MOST 168-Month Follow-up

Dataset Description

March 2023

Table of Contents

This document describes the MOST 168-month clinical dataset and data issues relevant to analysts. If you are unfamiliar with the data, it may be useful to begin by reviewing the annotated data collection forms to look for variables of interest.

FORMATS

SAS Format Library

The SAS format library (FORMATS.SAS7BDAT) contains all the formats used for the dataset.

DATASET

168-month Interview, Questionnaire, and Exam Measures Dataset (V9ENROLL.SAS7BDAT)
Observations: 3376 (1 record per participant)
Annotated Forms: V9AnnotatedForms.pdf
Variable Guide: VariableGuide_V9ENROLL.pdf
Distributions: Distributions_V9ENROLL.pdf
Cohort: New Cohort and Original Cohort

The MOST 168-month dataset includes data from the New Cohort 24-month and Original Cohort 168-Month Follow-up data. The 168-month dataset (V9ENROLL.SAS7BDAT) includes clinical data from the New Cohort 24-Month (N=1459) and the Original Cohort 168-Month follow-up (N=1917), including a telephone interview, two self-administered questionnaires (one done at home and the other done at the clinic), a clinic interview, and clinic visit. All participants enrolled at baseline and not deceased or withdrawn from the study were eligible for the 168-month contact.

Variables are sorted in the order of data collection ("creation order") – as if following the participant from the first telephone screening question to the last measurement at the clinic.

Refer to the annotated forms for the temporal context of each variable. Data for some variables was collected for the time period "since the last visit" and for others the time period was fixed (e.g., past 12 months, past 30 days, past 7 days).

SPECIAL MISSING VALUES

SAS datasets allow for stratification of missing values to indicate various reasons for missing data. For example, when data is not expected because responses are keyed to a skip pattern, the value is '.Q' (Not required). The value .P (Not expected) used when the whole section or instrument or clinic exam was skipped or not collected (not eligible, refused, any other reason).

Telephone Interview (Variables with V9 prefix)

The Telephone Interview was completed prior to the 168-Month Clinic Visit. This contact was required for inclusion in the V9ENROLL dataset (N=3376). The interview includes the following:

Knee Symptoms [1]
General Health (SF12)
Cognitive Assessment (MoCA© 5 minute protocol with 4 subtests) [2, 3]
MRI Eligibility (not released)
Clinic Visit Eligibility (not released)

Notes:

1. Knee symptoms / frequent knee pain (FKP) questions collected during telephone interview were used for the knee symptom calculated variables (V9R/L_FKP).

2. At the 168-month follow-up, the Montreal Cognitive Assessment (MoCA) ©Test was administered to participants age 70 years and older at the time of the Telephone Interview and who were not administered the test at the 144-month follow-up. It was designed as a rapid screening assessment for mild cognitive dysfunction. Participants with a score ≤17 points and interviewer determined cognitive difficulties would prevent participant from continuing in the study were not eligible for clinic visit. The MoCA© Test was used with permission from Dr. Ziad Nasreddine from the MoCA Clinic and Institute in Quebec, Canada.

3. For analytical information about the MoCA©Test, see:

   - Kennedy RE, et al. Performance of the NINDS-CSN 5-Minute Protocol in a National Population-Based Sample. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4452126/

   - Wong A. et al. The MoCA 5-min protocol is a brief, valid, reliable and feasible cognitive screen for telephone administration. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4373962/

Self-Administered Questionnaire (SAQ) – Home (Variables with V9 prefix)

The SAQ-Home was mailed to participants who were scheduled a Clinic Visit. Participants were asked to bring the completed questionnaire to the clinic on the day of the visit. If the participant did not complete the SAQ-Home Questionnaire, the SAQ-Home variables were coded with the special missing value '.P' (Not expected) – values are not expected because the SAQ-Home was not done.

