

Dataset Integrity Check for FL3X Study

Prepared by Michael Spriggs

IMS Inc.

3901 Calverton Blvd, Suite 200 Calverton, MD 20705

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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

The FL3X Adaptive Intervention is designed to increase adherence to T1D self-management including medical management (blood sugar testing and insulin dosing), diet, and physical activity. FL3X relies on MI, and problem-solving skills training (PSST) as the basis for the counseling strategy, and creates a coherent integration across three key components of 1) behavior family systems therapy focused on family communications and teamwork; 2) individualized diabetes education in response to knowledge gaps relevant to behavioral goal attainment; and 3) use of currently available communications technology to support behavioral goal attainment through participant-defined reminders and motivational boosters, and/or peer support.

3 Archived Datasets

All the SAS data files, as provided by the Data Coordinating Center (DCC), are located in the FL3X folder in the data package. For this replication, variables were taken from the agedur, basevars, cgm, f05, f26_ins, f28, lab, f03, spsi, f09, f08, f29, f0607, lbschild_raw, LBS_PARENT_RAW, f12, f11, and bmi_z20 datasets.

4 Statistical Methods

Analyses were performed to duplicate results for the data published by Mayer-Davis et al in Lancet Child Adolescent Health in 2018.

To verify the integrity of the dataset, Table 1 descriptive statistics were computed.

5 Results

For Table 1 in the publication [1], Table 1: Characteristics of the data analyzed, Table A lists the variables that were used in the replication and Table B compares the results calculated from the archived data files to the results published in Table 1. The results of the replication are a match to the published results within rounding or minor differences for all variables.

6 Conclusions

The NIDDK repository is confident that the FL3X data files to be distributed are a true copy of the study data.

7 References

[1] Mayer-Davis EJ, Maahs DM, Seid M, Crandell J, Bishop FK, Driscoll KA, et al. Efficacy of the flexible lifestyles empowering change intervention on metabolic and psychosocial outcomes in adolescents with type 1 diabetes (FLEX): a randomised controlled trial. *Lancet Child Adolesc Health* (2018) 2:635–46. doi: 10.1016/S2352-4642(18)30208-6

Table A: Variables used to replicate Table 1: Characteristics of the data analyzed

| Table Variable | dataset.variable |
|--|---|
| Age (years) | Agedur.age |
| Sex | Basevars.sex |
| Race and ethnicity | Basevars.raceeth_base |
| Public health insurance | Basevars.public_insurance_base |
| Single adult home | Basevars.single_adult_home_base |
| Duration of diabetes (years) | Agedur.dm_duration |
| HbA1c above 75 mmol/mol; 9.0% (%) | Basevars.hba1c_pcmt_base |
| Average number of hypoglycaemic (<3.88 mmol/L) episodes lasting 15 min or more per 24 h period | cgm.num_hypo70/ghhours*24; |
| Weight status | Bmiz20.weight_status |
| Insulin regimen | F26_INS.F26Q6_pump_or_injct_use_ystrday |
| Used CGM in past month | F28.CGM_use_recent |
| HbA1c (mmol/mol) | (lab.hba1c_pcmt-2.15)*10.929; |
| Motivation | F03.motivation_score |
| Intention | F03.intention_score |
| Problem solving (SPSI) | Spsi.spsi_total_stan |
| Diabetes self-management (DSMP) | F09.dsmp_youth_total F08.dsmp_parent_total |
| Depression symptoms (CES-D) | f29.CESDtot |
| Generic QOL (PedsQOL) Young person | f0607.pedsqol_youth |
| Generic QOL (PedsQOL) Parent | f0607.pedsqol_parent |
| Fear of hypoglycaemia in youth: Maintain high blood glucose | lbschild_raw.LBS_maintainhigh_child |
| Fear of hypoglycaemia in youth: Helplessness or worry | lbschild_raw.LBS_helpless_child |
| Fear of hypoglycaemia in youth: Worry about negative social consequences | lbschild_raw.LBS_NegSC_child |
| Fear of hypoglycaemia in caregiver: Maintain high blood glucose | LBS_PARENT_RAW.LBS_maintainhigh_parent |
| Fear of hypoglycaemia in caregiver: Helplessness or worry | LBS_PARENT_RAW.LBS_helpless_parent |

