

Dataset Integrity Check for the Teen-Labs 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 discrepancies that involve complex analyses, unless NIDDK Repository staff suspect that the observed discrepancy suggests that the dataset may have been corrupted in storage, transmission, or processing by repository staff. We do, however, document in footnotes to the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

2 Study Background

Extreme obesity affects a significant proportion of the US population and is associated with premature morbidity and mortality. While bariatric surgery can result in prolonged weight control and improvement in serious obesity comorbidities, surgery performed late in the course of comorbid conditions may not be as effective as surgery performed earlier. The Longitudinal Assessment of Bariatric Surgery (LABS) consortium was established by the NIDDK to provide a prospective observational study of adults undergoing bariatric surgery. As an ancillary study to LABS, Teen-LABS is also a prospective observational cohort study with the goal of collecting coordinated clinical, epidemiological and behavioral data in adolescent bariatric surgical patients. The current data package includes only the baseline data.

3 Archived Datasets

All SAS data files, as provided by the Data Coordinating Center (DCC), are located in the “data” file in the data package. For this replication, variables were taken from the “variable_listing_niddk_alterid” dataset.

4 Statistical Methods

Analyses were performed to duplicate results for the data published by The Teen-Labs Consortium, January 2014. To verify the integrity of the datasets, all tables from the manuscript were checked (Tables B)

5 Results

Replication of Tables 1 - 4 in the publication [1], Table A lists the variables that were used in the replication and Table B compares the results calculated from the archived data file to the results published in Tables 1 - 4.

The results of the replication are very similar to the published results. Note that there is one variable in the table that was redacted to protect the subjects' confidentiality. This variable is marked as "N/A" in the table below.

6 Conclusions

The NIDDK repository is confident that the Teen-Labs data files to be distributed are a copy of the manuscript data.

7 References

[1] Perioperative outcomes of adolescents undergoing bariatric surgery: the Teen–Longitudinal Assessment of Bariatric Surgery (Teen-LABS) Study. Inge TH, Zeller MH, Jenkins TM, et al; Teen-LABS Consortium. *JAMA Pediatrics*. 2014 Jan;47(7). doi:10.1001/jamapediatrics.2013.4296.

Table A: Variables used to replicate the following tables:
Demographic, Anthropometric, and Procedural Characteristics for the 242 Participants, Baseline Comorbidities and Conditions, Characteristics and Complications in the Perioperative Period, and Postoperative Characteristics and Complications Between Discharge and 30 Days

Table	Characteristic	Variable(s)
Table 1	Age at operation	surgage
Table 1	BMI	bmi
Table 1	Gender	sex
Table 1	Race	race
Table 1	Hispanic Ethnicity	N / A
Table 1	Waist circumference	waist
Table 1	Sagittal abdominal diameter	sad
Table 1	Surgical procedure	surg
Table 2	Dyslipidemia	Dyslipide
Table 2	Sleep apnea	SLPA
Table 2	Joint pain	JointP
Table 2	Hypertension	HyperTN
Table 2	Back pain	BackP
Table 2	Fatty liver disease	FLD
Table 2	PCOS	PCOSD
Table 2	Chronic kidney disease	CKD
Table 2	Diabetes mellitus	DMConfirm
Table 2	Blount disease	BlountD
Table 2	Pseudotumor cerebri	PTC
Table 3	Length of stay	los
Table 3	Operative technique	surgproc
Table 3	Reoperation for bowel obstruction/bleeding	re_bowl_1
Table 3	Reoperation for GI leak/sepsis	re_leak_1
Table 3	Reoperation for suspected sepsis	re_susp_sep_1
Table 3	Postoperative bleeding, transfusion required	bleed_trans_1
Table 3	Anticoagulation therapy for DVT	anti_dvt_1
Table 3	Unplanned splenectomy for injury	splen_inj_1
Table 3	GI leak, minimal	min_leak_1
Table 3	Postoperative bleeding, no transfusion	bleed_notrans_1
Table 3	Atelectasis/pneumonia	atel_1
Table 3	Urinary tract events	ut_events_1

