# Dataset Integrity Check for the Longitudinal Assessment of Bariatric Surgery 2 (LABS-2) Data Files

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#### **1** Standard Disclaimer

The intent of this DSIC is to provide confidence that the data distributed by the NIDDK repository is a true copy of the study data. Our intent is not to assess the integrity of the statistical analyses reported by study investigators. As with all statistical analyses of complex datasets, complete replication of a set of statistical results should not be expected in secondary analysis. This occurs for a number of reasons including differences in the handling of missing data, restrictions on cases included in samples for a particular analysis, software coding used to define complex variables, etc. Experience suggests that most discrepancies can ordinarily be resolved by consultation with the study data coordinating center (DCC), however this process is labor-intensive for both DCC and Repository staff. It is thus not our policy to resolve every discrepancy that is observed in an integrity check. Specifically, we do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancy suggests that the dataset may have been corrupted in storage, transmission, or processing by repository staff. We do, however, document in footnotes to the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

### 2 Study Background

The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium is a multicenter observational cohort study at ten US hospitals in six geographically diverse clinical centers. LABS had 3 phases; the second phase (LABS-2) focused on longer-term safety, outcomes, and durability of health changes. The major priorities for LABS-2 were to determine weight, medical, surgical, and behavioral outcomes, including incidence and remission of comorbid conditions, and to evaluate patient, procedure, and other characteristics that were associated with these outcomes. LABS-2 recruited adults undergoing first-time bariatric procedures between 2006 and 2009, and were followed up until September 2012. Participants completed research assessments prior to surgery and at 6 months, 12 months, and then annually after surgery. Three years after Roux-en-Y gastric bypass (RYGB) or laparoscopic adjustable gastric banding (LAGB), percent weight change from baseline and the percentage of participants with diabetes achieving hemoglobin A1c levels less than 6.5% or fasting plasma glucose values less than 126 mg/dL without pharmacologic therapy were assessed. Dyslipidemia and hypertension resolution at 3 years were also examined. It was found that among participants with severe obesity, there was substantial weight loss 3 years after bariatric surgery, with the majority experiencing maximum weight change during the first year. However, there was variability in the amount and trajectories of weight loss and in diabetes, blood pressure, and lipid outcomes.

#### **3 Archived Datasets**

The SAS data files, as provided by the Data Coordinating Center (DCC), are located in the "Data" folder in the data package. For this replication, variables were taken from the "sq", "po1", "age\_at\_surgery", "calcvar", "post2", "mort", "rcab", and "sbp" data files.

#### **4 Statistical Methods**

Analyses were performed to duplicate results for the data published by Courcoulas, et al. in JAMA in 2013 [1]. To verify the integrity of the datasets, descriptive statistics were computed.

#### **5** Results

For Table 1 in the publication [1], <u>Baseline Characteristics of the LABS-2 Cohort by Procedure</u>, Table A lists the variables that can be used in the replication. Table B compares the results calculated from the archived data file to the results published in Table 1. The results of the replication are almost an exact match.

For Table 2 in the publication [1], <u>Observed and Weighted Remission and Incident Rates 3 Years After</u> <u>Bariatric Surgery by Procedure</u>, Table C lists the variables that can be used in the replication. Table D compares the results calculated from the archived data file to the results published in Table 2. The results of the replication are almost an exact match.

For Table 3 in the publication [1], <u>Deaths and Subsequent Bariatric Surgery Procedures Within 3 Years of</u> <u>Initial Bariatric Surgery</u>, Table E lists the variables that can be used in the replication. Table F compares the results calculated from the archived data file to the results published in Table 3. The results of the replication are almost an exact match.

## **6** Conclusions

The NIDDK repository is confident that the LABS-2 data files to be distributed are a true copy of the manuscript data.

### References

Courcoulas, A.P., Christian, N.J., Belle, S.H., Berk, P.D., Flum, D.R., Garcia, L., Horlick, M., Kalarchian, M.A., King, W.C., Mitchell, J.E., Patterson, E.J., Pender, J.R., Pomp, A., Pories, W.J., Thirlby, R.C., Yanovski, S.Z., Wolfe, B.M. Weight Change and Health Outcomes at 3 Years After Bariatric Surgery Among Individuals with Severe Obesity. JAMA (2013); 310(22): 2416-2425.

| <b>Table A.</b> Valiables used to replicate Table 1. Daseline Characteristics of the LADS-2 Conort by Procedur | Table A: | Variables used to | replicate Table | e 1: Baseline C | Characteristics of t | the LABS-2 Coho | rt by Procedure |
|--|----------|-------------------|-----------------|-----------------|----------------------|-----------------|-----------------|
|--|----------|-------------------|-----------------|-----------------|----------------------|-----------------|-----------------|

| Table Variable     | dataset.variable   |
|--------------------|--|
| Procedure          | sq.surg  |
| Age                | age_at_surgery.age_s   |
| Weight             | rcab.wgt, po1.wgt  |
| BMI                | rcab.wgt, po1.wgt, po1.hgtft, po1.hgtin                          |
| Sex                | po1.sex  |
| Race               | po1.racew, po1.raceb, po1.racea, po1.racei, po1.raceh, po1.raceo |
| Ethnicity          | po1.ethn   |
| Diabetes           | calcvar.dm2_p  |
| Dyslipidemia       | calcvar.dyslipid_p   |
| Hyperlipidemia     | calcvar.hlipid_p   |
| Low HDL            | calcvar.lowHDL   |
| High triglycerides | calcvar.highTG_p   |
| Hypertension       | calcvar.htn_p  |

