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June 4, 2008

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

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 tabulations was performed to verify that published results from the DPP study can be reproduced using the archived datasets. Analyses of 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
>
> Prevention of Type 2 Diabetes with Troglitazone in the Diabetes Prevention Program (2005) *Diabetes* 54:1150-1156

An additional analysis was performed to attempt to replicate results published by the DPP Research Group in the following publication:

> Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin (2002) *NEJM* 346(6):393-403

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.

Our replicated analyses produced similar results to the published tabulations, however our analyses of glycemic changes indicated higher mean values in year 4 compared to the published results. 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 may have arisen since the closing date for the published article was March 31, 2001, whereas the repository includes data collected on or before July 31, 2001. Finally, it is possible that smaller sample sizes across time may make comparisons between published results and tabulations from the repository data more likely in the latter time periods.

The 2008 Full-Scale Data Release: Baseline and Follow-up Data

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 4 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 (2002) Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin *NEJM* 346(6):393-403.

The purpose of this manuscript was to compare the effectiveness of a lifestyle intervention and treatment with metformin in the prevention and/or delay of onset of type 2 diabetes in a population of adults at high risk for diabetes. A full copy of the manuscript is included in Attachment 1 and the STATA code for replication of Figure 1C and Figure 3 is shown in Attachment 2.

Figure 1C plots the percent of subjects classified as adhering to their prescribed medication protocol in the metformin and placebo groups. Medication adherence is defined as the proportion of participants who took at least 80 percent of the prescribed dose of the study medication. Variables used to compute medication adherence across the 4-year period are shown below.

NIDDK variables used in replication of Figure 1C

Figure 1 variable	**NIDDK variable used in replication**
Treatment assignment	DPP_REL.Basedata, assign
Medication adherence (annual visits)	DPP_REL.F01, amcompm, amtakm
Visit (Y01-Y03)	DPP_REL.F01, visit
Medication adherence (interim visits)	DPP_REL.F02, qmcompm, qmtakm
Visit (M03-M45)	DPP_REL.F02, visit

Tabulated results of medication adherence using data from the NIDDK repository are shown in **Figure 5.** Participants who were recorded as taking any coded medication since the last visit (amtakm, qmtakm) had their level of exposure assessed as <80% or ≥ 80% (or did not return the pill container; amcompm, qmcompm). Apparent 'divergences' between the published results and plotted data from the NIDDK archive occur at time points after year 3 – months 39, 42, 45, and 48. Our tabulated results indicate a steady decline in medication adherence from months 39 to 48 in the placebo group, whereas in the metformin group, adherence declines between months 39 and 42, increases in month 45 (to a level higher than that of the placebo group), followed by a decline to a level similar to that of the placebo group in month 48. This slightly contrasts with the published Figure 1C in which the metformin condition shows a leveling off in compliance (at approximately 66-67%) from year 3 to year 4, wheras the placebo group remains around 72-73% after a peak to near 75% in month 39. Overall compliance in the published figure fluctuates within a range of 72 to 80 percent in the placebo group and within the range of 67 to 74 percent in the metformin group. In our replicated results (Figure 5), compliance ranges from 65 to 80 percent in the placebo group and from 63 to 74 percent in the metformin group. Sample Ns and percentages for our adherence tabulations by treatment group over time are shown in **Table I.**

Tabulations of mean fasting plasma glucose concentrations and glycosylated hemoglobin values by treatment group as shown in Figure 3 of the published article are replicated in

Figure 6. The variables used to replicate these analyses are shown below. Mean fasting plasma glucose concentrations and mean glycosylated hemoglobin (percentages) over time by treatment using data from the 2008 repository data were plotted in Figure 6.

NIDDK variables used in replication of Figure 3

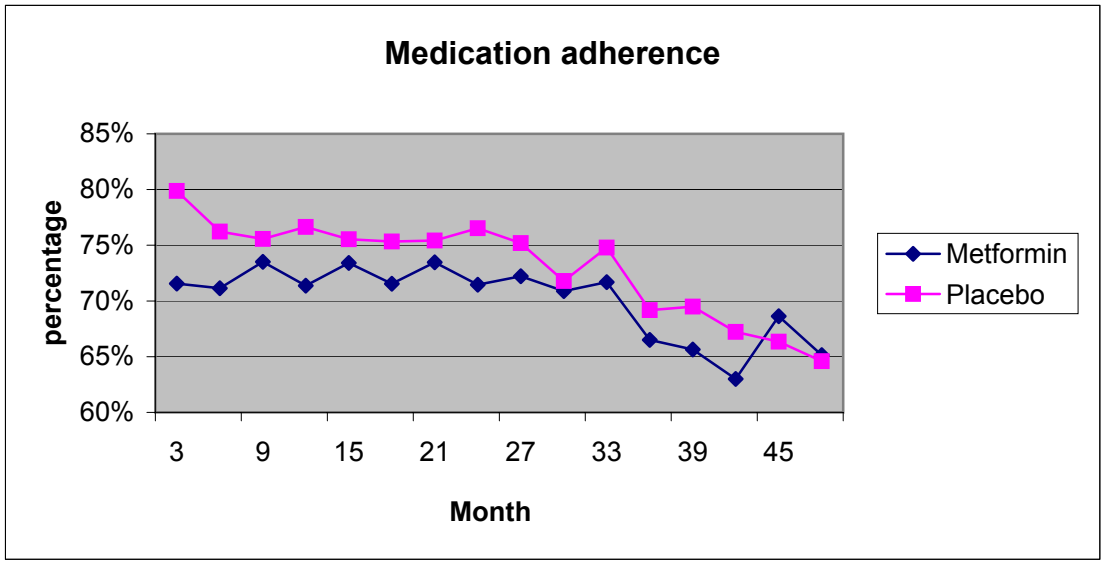
Figure 1 variable	**NIDDK variable used in replication**
Treatment assignment	DPP_REL.Basedata, assign
Fasting plasma glucose	DPP_REL.LAB, g000
Glycosylated hemoglobin	DPP_REL.LAB, hba1
Visit	DPP_REL.Basedata, visit

A comparison of Figure 6 with Figure 3, Panel A in the published manuscript indicates that our tabulated results are similar to the plots published in 2002 with some discrepancy arising from tabulation of the year 4 estimates. Whereas all three groups begin with near equivalent FPG values, the levels are consistently higher in the placebo group following randomization, with increases occurring after year 1 in all three treatment groups. Unlike the published figure, however, our tabulations indicate higher mean values in year 4, for all 3 treatments, exceeding 115 mg/dl in the placebo group and 110 mg/dl in both the metformin and lifestyle groups.

Similar to the published Figure 3, Panel B, our tabulations indicate a reduction in values for glycosylated hemoglobin (mean percentages) for the metformin and lifestyle groups in year 1, while the placebo group experienced a slight increase. Values rose in parallel in all three groups after year 1 with consistently higher mean values among the placebo group. Unlike the published results, however, mean values in our replicated analyses were a bit higher in year 4 than in the published Figure 3, approaching 6.3 for the placebo (approximately 6.1 in Figure 3) and 6.1 for the metformin and lifestyle groups (< 6.0 in Figure 3). Similar to fasting plasma glucose levels shown in Panel A, glycosylated hemoglobin values in the published figure actually decline for the metformin and lifestyle groups between years 3 and 4.

