Dataset Integrity Check for the Trans-MAPP Study of Urologic Chronic Pelvic Pain: Symptom Patterns Study (MAPP II)

Prepared by NIDDK-CR
May 9, 2023

Contents

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 second phase of the Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Network was designed to conduct a prospective, observational study of men and women with urologic chronic pelvic pain syndrome (UCPPS). The follow-up MAPP II Symptom Patterns Study (SPS) had pre-defined subgroups with longer follow-up periods (up to 36 months) to further investigate clinical and biologic factors associated with worsening and/or improvement of reported urinary and non-urinary symptoms.

Participants completed a series of in-clinic study visits at various time points, online internet-based questionnaires in clinic and off site/at home (assessing symptoms, health care utilization, flare status, and quality of life), a physical exam, a pelvic exam, and a prostate massage (optional for males only). The study also applied promising research methods in the pain field (e.g., functional, chemical, and structural neuroimaging, quantitative sensory testing) during the study (at baseline and then longitudinally) to better characterize men and women with UCPPS.

3 Archived Datasets

All data files, as provided by the Data Coordinating Center (DCC), are located in the MAPP II folder in the data package. A list of all archived datasets can be found in the roadmap file for MAPP II. For this replication, variables were taken from the “mapp2_baseline.sas7bdat” dataset.

4 Statistical Methods

Analyses were performed to replicate results for the data published by Clemens et al. [1]. To verify the integrity of the data, only descriptive statistics were computed.

5 Results

For Table 2 in the publication [1], Composition of MAPP I EPS, MAPP II SPS and MAPP II SPS/EPS Participants, 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 2. The results of the replication are within expected variation to the values in Table 2.

6 Conclusions

The NIDDK Central Repository is confident that the MAPP II data files to be distributed are a true copy of the study data as the results of the replication are within expected variation to the published results.

7 References

[1] Clemens JQ, Kutch JJ, Mayer EA, Naliboff BD, Rodriguez LV, Klumpp DJ, Schaeffer AJ, Kreder KJ, Clauw DJ, Harte SE, Schrepf AD, Williams DA, Andriole GL, Lai HH, Buchwald D, Lucia MS, van Bokhoven A, Mackey S, Moldwin RM, Pontari MA, Stephens-Shields AJ, Mullins C, Landis JR. The Multidisciplinary Approach to The Study of Chronic Pelvic Pain (MAPP) Research Network: Design and Implementation of the Symptom Patterns Study (SPS). Neurourology and Urodynamics, 39(6), 1803-1814, August 2020. doi: https://doi.org/10.1002/nau.24423

Table A: Variables used to replicate Table 2 – Composition of MAPP I EPS, MAPP II SPS and MAPP II SPS/EPS Participants

Table Variable	**dataset.variable**
Age	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.age
Sex	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.sex
Race	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.racecat
Employed	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.emp_status
Income	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.income_cat
Duration of Symptoms	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.symp_duration
Pain (0-10) (SYMQ-1)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.sym1_q1
Overall Pelvic/Urologic Symptoms (0-10) (SYMQ-5)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.symq_q5
GUPI Total Score (0-45)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.gupiscoretotal
GUPI Pain Subscale (0-23)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.gupiscore_pain
IC Symptom Index (0-20)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.icsitot
IC Problem Index (0-16)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.icpitot
AUA Symptom Index (0-35)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.auasi_total
Urologic Pain Severity Scale (0-28)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.pain_severity

Table Variable	dataset.variable
Urinary Severity Scale (0-25)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.urinary_severity
Overall Non-Pelvic/Non-Urologic Symptoms (0-10) (SYMQ-6)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.symq_q6
Fibromyalgia Total Score (0-31)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.fm_fibromyalgia_score
FM-WPI Score (0-19)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.fm_wpi
FM-SS Score (0-12)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.fm_ss
HADS Anxiety (0-21)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.hadsanxtot
HADS Depression (0-21)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.hadsdeptot
WHO-DAS (0-48)	mapp2_baseline.ucpps_bl_cohort mapp2_baseline.in_mapp1_and_mapp2 mapp2_baseline.whodas_total