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

| Characteristic                 | Overall<br>Manuscript<br>(N = 2458) | Overall DSIC<br>(N = 2458) | Difference<br>(N = 0) | Roux-en-Y<br>Gastric<br>Bypass<br>Manuscript<br>(n = 1738) | Roux-en-Y<br>Gastric<br>Bypass (n =<br>1738) | Difference<br>(n = 0) |
|--------------------------------|-------------------------------------|----------------------------|-----------------------|--|--|-----------------------|
| Age, median (IQR), y           | 46 (37-54)                          | 46 (37-54)                 | 0 (0-0)               | 45 (37-54)   | 45 (37-54)                                   | 0 (0-0)               |
| Range, y                       | 18-78                               | 18-78                      | 0-0                   | 19-75  | 19-75  | 0-0                   |
| Weight, median (IQR),<br>kg    | 129 (115-<br>147)                   | 128 (115-<br>147)          | 1 (0-0)               | 131 (116-<br>150)  | 130 (116-<br>150)                            | 1 (0-0)               |
| Range, kg                      | 75-290                              | 75-289                     | 0-1                   | 75-240   | 75-239                                       | 0-1                   |
| BMI, median (IQR)              | 45.9 (41.7-<br>51.5)                | 45.9 (41.8-<br>51.4)       | 0 (0.1-0.1)           | 46.6 (42.4-<br>51.9)                                       | 46.5 (42.4-<br>51.8)                         | 0.1 (0-0.1)           |
| Range                          | 33.0-94.3                           | 32.8-94.1                  | 0.2-0.2               | 33.7-81.0  | 33.7-81.0                                    | 0-0                   |
| Sex, No. (%)                   |                                     |                            |                       |  |  |                       |
| Female                         | 1931 (78.6)                         | 1931 (78.6)                | 0 (0)                 | 1389 (79.9)  | 1389 (79.9)                                  | 0 (0)                 |
| Male                           | 527 (21.4)                          | 527 (21.4)                 | 0 (0)                 | 349 (20.1)   | 349 (20.1)                                   | 0 (0)                 |
| Race, No. (%)                  |                                     |                            |                       |  |  |                       |
| White                          | 2102 (86.4)                         | 2102 (86.4)                | 0 (0)                 | 1463 (85.1)  | 1463 (85.1)                                  | 0 (0)                 |
| Black                          | 256 (10.5)                          | 256 (10.5)                 | 0 (0)                 | 196 (11.4)   | 196 (11.4)                                   | 0 (0)                 |
| Other                          | 75 (3.1)                            | 75 (3.1)                   | 0 (0)                 | 61 (3.5)   | 61 (3.6)                                     | 0 (0.1)               |
| Ethnicity, No. (%)             |                                     |                            |                       |  |  |                       |
| Hispanic                       | 119 (4.8)                           | 119 (4.9)                  | 0 (0.1)               | 85 (4.9)   | 85 (4.9)                                     | 0 (0)                 |
| Non-Hispanic                   | 2337 (95.2)                         | 2337 (95.2)                | 0 (0)                 | 1652 (95.1)  | 1652 (95.1)                                  | 0 (0)                 |
| Diabetes, No. (%)              | 774 (33.4)                          | 774 (33.5)                 | 0 (0.1)               | 583 (35.4)   | 583 (35.4)                                   | 0 (0)                 |
| Dyslipidemia, No. (%)          | 1252 (63.4)                         | 1254 (63.5)                | 2 (0.1)               | 901 (64.4)   | 903 (64.4)                                   | 2 (0)                 |
| Hyperlipidemia, No. (%)        | 725 (36.6)                          | 725 (36.5)                 | 0 (0.1)               | 515 (36.7)   | 515 (36.6)                                   | 0 (0.1)               |
| Low HDL, No. (%)               | 883 (37.5)                          | 883 (37.5)                 | 0 (0)                 | 648 (38.8)   | 648 (38.8)                                   | 0 (0)                 |
| High triglycerides, No.<br>(%) | 462 (22.9)                          | 463 (23.0)                 | 1 (0.1)               | 339 (23.8)   | 340 (23.8)                                   | 1 (0)                 |
| Hypertension, No. (%)          | 1601 (67.5)                         | 1601 (67.5)                | 0 (0)                 | 1159 (68.9)  | 1159 (68.9)                                  | 0 (0)                 |

