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MOST 144-Month Follow-up

Dataset Description

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This document describes the MOST 144-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

Baseline Telephone Screening and Enrollment Visit (New cohort); 144-Months Telephone Interview and Clinic Visit (Original cohort)

(V7ENROLL.SAS7BDAT)
Observations: 3702 (1 record per participant)
Annotated Forms: V7AnnotatedForms.pdf
Variable Guide: VariableGuide_V7ENROLL.pdf
Distributions: Distributions_V7ENROLL.pdf
Cohort: New Cohort and Original Cohort

The MOST 144-month dataset includes data from the New Cohort Baseline and Original Cohort 144-Month Follow-up data. The 144-month dataset (V7ENROLL.SAS7BDAT) includes clinical data from the New Cohort Baseline (N=1525) and the Original Cohort 144-Month Follow-up data (N=2177), including a telephone screening interview (new cohort), telephone interview (original cohort), two self-administered questionnaires (one done at home and the other done at the clinic), a clinic interview, and clinic visit. All original cohort participants enrolled at baseline and not deceased or withdrawn from the study were eligible for the 144-month contact.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 Screening Interview and Screen Visit (Variables with "TS7" and "SV7" prefix)

The 144-Month Telephone Screening Interview and Screen Visit determined New Cohort eligibility. The dataset includes the following components:

Telephone Screening Interview (to determine eligibility) [1]
Screen Visit: MRI Eligibility includes Pregnancy History, Menopause Status (Women Only)
Screen Visit: Knee Symptoms [2]
Screen Visit: Knee X-ray Tracking [3]
Screen Visit: Weight

Notes:

1. Dataset includes all those who are enrolled.

2. Knee symptoms / frequent knee pain (FKP) questions collected during screening visit were used for the knee symptom calculated variables (V7R/L_FKP).

3. Knee x-rays were read by a Radiologist to determine study eligibility based on Kellgren and Lawrence system classification of osteoarthritis. Screening KL grade parameters are not released. X-ray reading parameters for single 144m image or longitudinal paired knee x-ray images included in the released x-ray reading dataset (V79XRAY_OUTCOMES).

Interview, Questionnaire, and Exam Measures (Variables with "V7" prefix)

The 144-month visit dataset includes all enrolled participants who completed all or part of the following data collection components:

- Telephone Interview [Original Cohort participants only]
- Self-Administered Questionnaire (SAQ)-Home
- Self-Administered Questionnaire (SAQ)-Clinic
- Clinic Interview and Visit

Original Cohort participants who refused or were unable to participate in the 144-month clinic visit were asked to participate in an extended telephone interview (the Missed Clinic Visit Telephone Interview) that covered some questions from the SAQ-Home, SAQ-Clinic and Clinic Interview. Therefore, there are differences in numbers of missing values between questions that include data from the extended interview versus those that do not include data from the extended interview.

Telephone Interview: Original Cohort only

The telephone interview was conducted approximately 4 weeks before the clinic visit date to assess frequent knee symptoms, cognitive assessment (for older participants) and eligibility for MRI. The dataset includes the following components:

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 (V7R/L_FKP).

2. At the 144 month follow-up, the Montreal Cognitive Assessment (MoCA) ©Test was administered to Original Cohort participants age 70 years and older at the time of the Telephone Interview. 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 "V7" 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 / Tobacco Use [14]
Current Employment
Household Status (Ability to pay bills), Medical Care, Live Alone or With Others, and current Marital Status[15]
Helpful Aids and Devices (adapted from the Stanford Health Assessment Questionnaire©)[16]
Education And Weight History [17]
Life-Space Assessment [18]

Notes:

1. At 144 months, a rheumatoid arthritis (RA) indicator variable (V7_RADXRX) was calculated based on self-report of RA diagnosis, RA medication usage, and radiographic status.

2. At 144 months, the time period referenced in Charlson Comorbidity questions is "Have you ever …" or "Do you have…". Calculated variables are V7_DX, V7MCOCMOR and V7MCOCMUR_CUM. The modified Charlson Comorbidity instrument is described in Medical Care, 1996, "Can Comorbidity Be Measured By Questionnaire Rather than Medical Record Review"" by Dr. Jeff Katz, Harvard Medical School.

3. There are multiple response options for fracture locations when a participant responds “Yes” to the questions: “Did a doctor ever tell you that you broke or fractured a bone” or “Since last contact, did a doctor tell you that you broke or fractured a bone” (V7BONE). Variables indicating the locations (1=Yes) are prefixed “FX” (for example, V7FXHIP), except V7SPINE. Calculated variable V7_FXHIPSP is also included in the dataset. Note: During the Telephone Screening Interview, this question was included “after age 45” and in subsequent questionnaires “after age 45” was not part of question.

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 (V7_WSPA; V7_WSPB; V7_WSPC). The hand homunculus has calculated variables for hand pain location (V7R/L_HAND). The feet homunculus has calculated variables for pain location on the top (V7R/L_FFOOT) and bottom (V7R/L_BFOOT) of each foot.

6. When a participant reports limited activity during the past thirty days due to back pain (V7BPLA=1:Yes), the sum of the number of days spent in bed (V7BDDAY) and the number of days of limited activity (V7BPLAD) 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 (V7SLPQA). 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 144-month administration. Some SF-12 questions administered to participants 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 is included in the dataset.