Table	Characteristic	Variable(s)
Table 3	Bowel injury	bowl_inj_1
Table 3	Solid organ injury	organ_inj_1
Table 3	Mesenteric bleeding/hematoma	mesent_1
Table 3	Oversedation	sedate_1
Table 3	Hypertension	htn_1
Table 4	Deaths	postdie
Table 4	Discharged home	disloc
Table 4	Anticoagulation therapy for pulmonary embolus	anti_pe_2
Table 4	GI leaks not requiring reoperation	leak_nonop_2
Table 4	Suicidal ideation	suicid_2
Table 4	GI leaks requiring reoperation	re_leak_2
Table 4	Any TPN or enteral feeds after discharge	tpn_2
Table 4	Gastrojejunal anastomotic stricture	gj_stric_2
Table 4	Wound infection	wound_2
Table 4	Small-bowel obstruction/ileus	sb_obs_2
Table 4	Abdominal pain / diarrhea / dehydration / nausea	pain_dehy_2
Table 4	Acute pancreatitis	pancreat_2
Table 4	Urinary tract infection	uti_2

Table B: Comparison of values computed in integrity check to reference article Table 1-4 values

Characteristics from Table 1: Demographic, Anthropometric, and Procedural Characteristics for the 242 Participants	Manuscript (N = 242)	DSIC (N=242)	DIFF (N=0)
Age at surgery (Mean, SD)	17.1 (1.56)	17.1 (1.56)	0,0
13-15	65	65	0,0
16-17	91	91	0
18-19	86	86	0
Baseline BMI (Median, IQR)	50.5 (45.2-58.3)	50.5 (45.2-58.3)	0 (0-0)
<40	6	6	0
40-49	109	109	0
50-59	77	77	0
60+	50	50	0
Patient Gender			
Male	59	59	0
Female	183	183	0
Patient race			
White	174	174	0
Black	54	54	0
Other	14	14	0
Hispanic	17	N/A	N/A
Waist circumference, median (IQR)	145.9 (136.3-157.8)	145.9 (136.3-157.8)	0 (0-0)
Sagittal abdominal diameter, mean (SD)	31.7 (4.01)	31.7 (4.01)	0,0
Surgical procedure			
RYGB	161	161	0
AGB	14	14	0
VSG	67	67	0

Characteristics from Table 2: Baseline Comorbidities and Conditions	Manuscript (N <= 242)	DSIC (N <= 242)	Total (DIFF N=0)
Dyslipidemia	180 (74.4%)	180 (74.4%)	0,0
Sleep Apnea	137 (56.6%)	137 (56.6%)	0,0
Joint Pain	110 (45.6%)	110 (45.6%)	0,0
Hypertension	109 (45.0%)	106 (43.8%)	3,1.2
Back Pain	109 (45.2%)	109 (45.2%)	0,0
Fatty Liver Disease	89 (36.9%)	89 (36.9%)	0,0
PCOS, females only	38 (20.9%)	38 (20.9%)	0,0
Chronic kidney disease, any stage	43 (19.2%)	43 (19.2%)	0,0
Diabetes Mellitus	33 (13.6%)	33 (13.6%)	0,0
Blount Disease	9 (3.7%)	9 (3.7%)	0,0
Pseudotumor cerebri	6 (2.5%)	6 (2.5%)	0,0

Characteristics from Table 3: Characteristics and Complications in the Perioperative Period for subjects that received bypass surgery	Manuscript (N = 161)	DSIC (N = 161)	Total (DIFF N=0)
Length of stay (Median, IQR)	3.0 (2 - 4)	3.0 (3 - 4)	0,(-1,0)
Method of surgical procedure: Laparoscopic	160	160	0
Method of surgical procedure: Laparoscopic converted to open	1	1	0
Peri-Op Period: Reoperation for bowel obstruction /	3	3	0
Peri-Op Period: Reoperation for GI leak / sepsis	2	2	0
Peri-Op Period: Reoperation for suspected sepsis	1	1	0
Peri-Op Period: Postoperative bleeding, transfusion	4	4	0
Peri-Op Period: Anticoagulation therapy for DVT	1	1	0
Peri-Op Period: Unplanned splenectomy for injury	1	1	0
Peri-Op Period: GI leak, minimal	1	1	0
Peri-Op Period: Postoperative bleeding, no transfusion	2	2	0
Peri-Op Period: Atelectasis / pneumonia	1	1	0
Peri-Op Period: Urinary tract events	5	5	0
Peri-Op Period: Bowel injury	1	1	0
Peri-Op Period: Solid organ injury	1	1	0
Peri-Op Period: Mesenteric bleeding / hematoma	2	2	0
Peri-Op Period: Oversedation	0	0	0
Peri-Op Period: Hypertension	0	0	0