The dataset includes the following components:

Arthritis Diagnosis [1]
Health History and Medical Conditions (Modified Charlson Comorbidity Questionnaire) [2]
Injuries, Fractures, and Falls [3]
Coping Strategies Questionnaire© (CSQ) Pain Catastrophizing subscale [4]
Joint Pain, Aching, and Stiffness (homunculus: whole body, hands, feet) [5]
Back Pain and Function [6]
Sleep Habits (PSQI, Pittsburgh Sleep Quality Index) [7]
Arthritis Medications [8]
Health Survey (SF-12® and PF-10 scale from SF-36®) [9, 10]
Health Survey (CES-D Long version)
Sleep, Fatigue and Pain Interference (Pittsburgh Sleep Quality Index, PROMIS) [7, 11, 12]
Everyday Things (Modified late-life FDI – Disability Component) [13]
Current Tobacco Use [14]
Current Employment
Household Status (Ability to pay bills), Medical Care, Live Alone or With Others, and Marital Status[15]
Helpful Aids and Devices (adapted from the Stanford Health Assessment Questionnaire©)[16]
Life-Space Assessment [17]

Notes:

1. At 168 months, a rheumatoid arthritis (RA) indicator variable (V9_RADXRX) was calculated based on self-report of RA diagnosis, RA medication usage, and radiographic status.

2. At 168 months, the time period referenced in Charlson Comorbidity questions is "Have you ever …" or "Do you have…". Calculated variables in V9CALC are V9_DX, V9MCOMOR and

V9MCOMOR_CUM. Permission to use the modified Charlson Comorbidity instrument as described in Medical Care, 1996, "Can Comorbidity Be Measured By Questionnaire Rather than Medical Record Review"" was given by Dr. Jeff Katz, Harvard Medical School.

3. There are multiple response options for fracture locations when a participant responds "Yes" to the question "Did a doctor tell you that you broke or fractured a bone" (V9BONE). Variables indicating the locations (1=Yes) are prefixed "FX" (for example, V9FXHIP), except V9SPINE. Calculated variable V9_FXHIPSP is included.

4. The Coping Strategies Questionnaire© (CSQ) is a copyright protected instrument. Permission to use the catastrophizing subscale of the instrument was given by Dr. Francis Keefe, Duke University. For analytical information, see:

   - Jensen MP, Keefe FJ, Lefebvre JC, Romano JM, Turner JA. One- and two-item measures of pain beliefs and coping strategies. Pain. 2003 Aug;104(3):453-69. PMID: 12927618.

   - Rosenstiel AK, Keefe FJ. The use of coping strategies in chronic low back pain patients: relationship to patient characteristics and current adjustment. Pain. 1983 Sep;17(1):33-44. PMID: 6226916.

   - Sullivan MJL, Bishop SR, Pivik J. The Pain Catastrophizing Scale: Development and Validation. Psychological Assessment. 1995 Dec 7(4):524-532.

5. Whole body homunculus pain data has 3 calculated variables for different widespread pain definitions (V9_WSPA; V9_WSPB; V9_WSPC). The hand homunculus has calculated variables for hand pain location (V9R/L_HAND). The feet homunculus has calculated variables for pain location on the top (V9R/L_FFOOT) and bottom (V9R/L_BFOOT) of each foot.

6. When a participant reports limited activity during the past thirty days due to back pain (V9BPLA=1:Yes), the sum of the number of days spent in bed (V9BDDAY) and the number of days of limited activity (V9BPLAD) is designed to equal no more than a total of 30 days. Some participant responses may be inconsistent.

7. New Cohort participants completed the Pittsburgh Sleep Quality Index (PSQI) for the past 30 days. Both cohorts were asked about sleep quality overall in the past 7 days (V9SLPQA). UCSF received permission from Dr. Buysse, University of Pittsburgh Sleep and Chronobiology Center, to use the PSQI in MOST. For analytical information about the Pittsburg Sleep Quality Index, see:

   - Buysse DJ, Reynolds CF 3rd, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res. 1989 May;28(2):193-213. PMID: 2748771.

8. SAQ-Home arthritis medication data addresses frequency of use in the past 30 days. The V79MIF dataset addresses prescription medication (by ingredients) used in the past 30 days (see IDIS Legend document).

9. SF-36® (SF-12 and PF-10) licenses were obtained from Quality Metric for the 168-month administration. Some SF-12 questions included a "Don't Know" option for participants unable to rate the severity of knee pain because they avoid or are unable to do the activity in question.

10. Calculated variable for the PF-10 scale included.

11. The global fatigue question is modified from the general fatigue subscale described in Belza, BL, et al. Comparison of self-reported fatigue in rheumatoid arthritis and controls. https://www.ncbi.nlm.nih.gov/pubmed/7791155.

12. PROMIS® (Patient-Reported Outcomes Measurement Information System) questionnaires are open-source instruments that were developed with NIH funding and are owned by the U.S. Department of Health and Human Services.