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 Original Cohort participants and Tobacco Use (history) was administered to New Cohort 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. Education and Weight History questions were administered to New Cohort participants only (Original Cohort education and weight history data is included in V0ENROLL).

18. 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

Self-Administered Questionnaire (SAQ) – Clinic (Variables with "V7" 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.

Clinic Visit Interview (Variables with "V7" 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)
Physical Activity Scale for the Elderly (PASE©) [3]
Medication Inventory Form (MIF) [4]

Notes:

1. Knee symptoms / frequent knee pain (FKP) questions:

- Original Cohort participants were asked MOST knee symptom questions during the Telephone Interview and Clinic Visit Interview. Calculated variables V7R/L_FKP, V7_FKPSX (person-level variable), and V7_DATEDIFF (number of weeks between interviews) combine 144-Month Telephone Interview and Clinic Visit Interview responses.

- New Cohort participants were asked MOST knee symptom questions during the Screen Visit Interview and Clinic Visit Interview. Calculated variables V7R/L_FKP, V7_FKPSX (person-level variable), and V7_DATEDIFF (number of weeks between interviews) combine 144-month Screen Visit Interview and Clinic Visit Interview responses.

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. The PASE© measurement was modified to include a possible response of "Don't know/ Refused" in 7 of the 12 elements that contribute to the total score. All such responses are converted to missing in the calculation of the total score. For a description of the PASE calculation, see the document: Calculated Variable Descriptions and SAS Code. The measurement is not displayed in the annotated forms because it is copyright protected. Information about the measurement can be obtained through the PASE© product information website of New England Research Institutes (NERI) (http://www.neriscience.com/web/MultiPiecePage.asp_Q_PageID_E_253_A_PageName_E_ProductsResearchPhysicalActiv).

   The stair climbing question is not part of the PASE measurement and does not contribute to the summary score.

   For analytical information, see:

   - Washburn RA, Smith KW, Jette AM, Janney CA. The Physical Activity Scale for the Elderly (PASE): Development and Evaluation. J Clin Epidemiol. 1993 Feb;46(2):153-62. PMID: 8437031.

4. 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 "V7" prefix)

The dataset includes the following components:

Blood Pressure
Standing Height, Foot Length, Shoe Hardness
Weight
20-Meter Walk and 6-Minute Walk Test (includes Opal monitor) [1, 2]
Timed Up and Go (TUG) [3]
Chair Stands
Force of Heel Strike and Video for Gait Speed [4]
Hand Photo for Hand OA Assessment [5]
Quadriceps Power and Hip Strength [6]
Peripheral Neuropathy
Temporal Summation
Pressure Pain Threshold[7]
Conditioned Pain Modulation[7]
Hip Internal Rotation
Knee X-ray Tracking [8]
Full Limb X-ray Tracking [9]
CT Tracking
Knee MRI Eligibility and Tracking [8]
Accelerometry (AX3) Distribution[10]
Accelerometry (AX3) Return/Questionnaire[11]

Notes:

1. 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

2. Gait complexity was measured with Opal movement monitors (see Operations Manual) worn during the 20-meter, 6MWT and sway exams. Reading center datasets: V7OPAL20MWALK, V7OPAL6MWT and V7OPALSWAY.

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. Force of Heel Strike was measured with the AccuGait force platform (see Operations Manual) and Gait Speed calculated from the collected video. Reading Center dataset: V7FHS.

5. Hand photos were taken and read for hand osteoarthritis. Reading Center dataset: V7HANDOA.

6. Quadriceps Power and Hip Strength was collected with NORM equipment / HUMAC software (see Operations Manual). Reading Center datasets: V7QUADPOWER and V7HIPSTRENGTH.

7. V7ENROLL 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.

8. Original Cohort 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.

9. Full-limb X-ray were acquired in New Cohort participants. Reading Center dataset V79XRAY_OUTCOMES contains reading parameters from these images.

10. Accelerometry (AX3) data was collected with AX3 devices (see Operations Manual). Reading Center dataset: V7AX3_SUMMARY and AX3_DAYS.

11. The Accelerometry (AX3) questionnaire was given to participants at the clinic visit when they received the AX3 device. Participants were asked to complete the questionnaire after wearing the device for a week, and they were instructed to mail the questionnaire to the clinic with the device. A few participants did not return the device, and some participants did not return the questionnaire.

12. During clinic visit, urine and blood was collected in New Cohort participants – data not released (for details see Operations Manual chapter for enrollment visit).

Reading center datasets:

- V7AX3_SUMMARY and V7AX3_DAYS: 7 day physical activity
- V7CT_BUCKS: CT readings of mineralization at the knee using the BUCKS scoring method
- V7CT_BMD: CT readings of BMD parameters
- V7FHS: force of heel strike and gait speed measurement from video during force of heel strike exam
- V7HANDOA: hand OA readings from hand photographs
- V7HIPSTRENGTH: hip abduction muscle strength measurement
- V79MIF: details on active ingredients for RX only medications inventory
- V7OPAL20MWALK: Opal monitor gait complexity readings during 20-meter walk
- V7OPAL6MWT: Opal monitor gait complexity readings during 6 Minute Walk Test
- V7OPALSWAY: Opal monitor sway readings during standing
- V7QUADPOWER: quadriceps muscle power measurement
- V79MOAKS: paired MRI assessment (one knee per ppts)
- V79XRAY_OUTCOMES: paired and single knee x-ray reading parameters (both cohorts) and full limb x-ray reading parameters (new cohort)