998 discontinuation of troglitazone. To approximate the common closing date, participants randomized prior to January-March 1998 for the 0.5 year measurements were selected, those randomized prior to July-September 1997 were selected for the 1.0 year assessment, and participants randomized prior to January-March 1997 were included in the 1.5 year measurements.

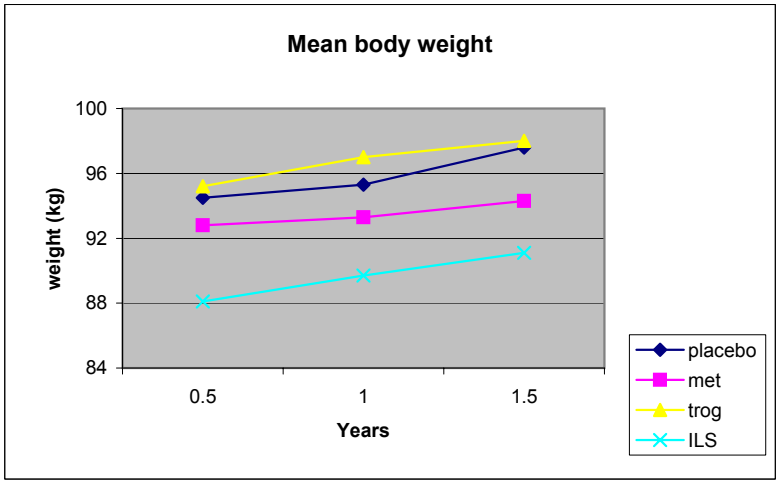
Mean body size and glucose measurements are graphed in Figure 1 of the manuscript and compared to the replicated results in **FIGURE 4**. A few differences are noted. Mean body weight increases across all treatment groups in the published Figure 1, although in the replicated results, mean weight for participants in the metformin assignment declines from year 1 to year 1.5; results for participants assigned to the other treatment groups are similar, but slightly higher in the replicated figure. (As noted previously, baseline body weight measurements were not included in the data repository.) Participants assigned to the placebo in the replicated results show a slight rise in waist circumference from baseline to year 1, unlike the published article. Patterns of FPG are similar in both the published and replicated results, although the mean values at 1.5 years are higher for those assigned to placebo and lifestyle groups in the published results. Mean 2-hr PG levels are similar in the published and replicated results.

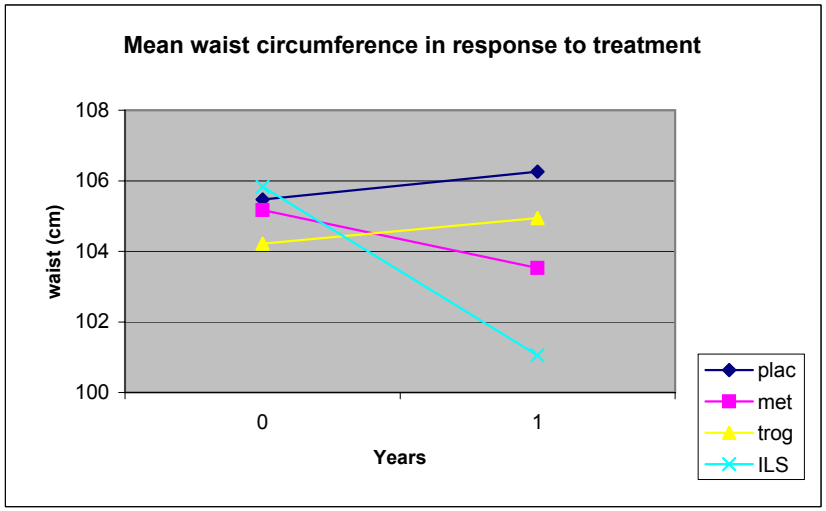
FIGURE 4. Comparison of body weight, waist circumference, and FPG and 2-h postload plasma glucose concentrations as reported in *Diabetes* 54:1152, 2005 and tabulations using 2008 DPP Final Data Release in NIDDK repository