|                         | Laparoscopic | Laparoscopic |            |             |               |             |
|-------------------------|--------------|--------------|------------|-------------|---------------|-------------|
|                         | Adjustable   | Adjustable   |            | Sleeve      |               |             |
|                         | Gastric Band | Gastric Band |            | Gastrectomy | Sleeve        |             |
|                         | Manuscript   | DSIC (n =    | Difference | Manuscript  | Gastrectomy   | Difference  |
| Characteristic          | (n = 610)    | 610)         | (n = 0)    | (n = 59)    | DSIC (n = 59) | (n = 0)     |
| Age, median (IQR), y    | 48 (37-56)   | 48 (37-56)   | 0 (0-0)    | 48 (36-55)  | 48 (35-55)    | 0 (1-0)     |
| Range, y                | 18-78        | 18-78        | 0-0        | 21-73       | 21-73         | 0-0         |
| Weight, median (IQR),   | 123 (111-    | 122 (111-    |            | 158 (134-   | 158 (132-     |             |
| kg                      | 139)         | 139)         | 1 (0-0)    | 180)        | 181)          | 0 (2-1)     |
| Range, kg               | 85-246       | 85-245       | 0-1        | 82-290      | 82-289        | 0-1         |
|                         | 43.9 (40.4-  | 43.7 (40.4-  |            | 57.7 (46.8- | 57.7 (46.6-   |             |
| BMI, median (IQR)       | 48.0)        | 48.0)        | 0.2 (0-0)  | 64.1)       | 64.2)         | 0 (0.2-0.1) |
| Range                   | 33.0-87.3    | 32.8-87.2    | 0.2-0.1    | 35.5-94.3   | 35.6-94.1     | 0.1-0.2     |
| Sex, No. (%)            |              |              |            |             |               |             |
| Female                  | 465 (76.2)   | 465 (76.2)   | 0 (0)      | 39 (66.1)   | 39 (66.1)     | 0 (0)       |
| Male                    | 145 (23.8)   | 145 (23.8)   | 0 (0)      | 20 (33.9)   | 20 (33.9)     | 0 (0)       |
| Race, No. (%)           |              |              |            |             |               |             |
| White                   | 543 (89.6)   | 543 (89.6)   | 0 (0)      | 47 (82.5)   | 47 (82.5)     | 0 (0)       |
| Black                   | 51 (8.4)     | 51 (8.4)     | 0 (0)      | 8 (14.0)    | 8 (14.0)      | 0 (0)       |
| Other                   | 12 (2.0)     | 12 (2.0)     | 0 (0)      | 2 (3.5)     | 2 (3.5)       | 0 (0)       |
| Ethnicity, No. (%)      |              |              |            |             |               |             |
| Hispanic                | 26 (4.3)     | 26 (4.3)     | 0 (0)      | 6 (10.2)    | 6 (10.2)      | 0 (0)       |
| Non-Hispanic            | 583 (95.7)   | 583 (95.7)   | 0 (0)      | 53 (89.8)   | 53 (89.8)     | 0 (0)       |
| Diabetes, No. (%)       | 164 (28.8)   | 164 (28.8)   | 0 (0)      | 15 (28.8)   | 15 (28.9)     | 0 (0.1)     |
| Dyslipidemia, No. (%)   | 291 (60.9)   | 291 (60.9)   | 0 (0)      | 33 (64.7)   | 33 (64.7)     | 0 (0)       |
| Hyperlipidemia, No.     |              |              |            |             |               |             |
| (%)                     | 177 (36.7)   | 177 (36.7)   | 0 (0)      | 22 (43.1)   | 22 (43.1)     | 0 (0)       |
| Low HDL, No. (%)        | 194 (33.3)   | 194 (33.3)   | 0 (0)      | 21 (37.5)   | 21 (37.5)     | 0 (0)       |
| High triglycerides, No. |              |              |            |             |               |             |
| (%)                     | 103 (21.1)   | 103 (21.1)   | 0 (0)      | 12 (21.8)   | 12 (21.8)     | 0 (0)       |
| Hypertension, No. (%)   | 367 (62.7)   | 367 (62.7)   | 0 (0)      | 44 (80.0)   | 44 (80.0)     | 0 (0)       |

|                                | BPDS<br>Manuscript | BPDS DSIC         | Difference    | Banded<br>Gastric<br>Bypass<br>Manuscript | Banded<br>Gastric<br>Bypass DSIC | Difference    |
|--------------------------------|--------------------|-------------------|---------------|---|----------------------------------|---------------|
| Characteristic                 | (n = 19)           | (n = 19)          | (n = 0)       | (n = 32)                                  | (n = 32)                         | (n = 0)       |
| Age, median (IQR), y           | 39 (35-46)         | 39 (33-47)        | 0 (2-1)       | 48 (40-54)                                | 48 (40-54)                       | 0 (0-0)       |
| Range, y                       | 26-60              | 26-60             | 0-0           | 21-69                                     | 21-69                            | 0-0           |
| Weight, median (IQR),<br>kg    | 136 (123-<br>151)  | 136 (120-<br>153) | 0 (3-2)       | 136 (116-<br>157)                         | 136 (116-<br>157)                | 0 (0-0)       |
| Range, kg                      | 110-192            | 110-192           | 0-0           | 92-227                                    | 97-227                           | 0-0           |
|                                | 50.0 (44.9-        | 49.9 (44.2-       |               | 49.2 (42.5-                               | 49.1 (42.3-                      |               |
| BMI, median (IQR)              | 52.3)              | 52.6)             | 0.1 (0.7-0.3) | 54.1)                                     | 54.3)                            | 0.1 (0.2-0.2) |
| Range                          | 37.9-62.6          | 38.0-62.5         | 0.1-0.1       | 36.2-76.0                                 | 36.0-75.9                        | 0.2-0.1       |
| Sex, No. (%)                   |                    |                   |               |   |                                  |               |
| Female                         | 14 (73.7)          | 14 (73.7)         | 0 (0)         | 24 (75.0)                                 | 24 (75.0)                        | 0 (0)         |
| Male                           | 5 (26.3)           | 5 (26.3)          | 0 (0)         | 8 (25.0)                                  | 8 (25.0)                         | 0 (0)         |
| Race, No. (%)                  |                    |                   |               |   |                                  |               |
| White                          | 18 (94.7)          | 18 (94.7)         | 0 (0)         | 31 (100.0)                                | 31 (100.0)                       | 0 (0)         |
| Black                          | 1 (5.3)            | 1 (5.3)           | 0 (0)         | 0 (0.0)                                   | 0 (0.0)                          | 0 (0)         |
| Other                          | 0 (0.0)            | 0 (0.0)           | 0 (0)         | 0 (0.0)                                   | 0 (0.0)                          | 0 (0)         |
| Ethnicity, No. (%)             |                    |                   |               |   |                                  |               |
| Hispanic                       | 0 (0.0)            | 0 (0.0)           | 0 (0)         | 2 (6.2)                                   | 2 (6.3)                          | 0 (0.1)       |
| Non-Hispanic                   | 19 (100.0)         | 19 (100.0)        | 0 (0)         | 30 (93.8)                                 | 30 (93.8)                        | 0 (0)         |
| Diabetes, No. (%)              | 7 (38.9)           | 7 (38.9)          | 0 (0)         | 5 (17.2)                                  | 5 (17.2)                         | 0 (0)         |
| Dyslipidemia, No. (%)          | 9 (52.9)           | 9 (52.9)          | 0 (0)         | 18 (64.3)                                 | 18 (64.3)                        | 0 (0)         |
| Hyperlipidemia, No. (%)        | 5 (29.4)           | 5 (29.4)          | 0 (0)         | 6 (21.4)                                  | 6 (21.4)                         | 0 (0)         |
| Low HDL, No. (%)               | 5 (27.8)           | 5 (27.8)          | 0 (0)         | 15 (50.0)                                 | 15 (50.0)                        | 0 (0)         |
| High triglycerides, No.<br>(%) | 5 (27.8)           | 5 (27.8)          | 0 (0)         | 3 (10.7)                                  | 3 (10.7)                         | 0 (0)         |
| Hypertension, No. (%)          | 10 (52.6)          | 10 (52.6)         | 0 (0)         | 21 (67.7)                                 | 21 (67.7)                        | 0 (0)         |