Characteristics from Table 3: Characteristics and Complications in the Perioperative Period for subjects that received Lap Band surgery	Manuscript (N = 14)	DSIC (N = 14)	Total (DIFF N=0)
Length of stay (Median, IQR)	1.0 (1 - 2)	1.0 (1 - 2)	0,(0,0)
Method of surgical procedure: Laparoscopic	14	14	0
Method of surgical procedure: Laparoscopic converted to open	0	0	0
Peri-Op Period: Reoperation for bowel obstruction /	0	0	0
Peri-Op Period: Reoperation for GI leak / sepsis	0	0	0
Peri-Op Period: Reoperation for suspected sepsis	0	0	0
Peri-Op Period: Postoperative bleeding, transfusion	0	0	0
Peri-Op Period: Anticoagulation therapy for DVT	0	0	0
Peri-Op Period: Unplanned splenectomy for injury	0	0	0
Peri-Op Period: GI leak, minimal	0	0	0
Peri-Op Period: Postoperative bleeding, no transfusion	0	0	0
Peri-Op Period: Atelectasis / pneumonia	0	0	0
Peri-Op Period: Urinary tract events	0	0	0
Peri-Op Period: Bowel injury	0	0	0
Peri-Op Period: Solid organ injury	1	1	0
Peri-Op Period: Mesenteric bleeding / hematoma	0	0	0
Peri-Op Period: Oversedation	0	0	0
Peri-Op Period: Hypertension	0	0	0

Characteristics from Table 3: Characteristics and Complications in the Perioperative Period for subjects that received Sleeve surgery	Manuscript (N = 67)	DSIC (N = 67)	Total (DIFF N=0)
Length of stay (Median, IQR)	3.0 (3 - 4)	3.0 (3 - 4)	0,(0,0)
Method of surgical procedure: Laparoscopic	67	67	0
Method of surgical procedure: Laparoscopic converted to open	0	0	0
Peri-Op Period: Reoperation for bowel obstruction / bleeding	0	0	0
Peri-Op Period: Reoperation for GI leak / sepsis	1	1	0
Peri-Op Period: Reoperation for suspected sepsis	0	0	0
Peri-Op Period: Postoperative bleeding, transfusion required	0	0	0
Peri-Op Period: Anticoagulation therapy for DVT	0	0	0
Peri-Op Period: Unplanned splenectomy for injury	0	0	0
Peri-Op Period: GI leak, minimal	0	0	0
Peri-Op Period: Postoperative bleeding, no transfusion	0	0	0
Peri-Op Period: Atelectasis / pneumonia	1	1	0
Peri-Op Period: Urinary tract events	1	1	0
Peri-Op Period: Bowel injury	0	0	0
Peri-Op Period: Solid organ injury	2	2	0
Peri-Op Period: Mesenteric bleeding / hematoma	0	0	0
Peri-Op Period: Oversedation	1	1	0
Peri-Op Period: Hypertension	1	1	0

Characteristics from Table 3: Characteristics and Complications in the Perioperative Period for all surgery types	Manuscript (N = 242)	DSIC (N = 242)	Total (DIFF N=0)
Length of stay (Median, IQR)	3.0 (2 - 4)	3.0 (3 - 4)	0,(-1,0)
Method of surgical procedure: Laparoscopic	241	241	0
Method of surgical procedure: Laparoscopic converted to open	1	1	0
Peri-Op Period: Reoperation for bowel obstruction / bleeding	3	3	0
Peri-Op Period: Reoperation for GI leak / sepsis	3	3	0
Peri-Op Period: Reoperation for suspected sepsis	1	1	0
Peri-Op Period: Postoperative bleeding, transfusion required	4	4	0
Peri-Op Period: Anticoagulation therapy for DVT	1	1	0
Peri-Op Period: Unplanned splenectomy for injury	1	1	0
Peri-Op Period: GI leak, minimal	1	1	0
Peri-Op Period: Postoperative bleeding, no transfusion	2	2	0
Peri-Op Period: Atelectasis / pneumonia	2	2	0
Peri-Op Period: Urinary tract events	6	6	0
Peri-Op Period: Bowel injury	1	1	0
Peri-Op Period: Solid organ injury	4	4	0
Peri-Op Period: Mesenteric bleeding / hematoma	2	2	0
Peri-Op Period: Oversedation	1	1	0
Peri-Op Period: Hypertension	1	1	0