While our calculations of glycemic changes and medication adherence using the repository data resemble results published in the 2002 article, some discrepancies arose, particularly in measurements for the later time periods. Small discrepancies may be expected given that some cases that were included in the published data were omitted from the repository data during de-identification and due to differences in the period of observation (the archive includes cases through 31 July, 1999 whereas the publication included data through 31 May, 1999). It is also possible that the smaller sample Ns available at the later months may make discrepancies between the datasets more likely in these time periods.

Figure 5. Tabulation of changes in adherence to medication regimen according to study group calculated from the 2008 DPP Full Scale Data Release in the NIDDK repository



Notes: Calculated from 2008 DPP Full Scale Data Release, DPP_REL.Basedata, DPP_REL.F01, DPP_REL.F02. Original figure published in: Diabetes Prevention Program Research Group (2002) Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *NEJM* 34696):393-403, Figure 1C.

Each point represents the mean value for all participants examined at that time. The number of participants decreased over time because of the variable length of time that persons were in the study. Medication adherence is defined as the proportion of participants who took at least 80 percent of the prescribed dose of the study medication.

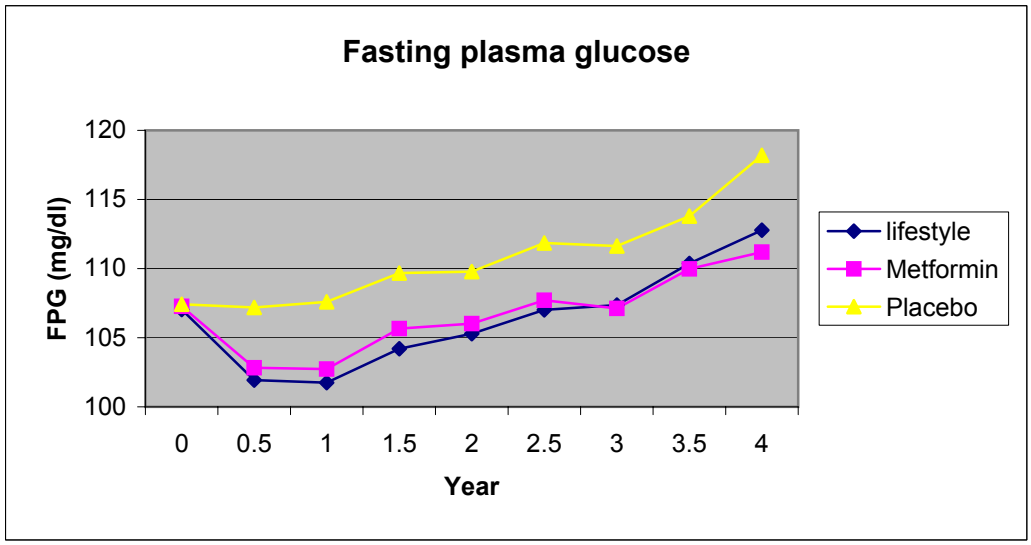
TABLE I. Tabulation of medication adherence by treatment group as reported in *NEJM* 346(6):396, 2002 with data from the 2008 DPP Full Scale Data Release in the NIDDK repository

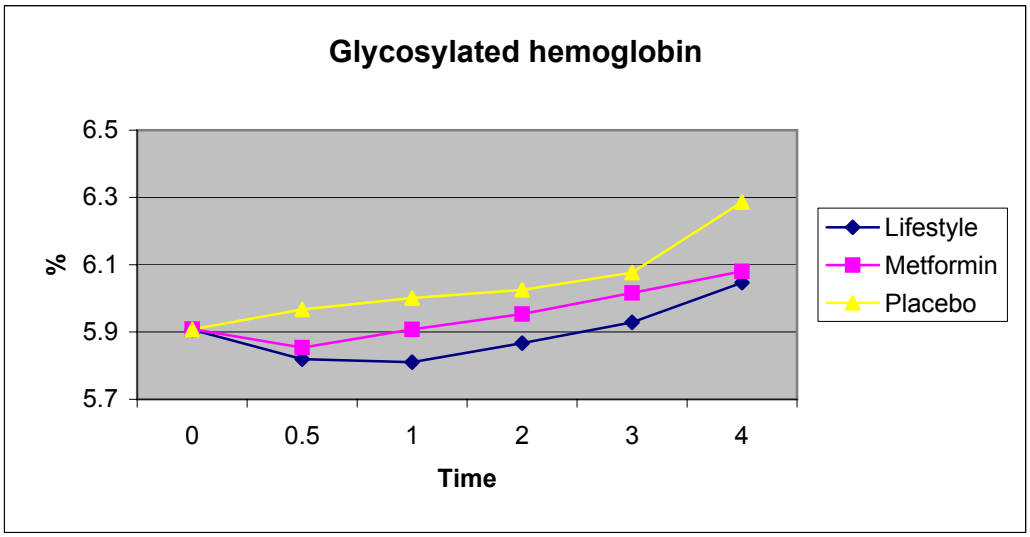
Tabulations for Figure 5. Adherence to medication regimen according to study group

Time (mos)	Metformin	Placebo
3	71.56%	79.88%
6	71.14%	76.23%
9	73.51%	75.57%
12	71.37%	76.64%
15	73.41%	75.54%
18	71.55%	75.34%
21	73.47%	75.43%
24	71.46%	76.53%
27	72.22%	75.19%
30	70.88%	71.79%
33	71.69%	74.79%
36	66.50%	69.18%
39	65.64%	69.48%
42	63.00%	67.22%
45	68.63%	66.35%
48	65.14%	64.60%

Notes: Calculated from 2008 DPP Full Scale Data Release, DPP_REL.Basedata, DPP.REL.F01, DPP.REL.F02.
The published article does not provide the raw data values for the sample Ns and means for Figure 1C.

Figure 6. Tabulation of fasting plasma glucose and glycosylated hemoglobin according to study group calculated from the 2008 DPP Full Scale Data Release in the NIDDK repository





Notes: Calculated from 2008 DPP Full Scale Data Release, DPP_REL.Basedata, DPP_REL.LAB. Original figure published in: Diabetes Prevention Program Research Group (2002) Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *NEJM* 34696):393-403, Figure 3. Each point represents the mean value for all participants examined at that time. The analysis included participants whether or not diabetes had been diagnosed. The number of participants decreased over time because of the variable length of time that persons were in the study.