**Table C:** Variables used to replicate Table 2: Observed and Weighted Remission and Incident Rates 3Years After Bariatric Surgery by Procedure

| Table Variable     | dataset.variable   |
|--------------------|--------------------|
| Procedure          | sq.surg            |
| Diabetes           | calcvar.dm2_p      |
| Dyslipidemia       | calcvar.dyslipid_p |
| Hyperlipidemia     | calcvar.hlipid_p   |
| Low HDL            | calcvar.lowHDL     |
| High triglycerides | calcvar.highTG_p   |
| Hypertension       | calcvar.htn_p      |

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

|                    | Roux-en-Y<br>Gastric<br>Bypass<br>Manuscript<br>(n = 1691) | Roux-en-Y<br>Gastric<br>Bypass DSIC<br>(n = 1692) | Difference<br>(n = 1) | Laparoscopic<br>Adjustable<br>Gastric Band<br>Manuscript<br>(n = 588) | Laparoscpoic<br>Adjustable<br>Gastric Band<br>DSIC (n =<br>587) | Difference<br>(n = 1) |
|--------------------|--|---|-----------------------|---|---|-----------------------|
|                    | Observed<br>No./Total<br>No. (%)                           |   |                       | Observed<br>No./Total<br>No. (%)                                      |   |                       |
| Diabetes           |  |   |                       |   |   |                       |
| Remission          | 216/320<br>(67.5)  | 216/320<br>(67.5)                                 | 0/0 (0)               | 28/98 (28.6)  | 28/98 (28.6)  | 0/0 (0)               |
| Incidence          | 5/560 (0.9)  | 5/562 (0.9)                                       | 0/2 (0)               | 8/247 (3.2)   | 8/247 (3.2)   | 0/0 (0)               |
| Dyslipidemia       |  |   |                       |   |   |                       |
|                    | 237/383  | 237/383   |                       | 39/144  | 39/144  |                       |
| Remission          | (61.9)   | (61.9)  | 0/0 (0)               | (27.1)  | (27.1)  | 0/0 (0)               |
| Incidence          | 7/221 (3.2)  | 7/222 (3.2)                                       | 0/1 (0)               | 15/94 (16.0)  | 15/94 (16.0)  | 0/0 (0)               |
| Hyperlipidemia     |  |   |                       |   |   |                       |
| Remission          | 151/253  | 151/253   | 0/0 (0)               | 22/97 (22 7)  | 22/97 (22 7)  | 0/0 (0)               |
|                    | (33.7)   | (35.7)  | 0,0(0)                | 21/143  | 21/143  | 0,0 (0)               |
| Incidence          | 9/353 (2.5)  | 9/354 (2.5)                                       | 0/1 (0)               | (14.7)  | (14.7)  | 0/0 (0)               |
| Low HDL            |  |   |                       |   |   |                       |
| Remission          | 292/341  | 293/342   | 1/1 (0.1)             | 76/113  | 76/113  | 0/0 (0)               |
| Incidence          | 9/616 (1.5)  | 9/616 (1.5)                                       | 0/0(0)                | 10/266 (3.8)  | 10/266 (3.8)  | 0/0 (0)               |
| High triglycerides | 5/010 (1.5)  | 3,010 (113)                                       | 0,0(0)                | 10/200 (0.0/  | 10/200 (0.0)  | 0,0 (0)               |
|                    | 139/162  | 139/162   |                       |   |   |                       |
| Remission          | (85.8)   | (85.8)  | 0/0 (0)               | 36/58 (62.1)  | 36/58 (62.1)  | 0/0 (0)               |
| Incidence          | 8/495 (1.6)  | 8/496 (1.6)                                       | 0/1 (0)               | 14/206 (6.8)  | 14/206 (6.8)  | 0/0 (0)               |
| Hypertension       |  |   |                       |   |   |                       |
|                    | 269/705  | 290/740   |                       | 43/247  | 51/256  |                       |
| Remission*         | (38.2)   | (39.2)  | 21/35 (1.0)           | (17.4)  | (19.9)  | 8/9 (2.5)             |
|                    | 39/309   | 40/331  |                       | 27/149  | 28/164  |                       |
| Incidence*         | (12.6)   | (12.1)  | 1/22 (0.5)            | (18.1)  | (17.1)  | 1/15 (1.0)            |

\*The variables in the data package that were used to calculate hypertension were corrected after the manuscript had been published. Therefore, the large differences between the DSIC and Manuscript values are expected.

**Table E:** Variables used to replicate Table 3: Deaths and Subsequent Bariatric Surgery Procedures Within

 3 Years of Initial Bariatric Surgery

| Table Variable                          | dataset.variable   |
|---|--|
| Procedure                               | sq.surg  |
| Death within 30 days of Surgery         | post2.postdie  |
| Cause of Death                          | mort.mortd, mort.mortds                                  |
| Subsequent bariatric surgery procedures | sbp.procprio, sq.surgdat sq.surg, sq.age s, sbp.nbaripro |
| Revision                                | sq.op_revis  |
| Reversal                                | sq.op_rever  |
| Band replacement                        | sq.op_rever, sq.op_revis                                 |
| Port revision                           | sq.surg, sbp.portprob                                    |
| Other revision                          | sq.surg, sq.op_rever, sq.op_revis, sbp.portprob          |
| Band removal                            | sq.surg, sq.op_rever, sq.op_revis, sbp.portprob          |
| Revision to another bariatric           |  |
| procedure                               | sq.surg, sq.op_rever, sq.op_revis, sbp.portprob          |