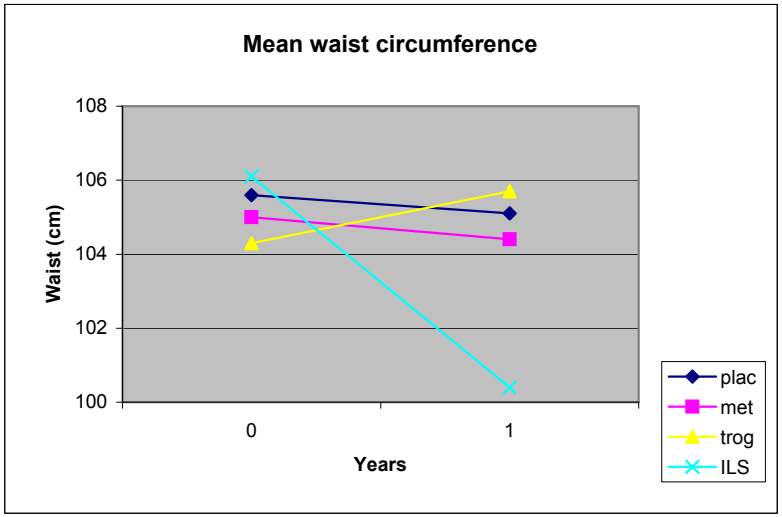
Recalculations using data in NIDDK repository [a]

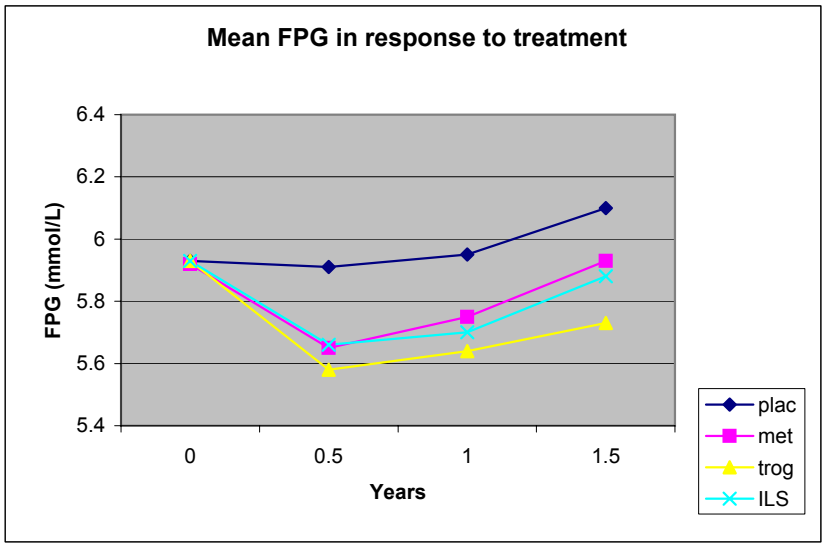


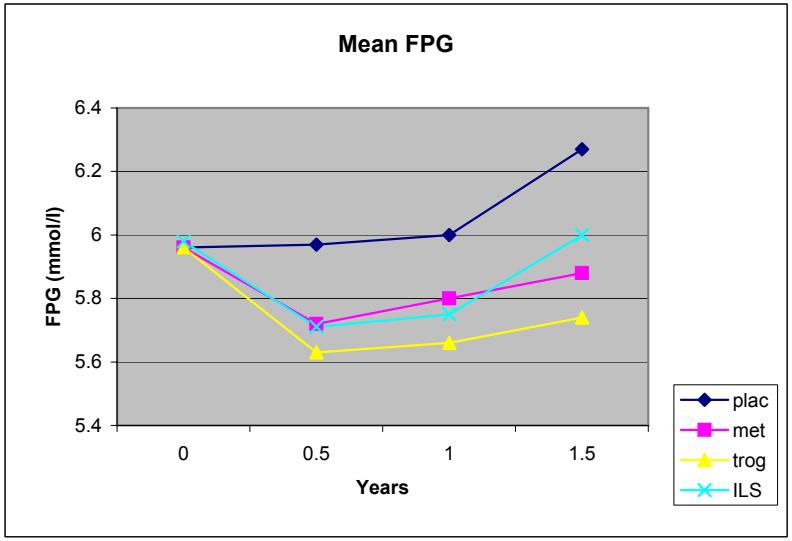
Published figure 1, Type 2 diabetes prevention with troglitazone [b]