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 (2002) Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin *NEJM* 346(6):393-403

ATTACHMENT 2

STATA/SE10 Code for Tabulations of reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin *NEJM* 346(6):393-403

```
------------------------------------------------------------------------------
      log:  C:\DPP\analyses\NEJM2002\adher.log
  log type:  text
 opened on:  23 May 2008, 14:50:13

. tab1 qmtakm qmdose qmcompm qmdaysm if visit=="M03"

-> tabulation of qmtakm if visit=="M03"

      coded |
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        990       28.45       28.45
          1 |      2,376       68.28       96.72
          2 |        114        3.28      100.00
------------+-----------------------------------
      Total |      3,480      100.00

-> tabulation of qmdose if visit=="M03"

    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,104       31.72       31.72
          1 |        277        7.96       39.68
          2 |      2,099       60.32      100.00
------------+-----------------------------------
      Total |      3,480      100.00

-> tabulation of qmcompm if visit=="M03"

 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,104       31.72       31.72
          1 |        399       11.47       43.19
          2 |      1,879       53.99       97.18
          3 |         98        2.82      100.00
------------+-----------------------------------
      Total |      3,480      100.00

-> tabulation of qmdaysm if visit=="M03"

     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,234       35.46       35.46
          1 |         13        0.37       35.83
          2 |         15        0.43       36.26
          3 |         32        0.92       37.18
          4 |         35        1.01       38.19
          5 |        104        2.99       41.18
          6 |        228        6.55       47.73
```

```
          7 |      1,819       52.27      100.00
------------+-----------------------------------
      Total |      3,480      100.00

.
. tab1 qmtakm qmdose qmcompm qmdaysm if visit=="M06"

-> tabulation of qmtakm if visit=="M06"

      coded |
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        993       29.06       29.06
          1 |      2,234       65.38       94.44
          2 |        190        5.56      100.00
------------+-----------------------------------
      Total |      3,417      100.00

-> tabulation of qmdose if visit=="M06"

    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,183       34.62       34.62
          1 |        183        5.36       39.98
          2 |      2,051       60.02      100.00
------------+-----------------------------------
      Total |      3,417      100.00

-> tabulation of qmcompm if visit=="M06"

 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,183       34.62       34.62
          1 |        399       11.68       46.30
          2 |      1,738       50.86       97.16
          3 |         97        2.84      100.00
------------+-----------------------------------
      Total |      3,417      100.00

-> tabulation of qmdaysm if visit=="M06"

     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,311       38.37       38.37
          1 |         16        0.47       38.84
          2 |         17        0.50       39.33
          3 |         18        0.53       39.86
          4 |         41        1.20       41.06
          5 |         96        2.81       43.87
          6 |        244        7.14       51.01
```

```
          7 |      1,674       48.99      100.00
------------+-----------------------------------
      Total |      3,417      100.00

. tab1 qmtakm qmdose qmcompm qmdaysm if visit=="M09"

-> tabulation of qmtakm if visit=="M09"

      coded |
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        950       29.36       29.36
          1 |      2,051       63.38       92.74
          2 |        235        7.26      100.00
------------+-----------------------------------
      Total |      3,236      100.00

-> tabulation of qmdose if visit=="M09"

    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,185       36.62       36.62
          1 |        166        5.13       41.75
          2 |      1,885       58.25      100.00
------------+-----------------------------------
      Total |      3,236      100.00

-> tabulation of qmcompm if visit=="M09"

 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,187       36.68       36.68
          1 |        320        9.89       46.57
          2 |      1,647       50.90       97.47
          3 |         82        2.53      100.00
------------+-----------------------------------
      Total |      3,236      100.00

-> tabulation of qmdaysm if visit=="M09"

     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,281       39.59       39.59
          1 |          5        0.15       39.74
          2 |         11        0.34       40.08
          3 |         20        0.62       40.70
          4 |         35        1.08       41.78
          5 |        118        3.65       45.43
          6 |        222        6.86       52.29
          7 |      1,544       47.71      100.00
```

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------------+-----------------------------------
      Total |      3,236      100.00

. tab1 qmtakm qmdose qmcompm qmdaysm if visit=="M15"

-> tabulation of qmtakm if visit=="M15"

      coded |
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        914       31.08       31.08
          1 |      1,785       60.69       91.77
          2 |        242        8.23      100.00
------------+-----------------------------------
      Total |      2,941      100.00

-> tabulation of qmdose if visit=="M15"

    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,156       39.31       39.31
          1 |        151        5.13       44.44
          2 |      1,634       55.56      100.00
------------+-----------------------------------
      Total |      2,941      100.00

-> tabulation of qmcompm if visit=="M15"

 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,157       39.34       39.34
          1 |        246        8.36       47.70
          2 |      1,481       50.36       98.06
          3 |         57        1.94      100.00
------------+-----------------------------------
      Total |      2,941      100.00

-> tabulation of qmdaysm if visit=="M15"

     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,225       41.65       41.65
          1 |          2        0.07       41.72
          2 |          6        0.20       41.92
          3 |         24        0.82       42.74
          4 |         35        1.19       43.93
          5 |         65        2.21       46.14
          6 |        190        6.46       52.60
          7 |      1,394       47.40      100.00
------------+-----------------------------------
```

```
      Total |      2,941      100.00

. tab1 qmtakm qmdose qmcompm qmdaysm if visit=="M18"

-> tabulation of qmtakm if visit=="M18"

      coded |
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        941       31.52       31.52
          1 |      1,745       58.46       89.98
          2 |        299       10.02      100.00
------------+-----------------------------------
      Total |      2,985      100.00

-> tabulation of qmdose if visit=="M18"

    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,240       41.54       41.54
          1 |        148        4.96       46.50
          2 |      1,597       53.50      100.00
------------+-----------------------------------
      Total |      2,985      100.00

-> tabulation of qmcompm if visit=="M18"

 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,240       41.54       41.54
          1 |        237        7.94       49.48
          2 |      1,464       49.05       98.53
          3 |         44        1.47      100.00
------------+-----------------------------------
      Total |      2,985      100.00

-> tabulation of qmdaysm if visit=="M18"

     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,309       43.85       43.85
          1 |          3        0.10       43.95
          2 |          7        0.23       44.19
          3 |         17        0.57       44.76
          4 |         27        0.90       45.66
          5 |         81        2.71       48.38
          6 |        181        6.06       54.44
          7 |      1,360       45.56      100.00
------------+-----------------------------------
      Total |      2,985      100.00
```

```
. tab1 qmtakm qmdose qmcompm qmdaysm if visit=="M21"

-> tabulation of qmtakm if visit=="M21"

      coded |
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        914       32.15       32.15
          1 |      1,639       57.65       89.80
          2 |        290       10.20      100.00
------------+-----------------------------------
      Total |      2,843      100.00

-> tabulation of qmdose if visit=="M21"

    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,204       42.35       42.35
          1 |        155        5.45       47.80
          2 |      1,484       52.20      100.00
------------+-----------------------------------
      Total |      2,843      100.00

-> tabulation of qmcompm if visit=="M21"

 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,204       42.35       42.35
          1 |        204        7.18       49.53
          2 |      1,404       49.38       98.91
          3 |         31        1.09      100.00
------------+-----------------------------------
      Total |      2,843      100.00

-> tabulation of qmdaysm if visit=="M21"

     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,273       44.78       44.78
          1 |          4        0.14       44.92
          2 |          3        0.11       45.02
          3 |         17        0.60       45.62
          4 |         26        0.91       46.54
          5 |         70        2.46       49.00
          6 |        190        6.68       55.68
          7 |      1,260       44.32      100.00
------------+-----------------------------------
      Total |      2,843      100.00
```

```
. tab1 qmtakm qmdose qmcompm qmdaysm if visit=="M27"

-> tabulation of qmtakm if visit=="M27"

      coded |
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        876       32.65       32.65
          1 |      1,536       57.25       89.90
          2 |        271       10.10      100.00
------------+-----------------------------------
      Total |      2,683      100.00

-> tabulation of qmdose if visit=="M27"