Characteristics from Table 4: <u>Postoperative Characteristics and Complications Between Discharge and 30 Days</u> for subjects that received bypass surgery	Manuscript (N = 161)	DSIC (N = 161)	Total (DIFF N=0)
Did the patient die?	0	0	0
Discharge Location	161	161	0
Discharge thru 30d: Anticoagulation therapy	1	1	0
Discharge thru 30d: GI leaks not requiring	2	2	0
Discharge thru 30d: Suicidal ideation	0	0	0
Discharge thru 30d: Reoperation for GI leak /	1	1	0
Discharge thru 30d: Any TPN or enteral feeds	0	0	0
Discharge thru 30d: Gastrojejunal anastomotic	6	6	0
Discharge thru 30d: Wound infection	3	3	0
Discharge thru 30d: Small-bowel obstruction /	1	1	0
Discharge thru 30d: Abdominal pain /	9	9	0
Discharge thru 30d: Acute pancreatitis	1	1	0
Discharge thru 30d: Urinary tract infection	1	1	0

Characteristics from Table 4: <u>Postoperative Characteristics and Complications Between Discharge and 30 Days</u> for subjects that received lap band surgery	Manuscript (N = 14)	DSIC (N = 14)	Total (DIFF N=0)
Did the patient die?	0	0	0
Discharge Location	14	14	0
Discharge thru 30d: Anticoagulation therapy	1	1	0
Discharge thru 30d: GI leaks not requiring	0	0	0
Discharge thru 30d: Suicidal ideation	0	0	0
Discharge thru 30d: Reoperation for GI leak /	0	0	0
Discharge thru 30d: Any TPN or enteral feeds	0	0	0
Discharge thru 30d: Gastrojejunal anastomotic	0	0	0
Discharge thru 30d: Wound infection	0	0	0
Discharge thru 30d: Small-bowel obstruction /	1	1	0
Discharge thru 30d: Abdominal pain /	0	0	0
Discharge thru 30d: Acute pancreatitis	0	0	0
Discharge thru 30d: Urinary tract infection	0	0	0

Characteristics from Table 4: <u>Postoperative Characteristics and Complications Between Discharge and 30 Days</u> for subjects that received sleeve surgery	Manuscript (N = 67)	DSIC (N = 67)	Total (DIFF N=0)
Did the patient die?	0	0	0
Discharge Location	67	67	0
Discharge thru 30d: Anticoagulation therapy	0	0	0
Discharge thru 30d: GI leaks not requiring	0	0	0
Discharge thru 30d: Suicidal ideation	1	1	0
Discharge thru 30d: Reoperation for GI leak /	1	1	0
Discharge thru 30d: Any TPN or enteral feeds	1	1	0
Discharge thru 30d: Gastrojejunal anastomotic	0	0	0
Discharge thru 30d: Wound infection	2	2	0
Discharge thru 30d: Small-bowel obstruction /	0	0	0
Discharge thru 30d: Abdominal pain /	2	2	0
Discharge thru 30d: Acute pancreatitis	0	0	0
Discharge thru 30d: Urinary tract infection	0	0	0