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

Characteristic	Pub: MAPP II SPS (n=620)	DSIC: MAPP II SPS (n=620)	Diff. (n=0)	Pub: MAPP II (Re-enrolled from MAPP I) (n=83)	DSIC: MAPP II (Re-enrolled from MAPP I) (n=83)	Diff. (n=0)
Age (Years)	44.4 (15.7)	44.8 (15.7)	0.4 (0)	48.8 (14.5)	48.8 (14.5)	0 (0)
Sex (Male)	210 (33.9)	210 (33.9)	0 (0)	45 (54.2)	45 (54.2)	0 (0)
Race (White)	543 (87.7)	543 (87.6)	0 (0.1)	81 (97.6)	81 (97.6)	0 (0)
Employed	394 (63.6)	394 (63.6)	0 (0)	53 (63.9)	53 (63.9)	0 (0)
Income						
$50,000 or less	201 (36.4)	201 (36.4)	0 (0)	26 (34.2)	26 (34.2)	0 (0)
$50,001 to $100,000	196 (35.4)	196 (35.4)	0 (0)	21 (27.6)	21 (27.6)	0 (0)
More than $100,000	156 (28.2)	156 (28.2)	0 (0)	29 (38.2)	29 (38.2)	0 (0)
Duration of Symptoms (Years)	11.9 (11.5)	11.9 (11.5)	0 (0)	13.0 (9.3)	13.0 (9.3)	0 (0)
Pain (0-10) (SYMQ-1)	4.8 (2.0)	4.4 (2.2)	0.4 (0.2)	4.0 (2.1)	3.7 (2.3)	0.3 (0.2)
Overall Pelvic/Urologic Symptoms (0-10) (SYMQ-5)	5.1 (2.2)	4.7 (2.4)	0.4 (0.2)	4.2 (2.2)	4.0 (2.4)	0.2 (0.2)
GUPI Total Score (0-45)	25.7 (8.5)	23.8 (8.9)	1.9 (0.4)	22.0 (8.9)	21.4 (8.7)	0.6 (0.2)
GUPI Pain Subscale (0-23)	12.8 (4.2)	11.8 (4.5)	1.0 (0.3)	11.4 (4.3)	11.1 (4.6)	0.3 (0.3)
IC Symptom Index (0-20)	10.0 (4.5)	9.2 (4.5)	0.8 (0)	9.6 (4.3)	9.0 (4.3)	0.6 (0)
IC Problem Index (0-16)	8.7 (4.0)	8.0 (4.1)	0.7 (0.1)	7.6 (4.1)	7.3 (3.7)	0.3 (0.4)
AUA Symptom Index (0-35)	14.8 (8.2)	14.8 (8.2)	0 (0)	14.5 (8.2)	14.5 (8.2)	0 (0)
Urologic Pain Severity Scale (0-28)	15.5 (5.2)	14.3 (5.6)	1.2 (0.4)	13.8 (5.4)	13.4 (5.8)	0.4 (0.4)
Urinary Severity Scale (0-25)	12.5 (6.0)	11.6 (6.2)	0.9 (0.2)	11.7 (5.8)	11.1 (5.7)	0.6 (0.1)
Overall Non-Pelvic/Non-Urologic Symptoms (0-10) (SYMQ-6)	3.5 (2.7)	3.5 (2.6)	0 (0.1)	3.5 (2.6)	3.4 (2.5)	0.1 (0.1)
Fibromyalgia Total Score (0-31)	8.5 (5.2)	8.3 (5.3)	0.2 (0.1)	7.9 (6.0)	7.6 (5.7)	0.3 (0.3)
FM-WPI Score (0-19)	2.9 (3.3)	2.7 (3.2)	0.2 (0.1)	2.9 (3.9)	2.6 (3.6)	0.3 (0.3)
FM-SS Score (0-12)	5.5 (3.0)	5.6 (3.1)	0.1 (0.1)	4.9 (3.1)	5.1 (3.2)	0.2 (0.1)
HADS Anxiety (0-21)	8.0 (4.7)	7.3 (4.8)	0.7 (0.1)	6.6 (4.3)	6.4 (4.4)	0.2 (0.1)
HADS Depression (0-21)	5.4 (4.0)	5.8 (4.5)	0.4 (0.5)	4.5 (3.6)	4.9 (3.9)	0.4 (0.3)
WHO-DAS (0-48)	11.1 (9.0)	10.7 (8.9)	0.4 (0.1)	8.8 (8.6)	8.9 (8.2)	0.1 (0.4)