13. The modified Late-Life FDI: Disability component was administered to Original Cohort participants only. For more information, see Jette AM, et al. Late life function and disability instrument: I. Development and evaluation of the disability component. J Gerontol A Biol Sci Med Sci. 2002 Apr;57(4):M209-16. PMID: 11909885

14. Current Tobacco Use was administered to all participants.

15. Medical Care questions from the CARDIA study "Do you have a usual source of medical care? / What is the source of medical care? / How do you pay for your medical care? / Was there any time during the past two years when you did not seek medical care…" were administered in MOST.

16. Assistive Aids and Devices measures are adapted from the Stanford Health Assessment Questionnaire Disability Index (HAQ-DI). This was administered to Original Cohort participants only. For analytical information, see:

    - Ramey DR, Fries JF, Singh G. The Health Assessment Questionnaire 1995 – Status and Review. In Spilker, B. Quality of Life and Pharmacoleconomics in Clinical Trials, 2nd ed. Philadelphia: Lippincott-Raven Pub.1996; 227-237.

    - Fries JF, Spitz P, Kraines G, Holman H. Measurement of Patient Outcome in Arthritis. Arthritis Rheum. 1980; 23:137-145.

17. Life-Space Assessment was administered to the Original Cohort participants used with permission from Dr. Richard Allman and Dr. Patricia Sawyer, University of Alabama at Birmingham. For analytical information, see:

    - Peel C, et al. Assessing Mobility in older adults: The UAB Study of Aging Life-Space Assessment https://www.ncbi.nlm.nih.gov/pubmed/16180950

    - Phillips J, et al. A population-based cross-sectional study that defined normative population data for the Life-Space Mobility Assessment-composite score. https://www.ncbi.nlm.nih.gov/pubmed/25546285

18. Clinic visit protocol was modified due to COVID-19 pandemic and clinic closures. With the uncertainty of when clinics would resume the 168-month clinic, the study pivoted and collected the majority of the standard instruments via Telephone Interview during the pandemic. When clinics were approved to reopen for study visits, 93 participants completed their clinic visit between July 2020-December 2020. The SAQ-Home data was not collected (repeated). Therefore, there are differences in numbers of missing values between participants who completed the Telephone Interview during the pandemic and those who did not.

Self-Administered Questionnaire (SAQ) – Clinic (Variables with V9 prefix)

The SAQ-Clinic was completed by participants during the Clinic Visit, few participants refused to complete SAQ. The dataset includes the following components:

Knee Symptoms (Modified WOMAC Osteoarthritis Index™)[1]
Physical Difficulty (Modified WOMAC Osteoarthritis Index™)[1]
Knee pain visual analog scale (VAS)
Physical Difficulty (Modified KOOS™ Function in Sports and Recreational Activities Subscale) [2]
painDETECT [3]

Notes:

1. WOMAC Osteoarthritis Index™ Likert version. This measurement was modified to include a "don't do" option for participants who cannot rate severity of pain during a particular activity because they avoid or are unable to do that activity.
   The WOMAC™ instrument is not displayed in the annotated forms because it is trademark and copyright protected. Information can be obtained by contacting the author, Dr. Nicholas Bellamy, via the WOMAC™ 3.1 Index website (http://www.auscan.org/womac).

   For analytical information, see:

   - Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. J Rheumatol. 1988 Dec;15(12):1833-40. PMID: 3068365.

2. KOOS Function in Sports and Recreational Activities Subscale, Likert version – new cohort only. This measurement was modified to include a "don't do" option for participants who cannot rate severity of pain during a particular activity because they avoid or are unable to do that activity. For analytical information, see:

   - Roos EM, Lohmander LS. Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. Health Qual Life Outcomes 2003;1:64.

3. The painDETECT® questionnaire requires a reference to the original publication:

   - Freynhagen R, et al. painDETECT®: A new screening questionnaire to identify neuropathic components in patients with back pain. Curr Med Res Opin 2006; 22(10): 1911-1920). https://www.ncbi.nlm.nih.gov/pubmed/17022849.

4. Clinic visit protocol was modified due to COVID-19 pandemic and clinic closures. Only Knee Symptoms and Physical Difficulty (Modified WOMAC Osteoarthritis Index™) were collected via telephone interview. Therefore, there are differences in numbers of missing values between participants who completed the Telephone Interview during the pandemic and those who did not.