**Table F:** Comparison of values computed in integrity check to reference article Table 3 values

|  |                        |                        | -          |
|--|------------------------|------------------------|------------|
|  | No. of<br>Participants | No. of<br>Participants |            |
|  | Manuscript             | DSIC                   | Difference |
| Roux-en-Y Gastric Bypass (n = 1738)          |                        |                        |            |
| Deaths                                       | 16                     | 16                     | 0          |
| Within 30 days of surgery                    | 3                      | 3                      | 0          |
| Sepsis                                       | 1                      | 1                      | 0          |
| Cardiovascular disease                       | 1                      | 1                      | 0          |
| Pulmonary embolism                           | 1                      | 1                      | 0          |
| More than 30 days after surgery              | 13                     | 13                     | 0          |
| Bowel obstruction                            | 1                      | 1                      | 0          |
| Sepsis                                       | 1                      | 1                      | 0          |
| Respiratory failure                          | 1                      | 1                      | 0          |
| Cardiovascular disease                       | 3                      | 3                      | 0          |
| Suicide/substance abuse                      | 2                      | 2                      | 0          |
| Cancer                                       | 1                      | 1                      | 0          |
| Indeterminate after adjudication             | 4                      | 4                      | 0          |
| Subsequent bariatric surgery procedures      | 4                      | 4                      | 0          |
| Revision                                     | 2                      | 2                      | 0          |
| Reversal                                     | 2                      | 2                      | 0          |
| Laparoscopic Adjustable Gastric Band (n=610) |                        |                        |            |
| Deaths                                       | 5                      | 5                      | 0          |
| Within 30 days of surgery                    | 0                      | 0                      | 0          |
| More than 30 days after surgery              | 5                      | 5                      | 0          |
| Organ failure                                | 2                      | 2                      | 0          |
| Respiratory failure                          | 1                      | 1                      | 0          |
| Cancer                                       | 1                      | 1                      | 0          |
| Indeterminate after adjudication             | 1                      | 1                      | 0          |
| Subsequent bariatric surgery procedures      | 77                     | 78                     | 1          |
| Band replacement                             | 7                      | 7                      | 0          |
| Port revision                                | 19                     | 19                     | 0          |
| Other revision                               | 10                     | 11                     | 1          |
| Band removal                                 | 21                     | 21                     | 0          |
| Revision to another bariatric procedure      | 20                     | 20                     | 0          |

#### Attachment A: SAS Code

```
**** LABS-2 DSIC;
**** Programmer: Allyson Mateja;
**** Date: July 5, 2016;
title1 "%sysfunc(getoption(sysin))";
title2 " ";
libname labs2 "/prj/niddk/ims_analysis/LABS/private_orig_data/Longitudinal Assessment of Bariatric Surgery (LABS-2)/SAS Database";
options nofmterr;
proc format;
       value sexf 1 = 'M'
                  2 = 'F';
       value surgf 1 = 'Roux-en-Y Gastric Bypass'
                   3 = 'BPDS'
                   4 = 'Laparoscopic Adjustable Gastric Band'
                   5 = 'Sleeve Gastrectomy'
                   7 = 'Other'
                   8 = 'Banded Gastric Bypass';
       value ethnf 0 = 'Hispanic'
                   1 = 'Non-Hispanic';
       value mortf 0
                          = 'Indeterminate after adjudication'
                   2,3
                        = 'Sepsis'
                   4
                          = 'Pulmonary embolism'
                   8
                          = 'Bowel obstruction'
                   11
                          = 'Respiratory failure'
                   13,16 = 'Suicide/substance abuse'
                   15
                          = 'Cancer'
                   6,7,17 = 'Cardiovascular disease'
                   18
                          = 'Organ failure';
/*data ae;
                            set labs2.ae;
                                                           run;
data agb;
                          set labs2.agb;
                                                         run;
data agbp;
                          set labs2.agbp;
                                                         run;*/
data age_at_surgery;
                          set labs2.age_at_surgery;
                                                         run;
/*data ascf;
                            set labs2.ascf;
                                                           run;
data bb;
                          set labs2.bb;
                                                         run;
data bdi;
                          set labs2.bdi;
                                                         run;
data bf;
                          set labs2.bf;
                                                         run;
                          set labs2.bio_status;
data bio_status;
                                                         run;
data bpds;
                          set labs2.bpds;
                                                         run;
data bs;
                          set labs2.bs;
                                                         run;
data bu;
                          set labs2.bu;
                                                         run;*/
data calcvar;
                          set labs2.calcvar;
                                                         run;
/*data cd;
                            set labs2.cd;
                                                           run;
data cdf;
                          set labs2.cdf;
                                                         run;
data cdfm;
                          set labs2.cdfm;
                                                         run;
```