Attachment A: SAS Code

```
libname mappii "X:\NIDDK\niddk-dr_studies3\private_created_data_MAPP_II\Redacted Data";

proc contents data=mappii.mapp2_baseline;
run;

proc means data=mappii.mapp2_baseline mean std;
var age;
run;

*creating dataset with just the participants for the paper;
proc freq data=mappii.mapp2_baseline;
tables in_mapp1_and_mapp2 ucpps_bl_cohort;
run;

data mapp; set mappii.mapp2_baseline;
where ucpps_bl_cohort ^= .;
run;

*Table 2;
*age;
proc means data=mapp n mean std;
var age;
class in_mapp1_and_mapp2;
run;

*sex;
proc freq data=mapp;
tables sex*in_mapp1_and_mapp2/norow;
run;

*race;
proc freq data=mapp;
tables racecat*in_mapp1_and_mapp2/norow;
run;

*employed;
proc freq data=mapp;
tables emp_status*in_mapp1_and_mapp2/norow;
run;

*income;
data mapp_1; set mapp;
income_cat = .;
if income <=3 then income_cat = 1;
if income = 4 then income_cat = 2;
```

```
if income = 5 then income_cat = 3;
run;

proc freq data=mapp_1;
tables income_cat*in_mapp1_and_mapp2/norow;
run;

*duration of symptoms;
proc means data=mapp_1 n mean std;
var symp_duration;
run;

proc means data=mapp_1 n mean std;
var symp_duration;
class in_mapp1_and_mapp2;
run;

*Pain (0-10 (SYMQ-1);
proc means data=mapp_1 n mean std;
var symq_q1;
run;

proc means data=mapp_1 n mean std;
var symq_q1;
class in_mapp1_and_mapp2;
run;

*symq-5;
proc means data=mapp_1 n mean std;
var symq_q5;
run;

proc means data=mapp_1 n mean std;
var symq_q5;
class in_mapp1_and_mapp2;
run;

*gupi total score;
proc means data=mapp_1 n mean std;
var gupiscoretotal;
run;

proc means data=mapp_1 n mean std;
var gupiscoretotal;
class in_mapp1_and_mapp2;
run;

*gupi pain subscale;
```

```
proc means data=mapp_1 n mean std;
var gupiscore_pain;
run;

proc means data=mapp_1 n mean std;
var gupiscore_pain;
class in_mapp1_and_mapp2;
run;

*IC symptom index;
proc means data=mapp_1 n mean std;
var icsitot;
run;

proc means data=mapp_1 n mean std;
var icsitot;
class in_mapp1_and_mapp2;
run;

*IC Problem Index;
proc means data=mapp_1 n mean std;
var icpitot;
run;

proc means data=mapp_1 n mean std;
var icpitot;
class in_mapp1_and_mapp2;
run;

*AUA symptom index;
proc means data=mapp_1 n mean std;
var auasi_total;
run;

proc means data=mapp_1 n mean std;
var auasi_total;
class in_mapp1_and_mapp2;
run;

*urologic pain severity;
proc means data=mapp_1 n mean std;
var pain_severity;
run;

proc means data=mapp_1 n mean std;
var pain_severity;
class in_mapp1_and_mapp2;
run;
```

```
*urinary pain severity;
proc means data=mapp_1 n mean std;
var urinary_severity;
run;

proc means data=mapp_1 n mean std;
var urinary_severity;
class in_mapp1_and_mapp2;
run;

*Overall non-pelvic/non-urologic symptoms;
proc means data=mapp_1 n mean std;
var symq_q6;
run;

proc means data=mapp_1 n mean std;
var symq_q6;
class in_mapp1_and_mapp2;
run;

*Fibromyalgia score;
proc means data=mapp_1 n mean std;
var fm_fibromyalgia_score;
run;

proc means data=mapp_1 n mean std;
var fm_fibromyalgia_score;
class in_mapp1_and_mapp2;
run;

*FM-WPI score;
proc means data=mapp_1 n mean std;
var fm_wpi;
run;

proc means data=mapp_1 n mean std;
var fm_wpi;
class in_mapp1_and_mapp2;
run;

*FM- SS score;
proc means data=mapp_1 n mean std;
var fm_ss;
run;

proc means data=mapp_1 n mean std;
var fm_ss;
```

```
class in_mapp1_and_mapp2;
run;

*HADS anxiety;
proc means data=mapp_1 n mean std;
var hadsanxtot;
run;

proc means data=mapp_1 n mean std;
var hadsanxtot;
class in_mapp1_and_mapp2;
run;

*HADS depression;
proc means data=mapp_1 n mean std;
var hadsdeptot;
run;

proc means data=mapp_1 n mean std;
var hadsdeptot;
class in_mapp1_and_mapp2;
run;

*WHO-DAS;
proc means data=mapp_1 n mean std;
var whodas_total;
run;

proc means data=mapp_1 n mean std;
var whodas_total;
class in_mapp1_and_mapp2;
run;
```