    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,147       42.75       42.75
          1 |        144        5.37       48.12
          2 |      1,392       51.88      100.00
------------+-----------------------------------
      Total |      2,683      100.00

-> tabulation of qmcompm if visit=="M27"

 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,147       42.75       42.75
          1 |        181        6.75       49.50
          2 |      1,332       49.65       99.14
          3 |         23        0.86      100.00
------------+-----------------------------------
      Total |      2,683      100.00

-> tabulation of qmdaysm if visit=="M27"

     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,206       44.95       44.95
          1 |          4        0.15       45.10
          2 |          2        0.07       45.17
          3 |          8        0.30       45.47
          4 |         26        0.97       46.44
          5 |         75        2.80       49.24
          6 |        173        6.45       55.68
          7 |      1,189       44.32      100.00
------------+-----------------------------------
      Total |      2,683      100.00

. tab1 qmtakm qmdose qmcompm qmdaysm if visit=="M30"
```

```
-> tabulation of qmtakm if visit=="M30"

      coded |
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        844       33.23       33.23
          1 |      1,388       54.65       87.87
          2 |        308       12.13      100.00
------------+-----------------------------------
      Total |      2,540      100.00

-> tabulation of qmdose if visit=="M30"

    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,152       45.35       45.35
          1 |        132        5.20       50.55
          2 |      1,256       49.45      100.00
------------+-----------------------------------
      Total |      2,540      100.00

-> tabulation of qmcompm if visit=="M30"

 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,152       45.35       45.35
          1 |        156        6.14       51.50
          2 |      1,210       47.64       99.13
          3 |         22        0.87      100.00
------------+-----------------------------------
      Total |      2,540      100.00

-> tabulation of qmdaysm if visit=="M30"

     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,183       46.57       46.57
          1 |          1        0.04       46.61
          2 |          4        0.16       46.77
          3 |          9        0.35       47.13
          4 |         19        0.75       47.87
          5 |         78        3.07       50.94
          6 |        172        6.77       57.72
          7 |      1,074       42.28      100.00
------------+-----------------------------------
      Total |      2,540      100.00

. tab1 qmtakm qmdose qmcompm qmdaysm if visit=="M33"
```

```
-> tabulation of qmtakm if visit=="M33"

      coded |
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        706       32.87       32.87
          1 |      1,189       55.35       88.22
          2 |        253       11.78      100.00
------------+-----------------------------------
      Total |      2,148      100.00

-> tabulation of qmdose if visit=="M33"

    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        959       44.65       44.65
          1 |        108        5.03       49.67
          2 |      1,081       50.33      100.00
------------+-----------------------------------
      Total |      2,148      100.00

-> tabulation of qmcompm if visit=="M33"

 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        959       44.65       44.65
          1 |        110        5.12       49.77
          2 |      1,055       49.12       98.88
          3 |         24        1.12      100.00
------------+-----------------------------------
      Total |      2,148      100.00

-> tabulation of qmdaysm if visit=="M33"

     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        997       46.42       46.42
          1 |          3        0.14       46.55
          2 |          3        0.14       46.69
          3 |         10        0.47       47.16
          4 |         16        0.74       47.91
          5 |         53        2.47       50.37
          6 |        145        6.75       57.12
          7 |        921       42.88      100.00
------------+-----------------------------------
      Total |      2,148      100.00

. tab1 qmtakm qmdose qmcompm qmdaysm if visit=="M39"

-> tabulation of qmtakm if visit=="M39"
```

```
      coded |
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        476       32.76       32.76
          1 |        775       53.34       86.10
          2 |        202       13.90      100.00
------------+-----------------------------------
      Total |      1,453      100.00

-> tabulation of qmdose if visit=="M39"

    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        678       46.66       46.66
          1 |         72        4.96       51.62
          2 |        703       48.38      100.00
------------+-----------------------------------
      Total |      1,453      100.00

-> tabulation of qmcompm if visit=="M39"

 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        678       46.66       46.66
          1 |         99        6.81       53.48
          2 |        658       45.29       98.76
          3 |         18        1.24      100.00
------------+-----------------------------------
      Total |      1,453      100.00

-> tabulation of qmdaysm if visit=="M39"

     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        712       49.00       49.00
          1 |          1        0.07       49.07
          2 |          3        0.21       49.28
          3 |          6        0.41       49.69
          4 |         16        1.10       50.79
          5 |         48        3.30       54.09
          6 |         80        5.51       59.60
          7 |        587       40.40      100.00
------------+-----------------------------------
      Total |      1,453      100.00

. tab1 qmtakm qmdose qmcompm qmdaysm if visit=="M42"

-> tabulation of qmtakm if visit=="M42"
```

```
      coded |
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        411       32.72       32.72
          1 |        641       51.04       83.76
          2 |        204       16.24      100.00
------------+-----------------------------------
      Total |      1,256      100.00

-> tabulation of qmdose if visit=="M42"

    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        615       48.96       48.96
          1 |         67        5.33       54.30
          2 |        574       45.70      100.00
------------+-----------------------------------
      Total |      1,256      100.00

-> tabulation of qmcompm if visit=="M42"

 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        615       48.96       48.96
          1 |         73        5.81       54.78
          2 |        550       43.79       98.57
          3 |         18        1.43      100.00
------------+-----------------------------------
      Total |      1,256      100.00

-> tabulation of qmdaysm if visit=="M42"

     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        639       50.88       50.88
          1 |          3        0.24       51.11
          2 |          4        0.32       51.43
          3 |          8        0.64       52.07
          4 |         10        0.80       52.87
          5 |         30        2.39       55.25
          6 |         60        4.78       60.03
          7 |        502       39.97      100.00
------------+-----------------------------------
      Total |      1,256      100.00

. tab1 qmtakm qmdose qmcompm qmdaysm if visit=="M45"

-> tabulation of qmtakm if visit=="M45"

      coded |
```

```
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        330       33.88       33.88
          1 |        490       50.31       84.19
          2 |        154       15.81      100.00
------------+-----------------------------------
      Total |        974      100.00
```

```
-> tabulation of qmdose if visit=="M45"
```

```
    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        484       49.69       49.69
          1 |         52        5.34       55.03
          2 |        438       44.97      100.00
------------+-----------------------------------
      Total |        974      100.00
```

```
-> tabulation of qmcompm if visit=="M45"
```

```
 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        484       49.69       49.69
          1 |         50        5.13       54.83
          2 |        432       44.35       99.18
          3 |          8        0.82      100.00
------------+-----------------------------------
      Total |        974      100.00
```

```
-> tabulation of qmdaysm if visit=="M45"
```

```
     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        504       51.75       51.75
          1 |          2        0.21       51.95
          3 |          9        0.92       52.87
          4 |          2        0.21       53.08
          5 |         18        1.85       54.93
          6 |         63        6.47       61.40
          7 |        376       38.60      100.00
------------+-----------------------------------
      Total |        974      100.00
```

```
. use "C:\DPP\Data\Form Data\f02.dta", clear
. tab1 amtakm amdose amcompm amdaysm if visit=="Y01"
```

```
-> tabulation of amtakm if visit=="Y01"

      coded |
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        973       30.46       30.46
          1 |      1,950       61.05       91.52
          2 |        271        8.48      100.00
------------+-----------------------------------
      Total |      3,194      100.00