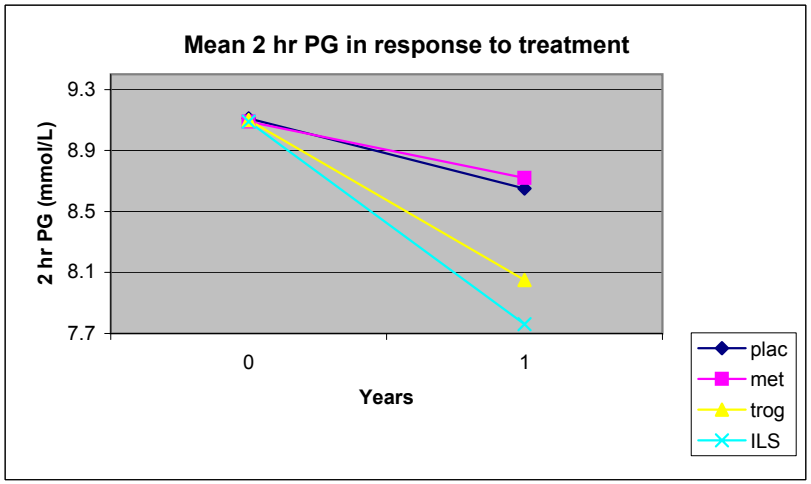


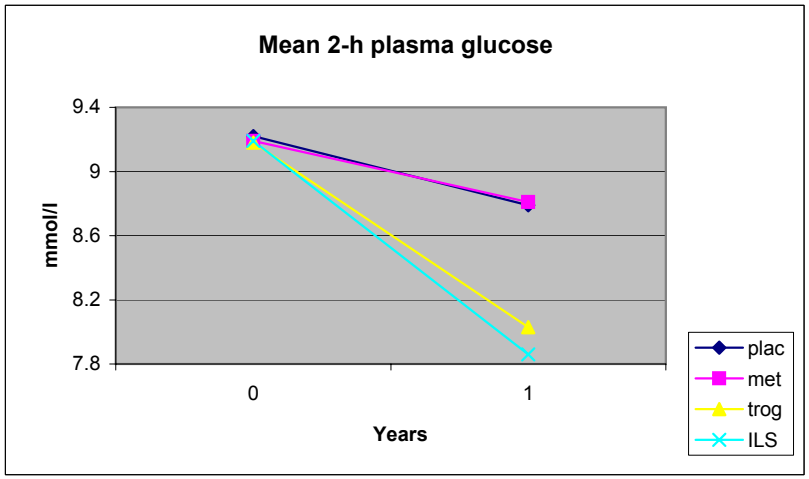












Note; *Data presented in TABLE H.*

[a] Calculated using data from the 2008 DPP Full Scale Data Release in the NIDDK repository [DPP.REL.Basedata, DPP.REL.events, DPP.REL.F02, DPP.REL.F02, DPP.REL.S05, DPP.REL.LAB]

[b] From: The Diabetes Prevention Program Research Group (2005) Prevention of type 2 diabetes with troglitazone in the Diabetes Prevention Program (2005) *Diabetes* 54:1150-1156, Table 2

TABLE H. Comparison of body weight, waist circumference, FPG, and 2-hr postload glucose concentrations as published in *Diabetes* 54:1152, 2005 with tabulations from 2008 DPP Full Scale Data Release in the NIDDK repository

Table 2. Body weight, waist circumference, and FPG and 2-h postload plasma glucose concentrations

Published table (*Diabetes* 54:1150-56 (2005) Table 2) [a]

	Time	Placebo		Metformin		Troglitazone		ILS	
	(years)	*n*	Mean	*n*	Mean	*n*	Mean	*n*	Mean
Variable									
Body weight (kg)	0.0	582	94.6	587	94.5	585	93.3	589	95.5
	0.5	384	94.5	389	92.8	378	95.2	386	88.1
	1.0	182	95.3	172	93.3	196	97	191	89.7
	1.5	58	97.6	59	94.3	72	98	53	91.1
Waist circumference (cm)	0.0	582	105.6	586	105	585	104.3	588	106.1
	1.0	180	105.1	172	104.4	197	105.7	191	100.4
FPG (mmol/l)	0.0	582	5.96	587	5.96	585	5.96	589	5.98
	0.5	388	5.97	394	5.72	383	5.63	388	5.71
	1.0	182	6	172	5.8	197	5.66	190	5.75
	1.5	58	6.27	61	5.88	72	5.74	54	6
2-h plasma glucose (mmol/l)	0.0	582	9.22	587	9.19	585	9.18	589	9.19
	1.0	174	8.79	172	8.81	196	8.03	188	7.86