Characteristics from Table 4: <u>Postoperative Characteristics and Complications Between Discharge and 30 Days</u> for all subjects	Manuscript (N = 242)	DSIC (N = 242)	Total (DIFF N=0)
Did the patient die?	0	0	0
Discharge Location	242	242	0
Discharge thru 30d: Anticoagulation therapy	2	2	0
Discharge thru 30d: GI leaks not requiring	2	2	0
Discharge thru 30d: Suicidal ideation	1	1	0
Discharge thru 30d: Reoperation for GI leak /	2	2	0
Discharge thru 30d: Any TPN or enteral feeds	1	1	0
Discharge thru 30d: Gastrojejunal anastomotic	6	6	0
Discharge thru 30d: Wound infection	5	5	0
Discharge thru 30d: Small-bowel obstruction /	2	2	0
Discharge thru 30d: Abdominal pain /	11	11	0
Discharge thru 30d: Acute pancreatitis	1	1	0
Discharge thru 30d: Urinary tract infection	1	1	0

```

libname labs '/prj/niddk/ims_analysis/Teen_Labs/private_orig_data/BaselineToNIDDK20141216/';
data teenlabs;
  set labs.variable_listing_niddk_alterid;
  **Use labels from dataset documentation as existing labels are not descriptive;
  %include '/prj/niddk/ims_analysis/Teen_Labs/private_orig_data/BaselineToNIDDK20141216/labels.txt';
run;

**Recode continuous variables in table 1 from character to numeric, replace cutoff values with an estimate of the correct value;
data teenlabs;
  set teenlabs;
  if bmi = ">75.8" then bmi_n = 82; **This is approximately the mean of the subjects with bmis over the cutoff;
  else if not missing(bmi) then bmi_n = bmi * 1;

  if waist = ">188.9" then waist_n = 194.0 ;**This is the max listed in the paper, mean/std within roundoff with this value;
  else if not missing(waist) then waist_n = waist * 1;

  if sad = ">41.7" then sad_n = 43; **approximate, makes the mean/std correct (only 1 person with this value);
  else if not missing(sad) then sad_n = sad * 1;

  **Create binary for chronic kidney disease;
  if ckd = 1 then ckd_2 = 0;
  else if ckd > 1 then ckd_2 = 1;

  **Recode males to missing instead of special value;
  if PCOSD = -2 then PCOSD = .;
  label
  waist_n = 'Iliac waist circumference (cm)'
  sad_n = 'Sagittal abdominal diameter (cm)'
  bmi_n = 'baseline BMI'
  ;
run;
proc format;
  value agegrp
  13-<16 = "13-15"
  16-<18 = "16-17"
  18-<20 = "18-19"
  ;
  value bmif
  0-39.9 = "<40"
  40-49.9 = "40-49"
  50-59.9 = "50-59"
  60-89.9 = "60+"
  ;
  value racef
  1 = "White"
  2 = "Black"
  3 = "Other"
  ;
  value surgtypef
  1 = "RYGB"
  4 = "AGB"
  5 = "VSG"
  ;
  value surgtype2f
  1 = "Bypass (N = 161)"
  4 = "Band (N = 14)"

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5 = "Sleeve (N = 67)"
;
value gendf
1 = "Male"
2 = "Female"
;
value surgprocf
1 = "Laparoscopic"
2 = "Laparoscopic converted to open"
;

run;

title2 "Manuscript Table 1";
proc tabulate data = teenlabs;
class surgage bmi_n sex race surg;
format bmi_n bmif_ surgage agegrp_ race racef_ sex gendf_ surg surgtypef_ ;
table (surgage bmi_n sex race surg),all*(N*f=3.0 PCTN*f=4.1); **Manuscript Table 1;

run;

proc means data = teenlabs n mean std median q1 q3 min max MAXDEC=2;
format surgage bmi_n waist_n sad_n 5.2;
var surgage bmi_n waist_n sad_n;

run;

title2 "Manuscript Table 2";
proc tabulate data = teenlabs;
var Dyslipide SLPA JointP HyperTN BackP FLD PCOSD ckd_2 DMCONFIRM BlountD PTC ;
table (Dyslipide SLPA JointP HyperTN BackP FLD PCOSD ckd_2='CKD (any stage)' DMCONFIRM='Diabetes Mellitus' BlountD PTC ),
all*(sum='No.'*f=3.0 mean='Percent'*f=PercentN8.1); **Manuscript Table 2;

run;

title2 "Manuscript Table 3";
proc tabulate data = teenlabs;
class surg surgproc;
var los re_bowl_1 re_leak_1 re_susp_sep_1 bleed_trans_1 anti_dvt_1 splen_inj_1
min_leak_1 bleed_notrans_1 atel_1 ut_events_1 bowel_inj_1 organ_inj_1 mesent_1 sedate_1 htn_1;
table los,(surg all='Total (N=242)') * (median='Median'*f=3.1 q1='Q1'*f=3.0 q3='Q3'*f=3.0) / ;
table surgproc,(surg all='Total (N=242)') * (N*f=3.0 COLPCTN='Pct.'*f=5.1) / misstext = "0";
table re_bowl_1 re_leak_1 re_susp_sep_1 bleed_trans_1 anti_dvt_1 splen_inj_1
min_leak_1 bleed_notrans_1 atel_1 ut_events_1 bowel_inj_1 organ_inj_1 mesent_1 sedate_1 htn_1
,(surg all='Total (N=242)')*(sum='No.'*f=3.0 mean='Percent'*f=PercentN8.1) / misstext = "0";
format surg surgtype2f. surgproc surgprocf.;

run;

title2 "Manuscript Table 4";
proc tabulate data = teenlabs;
class surg;
var postdie disloc anti_pe_2 leak_nonop_2 suicid_2 re_leak_2
tpn_2 gj_stric_2 wound_2 sb_obs_2 pain_dehy_2 pancreat_2 uti_2;
table postdie disloc anti_pe_2 leak_nonop_2 suicid_2 re_leak_2
tpn_2 gj_stric_2 wound_2 sb_obs_2 pain_dehy_2 pancreat_2 uti_2
,(surg all)*(sum='No.'*f=3.0 mean='Percent'*f=PercentN8.1) / misstext = "0";
format surg surgtype2f. surgproc surgprocf.;

run;

```