-> tabulation of amdose if visit=="Y01"

    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,244       38.95       38.95
          1 |        166        5.20       44.15
          2 |      1,784       55.85      100.00
------------+-----------------------------------
      Total |      3,194      100.00

-> tabulation of amcompm if visit=="Y01"

 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,244       38.95       38.95
          1 |        293        9.17       48.12
          2 |      1,599       50.06       98.18
          3 |         58        1.82      100.00
------------+-----------------------------------
      Total |      3,194      100.00

-> tabulation of amdaysm if visit=="Y01"

     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,336       41.83       41.83
          1 |          3        0.09       41.92
          2 |          7        0.22       42.14
          3 |         17        0.53       42.67
          4 |         30        0.94       43.61
          5 |         87        2.72       46.34
          6 |        185        5.79       52.13
          7 |      1,529       47.87      100.00
------------+-----------------------------------
      Total |      3,194      100.00

. tab1 amtakm amdose amcompm amdaysm if visit=="Y02"

-> tabulation of amtakm if visit=="Y02"
```

```
      coded |
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        947       32.94       32.94
          1 |      1,621       56.38       89.32
          2 |        307       10.68      100.00
------------+-----------------------------------
      Total |      2,875      100.00

-> tabulation of amdose if visit=="Y02"

    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,254       43.62       43.62
          1 |        158        5.50       49.11
          2 |      1,463       50.89      100.00
------------+-----------------------------------
      Total |      2,875      100.00

-> tabulation of amcompm if visit=="Y02"

 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,254       43.62       43.62
          1 |        162        5.63       49.25
          2 |      1,423       49.50       98.75
          3 |         36        1.25      100.00
------------+-----------------------------------
      Total |      2,875      100.00

-> tabulation of amdaysm if visit=="Y02"

     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,320       45.91       45.91
          1 |          2        0.07       45.98
          2 |          6        0.21       46.19
          3 |         10        0.35       46.54
          4 |         22        0.77       47.30
          5 |         73        2.54       49.84
          6 |        195        6.78       56.63
          7 |      1,247       43.37      100.00
------------+-----------------------------------
      Total |      2,875      100.00

. tab1 amtakm amdose amcompm amdaysm if visit=="Y03"

-> tabulation of amtakm if visit=="Y03"
```

```
      coded |
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        604       33.04       33.04
          1 |        967       52.90       85.94
          2 |        257       14.06      100.00
------------+-----------------------------------
      Total |      1,828      100.00
```

```
-> tabulation of amdose if visit=="Y03"
```

```
    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        861       47.10       47.10
          1 |         94        5.14       52.24
          2 |        873       47.76      100.00
------------+-----------------------------------
      Total |      1,828      100.00
```

```
-> tabulation of amcompm if visit=="Y03"
```

```
 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        862       47.16       47.16
          1 |        114        6.24       53.39
          2 |        830       45.40       98.80
          3 |         22        1.20      100.00
------------+-----------------------------------
      Total |      1,828      100.00
```

```
-> tabulation of amdaysm if visit=="Y03"
```

```
     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        901       49.29       49.29
          1 |          1        0.05       49.34
          2 |          4        0.22       49.56
          3 |          5        0.27       49.84
          4 |          9        0.49       50.33
          5 |         48        2.63       52.95
          6 |        114        6.24       59.19
          7 |        746       40.81      100.00
------------+-----------------------------------
      Total |      1,828      100.00
```

```
. tab1 amtakm amdose amcompm amdaysm if visit=="Y04"

-> tabulation of amtakm if visit=="Y04"

      coded |
```

```
  metformin |
 since last |
        vst |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        230       34.12       34.12
          1 |        324       48.07       82.20
          2 |        120       17.80      100.00
------------+-----------------------------------
      Total |        674      100.00

-> tabulation of amdose if visit=="Y04"

    dose of |
  metformin |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        350       51.93       51.93
          1 |         29        4.30       56.23
          2 |        295       43.77      100.00
------------+-----------------------------------
      Total |        674      100.00

-> tabulation of amcompm if visit=="Y04"

 metf:estmt |
   cmplianc |
 pill takng |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        350       51.93       51.93
          1 |         32        4.75       56.68
          2 |        288       42.73       99.41
          3 |          4        0.59      100.00
------------+-----------------------------------
      Total |        674      100.00

-> tabulation of amdaysm if visit=="Y04"

     # days |
  metformin |
pills taken |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        360       53.41       53.41
          2 |          1        0.15       53.56
          3 |          2        0.30       53.86
          4 |          6        0.89       54.75
          5 |         14        2.08       56.82
          6 |         36        5.34       62.17
          7 |        255       37.83      100.00
------------+-----------------------------------
      Total |        674      100.00



. use "C:\DPP\analyses\NEJM2002\adher_total.dta", clear

. gen comp_3=1 if qmcompm_3==2
(1786 missing values generated)
```

```
. replace comp_3=0 if qmcompm_3<2 | qmcompm_3==3
(1601 real changes made)

. gen comp_6=1 if qmcompm_6==2
(1927 missing values generated)

. replace comp_6=0 if qmcompm_6<2 | qmcompm_6==3
(1679 real changes made)

. gen comp_9=1 if qmcompm_9==2
(2018 missing values generated)

. replace comp_9=0 if qmcompm_9<2 | qmcompm_9==3
(1589 real changes made)

. gen comp_12=1 if amcompm_1==2
(2066 missing values generated)

. replace comp_12=0 if amcompm_1<2 | amcompm_1==3
(1595 real changes made)

. gen comp_15=1 if qmcompm_15==2
(2184 missing values generated)

. replace comp_15=0 if qmcompm_15<2 | qmcompm_15==3
(1460 real changes made)

. gen comp_18=1 if qmcompm_18==2
(2201 missing values generated)

. replace comp_18=0 if qmcompm_18<2 | qmcompm_18==3
(1521 real changes made)

. gen comp_21=1 if qmcompm_21==2
(2261 missing values generated)

. replace comp_21=0 if qmcompm_21<2 | qmcompm_21==3
(1439 real changes made)

. gen comp_24=1 if amcompm_2==2
(2242 missing values generated)

. replace comp_24=0 if amcompm_2<2 | amcompm_2==3
(1452 real changes made)

. gen comp_27=1 if qmcompm_27==2
(2333 missing values generated)

. replace comp_27=0 if qmcompm_27<2 | qmcompm_27==3
(1351 real changes made)

. gen comp_30=1 if qmcompm_30==2
(2455 missing values generated)

. replace comp_30=0 if qmcompm_30<2 | qmcompm_30==3
(1330 real changes made)
```

```
. gen comp_33=1 if qmcompm_33==2
(2610 missing values generated)

. replace comp_33=0 if qmcompm_33<2 | qmcompm_33==3
(1093 real changes made)

. gen comp_36=1 if amcompm_3==2
(2835 missing values generated)

. replace comp_36=0 if amcompm_3<2 | amcompm_3==3
(998 real changes made)

. gen comp_39=1 if qmcompm_39==2
(3007 missing values generated)

. replace comp_39=0 if qmcompm_39<2 | qmcompm_39==3
(795 real changes made)