Clinic Visit Interview (Variables with V9 prefix)

An interviewer-administered questionnaire was conducted at the Clinic Visit, few participants refused to complete interview. The dataset includes the following components:

Right Knee Symptoms [1]
Right Knee Pain – Intermittent and Constant Osteoarthritis Pain (ICOAP) [2]
Right Knee Pain Location
Left Knee Symptoms [1]
Left Knee Pain – Intermittent and Constant Osteoarthritis Pain (ICOAP) [2]
Left Knee Pain Location
Knee Buckling
Knee Injury and Surgery
Hip Pain and Surgery
Knee and Hip Replacements (see V99OUTCOMES dataset)
Physical Therapy
Medication History (Bisphosphonates and Knee Injections)
Medication History (Estrogens)
Medication Use (Vitamin D)
Medication Inventory Form (MIF) [3]

Notes:

1. Knee symptoms / frequent knee pain (FKP) questions:
   All participants were asked MOST knee symptom questions during the Telephone Interview and Clinic Visit Interview. Calculated variables V9R/L_FKP, V9_FKPSX (person-level variable), and V9_DATEDIFF (number of weeks between interviews) combine 168-Month Telephone Interview and Clinic Visit Interview responses.
   Due to COVID-19 pandemic and clinic closures, clinic visit was delayed in 93 participants. Telephone Interview was not re-administered in these 93 participants who had their clinic visit completed July 2020-December 2020.

2. For analytical information about the Intermittent and Constant Osteoarthritis Pain (ICOAP), see OARSI-OMERACT Initiative: A New OA Pain Measure (OARSI Publications). Also see:

- Hawker GA, Davis AM, French MR, Cibere J, Jordan JM, March L, Suarez-Almazor M, Katz JN, Dieppe P. Development and preliminary psychometric testing of a new OA pain measure – an OARSI/OMERACT initiative. Osteoarthritis Cartilage. 2008 Apr;16(4):409-14. PMID: 18381179.

3. Participants were asked to bring all prescription medications taken in the last 30 days to be recorded. Medication ingredients, coded by the UCSF MIF group using the Iowa Drug Information Service (IDIS) dictionary, are included in Yes/No format, meaning used or not used during the last 30 days. Formulation code, duration, and frequency are included in the separate dataset, V79MIF. For further information about IDIS, see Pahor M, Chrischilles EA, and Guralnik, JM. Drug data coding and analysis in epidemiologic studies. Eur J Epidemiol. 1994 Aug;10(4):405-11.

Clinic Visit (Variables with V9 prefix)

The dataset includes the following components:

Blood Pressure
Weight [1]
20-Meter Walk and 6-Minute Walk Test [2]
Timed Up and Go (TUG) [3]
Chair Stands
Peripheral Neuropathy [4]
Temporal Summation [4]
Pressure Pain Threshold [4,5]
Conditioned Pain Modulation [4,5]
Knee X-ray Tracking [6]
Knee MRI Eligibility and Tracking [6]

Notes:

1. The current weight (V9WGHT) collected at 168-Months visit and height measurement collected in any most recent prior visit (priority order: V7HT, V5HT, V3HT or V0HT) was used to calculate BMI (V9BMI).

2. The Borg Scale was administered after the 6MWT as recommended by the American Thoracic Society in the ATS Statement: Guidelines for the Six-Minute Walk Test. https://www.ncbi.nlm.nih.gov/pubmed/12091180

3. The TUG was administered to Original Cohort participants. For analytic information, see:

   - Podsiallo D, Richardson S. The *timed* "*Up* & *Go*": a test of basic functional mobility for frail elderly persons. https://www.ncbi.nlm.nih.gov/pubmed/1991946.

4. When a single test/trial was not done during the Quantitative Sensory Testing exams (peripheral neuropathy, temporal summation, pressure pain threshold, conditioned pain modulation) due to ineligibility or participant refusal, the data is marked accordingly.

5. V9ENROLL dataset includes some continuous variables with a special value assigned to indicate when a maximum value was exceeded. Analysts using these continuous variables should consider using a right-censored data technique. See:
   - Bland JM, Altman DG. Survival probabilities (the Kaplan-Meier method). BMJ. 1998 Dec 5;317(7172):1572. PMID: 9836663.
   - Lindsey JC, Ryan LM. Tutorial in biostatistics methods for interval-censored data. Stat Med. 1998 Jan 30;17(2):219-38. PMID: 9483730.

6. Participants did not have any knee radiographs or MRI if they had bilateral exclusions including end stage knee osteoarthritis (K/L 3 or 4, knee replacement) or other radiograph exclusions such as osteonecrosis.