Recalculations from NIDDK Data Repository [b]

	Time	*Placebo*		*Metformin*		*Troglitazone*		*ILS*	
	(years)	*n*	*Mean*	*n*	*Mean*	*n*	*Mean*	*n*	*Mean*
Variable									
Body weight (kg)	*0.0*	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*
	0.5	*409*	*95.47*	*419*	*91.55*	*410*	*95.33*	*415*	*88.73*
	1.0	*211*	*96.76*	*200*	*91.94*	*218*	*95.99*	*217*	*90.63*
	1.5	*75*	*99.44*	*69*	*89.38*	*93*	*98.06*	*73*	*93.42*
Waist circumference (cm)	*0.0*	*636*	*105.47*	*614*	*105.17*	*584*	*104.22*	*629*	*105.83*
	1.0	*209*	*106.26*	*200*	*103.53*	*218*	*104.94*	*215*	*101.05*
FPG (mmol/l)	*0.0*	*636*	*5.93*	*615*	*5.92*	*584*	*5.93*	*630*	*5.93*
	0.5	*414*	*5.91*	*424*	*5.65*	*415*	*5.58*	*417*	*5.66*
	1.0	*210*	*5.95*	*200*	*5.75*	*220*	*5.64*	*216*	*5.7*
	1.5	*75*	*6.1*	*70*	*5.93*	*93*	*5.73*	*71*	*5.88*
2-h plasma glucose (mmol/l)	*0.0*	*636*	*9.11*	*615*	*9.09*	*584*	*9.1*	*630*	*9.09*
	1.0	*199*	*8.65*	*199*	*8.72*	*217*	*8.05*	*214*	*7.76*

Notes:
n/a Baseline body weight measurements are not included in data repository.

[a] From: The Diabetes Prevention Program Research Group (2005) Prevention of type 2 diabetes with troglitazone in the Diabetes Prevention Program (2005) *Diabetes* 54:1150-1156, Table 2. Tabulations based on 2,363 participants who were randomized to one of four treatment groups prior to 4 June 1998.

[b] Tabulations based on 2,465 participants in the NIDDK repository who were randomized prior to June 1998 using DPP_REL.F01, DPP_REL.F02, DPP_REL.lab, DPP_REL.S03, DPP_REL.S05, DPP_REL.baseline, and DPP_REL.events. Sample Ns from published table and recalculations from repository data do not match since: 1) published baseline data exclude subjects who were randomized after 4 June 1998; repository data do not include dates, so this number is estimated from the variable *rand_per* [Basedata.REL] and selects randomization prior to the period May-June 1998, 2) published follow-up data exclude subjects who were not followed-up prior to 4 June 1998; this date is estimated from the variable *rand_per* and the time of follow-up.

ATTACHMENT 1

The full text of the article referenced will be provided to approved data requestors along with the archived data.

The Diabetes Prevention Program Research Group (2005) Prevention of Type 2 Diabetes with Troglitazone in the Diabetes Prevention Program. *Diabetes* 54:1150-1156

ATTACHMENT 2

STATA/SE10 Code for Tabulations of Prevention of Type 2 Diabetes with Troglitazone from the DPP Dataset in the NIDDK Repository