. gen comp_42=1 if qmcompm_42==2
(3115 missing values generated)

. replace comp_42=0 if qmcompm_42<2 | qmcompm_42==3
(706 real changes made)

. gen comp_45=1 if qmcompm_45==2
(3233 missing values generated)

. replace comp_45=0 if qmcompm_45<2 | qmcompm_45==3
(542 real changes made)

. gen comp_48=1 if amcompm_4==2
(3377 missing values generated)

. replace comp_48=0 if amcompm_4<2 | amcompm_4==3
(386 real changes made)

.
. gen treatgrp=.
(3665 missing values generated)

. replace treatgrp=1 if assign=="Placebo"
(1030 real changes made)

. replace treatgrp=2 if assign=="Metformin"
(1027 real changes made)

. label define treatgrp 1"Placebo" 2"metformin"

. label values treatgrp treatgrp

. sort treatgrp

. by treatgrp: summarize comp_3-comp_48

------------------------------------------------------------------------------
-> treatgrp = Placebo
```

Variable	Obs	Mean	Std. Dev.	Min	Max
comp_3	979	.7987743	.4011213	0	1
comp_6	976	.7622951	.4258957	0	1
comp_9	966	.7556936	.4298978	0	1
comp_12	976	.7663934	.4233417	0	1
comp_15	924	.7554113	.4300759	0	1
comp_18	953	.7534103	.4312521	0	1
comp_21	940	.7542553	.430757	0	1
comp_24	963	.7653167	.4240209	0	1
comp_27	907	.7519294	.4321313	0	1
comp_30	858	.7179487	.4502606	0	1
comp_33	730	.7479452	.4344903	0	1
comp_36	623	.6918138	.462115	0	1
comp_39	485	.6948454	.4609483	0	1
comp_42	418	.6722488	.4699561	0	1
comp_45	318	.663522	.4732492	0	1
comp_48	226	.6460177	.4792653	0	1

-> treatgrp = metformin

Variable	Obs	Mean	Std. Dev.	Min	Max
comp_3	981	.7155963	.45136	0	1
comp_6	984	.7113821	.4533503	0	1
comp_9	955	.7350785	.4415226	0	1
comp_12	971	.7136972	.4522656	0	1
comp_15	925	.7340541	.4420746	0	1
comp_18	956	.7154812	.4514211	0	1
comp_21	931	.7346939	.4417334	0	1
comp_24	960	.7145833	.4518481	0	1
comp_27	900	.7222222	.4481523	0	1
comp_30	838	.7088305	.4545727	0	1
comp_33	710	.7169014	.4508215	0	1
comp_36	600	.665	.4723843	0	1
comp_39	489	.6564417	.4753821	0	1
comp_42	427	.6299766	.483377	0	1
comp_45	322	.6863354	.464704	0	1
comp_48	218	.6513761	.4776314	0	1

. tab qmcompm_3 treatgrp, col

Key
frequency
column percentage

qmcompm_3	treatgrp Placebo	metformin	Total
0	31	31	62
	3.17	3.16	3.16
1	135	203	338
	13.79	20.69	17.24
2	782	702	1,484
	79.88	71.56	75.71
3	31	45	76
	3.17	4.59	3.88
Total	979	981	1,960
	100.00	100.00	100.00

. tab qmcompm_6 treatgrp, col

Key
frequency
column percentage

qmcompm_6	treatgrp Placebo	metformin	Total
0	59	54	113
	6.05	5.49	5.77
1	133	196	329
	13.63	19.92	16.79
2	744	700	1,444
	76.23	71.14	73.67
3	40	34	74
	4.10	3.46	3.78
Total	976	984	1,960
	100.00	100.00	100.00

. tab qmcompm_9 treatgrp, col

Key
frequency
column percentage

```
           |       treatgrp
 qmcompm_9 |   Placebo  metformin |     Total
-----------+----------------------+----------
         0 |        81         67 |       148
           |      8.39       7.02 |      7.70
-----------+----------------------+----------
         1 |       123        153 |       276
           |     12.73      16.02 |     14.37
-----------+----------------------+----------
         2 |       730        702 |     1,432
           |     75.57      73.51 |     74.54
-----------+----------------------+----------
         3 |        32         33 |        65
           |      3.31       3.46 |      3.38
-----------+----------------------+----------
     Total |       966        955 |     1,921
           |    100.00     100.00 |    100.00
```

```
. tab amcompm_1 treatgrp, col

+--------------------+
| Key                |
|--------------------|
|     frequency      |
| column percentage |
+--------------------+

           |       treatgrp
 amcompm_1 |   Placebo  metformin |     Total
-----------+----------------------+----------
         0 |       100         89 |       189
           |     10.25       9.17 |      9.71
-----------+----------------------+----------
         1 |       106        164 |       270
           |     10.86      16.89 |     13.87
-----------+----------------------+----------
         2 |       748        693 |     1,441
           |     76.64      71.37 |     74.01
-----------+----------------------+----------
         3 |        22         25 |        47
           |      2.25       2.57 |      2.41
-----------+----------------------+----------
     Total |       976        971 |     1,947
           |    100.00     100.00 |    100.00
```

```
. tab qmcompm_15 treatgrp, col

+--------------------+
| Key                |
|--------------------|
|     frequency      |
| column percentage |
+--------------------+

           |       treatgrp
```

qmcompm_15	Placebo	metformin	Total
0	93	95	188
	10.06	10.27	10.17
1	101	132	233
	10.93	14.27	12.60
2	698	679	1,377
	75.54	73.41	74.47
3	32	19	51
	3.46	2.05	2.76
Total	924	925	1,849
	100.00	100.00	100.00

. tab qmcompm_18 treatgrp, col

Key
frequency
column percentage

qmcompm_18	treatgrp Placebo	metformin	Total
0	119	127	246
	12.49	13.28	12.89
1	97	126	223
	10.18	13.18	11.68
2	718	684	1,402
	75.34	71.55	73.44
3	19	19	38
	1.99	1.99	1.99
Total	953	956	1,909
	100.00	100.00	100.00

. tab qmcompm_21 treatgrp, col

Key
frequency
column percentage

	treatgrp

qmcompm_21	Placebo	metformin	Total
0	115	130	245
	12.23	13.96	13.09
1	102	100	202
	10.85	10.74	10.80
2	709	684	1,393
	75.43	73.47	74.45
3	14	17	31
	1.49	1.83	1.66
Total	940	931	1,871
	100.00	100.00	100.00

. tab amcompm_2 treatgrp, col

Key
frequency
column percentage

	treatgrp		
amcompm_2	Placebo	metformin	Total
0	145	157	302
	15.06	16.35	15.70
1	67	95	162
	6.96	9.90	8.42
2	737	686	1,423
	76.53	71.46	74.00
3	14	22	36
	1.45	2.29	1.87
Total	963	960	1,923
	100.00	100.00	100.00

. tab qmcompm_27 treatgrp, col

Key
frequency
column percentage

	treatgrp		
qmcompm_27	Placebo	metformin	Total