| <pre>data central_lab_results;</pre> | <pre>set labs2.central_lab_results;</pre> | run;   |
|--------------------------------------|---|--------|
| data clab_status;                    | <pre>set labs2.clab_status;</pre>         | run;   |
| data dib;                            | set labs2.dib;                            | run;   |
| data dif;                            | <pre>set labs2.dif;</pre>                 | run;*/ |
| data ds;                             | set labs2.ds;                             | run;   |
| /*data ec;                           | set labs2.ec;                             | run;*/ |
| data ef;                             | <pre>set labs2.ef;</pre>                  | run;   |
| /*data ef_nocons;                    | <pre>set labs2.ef_nocons;</pre>           | run;   |
| data eq5d;                           | set labs2.eq5d;                           | run;   |
| data ess;                            | set labs2.ess;                            | run;   |
| data fo6;                            | <pre>set labs2.fo6;</pre>                 | run;   |
| data gen_status;                     | set labs2.gen_status;                     | run;   |
| data gs;                             | set labs2.gs;                             | run;   |
| data gsrs;                           | set labs2.gsrs;                           | run;*/ |
| data in2;                            | set labs2.in2;                            | run;   |
| /*data in2_excluded;                 | <pre>set labs2.in2_excluded;</pre>        | run;   |
| data isel;                           | set labs2.isel;                           | run;   |
| data iw;                             | set labs2.iw;                             | run;   |
| data leak;                           | set labs2.leak;                           | run;   |
| data 11;                             | set labs2.11;                             | run;*/ |
| data mab;                            | set labs2.mab;                            | run;   |
| /*data maf;                          | set labs2.maf;                            | run;   |
| data mag;                            | set labs2.mag;                            | run;   |
| data med;                            | set labs2.med;                            | run;   |
| data medrx;                          | set labs2.medrx;                          | run;*/ |
| data mort:                           | set labs2 mort:                           | run:   |
| /*data myf:                          | set labs? myf:                            | run:   |
| data mwf:                            | set labs2 mwf:                            | run:   |
| data ndi:                            | set labs2.mwi;                            | run:   |
| data niv:                            | set labs2 niv:                            | run:   |
| data off:                            | set labs2.miv;                            | run:   |
| data path:                           | set labs2.011/                            | run;   |
| data patri                           | set labs2.path/                           | run;   |
| data petsor                          | set labs2.petsb/                          | run:*/ |
| data pelsi,                          | set labs2.pets1,                          | run;   |
| data post?:                          | set labs2.poi/                            | run;   |
| (*data postz;                        | set labs2.post2,                          | rull,  |
| data pul:                            | act labe2 pu2:                            | run:   |
| data puzi                            | set labs2.puz/                            | run,   |
| (tdata read;                         | set labs2.rcab;                           | rull,  |
| / data real;                         | set labs2.rcal,                           | run,   |
| data mbf:                            | set labs2.fild;                           | run;   |
| data rill,                           | set labs2.rni;                            | run,   |
| data rnp;                            | set labs2.rnp;                            | run;   |
| data rsi,                            | set labs2.rs1,                            | run,   |
| data rsi;                            | set labs2.rs1;                            | run;   |
| data ryb;                            | set labs2.ryb;                            | run;*/ |
| data sop;                            | set labs2.sbp;                            | run;   |
| /*data sbq;                          | set labs2.sbq;                            | run;   |
| data soqt;                           | set labs2.sbqt;                           | run;   |
| data st36;                           | set labs2.st36;                           | run;   |
| data sfb;                            | set labs2.sfb;                            | run;   |
| data sff;                            | set labs2.sff;                            | run;   |
| data short;                          | set labs2.short;                          | run;   |
| data sl;                             | set labs2.sl;                             | run;   |
| data sls;                            | set labs2.sls;                            | run;   |
| data smab;                           | set labs2.smab;                           | run;   |

```
data smaf;
                          set labs2.smaf;
                                                          run;*/
data sq;
                          set labs2.sq;
                                                          run;
/*data sw_minute;
                            set labs2.sw_minute;
                                                           run;
data sw_summary;
                          set labs2.sw_summary;
                                                          run;
data uevnt;
                          set labs2.uevnt;
                                                          run;
data uib;
                          set labs2.uib;
                                                         run;
                          set labs2.uif;
data uif;
                                                          run;
data vtype;
                          set labs2.vtype;
                                                         run;
data wef;
                          set labs2.wef;
                                                         run;
data wgt;
                          set labs2.wgt;
                                                         run;
data whq;
                          set labs2.whq;
                                                         run;
data wpai;
                          set labs2.wpai;
                                                          run;*/
proc sort data = ef nodupkey;
       by id;
proc sort data = sq;
       by id surgdat;
/*data sq;
       set sq;
       by id;
       if last.id then output;*/
proc sort data = pol nodupkey;
       by id;
proc sort data = pu2 ;
       by id surgdat;
proc sort data = age_at_surgery;
       by id surgdate;
proc sort data = mab nodupkey;
       by id;
proc freq data = calcvar;
       tables visit;
data baseline_calcvar;
       set calcvar;
       if visit = 1;
data year3_calcvar;
       set calcvar;
       if visit = 36;
proc sort data = baseline_calcvar nodupkey;
       by id;
proc contents data = sq;
proc sort data = rcab nodupkey;
       by id;
data po_updates;
```

```
merge sq (in=val1)
             pu2 (keep=id surgdat wgt)
             age at surgery (keep=id surgdate primary age s canceled rename = (surgdate = surgdat));
       by id surqdat;
       if vall then output po_updates;
data surgeries;
       merge ef (in=vall keep=id)
             pol (keep = id poldat age_c wgt sex racew raceb racea racei raceh raceo ethn hgtft hgtin)
             po_updates (in=val2 rename = (wgt = wgt_upd))
             baseline_calcvar (keep=id dm2_p dyslipid_p hlipid_p lowHDL highTG_p htn_p)
             rcab (in=val1 keep=id wgt rename = (wgt=rcab_wgt));
       by id;
       if racew=1 and raceb=0 and racea=0 and racei=0 and raceh=0 and raceo=0 then race = 'W';
       else if racew=0 and raceb=1 and racea=0 and racei=0 and raceh=0 and raceo=0 then race = 'B';
       else if racew in (-3, -4) and raceb in (-3, -4) and racea in (-3, -4) and racei in (-3, -4) and raceb in (-3, -4) and raceo in (-3, -4) then race = '';
       else race = '0';
       if val1 and val2 then output surgeries;
proc freq data = surgeries;
       tables surgno /list missing;
data surgeries;
       set surgeries;
       if surgno = 0;
proc freq data = surgeries;
       tables surg*primary /list missing;
data surgeries secondary_surgery;
       set surgeries;
       if primary = 1 then output surgeries;
       else output secondary_surgery;
data surgeries;
       set surgeries;
       surg_time = surgdat - poldat;
       if wgt_upd ne . and surg_time > 30 then wgt = wgt_upd;
       wqt kq = round(wqt*0.453592,1);
       rcab_wgt_kg = round(rcab_wgt*0.453592,1);
       if rcab wqt kq < 0 then rcab wqt kq = wqt kq;
       height total = (hgtft + (hgtin/12))*0.3048;
       bmi = round(rcab_wgt_kg/(height_total**2), 0.1);
proc freq data = surgeries;
       tables surg;
       format surg surgf.;
       title3 'Table 1 - Procedure';
proc sort data = surgeries;
       by surg;
proc means data = surgeries n median p25 p75 min max;
       var age s;
       class surg;
       types () surg;
                                                                               16
```

```
format surg surgf.;
       title3 'Table 1 - Age';
proc means data = surgeries n median p25 p75 min max;
       var rcab_wgt_kg;
       class surg;
       types () surg;
       format surg surgf.;
       title3 'Table 1 - Weight';
proc means data = surgeries n median p25 p75 min max;
       var bmi;
       class surg;
       types () surg;
       format surg surgf.;
       title3 'Table 1 - BMI';
proc freq data = surgeries;
       tables sex;
       format sex sexf.;
       title3 'Table 1 - Sex';
proc freq data = surgeries;
       tables sex;
       by surg;
       format sex sexf. surg surgf.;
proc freq data = surgeries;
       tables race ;
       title3 'Table 1 - Race';
proc freq data = surgeries;
       tables race;
       by surg;
       format surg surgf.;
proc freq data = surgeries;
       tables ethn;
       where ethn ne -3;
       format ethn ethnf.;
       title3 'Table 1 - Ethnicity';
proc freq data = surgeries;
       tables ethn;
       where ethn ne -3;
       by surg;
       format ethn ethnf. surg surgf.;
proc freq data = surgeries;
       tables dm2 p;
       title3 'Table 1 - Diabetes';
proc freq data = surgeries;
       tables dm2_p;
       by surg;
       format surg surgf.;
```