[*Diabetes* 54: 1150-1156, 2005; Table 2, Figure 1]

```
-------------------------------------------------------------------------------
**merge events and basedata, add F02 body wt & waist circum and lab FPG & 2h PG
*********select R randomized prior to June 1998*************

**create FPG and 2h PG variables for 6mo intervals, baseline to year 1.5,TABLE 2
use "C:\DPP\Data\Non-Form Data\base-lab.dta", clear
keep if visit=="BAS"
tab g000 if visit=="BAS"
gen g000_b=g000 if visit=="BAS"
label var g000_b "FPG baseline"
tab g000_b

tab g120 if visit=="BAS"
gen g120_b=g120 if visit=="BAS"
label var g120_b "2h PG baseline"
tab g120_b

list release_id g000_b g120_b in 1/10
keep release_id g000_b g120_b daysrand assign sex agegroup race_eth
save c:\DPP\analyses\Diab2005\labpg_b.dta

use "C:\DPP\Data\Non-Form Data\base-lab.dta", clear
keep if visit=="M06"
tab g000 if visit=="M06"
gen g000_6=g000 if visit=="M06"
label var g000_6 "FPG @ 6 mos"
tab g000_6

list release_id g000_6 in 1/5
keep release_id g000_6
save c:\DPP\analyses\Diab2005\labpg_6.dta


use "C:\DPP\Data\Non-Form Data\base-lab.dta", clear
keep if visit=="Y01"
tab g000 if visit=="Y01"
gen g000_12=g000 if visit=="Y01"
label var g000_12 "FPG @ 1 yr"
tab g000_12
tab g120 if visit=="Y01"
gen g120_12=g120 if visit=="Y01"
label var g120_12 "2h PG @ 1 yr"
tab g120_12

list release_id g000_12 g120_12 in 1/5
keep release_id g000_12 g120_12
save c:\DPP\analyses\Diab2005\labpg_12.dta


use "C:\DPP\Data\Non-Form Data\base-lab.dta", clear
keep if visit=="M18"
tab g000 if visit=="M18"
gen g000_18=g000 if visit=="M18"
label var g000_18 "FPG @ 18 mos"
tab g000_18

list release_id g000_18 in 1/10
```

```
keep release_id g000_18
save c:\DPP\analyses\Diab2005\labpg_18.dta

*sort and merge labpg files to labpg_M.dta
*merge with c:\DPP\Data\Non-Form Data\events.dta _merge4
save c:\DPP\analyses\Diab2005\labpg_ev.dta

*********add BW and waist circum data for Y01 from F02; midyr from F01
use C:\DPP\Data\Form Data\f02.dta, clear
keep if visit=="Y01"
gen BW1_12=apwght1 if visit=="Y01"
label var BW1_12 "1st BW Yr 1"
gen BW2_12=apwght2 if visit=="Y01"
label var BW2_12 "2nd BW Yr 1"
gen BW3_12=apwght3 if visit=="Y01"
label var BW3_12 "3rd BW Yr 1"
replace BW3_12=0 if apwght3==.
gen avBW_12=(BW1_12+BW2_12)/2 if BW3_12==0
replace avBW_12=(BW1_12+BW2_12+BW3_12)/3 if BW3_12 >0
label var avBW_12 "av BW Yr 1"
list release_id apwght1 BW1_12 apwght2 BW2_12 apwght3 BW3_12 avBW_12 in 1/6


gen WC1_12=apwstc1 if visit=="Y01"
label var WC1_12 "1st waist yr 1"
gen WC2_12=apwstc2 if visit=="Y01"
label var WC2_12 "2nd wasit yr 1"
gen WC3_12=apwstc3 if visit=="Y01"
replace WC3_12=0 if apwstc3==.
gen avWC_12=(WC1_12+WC2_12)/2 if WC3_12==0
replace avWC_12=(WC1_12+WC2_12+WC3_12)/3 if WC3_12 >0
label var avWC_12 "av waist circum Yr 1"
list release_id apwstc1 WC1_12 apwstc2 WC2_12 apwstc3 WC3_12 avWC_12 in 1/5

keep release_id apwght1 apwght2 apwght3 apwstc1 apwstc2 apwstc3 BW1_12 BW2_12
BW3_12 avBW_12 WC1_12 WC2_12 WC3_12 avWC_12
save c:\DPP\analyses\Diab2005\wwgt_12.dta


use "C:\DPP\Data\Form Data\s05.dta", clear
*visit=="RUN"
*tabulate baseline waist circumference; baseline weight not included in
repository
summarize siwstc1 siwstc2 siwstc3
gen newvar=siwstc3
replace newvar=0 if siwstc3==.
list release_id siwstc1 siwstc2 siwstc3 newvar in 451/458
gen avwstc_b=(siwstc1+siwstc2)/2 if newvar==0
replace avwstc_b=(siwstc1+siwstc2+newvar)/3 if newvar >0
list release_id siwstc1 siwstc2 siwstc3 newvar avwstc_b in 451/458
label var avwstc_b "av waist circum baseline"

keep release_id siwstc1 siwstc2 siwstc3 newvar avwstc_b
save c:\DPP\analyses\Diab2005\wst_base.dta


*tabulate body weight at midyear, 6 and 18 mos
```

```
set memory 20m
use "C:\DPP\Data\Form Data\f01.dta"
keep if visit=="M06"
summarize qpwght1 qpwght2 qpwght3 if visit=="M06"
gen BW1_6=qpwght1 if visit=="M06"
label var BW1_6 "weight 1 @ 6 mo"
gen BW2_6=qpwght2 if visit=="M06"
label var BW2_6 "weight 2 @ 6 mo"
gen BW3_6=qpwght3 if visit=="M06"
label var BW3_6 "BW 3 @ 6 mo"
replace BW3_6=0 if qpwght3==.
gen avBW_6=(BW1_6+BW2_6)/2 if BW3_6==0
replace avBW_6=(BW1_6+BW2_6+BW3_6)/3 if BW3_6 >0
label var avBW_6 "av BW 6 mos"
list release_id visit qpwght1 BW1_6 qpwght2 BW2_6 qpwght3 BW3_6 avBW_6 in 1/6
keep release_id visit qpwght1 BW1_6 qpwght2 BW2_6 qpwght3 BW3_6 avBW_6
save c:\DPP\analyses\Diab2005\wgt6.dta

use "C:\DPP\Data\Form Data\f01.dta"
keep if visit=="M18"
summarize qpwght1 qpwght2 qpwght3 if visit=="M18"
gen BW1_18=qpwght1 if visit=="M18"
label var BW1_18 "weight 1 @ 18 mo"
gen BW2_18=qpwght2 if visit=="M18"
label var BW2_18 "weight 2 @ 18 mo"
gen BW3_18=qpwght3 if visit=="M18"
label var BW3_18 "BW 3 @ 18 mo"
replace BW3_18=0 if qpwght3==.
gen avBW_18=(BW1_18+BW2_18)/2 if BW3_18==0
replace avBW_18=(BW1_18+BW2_18+BW3_18)/3 if BW3_18 >0
label var avBW_18 "av BW 18 mos"
list release_id visit qpwght1 BW1_18 qpwght2 BW2_18 qpwght3 BW3_18 avBW_18 in
308/315

keep release_id visit qpwght1 BW1_18 qpwght2 BW2_18 qpwght3 BW3_18 avBW_18
save c:\DPP\analyses\Diab2005\wgt18.dta
```

```
      log:  C:\DPP\analyses\Diab2005\table2.log
  log type:  text
 opened on:  12 May 2008, 16:40:48

. ***get table2.dta
. tab rand_per

randomizati |