```
-----------+----------------------+----------
         0 |       130        141 |       271
           |     14.33      15.67 |     15.00
-----------+----------------------+----------
         1 |        85         96 |       181
           |      9.37      10.67 |     10.02
-----------+----------------------+----------
         2 |       682        650 |     1,332
           |     75.19      72.22 |     73.71
-----------+----------------------+----------
         3 |        10         13 |        23
           |      1.10       1.44 |      1.27
-----------+----------------------+----------
     Total |       907        900 |     1,807
           |    100.00     100.00 |    100.00
```

```
. tab qmcompm_30 treatgrp, col

+--------------------+
| Key                |
|--------------------|
|     frequency      |
| column percentage  |
+--------------------+

           |       treatgrp
qmcompm_30 |   Placebo  metformin |     Total
-----------+----------------------+----------
         0 |       149        159 |       308
           |     17.37      18.97 |     18.16
-----------+----------------------+----------
         1 |        78         78 |       156
           |      9.09       9.31 |      9.20
-----------+----------------------+----------
         2 |       616        594 |     1,210
           |     71.79      70.88 |     71.34
-----------+----------------------+----------
         3 |        15          7 |        22
           |      1.75       0.84 |      1.30
-----------+----------------------+----------
     Total |       858        838 |     1,696
           |    100.00     100.00 |    100.00
```

```
. tab qmcompm_33 treatgrp, col

+--------------------+
| Key                |
|--------------------|
|     frequency      |
| column percentage  |
+--------------------+

           |       treatgrp
qmcompm_33 |   Placebo  metformin |     Total
-----------+----------------------+----------
```

```
         0 |       129        122 |       251
           |     17.67      17.18 |     17.43
-----------+----------------------+----------
         1 |        45         65 |       110
           |      6.16       9.15 |      7.64
-----------+----------------------+----------
         2 |       546        509 |     1,055
           |     74.79      71.69 |     73.26
-----------+----------------------+----------
         3 |        10         14 |        24
           |      1.37       1.97 |      1.67
-----------+----------------------+----------
     Total |       730        710 |     1,440
           |    100.00     100.00 |    100.00
```

```
. tab amcompm_3 treatgrp, col

+--------------------+
| Key                |
|--------------------|
|     frequency      |
| column percentage  |
+--------------------+

           |       treatgrp
 amcompm_3 |   Placebo  metformin |     Total
-----------+----------------------+----------
         0 |       123        134 |       257
           |     19.74      22.33 |     21.01
-----------+----------------------+----------
         1 |        60         54 |       114
           |      9.63       9.00 |      9.32
-----------+----------------------+----------
         2 |       431        399 |       830
           |     69.18      66.50 |     67.87
-----------+----------------------+----------
         3 |         9         13 |        22
           |      1.44       2.17 |      1.80
-----------+----------------------+----------
     Total |       623        600 |     1,223
           |    100.00     100.00 |    100.00
```

```
. tab qmcompm_39 treatgrp, col

+--------------------+
| Key                |
|--------------------|
|     frequency      |
| column percentage  |
+--------------------+

           |       treatgrp
qmcompm_39 |   Placebo  metformin |     Total
-----------+----------------------+----------
         0 |        97        102 |       199
```

```
           |     20.00      20.86 |     20.43
-----------+----------------------+----------
         1 |        43         56 |        99
           |      8.87      11.45 |     10.16
-----------+----------------------+----------
         2 |       337        321 |       658
           |     69.48      65.64 |     67.56
-----------+----------------------+----------
         3 |         8         10 |        18
           |      1.65       2.04 |      1.85
-----------+----------------------+----------
     Total |       485        489 |       974
           |    100.00     100.00 |    100.00
```

```
. tab qmcompm_42 treatgrp, col
```

```
+--------------------+
| Key                |
|--------------------|
|     frequency      |
| column percentage  |
+--------------------+
```

```
           |       treatgrp
qmcompm_42 |   Placebo  metformin |     Total
-----------+----------------------+----------
         0 |        98        106 |       204
           |     23.44      24.82 |     24.14
-----------+----------------------+----------
         1 |        32         41 |        73
           |      7.66       9.60 |      8.64
-----------+----------------------+----------
         2 |       281        269 |       550
           |     67.22      63.00 |     65.09
-----------+----------------------+----------
         3 |         7         11 |        18
           |      1.67       2.58 |      2.13
-----------+----------------------+----------
     Total |       418        427 |       845
           |    100.00     100.00 |    100.00
```

```
. tab qmcompm_45 treatgrp, col
```

```
+--------------------+
| Key                |
|--------------------|
|     frequency      |
| column percentage  |
+--------------------+
```

```
           |       treatgrp
qmcompm_45 |   Placebo  metformin |     Total
-----------+----------------------+----------
         0 |        75         75 |       150
           |     23.58      23.29 |     23.44
```

```
-----------+----------------------+----------
         1 |         28         22 |         50
           |       8.81       6.83 |       7.81
-----------+----------------------+----------
         2 |        211        221 |        432
           |      66.35      68.63 |      67.50
-----------+----------------------+----------
         3 |          4          4 |          8
           |       1.26       1.24 |       1.25
-----------+----------------------+----------
     Total |        318        322 |        640
           |     100.00     100.00 |     100.00


. tab amcompm_4 treatgrp, col

+--------------------+
| Key                |
|--------------------|
|     frequency      |
| column percentage  |
+--------------------+

           |       treatgrp
 amcompm_4 |   Placebo  metformin |     Total
-----------+----------------------+----------
         0 |         62         58 |       120
           |      27.43      26.61 |     27.03
-----------+----------------------+----------
         1 |         16         16 |        32
           |       7.08       7.34 |      7.21
-----------+----------------------+----------
         2 |        146        142 |       288
           |      64.60      65.14 |     64.86
-----------+----------------------+----------
         3 |          2          2 |         4
           |       0.88       0.92 |      0.90
-----------+----------------------+----------
     Total |        226        218 |       444
           |     100.00     100.00 |    100.00


.
. log close
```

```
-------------------------------------------------------------------------------
      log:  C:\DPP\analyses\NEJM2002\glycem.log
  log type:  text
 opened on:   2 Jun 2008, 15:33:15

. *random variable excludes Rs assigned to Troglitazone
. *gen random=.
. *replace random=1 if assign=="Lifestyle"
. *replace random=2 if assign=="Metformin"
. *replace random=3 if assign=="Placebo"
. *label define random 1"Lifestyle" 2"Metformin" 3"Placebo"
. *label val random random
.
. tab random

     random |      Freq.     Percent        Cum.
------------+-----------------------------------
  Lifestyle |      7,628       29.22       29.22
  Metformin |      9,146       35.04       64.26
    Placebo |      9,329       35.74      100.00
------------+-----------------------------------
      Total |     26,103      100.00

. tab visit

    outcome |
      visit |      Freq.     Percent        Cum.
------------+-----------------------------------
        BAS |      3,665       11.52       11.52
        CON |      1,567        4.93       16.45
        M03 |      2,487        7.82       24.26
        M06 |      3,505       11.02       35.28
        M09 |        693        2.18       37.46
        M15 |        192        0.60       38.06
        M18 |      3,359       10.56       48.62
        M21 |        161        0.51       49.12
        M27 |        157        0.49       49.62
        M30 |      3,048        9.58       59.20
        M33 |        214        0.67       59.87
        M36 |          1        0.00       59.87
        M39 |        142        0.45       60.32
        M42 |      1,662        5.22       65.54
        M45 |        170        0.53       66.08
        M51 |         94        0.30       66.37
        M54 |        353        1.11       67.48
        M57 |         57        0.18       67.66
        POV |        204        0.64       68.30
        Y01 |      3,450       10.84       79.15
        Y02 |      3,386       10.64       89.79
        Y03 |      2,345        7.37       97.16
        Y04 |        903        2.84      100.00
------------+-----------------------------------
      Total |     31,815      100.00

.
. . by random:summarize g000
```

```
-------------------------------------------------------------------------------
-> random = Lifestyle

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
        g000 |      7441    106.2455    13.98965         27        331

-------------------------------------------------------------------------------
-> random = Metformin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
        g000 |      7640    106.7832    13.21878         45        267

-------------------------------------------------------------------------------
-> random = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
        g000 |      7814    110.9987    16.51255         71        382

-------------------------------------------------------------------------------
-> random = .

