

MOST 60-MONTH FOLLOW-UP

DATASET DESCRIPTION

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This document describes the MOST 60-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

60-month Telephone Interview and Clinic Visit (V3ENROLL.SAS7BDAT)

Observations: 2768 (1 record per participant)

Annotated Forms: AnnotatedForms_60m.pdf

Variable Guide: VariableGuide_V3ENROLL.pdf

Distributions: Distributions_V3ENROLL.pdf

The 60-month dataset (V3ENROLL.SAS7BDAT) includes clinical data from the 60-month follow-up study contacts (N=2768), 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 All participants enrolled at baseline and not deceased or withdrawn from the study were eligible for the 60-month clinic visit. If the participant did not consent to share data, data values are set to the missing value, “Not expected”, in the dataset.

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 measurement questions was collected for the time period “since the last visit” while for others the time period was fixed (e.g., past 12 months).

See additional information about the standardized instruments and exams referenced in this document in the DatasetDescription_Baseline.pdf.

Telephone Interview (Variables with ‘V3’ prefix)

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

Knee symptoms (pain, aching, and stiffness)

Self-Administered Questionnaire (SAQ) – Home (Variables with “V3” prefix)

The SAQ-Home was mailed to participants after the telephone interview. Participants were instructed to complete the questionnaire at home prior to departure for the clinic visit. The dataset includes the following components:

Arthritis diagnosis¹
Charlson Comorbidity Index – Katz Questionnaire Adaptation^{1,2}
Injuries, Fractures and Falls^{1,3}
Balance confidence (Activities-Specific Balance Confidence (ABC) Scale)⁴
Coping Strategies Questionnaire[®] (CSQ) Pain Catastrophizing subscale⁵
Joint pain, aching, and stiffness (homunculus diagram)
Back pain and function
Targeted arthritis medications for joint pain or arthritis
Health Survey (Modified SF-12 U.S. version 1.0 and PF-10 scale from SF-36)^{1,6}
CES-D (Depression scale)
Sleep (question from Pittsburgh Sleep Quality Index) and fatigue⁷
Late Life Function and Disability Instrument (LLFDI) – Modified Disability Component^{8,9}
Assistive Aids and Devices (Stanford Health Assessment Questionnaire[®])¹⁰
Current employment
Household Living and Financial Difficulty

Notes:

¹ Participants who refused or were unable to participate in the 60-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 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.

² Charlson Comorbidity Index – Katz Questionnaire Adaptation. At 60 months, the time period referenced in some Charlson Comorbidity questions was changed from “Have you ever ...” to “Since we last contacted you about two years ago ...”

³At 60 months, an expanded list of fracture locations was added to the response options when a participant responded “Yes” to the question “Did a doctor tell you that you broke or fractured a bone” (V3BONE). Variables indicating the locations (1=Yes) are prefixed “FX” (for example, V3FXHIP), except V3SPINE.

⁴For analytical information about the Activities-Specific Balance Confidence (ABC) Scale see:

• Filiatrault J, Gauvin L, Fournier M, Parisien M, Robitaille Y, Laforest S, Corriveau H, Richard L. [Evidence of the psychometric qualities of a simplified version of the Activities Specific Balance Confidence scale for community-dwelling seniors](#). Arch Phys

Med Rehabil. 2007 May; 88(5):664-72. 17466738.

• Hill K. [Activities-specific and Balance Confidence \(ABC\) Scale](#). Aust J Physiother. 2005;51(3):197. PMID: 16187458.

⁵The Coping Strategies Questionnaire© (CSQ) is a copyright protected instrument. Permission to use the catastrophizing subscale of the instrument was given by 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.

⁶SF-36® (SF-12 and PF-10) licenses were obtained from Quality Metric for the study administration. At previous visits, the 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. At 60 months, “Don’t Know” was no longer an option. This is consistent with SF-12 version 1.0 without modifications. Analysts doing a cross tabulation by study time points should pay attention to revised response options, since participants who previously responded “Don’t Know” will have missing scores.

⁷The 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>.

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.

⁸Late-Life Function and Disability Instrument (LLFDI) – Modified Disability Component. This measurement was shortened to 12 of the authors’ 16 disability subscale questions and included only the extent of limitation performing activities (“To what extent do you feel limited in ...?”). Frequency performing activities (“How often do you ..?”) was not collected and the last of 5 options – [Not at all] [A little] [Somewhat] [A lot] [Completely, cannot do] – was modified with “cannot do” dropped.

⁹ Scoring of the LLFDI measurement was modified to handle missing values in a way that is consistent with how MOST analysts scored the WOMAC™ and SF-12 measures. For more information, refer to the document Calculated Variable Descriptions and SAS Code, and also 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.

