

Fracture Data Endpoints Documentation

Four clinical sites individually collect SOF fracture data. Participants are asked to complete tri-annual questionnaires in regards to the occurrence of falls and fractures during the previous four-month interval. When questionnaires are not returned, participants are then contacted by phone. Occasionally fracture notification is received directly from participants, physician, or hospital discharge records sent to the clinical sites.

A three-point adjudication process begins with the clinic Principal Investigator's initial diagnosis, circumstance of fracture, and degree of trauma reports. The reports and medical records pertinent to the case are sent to the Coordinating Center for review and pre-adjudication by the Endpoints Specialist before a physician concludes a final adjudication.

Once the fracture data are entered and coded, a number of variables are calculated. For example, indicators of occurrence of a non-trauma fracture of a particular type and corresponding follow-up time (time to fracture, for survival model) are calculated and can be used for non-trauma fracture analysis.

General Naming Conventions:

The variable name is a combination of 3 factors: starting visit, fracture location, and type of variable.

1. For all of the fractures, variables are calculated based on a specific starting visit for all except visit 7.
2. Fracture location can be either 3 or 4 characters long, for example, HIP for hip fracture and WRST for wrist fracture.
3. There are 3 types of variables available for each particular type of fracture: indicator of occurrence of fracture (I), number of fracture occurred (N), and corresponding follow-up time defined as days from individual participant's visit date for a particular visit to the first fracture date (F).

For example,

- a. variable name for the indicator of wrist fracture since visit 3 would be V3WRSTI,
- b. variable name for the number of foot fractures since visit 2 would be V2FOOTN, and
- c. variable name for follow-up time to the first humerus fracture since visit 5 would be V5HUMF.

Hip fracture only:

We classified 3 subregions of fractures under the hip fracture category: femoral neck, intertrochanteric and other. We created variables for all hip (HIP), femoral neck (FEM), and intertrochanteric fractures (INT). In addition to regular indicator of any type of hip fracture, an indicator for fracture excluding prior hip fracture is also created with variable name ended with “X”. And the corresponding follow-up time for hip fracture excluding prior hip fracture is also created with variable name as V#HIPXF.

The following missing codes apply to femoral neck fracture variables (V#FEMI and V#FEMX):

.B = 2 different types of hip fractures, 2nd one is a femoral neck fracture
.I = intertrochanteric fracture only
.H = other hip fracture only (neither femoral neck nor intertrochanteric fracture)
.N = no visit
.P = past hip fracture
.T = traumatic fracture

The following missing codes applied to intertrochanteric fracture variables (V#INTI and V#INTX):

.B = 2 different types of hip fractures, 2nd one is an intertrochanteric fracture
.F = femoral neck fracture only
.H = other hip fracture only (neither femoral neck nor intertrochanteric fracture)
.N = no visit
.P = past hip fracture
.T = traumatic fracture

For any femoral neck or intertrochanteric fracture indicators, use the hip fracture follow-up time (V#HIPF and V#HIPXF).

Special case:

1. If investigator decides to code .F, .I, .H to “NO” fracture, the follow-up time needs to be substituted from overall follow-up time (such as V1FOLALL, etc.).
2. For femoral neck fracture, if investigator decides to code .B (which means 2 different types of hip fractures with 2nd one was a femoral neck fracture) to “YES”, the follow-up time needs to be substituted by corresponding date of fracture and current visit date. For example, for calculating femoral neck fracture since visit 2, use V2FEMD and V2DATE.
3. For intertrochanteric fracture, if investigator decides to code .B (which means 2 different types of hip fractures with 2nd one was an intertrochanteric fracture) to “YES”, the follow-up time needs to be substituted by corresponding date of fracture and current visit date. For example, for calculating intertrochanteric fracture since visit 3, use V3INTD and V3DATE.
4. Use follow-up time for V#FEMI for the follow-up time of V#FEMX. Use follow-up time for V#INTI for the follow-up time of V#INTX.