| | |
|--|--|
| Fear of hypoglycaemia in caregiver: Worry about negative social consequences | LBS_PARENT_RAW.LBS_NegSC_parent |
| Diabetes family conflict: Young people | F12.IP_total_participant |
| Diabetes family conflict: Caregiver | F11.IP_total_parent |
| BMI Z score | bmi_z20.bmiz |
| Total cholesterol (mmol/L) | LAB.tchol_mgdl/38; |
| LDL cholesterol (mmol/L) | LAB.ldl_mgdl/38; |
| HDL cholesterol (mmol/L) | LAB.hdl_mgdl/38; |
| Triglycerides (mmol/L) | LAB.trig_mgdl/88; |
| Systolic blood pressure (mmHg) | F05.sbp |
| Diastolic blood pressure (mmHg) | F05.dbp |
| CGM time (min/day) | Cgm.Glubelow54*1440; Cgm.gluBelow70*1440; Cgm.Gluabove180*1440; Cgm.Gluabove250*1440; |

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

| Variable | Control Manuscript (n=128) | Control DSIC (n=128) | Diff. (n=0) | FLEX Intervention Manuscript (n=130) | FLEX Intervention (n=130) | Diff. (n=0) |
|--|----------------------------|----------------------|-------------|--------------------------------------|---------------------------|-------------|
| Age (years) | 14.9 (1.1) | 14.9 (1.1) | 0 (0) | 14.8 (1.1) | 14.8 (1.1) | 0 (0) |
| Female sex | 54 | 54% | 0 | 45 | 45% | 0 |
| Race and ethnicity | | | | | | |
| Non-Hispanic white | 100 (78%) | 100 (78%) | 0 (0) | 100 (77%) | 100 (77%) | 0 (0) |
| Black | 4 (3%) | 4 (3%) | 0 (0) | 7 (5%) | 7 (5%) | 0 (0) |
| Hispanic | 17 (13%) | 17 (13%) | 0 (0) | 16 (12%) | 16 (12%) | 0 (0) |
| Other | 7 (6%) | 7 (6%) | 0 (0) | 7 (5%) | 7 (5%) | 0 (0) |
| Public health insurance | 20 (16%) | 20 (16%) | 0 (0) | 27 (21%) | 27 (21%) | 0 (0) |
| Single adult home | 19 (15%) | 19 (15%) | 0 (0) | 15 (12%) | 15 (12%) | 0 (0) |
| Duration of diabetes (years) | 6.4 (3.7) | 6.4 (3.7) | 0 (0) | 6.5 (3.8) | 6.5 (3.8) | 0 (0) |
| HbA1c above 75 mmol/mol; | 79 (62%) | 79 (62%) | 0 (0) | 91 (70%) | 91 (70%) | 0 (0) |
| Average number of hypoglycaemic (<3.88 mmol/L) episodes lasting 15 min or more per 24 h period | 0.47 (0.86) | 0.47(0.85) | 0 (0.01) | 0.45 (0.80) | 0.45(0.83) | 0 (0.03) |
| Weight status | | | | | | |
| Under or normal weight | 78 (61%) | 78 (61%) | 0 (0) | 86 (66%) | 86 (66%) | 0 (0) |
| Overweight | 33 (26%) | 33 (26%) | 0 (0) | 26 (20%) | 26 (20%) | 0 (0) |
| Obese | 17 (13%) | 17 (13%) | 0 (0) | 18 (14%) | 18 (14%) | 0 (0) |
| Insulin regimen | | | | | | |
| Multiple daily injection | 34 (27%) | 34 (27%) | 0 (0) | 41 (32%) | 41 (32%) | 0 (0) |
| Pump | 93 (73%) | 93 (73%) | 0 (0) | 88 (68%) | 88 (68%) | 0 (0) |
| Used CGM in past month | 29 (23%) | 29 (23%) | 0 (0) | 24 (19%) | 24 (18%) | 0(-1%) |
| Primary outcome | | | | | | |
| HbA1c (mmol/mol) | 80 (4) | 80(14) | 0(-10) | 83 (13) | 83(13) | 0(0) |
| Secondary outcomes | | | | | | |
| Motivation | 7.7 (1.6) | 7.7 (1.6) | 0 (0) | 7.5 (1.6) | 7.5 (1.6) | 0 (0) |
| Intention | 9.1 (1.0) | 9.1 (1.0) | 0 (0) | 9.1 (1.0) | 9.1 (1.0) | 0 (0) |
| Problem solving (SPSI) | 106.3 (12.3) | 106.3 (12.3) | 0 (0) | 105.1 (13.3) | 96.7(15.3) | 0 (0) |
| Diabetes self-management | | | | | | |
| Young person | 55.5 (11.4) | 55.5 (11.4) | 0 (0) | 54.6 (11.7) | 54.6 (11.7) | 0 (0) |
| Parent | 52.7 (11.6) | 52.7 (11.6) | 0 (0) | 50.6 (12.3) | 50.6 (12.3) | 0 (0) |
| Depression symptoms (CES-D) | 9.16 (7.73) | 9.16 (7.73) | 0 (0) | 9.25 (8.91) | 9.25 (8.91) | 0 (0) |
| Generic QOL (PedsQOL) | | | | | | |
| Young person | 81.1 (11.7) | 81.1 (11.7) | 0 (0) | 80.7 (13.1) | 80.7 (13.1) | 0 (0) |
| Parent | 78 (14.0) | 78 (14.0) | 0 (0) | 77.1 (14.8) | 77.1 (14.8) | 0 (0) |
| Fear of hypoglycaemia in youth | | | | | | |