proc freq data = surgeries; tables dyslipid\_p; title3 'Table 1 - Dyslipidemia'; proc freq data = surgeries; tables dyslipid\_p; by surg; format surg surgf.; proc freq data = surgeries; tables hlipid\_p; title3 'Table 1 - Hyperlipidemia'; proc freq data = surgeries; tables hlipid\_p; by surg; format surg surgf.; proc freq data = surgeries; tables lowHDL; title3 'Table 1 - Low HDL'; proc freq data = surgeries; tables lowHDL; by surg; format surg surgf.; proc freq data = surgeries; tables highTG\_p; title3 'Table 1 - High Triglycerides'; proc freq data = surgeries; tables highTG\_p; by surg; format surg surgf.; proc freq data = surgeries; tables htn p; title3 'Table 1 - Hypertension'; proc freq data = surgeries; tables htn\_p; by surg; format surg surgf.; proc sort data = year3\_calcvar; by id; proc sort data = surgeries; by id; proc sort data = in2 nodupkey; by id; proc sort data = post2 nodupkey;

```
by id surgdat;
proc sort data = mort nodupkey;
       by id;
proc sort data = mort;
       by id surgdat;
data table3;
       merge surgeries (in=vall keep=id surg surgdat age_c age_s op_rever op_revis surgs)
                        (keep=id surgdat postdie)
             post2
             mort
                        (keep=id surgdat mortd mortds mortdat age d);
       by id surgdat;
       death time = age d-age c_i
       year_time = floor((mortdat-surgdat)/365.25);
       if year time > 3 and death time = 3 then death time = 4;
       if mortds in ('COMPLICATIONS OF HYPERTENSIVE CV DISEASE', 'FATAL ARRHYTHMIA/CARDIOMYOPATHY') then mortd = 17;
       if mortds in ('LIVER/HEPATIC FAILURE', 'MSOF') then mortd = 18;
       if vall and surg in (1,4) then output table3;
proc sort data = table3 nodupkey;
       by id;
data table2;
       merge year3_calcvar (in=val1 keep=id dm2_p dyslipid_p hlipid_p lowHDL highTG_p htn_p rename = (dm2_p = dm2_p_yr3 dyslipid_p = dyslipid_p_yr3 hlipid_p =
hlipid_p_yr3
                            lowHDL = lowHDL_yr3 highTG_p = highTG_p_yr3 htn_p = htn_p_yr3))
                            (in=val2 keep=id surg age_s surgdat dm2_p dyslipid_p hlipid_p lowHDL highTG_p htn_p rename = (dm2_p = dm2_p_bl dyslipid_p =
             surgeries
dyslipid p bl hlipid p = hlipid p bl
                            lowHDL = lowHDL_bl highTG_p = highTG_p_bl htn_p = htn_p_bl))
             in2
                           (keep=id age_i in2dat)
                           (keep=id death_time postdie mortd);
             table3
       bv id;
       inactive_time = (age_i-age_s);
       inactive time2 = floor((in2dat-surgdat)/365.25);
       if mortd = . or death_time > 3 then death = 0;
       else if (mortd ne . and 0 \le \text{death time} \le 3) then death = 1;
       if dm2_pbl = 0 and dm2_pyr3 = 1 then diabetes_incidence = 1;
       else if dm2 p bl = 0 and dm2 p yr3 = 0 then diabetes incidence = 0;
       if dm2_pbl = 1 and dm2_pyr3 = 0 then diabetes_remission = 1;
       else if dm2 p bl = 1 and dm2 p yr3 = 1 then diabetes remission = 0;
       if dyslipid_p_bl = 0 and dyslipid_p_yr3 = 1 then dyslipidemia_incidence = 1;
       else if dyslipid_p_bl = 0 and dyslipid_p_yr3 = 0 then dyslipidemia_incidence = 0;
       if dyslipid_p_bl = 1 and dyslipid_p_yr3 = 0 then dyslipidemia_remission = 1;
       else if dyslipid_p_bl = 1 and dyslipid_p_yr3 = 1 then dyslipidemia_remission = 0;
       if hlipid_p_bl = 0 and hlipid_p_yr3 = 1 then hyperlipidemia_incidence = 1;
       else if hlipid_p_bl = 0 and hlipid_p_yr3 = 0 then hyperlipidemia_incidence = 0;
       if hlipid_p_bl = 1 and hlipid_p_yr3 = 0 then hyperlipidemia_remission = 1;
       else if hlipid_p_bl = 1 and hlipid_p_yr3 = 1 then hyperlipidemia_remission = 0;
       if lowHDL bl = 0 and lowHDL yr3 = 1 then lowHDL incidence = 1;
       else if lowHDL_bl = 0 and lowHDL_yr3 = 0 then lowHDL_incidence = 0;
       if lowHDL_bl = 1 and lowHDL_yr3 = 0 then lowHDL_remission = 1;
       else if lowHDL_bl = 1 and lowHDL_yr3 = 1 then lowHDL_remission = 0;
       if highTG_p_bl = 0 and highTG_p_yr3 = 1 then highTG_incidence = 1;
       else if highTG_p_bl = 0 and highTG_p_yr3 = 0 then highTG_incidence = 0;
       if highTG_p_bl = 1 and highTG_p_yr3 = 0 then highTG_remission = 1;
```

```
else if highTG_p_bl = 1 and highTG_p_yr3 = 1 then highTG_remission = 0;
       if htn_p_bl = 0 and htn_p_yr3 = 1 then htn_incidence = 1;
       else if htn_p_bl = 0 and htn_p_yr3 = 0 then htn_incidence = 0;