¹⁰Assistive Aids and Devices measures are adapted from the Stanford Health Assessment Questionnaire (HAQ), a copyright protected instrument. 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 Pharmacoeconomics 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.

Self-Administered Questionnaire (SAQ) – Clinic (Variables with “V3” prefix)

The SAQ-Clinic was administered during the 60-month clinic visit. The dataset includes the following components:

- Modified WOMAC™ knee pain and stiffness^{1,2}
- Modified WOMAC™ degree of difficulty performing daily activities^{1,2}
- Knee pain visual analog scale (VAS)
- Modified KOOS Function in sports and recreational activities subscale³

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.

² 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, Nicholas Bellamy, via the WOMAC™ 3.1 Index website (<http://www.auscan.org/womac>).

³ KOOS Function in Sports and Recreational Activities Subscale, 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.

Clinic Interview (Variables with “V3” prefix)

The clinic interview is an interviewer-administered questionnaire conducted during the 60-month clinic visit. The dataset includes the following components:

- Right knee symptoms
- Right knee pain – Intermittent and Constant Osteoarthritis Pain (ICOAP)¹
- Right knee pain location map
- Left knee symptoms
- Left knee pain – Intermittent and Constant Osteoarthritis Pain (ICOAP)¹
- Left knee pain location map
- Knee buckling²
- Knee injury and surgery^{2,3}
- Hip pain, aching, and stiffness^{2,3}
- Medication history (bisphosphonates, knee injections for arthritis², estrogen)
- Medication use (vitamin D)

Medication Inventory Form (MIF)^{4,5}
Fillit Cognitive Impairment Screen⁶

Notes:

¹For 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.

² Participants who refused or were unable to participate in the 60-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 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.

³ Knee and hip replacement data, baseline through 84 months, is released in the dataset OUTCOMES.SAS7BDAT.

⁴ Participants were asked to bring all prescription medications taken in the last 30 days and only prescription medications were recorded unlike previous visits. Analyst comparing the medication usage across visits should be aware of this important change in the collection protocol.

⁵ Medication ingredients, coded by the UCSF MIF group using the Iowa Drug Information Service (IDIS) dictionary, are released in Yes/No format, meaning used or not used during the last 30 days. Formulation code, duration, and frequency are released in a separate dataset (V3MIF). 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.

⁶ For analytical information about the Fillit cognitive impairment screening instrument, see:

- Fillit H, Mohs RC, Lewis BE, Sewell MC, Mills CS, Tsymuk M, Hill J. [A Brief Telephonic Instrument to Screen for Cognitive Impairment in a Managed Care Population](#). J Clin Outcomes Manage 2003 Aug;10(8):419-429. (PMID not available.)

Clinic Visit (Variables with “V3” prefix)

Selected exams were conducted at the baseline clinic visit. The dataset includes the following components:

Blood pressure
Standing Height and Weight
20-meter walk

Chair stands
Isokinetic Strength and sEMG^{1,2}
Rapid step up³
Maximal step length^{4,5}
Gaitrite⁶
Plantar pressure
Peripheral Neuropathy
Vibration perception threshold^{5,7}
Pain sensitivity (touch - 2g & 26g von Frey filament; temporal summation, pinprick)
Pressure pain threshold^{5,8}
Knee x-ray⁹
OrthOne 1.0T knee MRI⁹
Initial knee pain¹⁰

Notes:

¹Prior to June 2009, eligible participants had bilateral Isokinetic Strength and sEMG exams. Subsequently, eligible participants with any knee replacement had bilateral exams, whereas those without knee replacements had unilateral exams (right side preferred). For analytical information about the Isokinetic Strength measures, see:

- Segal NA, Glass NA, Felson DT, Hurley M, Yang M, Nevitt M, Lewis CE, Torner JC. [Effect of quadriceps strength and proprioception on risk for knee osteoarthritis](#). Med Sci Sports Exerc. 2010 Nov;42(11):2081-8. PMID: 20351594.
- Segal NA, Glass NA, Torner J, Yang M, Felson DT, Sharma L, Nevitt M, Lewis CE. [Quadriceps weakness predicts risk for knee joint space narrowing in women in the MOST cohort](#). Osteoarthritis Cartilage. 2010 Jun;18(6):769-75. Epub 2010 Feb 11. PMID: 20188686.
- Segal NA, Torner JC, Felson D, Niu J, Sharma L, Lewis CE, Nevitt M. [Effect of thigh strength on incident radiographic and symptomatic knee osteoarthritis in a longitudinal cohort](#). Arthritis Rheum. 2009 Sep 15;61(9):1210-7. PMID: 19714608.
- Segal NA, Torner JC, Yang M, Curtis JR, Felson DT, Nevitt MC; Multicenter Osteoarthritis Study Group. [Muscle mass is more strongly related to hip bone mineral density than is quadriceps strength or lower activity level in adults over age 50 year](#). J Clin Densitom. 2008 Oct-Dec;11(4):503-10. Epub 2008 May 5. PMID: 18456530.