| Variable | Control Manuscript (n=128) | Control DSIC (n=128) | Diff. (n=0) | FLEX Intervention Manuscript (n=130) | FLEX Intervention (n=130) | Diff. (n=0) |
|--|----------------------------|----------------------|--------------|--------------------------------------|---------------------------|--------------|
| Maintain high blood glucose | 1.25 (0.88) | 1.25 (0.88) | 0 (0) | 1.17 (0.91) | 1.17 (0.91) | 0 (0) |
| Helplessness or worry | 1.11 (0.57) | 1.11 (0.57) | 0 (0) | 1.13 (0.57) | 1.13 (0.57) | 0 (0) |
| Worry about negative social consequences | 1.04 (0.76) | 1.04 (0.76) | 0 (0) | 1.12 (0.70) | 1.12 (0.70) | 0 (0) |
| Fear of hypoglycaemia in caregiver | | | | | | |
| Maintain high blood glucose | 1.11 (0.79) | 1.11 (0.79) | 0 (0) | 1.11 (0.74) | 1.11 (0.74) | 0 (0) |
| Helplessness or worry | 1.45 (0.74) | 1.45 (0.74) | 0 (0) | 1.49 (0.73) | 1.49 (0.73) | 0 (0) |
| Worry about negative social consequences | 0.52 (0.58) | 0.52 (0.58) | 0 (0) | 0.59 (0.61) | 0.59 (0.61) | 0 (0) |
| Diabetes family conflict:Young | 1.36 (0.36) | 1.36 (0.36) | 0 (0) | 1.35 (0.30) | 1.35 (0.30) | 0 (0) |
| Diabetes family conflict: Caregiver | 1.41 (0.28) | 1.41 (0.28) | 0 (0) | 1.45 (0.33) | 1.45 (0.33) | 0 (0) |
| BMI Z score | 0.71 (0.89) | 0.71 (0.89) | 0 (0) | 0.60 (0.98) | 0.60 (0.98) | 0 (0) |
| Total cholesterol (mmol/L) | 4.47 (0.84) | 4.55(0.86) | -0.08(-0.02) | 4.40 (0.87) | 4.47(0.89) | -0.07(-0.02) |
| LDL cholesterol (mmol/L) | 2.59 (0.77) | 2.63(0.78) | -0.04(-0.01) | 2.46 (0.70) | 2.50(0.72) | -0.04(-0.02) |
| HDL cholesterol (mmol/L) | 1.43 (0.32) | 1.46(0.33) | -0.03(-0.01) | 1.43 (0.35) | 1.45(0.36) | -0.02(-0.01) |
| Triglycerides (mmol/L) | 0.99 (0.54) | 0.99(0.54) | 0 (0) | 1.26 (2.31) | 1.27(2.32) | -0.01(-0.01) |
| Systolic blood pressure | 101 (9) | 101 (9) | 0 (0) | 102 (9) | 102 (9) | 0 (0) |
| Diastolic blood pressure | 66 (7) | 66 (7) | 0 (0) | 67 (9) | 67 (9) | 0 (0) |
| CGM time (min/day) | | | | | | |
| <3.0 mmol/L | 4.5 (0-31.5) | 4.5(0-31.5) | 0(0-0) | 4.3 (0-31.5) | 4.3(0-31.5) | 0(0-0) |
| <3.9 mmol/L | 28.8 (5.2-80.7) | 28.8(5.2-80.7) | 0(0-0) | 31.4 (5.0-72.1) | 31.4(5.0-72.1) | 0(0-0) |
| >10.0 mmol/L | 846 (733-1082) | 846(734-1083) | 0(-1- -1) | 906 (764-1055) | 906(764-1055) | 0(0-0) |
| >13.9 mmol/L | 486 (327-706) | 486(327-706) | 0(0-0) | 535 (336-649) | 535(336-649) | 0(0-0) |