       if htn_p_bl = 1 and htn_p_yr3 = 0 then htn_remission = 1;
       else if htn_p_bl = 1 and htn_p_yr3 = 1 then htn_remission = 0;
       if vall and val2 and ((inactive_time = . or inactive_time > 3) or (inactive_time2 = . or inactive_time2 > 3)) then output table2;
data table2;
       set table2;
       if surg in (1,4) and death = 0;
proc freq data = table2;
       tables surg /list missing;
       format surg surgf.;
       title3 'Table 2 - Procedures';
proc sort data = table2;
       by surg;
proc freq data = table2;
       tables diabetes_remission diabetes_incidence /list;
       by surg;
       format surg surgf.;
       title3 'Table 2 - Diabetes';
proc freq data = table2;
       tables dyslipidemia_remission dyslipidemia_incidence /list;
       by surg;
       format surg surgf.;
       title3 'Table 2 - Dyslipidemia';
proc freg data = table2;
       tables hyperlipidemia_remission hyperlipidemia_incidence /list;
       by surg;
       format surg surgf.;
       title3 'Table 2 - Hyperlipidemia';
proc freq data = table2;
       tables lowHDL remission lowHDL incidence /list;
       by surg;
       format surg surgf.;
       title3 'Table 2 - Low HDL';
proc freq data = table2;
       tables highTG_remission highTG_incidence /list;
       by surg;
       format surg surgf.;
       title3 'Table 2 - High triglycerides';
proc freq data = table2;
       tables htn_remission htn_incidence /list ;
       by surg;
       format surg surgf.;
       title3 'Table 2 - Hypertension';
```

```
proc freq data = table3;
```

```
tables surg;
       format surg surgf.;
       title3 'Table 3 - Procedures';
proc sort data = table3;
       by surg;
proc freq data = table3;
       tables postdie;
       by surg;
       format surg surgf.;
proc freq data = table3;
       tables mortd /list;
       where postdie = 1;
       by surg;
       format surg surgf. mortd mortf.;
proc freq data = table3;
       tables mortd /list ;
       where postdie ne 1 and (death_time <= 3);
       by surg;
       format surg surgf. mortd mortf.;
proc sort data = sq;
       by id surqdat;
proc sort data = secondary_surgery;
       by id surgdat;
proc sort data = post2;
       by id surgdat;
proc sort data = sbp;
       by id surgdat;
data subsequent_surgeries;
       merge sq
                                 (in=val1 keep=id surg surgdat op_rever op_revis surgs)
             secondary surgery (in=val2 keep=id surgdat age s primary canceled)
                                 (keep=id surgdat postdie)
             post2
             sbp
                                 (keep=id surgdat revbari nbaripro portprob procprio);
       by id surqdat;
       if val1 and val2 and postdie = 0 and procprio = 1 then output subsequent_surgeries;
proc sort data = surgeries;
       by id;
proc sort data = table3;
       by id;
data subsequent_surgeries;
       merge subsequent_surgeries (in=val1)
             surgeries
                                   (keep=id surgdat age_s surg rename = (surgdat = orig_surgdat age_s = orig_age_s surg = orig_surg));
       by id;
       surg_time = ((surgdat - orig_surgdat)/365.25);
       surg_time2 = age_s - orig_age_s;
```

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if vall and (surg\_time <= 3 and surg\_time2 <= 3) and orig\_surg in (1,4) then output;

```
data subsequent_surgeries;
       length sub_surg $50.;
       set subsequent_surgeries;
       if orig_surg = 1 then do;
               if op_rever = 1 then sub_surg = 'Reversal';
               if op_revis = 1 then sub_surg = 'Revision';
       end;
       if orig_surg = 4 then do;
               if surg = 7 then sub_surg = 'Port revision';
               if surg in (1,5) then sub_surg = 'Revision to another bariatric procedure';
               if surg = 4 and op_rever = 1 and op_revis = 1 then sub_surg = 'Band replacement';
               if surg = 4 and ((op_rever = 1 and op_revis = 0) or portprob = 1) then sub_surg = 'Band removal';
               if surg = 4 and op_rever = 0 and op_revis = 1 and portprob = 0 then sub_surg = 'Other revision';
               if surg = 4 and nbaripro = 1 then sub_surg = 'Ignore';
       end;
       if sub_surg ne 'Ignore';
proc sort data = subsequent_surgeries;
       by orig_surg;
proc freq data = subsequent_surgeries;
       tables sub_surg /list missing;
       by orig_surg;
       format orig_surg surgf.;
```