²For analytical information about the sEMG measures, see:

- Law LF, Krishnan C, Avin K. [Modeling nonlinear errors in surface electromyography due to baseline noise: a new methodology](#). J Biomech. 2011 Jan 4;44(1):202-5. Epub 2010 Sep 25. PMID: 20869716.
- Kellis E, Baltzopoulos V. [The effects of normalization method on antagonistic activity patterns during eccentric and concentric isokinetic knee extension and flexion](#). J Electromyogr Kinesiol. 1996 Dec;6(4):235-45. PMID: 20719680.

³For analytical information about the Rapid Step Up and Maximal Step Length measures, see:

- Cho BL, Scarpace D, Alexander NB. [Tests of stepping as indicators of mobility, balance, and fall risk in balance-impaired older adults](#). J Am Geriatr Soc. 2004 Jul;52(7):1168-73. PMID: 15209657.
- Medell JL, Alexander NB. [A clinical measure of maximal and rapid stepping in older women](#). J Gerontol A Biol Sci Med Sci. 2000 Aug;55(8):M429-33. PMID: 10952364.

⁴Maximal Step Length: Measurements greater than 40 inches are coded with the special value of 41 – a special value that analysts should treat as an extreme value.

⁵The V3ENROLL dataset includes some continuous variables with a special value assigned to indicate when a maximum value was exceeded. Analysts using continuous variables from the Maximal Step Length, Vibration Perception Threshold, and Pressure Pain Threshold exams 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.

⁶For analytical information about the GaitRite measures, see:

- Webster KE, Wittwer JE, Feller JA. [Validity of the GAITRite walkway system for the measurement of averaged and individual step parameters of gait](#). Gait Posture. 2005 Dec;22(4):317-21. Epub 2004 Dec 10. PMID: 16274913.
- Menz HB, Latt MD, Tiedemann A, Mun San Kwan M, Lord SR. [Reliability of the GAITRite walkway system for the quantification of temporo-spatial parameters of gait in young and older people](#). Gait Posture. 2004 Aug;20(1):20-5. PMID: 15196515.
- Bilney B, Morris M, Webster K. [Concurrent related validity of the GAITRite walkway system for quantification of the spatial and temporal parameters of gait](#). Gait Posture. 2003 Feb;17(1):68-74. PMID: 12535728

⁷Vibration Perception Threshold variables are coded with the special value of 51 when no vibration was felt by the participant at the maximum voltage of 50 volts. For analytical information about the Vibration Perception Threshold instrument, see:

- Shakoor N, Lee KJ, Fogg LF, Block JA. [Generalized vibratory deficits in osteoarthritis of the hip](#). Arthritis Rheum. 2008 Sep 15;59(9):1237-40. PMID: 18759259.
- Shakoor N, Agrawal A, Block JA. [Reduced lower extremity vibratory perception in osteoarthritis of the knee](#). Arthritis Rheum. 2008 Jan 15;59(1):117-21. PMID: 18163397.

⁸Pressure Pain Threshold variables are coded with the special value of 9.1 when no pressure was felt by the participant at the maximum pressure of 9.0 kg – an upper limit specified for safety. For analytical information about the Pressure Pain Threshold measure, see:

- Reeves JL, Jaeger B, Graff-Radford SB. [Reliability of the pressure algometer as a measure of myofascial trigger point sensitivity](#). Pain. 1986 Mar;24(3):313-21. PMID: 3960573.
- Wessel J. [The reliability and validity of pain threshold measurements in osteoarthritis of the knee](#). Scand J Rheumatol. 1995;24(4):238-42. PMID: 7481589.
- Kosek E, Ordeberg G. [Lack of pressure pain modulation by heterotopic noxious conditioning stimulation in patients with painful osteoarthritis before, but not following, surgical pain relief](#). Pain. 2000 Oct;88(1):69-78. PMID: 11098101.

⁹ Starting at 60 months, knees with end-stage osteoarthritis (K/L 3.5 or 4) were excluded from x-ray lateral view and MRI exam. Some participants returned to the clinic to repeat x-ray and MRI exams when image quality was not adequate for reading. Repeat data is not included in the dataset.

¹⁰Initial knee pain assessed at the beginning of the visit prior to biospecimen collection