Attachment A: SAS Code

```
*****
**
** Program: P:\niddk\ims_analysis\FL3X\prog_initial_analysis\flex_table1_20mar2019.sas
** Programmer: Michael Spriggs
** Date Created: Feb 12, 2019 by Michael Spriggs
** Last Modified: Mar 20, 2019 by Michael Spriggs
**
*****;
title1 "%sysfunc(getoption(sysin))";
title2 " ";

OPTIONS nofmterr;

LIBNAME cre_dat "/prj/niddk/ims_analysis/FL3X/private_created_data/FL3X 19mar2019/DATASETS AND CONTENTS/";
%include '/prj/biolincc/ims_analysis/sas_macros/redaction_data_summary.sas';

proc format;
    value hbf 0-9="At or Below 9%"
                9<-100="Above 9%"
                ;
    value bmif 0-<25="Under to Normal"
                25-<30="Overweight"
                30-high="Obese"
                ;
    value cgmf 1="No"
                2-5="Used in Past Month"
                ;
data agedur      ; set cre_dat.agedur      ;
data basevars    ; set cre_dat.basevars    ;
data bmiz20      ; set cre_dat.bmiz20      ;
data cgm         ; set cre_dat.cgm         ;
data f03         ; set cre_dat.f03         ;
data f05         ; set cre_dat.f05         ;
data f0607       ; set cre_dat.f0607       ;
data f08         ; set cre_dat.f08         ;
data f09         ; set cre_dat.f09         ;
data f10         ; set cre_dat.f10         ;
data f11         ; set cre_dat.f11         ;
data f12         ; set cre_dat.f12         ;
data f13         ; set cre_dat.f13         ;
data f14         ; set cre_dat.f14         ;
data f15         ; set cre_dat.f15         ;
data f16         ; set cre_dat.f16         ;
data f17         ; set cre_dat.f17         ;
data f18         ; set cre_dat.f18         ;
data f19         ; set cre_dat.f19         ;
data f20         ; set cre_dat.f20         ;
```

```

data f21          ; set cre_dat.f21          ;
data f26_ins     ; set cre_dat.f26_ins     ;
data f28         ; set cre_dat.f28         ;
data f29         ; set cre_dat.f29         ;
data f30         ; set cre_dat.f30         ;
data f31         ; set cre_dat.f31         ;
data f38         ; set cre_dat.f38         ;
data f39         ; set cre_dat.f39         ;
data group      ; set cre_dat.group      ;
data hui        ; set cre_dat.hui        ;
data lab        ; set cre_dat.lab        ;
data pdpar      ; set cre_dat.pdpar      ;
data recall124  ; set cre_dat.recall124  ;
data spsi       ; set cre_dat.spsi       ;

```

```

proc sort data=agedur  nodupkey; by newid visit;
proc sort data=basevars nodupkey; by newid;
proc sort data=bmiz20  nodupkey; by newid;
proc sort data=cgm     nodupkey; by newid visit;
proc sort data=f03     nodupkey; by newid visit;
proc sort data=f05     nodupkey; by newid visit;
proc sort data=f0607   nodupkey; by newid visit;
proc sort data=f08     nodupkey; by newid visit;
proc sort data=f09     nodupkey; by newid visit;
proc sort data=f10     nodupkey; by newid visit;
proc sort data=f11     nodupkey; by newid visit;
proc sort data=f12     nodupkey; by newid visit;
proc sort data=f13     nodupkey; by newid visit;
proc sort data=f14     nodupkey; by newid visit;
proc sort data=f15     nodupkey; by newid visit;
proc sort data=f16     nodupkey; by newid visit;
proc sort data=f17     nodupkey; by newid visit;
proc sort data=f18     nodupkey; by newid visit;
proc sort data=f19     nodupkey; by newid visit;
proc sort data=f20     nodupkey; by newid visit;
proc sort data=f21     nodupkey; by newid visit;
proc sort data=f26_ins nodupkey; by newid visit;
proc sort data=f28     nodupkey; by newid visit;
proc sort data=f29     nodupkey; by newid visit;
proc sort data=f30     nodupkey; by newid visit;
proc sort data=f31     nodupkey; by newid visit;
proc sort data=f38     nodupkey; by newid visit;
proc sort data=f39     nodupkey; by newid visit;
proc sort data=group   nodupkey; by newid;