  on period |      Freq.     Percent        Cum.
------------+-----------------------------------
          1 |         62        1.69        1.69
          2 |        283        7.72        9.41
          3 |        236        6.44       15.85
          4 |        329        8.98       24.83
          5 |        411       11.21       36.04
          6 |        432       11.79       47.83
          7 |        354        9.66       57.49
          8 |        358        9.77       67.26
          9 |        420       11.46       78.72
         10 |        391       10.67       89.39
```

```
         11 |        277        7.56       96.94
         12 |        112        3.06      100.00
------------+-----------------------------------
      Total |      3,665      100.00

. gen rand_date=rand_per

. *if rand_per prior to/include April-June 1998
. replace rand_date=1 if rand_per <=8
(2403 real changes made)

. replace rand_date=2 if rand_per >8
(1200 real changes made)

. label var rand_date "random prior/after June 1998"

. tab rand_date

     random |
prior/after |
  June 1998 |      Freq.     Percent        Cum.
------------+-----------------------------------
          1 |      2,465       67.26       67.26
          2 |      1,200       32.74      100.00
------------+-----------------------------------
      Total |      3,665      100.00

.
. keep if rand_date==1
(1200 observations deleted)

. tab assign if rand_per==7

   treatment |
  assignment |      Freq.     Percent        Cum.
-------------+-----------------------------------
   Lifestyle |         90       25.42       25.42
   Metformin |         84       23.73       49.15
     Placebo |         92       25.99       75.14
Troglitazone |         88       24.86      100.00
-------------+-----------------------------------
       Total |        354      100.00

. tab assign if rand_per==8

   treatment |
  assignment |      Freq.     Percent        Cum.
-------------+-----------------------------------
   Lifestyle |        109       30.45       30.45
   Metformin |         82       22.91       53.35
     Placebo |        107       29.89       83.24
Troglitazone |         60       16.76      100.00
-------------+-----------------------------------
       Total |        358      100.00

.
end of do-file

.. *BW at baseline not provided in repository
. *av BW if randomized by May-June 1998 and f/u by June 1998
. sort assign
```

```
. by assign:summarize avBW_6 if rand_per <=6

-------------------------------------------------------------------------------------------
-> assign = Lifestyle

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      avBW_6 |       415    88.73153    21.27207       46.5     179.05

-------------------------------------------------------------------------------------------
-> assign = Metformin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      avBW_6 |       419    91.55318    19.35651       50.5      185.9

-------------------------------------------------------------------------------------------
-> assign = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      avBW_6 |       409    95.47262     20.8048      52.55      198.4

-------------------------------------------------------------------------------------------
-> assign = Troglitazone

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      avBW_6 |       410    95.32602    20.07191       58.3      180.7


. by assign:summarize avBW_12 if rand_per <=4

-------------------------------------------------------------------------------------------
-> assign = Lifestyle

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     avBW_12 |       217    90.63717    23.07432        52      176.4

-------------------------------------------------------------------------------------------
-> assign = Metformin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     avBW_12 |       200    91.94367    18.97984       55.7      168.7

-------------------------------------------------------------------------------------------
-> assign = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     avBW_12 |       211    96.76303    19.38868       60.4      169.8

-------------------------------------------------------------------------------------------
-> assign = Troglitazone

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     avBW_12 |       218    95.99083    19.67711       58.8      164.3
```

```
. by assign:summarize avBW_18 if rand_per <=2

-------------------------------------------------------------------------------------------
-> assign = Lifestyle

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     avBW_18 |        73    93.41918    26.09292       53.5        179

-------------------------------------------------------------------------------------------
-> assign = Metformin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     avBW_18 |        69    89.37826     20.2033      58.35      178.2

-------------------------------------------------------------------------------------------
-> assign = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     avBW_18 |        75    99.44244    20.68471       65.5      172.5