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
        g000 |      4826    109.4194    16.28819         74        436


. gen fpg_b=g000 if visit=="BAS"
(28150 missing values generated)

. gen fpg_6=g000 if visit=="M06"
(28311 missing values generated)

. gen fpg_12=g000 if visit=="Y01"
(28368 missing values generated)

. gen fpg_18=g000 if visit=="M18"
(28462 missing values generated)

. gen fpg_24=g000 if visit=="Y02"
(28429 missing values generated)

. gen fpg_36=g000 if visit=="Y03"
(29475 missing values generated)

. gen fpg_48=g000 if visit=="Y04"
(30915 missing values generated)

. gen fpg_30=g000 if visit=="M30"
(28772 missing values generated)

. gen fpg_42=g000 if visit=="M42"
(30156 missing values generated)
```

```
. by random: summarize fpg_b fpg_6 fpg_12 fpg_18 fpg_24 fpg_30 fpg_36 fpg_42
fpg_48

-------------------------------------------------------------------------------
-> random = Lifestyle

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
       fpg_b |      1024      107.04    7.450151          99        139
       fpg_6 |       993    101.9335     10.0867          75        181
      fpg_12 |       971    101.7446    11.56856          73        222
      fpg_18 |       935    104.2032    11.84036          27        194
      fpg_24 |       946    105.2918    14.88295          74        331
-------------+--------------------------------------------------------
      fpg_30 |       840    107.0155    12.82981          58        195
      fpg_36 |       600    107.3617    14.70832          79        246
      fpg_42 |       404    110.3738    17.69121          82        235
      fpg_48 |       228    112.7763    22.80656          71        270

-------------------------------------------------------------------------------
-> random = Metformin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
       fpg_b |      1027    107.2707    7.860674          99        138
       fpg_6 |       983    102.8281    10.85087          73        208
      fpg_12 |       969    102.7265    11.31866          74        261
      fpg_18 |       951    105.6604    12.44522          72        267
      fpg_24 |       957     106.024    12.80235          78        208
-------------+--------------------------------------------------------
      fpg_30 |       833    107.7035    13.39542          78        246
      fpg_36 |       597    107.1223    13.67848          77        175
      fpg_42 |       425    109.9718    15.35029          80        194
      fpg_48 |       217    111.1889    15.26726          83        186

-------------------------------------------------------------------------------
-> random = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
       fpg_b |      1030    107.4194    7.827639          99        139
       fpg_6 |       973     107.185     12.4831          71        173
      fpg_12 |       975    107.5949    15.20655          78        286
      fpg_18 |       946    109.6776    13.12523          74        210
      fpg_24 |       962    109.7786    14.33601          77        208
-------------+--------------------------------------------------------
      fpg_30 |       852    111.8545    16.10446          81        316
      fpg_36 |       620    111.6371    18.37983          77        336
      fpg_42 |       416    113.7957    17.69607          83        250
      fpg_48 |       224    118.1964    27.17501          87        371

> random = .

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
       fpg_b |       584    107.7774    7.759359          99        139
       fpg_6 |       555    102.0036    10.86843          78        202
```

```
      fpg_12 |       532    103.8327    12.99457         76        277
      fpg_18 |       521    107.1382    13.73989         75        284
      fpg_24 |       521    108.5432    13.42109         76        181
-------------+--------------------------------------------------------
      fpg_30 |       518    111.2143    17.03706         74        328
      fpg_36 |       523    111.7686    21.38701         82        436
      fpg_42 |       414    112.8744    15.87752         80        217
      fpg_48 |       231    115.1515      19.174         84        211


. 
. **Glycosylated hemoglobin
. gen gh_b=hba1 if visit=="BAS"
(28160 missing values generated)

. gen gh_6=hba1 if visit=="M06"
(28326 missing values generated)

. gen gh_12=hba1 if visit=="Y01"
(28392 missing values generated)

. gen gh_24=hba1 if visit=="Y02"
(28443 missing values generated)

. gen gh_36=hba1 if visit=="Y03"
(29475 missing values generated)

. gen gh_48=hba1 if visit=="Y04"
(30917 missing values generated)

. by random: summarize gh_b gh_6 gh_12 gh_24 gh_36 gh_48

-------------------------------------------------------------------------------
-> random = Lifestyle

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
        gh_b |      1021    5.906954    .5041403         4.1        8.5
        gh_6 |       988    5.819231    .4819693         3.7        7.9
       gh_12 |       966    5.810352     .501724         3.7        8.4
       gh_24 |       944    5.866843    .5693964         4.1       12.2
       gh_36 |       602    5.928738    .5876896         3.9       10.9
-------------+--------------------------------------------------------
       gh_48 |       227    6.046696    .6984972         4.7        9.9

> random = Metformin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
        gh_b |      1025    5.908683    .5079761         4.1        8.2
        gh_6 |       979    5.853626    .5066376         4.1        8.7
       gh_12 |       964     5.90778    .4858663         4.2        8.8
       gh_24 |       956    5.953452    .5327972         4.1          9
       gh_36 |       599    6.016194    .5742421         3.4          9
-------------+--------------------------------------------------------
       gh_48 |       217    6.080645    .5793463         4.1        7.9
```

```
-> random = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
        gh_b |      1027    5.908082    .5034607        3.2        7.5
        gh_6 |       969    5.967079    .5229247        3.7        8.4
       gh_12 |       968     6.00093      .59131        3.6       11.8
       gh_24 |       956    6.025314    .5946775        3.9       10.3
       gh_36 |       619    6.076898     .666294        3.7       12.5
-------------+--------------------------------------------------------
       gh_48 |       224    6.286607    .7475515        4.7         12

-------------------------------------------------------------------------------
-> random = .

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
        gh_b |       582    5.873196      .51031        4.1        7.7
        gh_6 |       553    5.825678    .4920663        4.2        7.8
       gh_12 |       525    5.881524    .5826545        4.1       10.9
       gh_24 |       516    5.981395    .5713235        4.1        8.7
       gh_36 |       520    5.995192    .6995429        4.3       13.6
-------------+--------------------------------------------------------
       gh_48 |       230    6.043913    .7443719        4.2       10.3


. 
 log close
      log:  C:\DPP\analyses\NEJM2002\glycem.log
  log type:  text
 closed on:   2 Jun 2008, 15:34:56
-------------------------------------------------------------------------------
```