

MOST 84-MONTH FOLLOW-UP

DATASET DESCRIPTION

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This document describes the MOST 84-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

84-month Telephone Interview and Clinic Visit (V5ENROLL.SAS7BDAT)

Observations: 2638 (1 record per participant)

Annotated Forms: AnnotatedForms_84m.pdf

Variable Guide: VariableGuide_V5ENROLL.pdf

Distributions: Distributions_V5ENROLL.pdf

The 84-month dataset (V5ENROLL.SAS7BDAT) includes clinical data from the 84-month follow-up study contacts (N=2638), 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 All participants enrolled at baseline and not deceased or withdrawn from the study were eligible for the 84-month clinic visit.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 and DatasetDescription_60m.pdf.

Telephone Interview (Variables with ‘V5’ 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)
Cognitive Assessment (Callahan Six-Item Screener™)

Note:

For analytical information about the Callahan screener, see:

• Callahan CM, Unverzagt FW, Hui SL, Perkins AJ, Hendrie HC. [Six-item screener to identify cognitive impairment among potential subjects for clinical research](#). Med Care. 2002 Sep;40(9):771-81. PMID:12218768.

Self-Administered Questionnaire (SAQ) – Home (Variables with “V5” 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 from SF-36)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 tobacco use
Current employment
Household Living, Medical care and Marital Status

Notes:

¹ Participants who refused or were unable to participate in the 84-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 and 84 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 and 84 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” (V5BONE). Variables indicating the locations (1=Yes) are prefixed “FX” (for example, V5FXHIP), except V5SPINE.

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. PMID: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.

⁵ SF-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 and 84 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

⁶The 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 Pittsburgh 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 Late-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.

⁹Scoring 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. Additional options were inserted at 84 months version. 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 “V5” prefix)

The SAQ-Clinic was administered during the 84-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 “V5” prefix)

The clinic interview is an interviewer-administered questionnaire conducted during the 84-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
Left knee symptoms
Left knee pain – Intermittent and Constant Osteoarthritis Pain (ICOAP)¹
Left knee pain location
Knee buckling²
Knee injury²
Knee 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}
Modified Physical Activity Scale for the Elderly (PASE)^{6,7}
Physical activity – Climbing flights of stairs⁸

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.

²Participants who refused or were unable to participate in the 84-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.

⁴Participants 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.

⁵Medication 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 (V5MIF). 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.

⁶The Physical Activity Scale for the Elderly (PASE©) is a copyright protected instrument. For information about the instrument, see the [New England Research Institutes' PASE instrument website](#). 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.

The PASE instrument was administered at 84 months to a subset of 890 participants based on eligibility for the accelerometry measure (if eligible but unwilling or unable to do accelerometry then eligible for PASE) and willingness to complete the interview.

⁷The 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).

⁸The stair climbing question is not part of the PASE measurement and does not contribute to the summary score.

Clinic Visit (Variables with “V5” prefix)

Selected exams were conducted at the 84-month clinic visit. The dataset includes the following components:

- Blood pressure
- Weight
- Standing height¹
- 20-meter walk
- Chair stands
- Knee range of motion
- Pain sensitivity (touch - 2g & 26g von Frey filament; temporal summation, pinprick)
- Pressure pain threshold^{2,3}
- Knee x-ray⁴
- OrthOne 1.0T knee MRI⁴
- Step watch questionnaire^{5,6}

Notes:

¹ Exam done at 84 months only if not done at 60 months and if participant is able to stand for the measurement.

²The V5ENROLL dataset includes some continuous variables with a special value assigned to indicate when a maximum value was exceeded. Analysts using continuous variables from the 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.

³Pressure 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.

⁴Starting 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.

⁵For analytical information about the StepWatch device, see Orthocare Innovations' StepWatch™ product website. For analytical information, see:

- Song J, Semanik P, Sharma L, Chang RW, Hochberg MC, Mysiw WJ, Bathon JM, Eaton CB, Jackson R, Kwok CK, Nevitt M, Dunlop DD. [Assessing physical activity in persons with knee osteoarthritis using accelerometers: data from the osteoarthritis initiative](#). Arthritis Care Res (Hoboken). 2010 Dec;62(12):1724-32. PMID: 20806273.
- Cavanaugh JT, Coleman KL, Gaines JM, Laing L, Morey MC. [Using step activity monitoring to characterize ambulatory activity in community-dwelling older adults](#). J Am Geriatr Soc. 2007 Jan;55(1):120-4. PMID: 17233695.
- Foster RC, Lanningham-Foster LM, Manohar C, McCrady SK, Nysse LJ, Kaufman KR, Padgett DJ, Levine JA. [Precision and accuracy of an ankle-worn accelerometer-based pedometer in step counting and energy expenditure](#). Prev Med. 2005 Sep-Oct;41(3-4):778-83. PMID: 16125760.

⁶The Accelerometry (StepWatch) questionnaire was given to participants at the clinic visit when they received the StepWatch 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 a few participants did not return the questionnaire.