-------------------------------------------------------------------------------------------
-> assign = Troglitazone

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     avBW_18 |        93    98.06201     20.7172       65.4      158.7


.
. by assign:summarize avwstc_b

-------------------------------------------------------------------------------------------
-> assign = Lifestyle

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
    avwstc_b |       629    105.8303    15.42155   74.23333        168

-------------------------------------------------------------------------------------------
-> assign = Metformin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
    avwstc_b |       614    105.1684    13.92189   73.53333        152

-------------------------------------------------------------------------------------------
-> assign = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
    avwstc_b |       636    105.4747    13.79239       75.6        160

-------------------------------------------------------------------------------------------
-> assign = Troglitazone

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
    avwstc_b |       584    104.2217    13.91041        44   150.1333
```

```
. by assign:summarize avWC_12 if rand_per <=4

-------------------------------------------------------------------------------------------
-> assign = Lifestyle

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     avWC_12 |       215     101.054    17.26031       67.5      165.1

-------------------------------------------------------------------------------------------
-> assign = Metformin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     avWC_12 |       200     103.532    13.84202       76.1        150

-------------------------------------------------------------------------------------------
-> assign = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     avWC_12 |       209    106.2568    13.42191      75.75      149.9

-------------------------------------------------------------------------------------------
-> assign = Troglitazone

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     avWC_12 |       218     104.942    14.42074         71      146.7


.
end of do-file

. summarize g000_b

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      g000_b |      2465    107.7363    7.939212         99        139

. gen FPG_b=g000_b*.055

. summarize FPG_b

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
       FPG_b |      2465    5.925497    .4366566      5.445      7.645

. summarize g000_6

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      g000_6 |      2334    102.9692     11.2648         73        208

. gen FPG_6=g000_6*.055
(131 missing values generated)

. summarize FPG_6 if rand_per <=6

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
       FPG_6 |      1670    5.698889    .6259147      4.015      11.44
```

```
. summarize g000_12

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     g000_12 |      2287    103.4202    13.46823         73        286

. gen FPG_12=g000_12*.055
(178 missing values generated)

. summarize FPG_12 if rand_per <=4

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      FPG_12 |       846    5.758422    .8060968       4.07     14.355

. summarize g000_18

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     g000_18 |      2222    106.6179    12.89756         59        284

. gen FPG_18=g000_18*.055
(243 missing values generated)

. summarize FPG_18 if rand_per <=2

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      FPG_18 |       309    5.900129    .7893837      4.235      11.55

. by assign:summarize FPG_b

-------------------------------------------------------------------------------------------
-> assign = Lifestyle

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
       FPG_b |       630    5.927429    .4272967      5.445      7.645

-------------------------------------------------------------------------------------------
-> assign = Metformin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
       FPG_b |       615     5.91648    .4436937      5.445       7.59

-------------------------------------------------------------------------------------------
-> assign = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
       FPG_b |       636    5.930228    .4486889      5.445      7.645

-------------------------------------------------------------------------------------------
-> assign = Troglitazone

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
       FPG_b |       584    5.927757    .4267647      5.445      7.645


. by assign:summarize FPG_6 if rand_per <=6
```

```
-------------------------------------------------------------------------------------------
-> assign = Lifestyle

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
       FPG_6 |       417    5.657482    .5804089      4.125      9.955

-------------------------------------------------------------------------------------------
-> assign = Metformin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
       FPG_6 |       424    5.650601    .6073886      4.015      11.44

-------------------------------------------------------------------------------------------