```

```

data lab;
  set lab;
  where visit="baseline";

```

```

proc sort data=lab      nodupkey; by newid visit;
proc sort data=pdpar    nodupkey; by newid visit;

```

```
proc sort data=spsi      nodupkey; by newid visit;
```

```
data onevis;  
  merge basevars          bmiz20  
        group  
        ;  
  by newid;
```

```
data omnibus;  
  merge agedur  
        cgm  
        f03  
        f05  
        f0607  
        f08  
        f09  
        f10  
        f11  
        f12  
        f13  
        f14  
        f15  
        f16  
        f17  
        f18  
        f19  
        f20  
        f21  
        f26_ins  
        f28  
        f29  
        f30  
        f31  
        f38  
        f39  
        lab  
        pdpar  
        spsi  
        ;  
  by newid visit;
```

```
tchol_mmoll=tchol_mgd1/38;  
ldl_mmoll  =ldl_mgd1  /38;  
hdl_mmoll  =hdl_mgd1  /38;  
trig_mmoll =trig_mgd1 /88;
```

```
episode_hypo70=num_hypo70/ghuhours*24;
```

```
mins_Glubelow54 =Glubelow54 *1440;
```

```

mins_gluBelow70 =gluBelow70 *1440;
mins_Gluabove180=Gluabove180*1440;
mins_Gluabove250=Gluabove250*1440;

data omnibus;
  set omnibus;
  where visit="baseline";

data for_ana;
  merge onevis(in=inov) omnibus;
  by newid;
  hbalc_mmolmol=(hbalc_pcnc-2.15)*10.929;
  if inov then output;

proc means data=for_ana maxdec=1;
  var age;
  class group;

proc freq data=for_ana;
  tables (sex raceeth_base public_insurance_base single_adult_home_base)*Group
  /missing;
  title 'Check';

proc means data=for_ana maxdec=1;
  var dm_duration ;
  class group;

proc freq data=for_ana;
  tables hbalc_pcnc*group
  /missing;
  format hbalc_pcnc hbf.;
  title 'Check';

proc means data=for_ana maxdec=2 median p25 p75;
  var episode_hypo70;
  class group;
  title 'episode_hypo';

proc freq data=for_ana;
  tables
  (
weight_status
F26Q6_pump_or_injct_use_ystrday
CGM_use_recent
  )*group/missing;
format CGM_use_recent cgmf.;
title 'Check';

```

```

proc means data=for_ana maxdec=0;
  var hba1c_mmolmol;
  class group;

proc means data=for_ana maxdec=1;
  var motivation_score
  intention_score
  spsi_total_stan;
  class group;

proc means data=for_ana maxdec=2;
  var
  CESDtot;
  class group;

proc means data=for_ana maxdec=1;
  var
  pedsql_youth
  pedsql_parent;
  class group;

proc means data=for_ana maxdec=2 mean stddev;
  var
  LBS_maintainhigh_child
  LBS_helpless_child
  LBS_NegSC_child
  LBS_maintainhigh_parent
  LBS_helpless_parent
  LBS_NegSC_parent
  ;
  class group;

proc means data=for_ana maxdec=1 mean stddev;
  var
  dsmp_youth_total
  dsmp_parent_total
  ;
  class group;

proc means data=for_ana maxdec=0 mean stddev;
  var
  sbp
  dbp
  ;
  class group;

proc means data=for_ana maxdec=1 median p25 p75;
  var
  cgm_median
  ;
  class group;

```

```
proc means data=for_ana maxdec=2 mean stddev;
  var
    IP_total_participant
    IP_total_parent
    bmic
    tchol_mmoll
    ldl_mmoll
    hdl_mmoll
    trig_mmoll
  ;
  class group;

proc means data=for_ana maxdec=1 median p25 p75;
  var
    mins_Glubelow54
    mins_gluBelow70
  ;
  class group;

proc means data=for_ana maxdec=0 median p25 p75;
  var
    mins_Gluabove180
    mins_Gluabove250
  ;
  class group;
```