-> assign = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
       FPG_6 |       414    5.905857    .7076504        4.4       9.24

-------------------------------------------------------------------------------------------
-> assign = Troglitazone

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
       FPG_6 |       415    5.583361    .5514041       4.29      8.305


. by assign:summarize FPG_12 if rand_per <=4

-------------------------------------------------------------------------------------------
-> assign = Lifestyle

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      FPG_12 |       216    5.704468    .8159178      4.235      12.21

-------------------------------------------------------------------------------------------
-> assign = Metformin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      FPG_12 |       200      5.7475    .8793779       4.07     14.355

-------------------------------------------------------------------------------------------
-> assign = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      FPG_12 |       210    5.954405    .9056029      4.455       12.1

-------------------------------------------------------------------------------------------
-> assign = Troglitazone

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      FPG_12 |       220     5.63425    .5594402        4.4      7.975


. by assign:summarize FPG_18 if rand_per <=2

-------------------------------------------------------------------------------------------
```

```
-> assign = Lifestyle

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      FPG_18 |        71    5.882676    .8686039      4.235      10.67

-------------------------------------------------------------------------------------------
-> assign = Metformin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      FPG_18 |        70    5.932143    .7608522       4.51      7.975

-------------------------------------------------------------------------------------------
-> assign = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      FPG_18 |        75    6.095467    .8989973       4.84      11.55

-------------------------------------------------------------------------------------------
-> assign = Troglitazone

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      FPG_18 |        93    5.731828    .6058608       4.62      7.315


.
. summarize g120_b

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      g120_b |      2465    165.4166    17.28088        140        199

. gen PG2h_b=g120_b*.055

. summarize PG2h_b

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      PG2h_b |      2465    9.097915    .9504482        7.7     10.945

. summarize g120_12

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     g120_12 |      2247    149.2025    39.62449         55        473

. gen PG2h_12=g120_12*.055
(218 missing values generated)

. summarize PG2h_12

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     PG2h_12 |      2247    8.206137    2.179347      3.025     26.015

. by assign: summarize PG2h_b

-------------------------------------------------------------------------------------------
-> assign = Lifestyle
```

```
    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      PG2h_b |       630    9.085913    .9401939        7.7     10.945

-------------------------------------------------------------------------------
-> assign = Metformin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      PG2h_b |       615    9.093959    .9629693        7.7     10.945

-------------------------------------------------------------------------------
-> assign = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      PG2h_b |       636    9.112445    .9577206        7.7     10.945

-------------------------------------------------------------------------------
-> assign = Troglitazone

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      PG2h_b |       584    9.099204    .9424259        7.7     10.945


. by assign: summarize PG2h_12 if rand_per <=4

-------------------------------------------------------------------------------
-> assign = Lifestyle

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     PG2h_12 |       214    7.764509    2.243729      3.135     16.775

-------------------------------------------------------------------------------
-> assign = Metformin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     PG2h_12 |       199    8.720955    2.096907       3.96     14.465

-------------------------------------------------------------------------------
-> assign = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     PG2h_12 |       199    8.654347    2.214568      3.355     20.185

-------------------------------------------------------------------------------
-> assign = Troglitazone

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
     PG2h_12 |       217    8.047995    2.177657      3.905     17.325


. log close
      log:  C:\DPP\analyses\Diab2005\table2.log
  log type:  text
 closed on:  12 May 2008, 16:46:49
-------------------------------------------------------------------------------
```