Heart Failure Hospitalization Incidence Data Justification:

Since Heart Failure Hospitalization event is only adjudicated after 01/01/2005 in Jackson Heart Study, the purpose of this document is to describe the strategy and justification to derive the incidence data of Heart Failure Hospitalization. Here are several important facts:

1. We do not have related question and assessment for Heart Failure Hospitalization status at Visit 1 Exam, so Heart Failure Hospitalization Status is not accessible at beginning of JHS.
2. To assess Heart Failure Hospitalization status of the JHS participants, we should depend on self-reported annual follow up questionnaire data (lack of quality control).

Majority of information came from AFU data using AFU form version A (form effective date 8/23/2001), and we may also depend on some AFU data using AFU form version C (form effective date 10/14/2008).

In AFU form version A/B, we only have one question related to Heart Failure Hospitalization, as following:

Question 7. Has a doctor **ever** said you had any of the following?

b. Heart failure or congestive heart failure?

In AFU form version C, we have three questions related to Heart Failure Hospitalization, as following:

Question 7b. Has participant ever reported a heart failure diagnosis in AFU without a documented HF hospitalization in the Jackson Heart Study database? (to be done for 1 year only).

Question 8. In a previous JHS phone call in [< year >], you indicated that you had been diagnosed with heart failure or congestive heart failure. Do you recall that you had such a diagnosis of heart failure?

Question 9. **Since we last contacted you on mm /dd/ yyyy,** has a doctor said that you had heart failure or congestive heart failure?

We derived two variables HFEVER and HFLASTCNTCT based on answers from above four questions in AFULONG data sets which will be used to derive HF Hospitalization incidence data set:

HFEVER: *Has a doctor said that you have heart failure or congestive heart failure?*

HFLASTCNTCT: *Since our last contact, has a doctor said that you had heart failure or congestive heart failure?*

To use non-quality controlled AFU data to identify Heart Failure Hospitalization status should be one limitation of our data.

We derived two sets of HF hospitalization incident data sets, one is suggested by the JHS data coordinating center to be used as the main analysis and the second set is suggested to be used as the sensitivity analysis.

Part I: Derivation of Incident HF Hospitalization from 01/01/2005 using AFU data to determine HF Hospitalization status on 01/01/2005 – Main Analysis Variable Derivation

Start Population:

The following table lists the categorization of total start population (5042 subjects with consent “yes” and alive on 01/01/2005 for HF adjudication), and the subjects we can include for incidence study is 3530 (on 01/01/2005) + 932 (on the date of first AFU after 01/01/2005) = 4462

Total Population 5042:

|  |  |
| --- | --- |
| Category | Number of Subjects |
| Individuals that reported HF Hospitalization before 01/01/2005 | 181 |
| *“Yes” at one AFU and no “No” answer afterward* | *134 (Cat = 1)* |
| *“Yes” at one AFU and “No” answer afterward* | *47 (Cat = 2)* |
| Individuals that did not report HF Hospitalization at any AFU before 01/01/2005 | 3713 |
| *“No” at the first AFU after 01/01/2005* | 3543 |
| *Adjudicated HF Hospitalization Event detected between 01/01/2005 and First AFU after 01/01/2005 --- Inconsistent AFU results* | *13 (Cat = 3)* |
| *Adjudicated HF Hospitalization Event not detected between 01/01/2005 and First AFU after 01/01/2005* | *3530(Cat = 4)* |
| *“Yes” at the first AFU after 01/01/2005* | *66 (Cat = 5)* |
| *Missing at all AFU after 01/01/2005* | *104 (Cat = 6)* |
| Individuals missing HF question answer for all AFUs before 01/01/2005 | 1148 |
| *“No” at the first AFU after 01/01/2005* | 1051 |
| *Adjudicated HF Hospitalization Event detected between 01/01/2005 and First AFU after 01/01/2005 --- Inconsistent AFU results* | *1 (Cat = 7)* |
| *“No” answer is from Form A Question 7b “****ever****”. Adjudicated HF Hospitalization Event not detected between 01/01/2005 and First AFU after 01/01/2005* | *932 (Cat = 8)* |
| *“No” answer is from Form C Question 9 “****since last contact time****”. Adjudicated HF Hospitalization Event not detected between 01/01/2005 and First AFU after 01/01/2005* | *118 (Cat = 9)* |
| *“Yes” at the first AFU after 01/01/2005* | *25 (Cat = 10)* |
| *Missing at all the AFUs after 01/01/2005* | *72 (Cat = 11)* |

In addition, for other 264 subjects that deceased or gave negative consent for medical record review before 01/01/2005, we assumed their “cat” variable as 12.

To summarize, the main analysis incident HF Hospitalization variable (HF, Examdate, Date, Year, Years and Days) was assessed from 01/01/2005 (for cat = 4 participants) or first AFU after 01/01/2005 (for cat = 8 participants) to 12/31/2012, and all HF Hospitalization Events are adjudicated.

Part II: Derivation of Incident HF Hospitalization from V1 by combining AFU HF Identification Information – Sensitivity Analysis Variable Derivation

Start Population: N = 5306

The subjects we can include for incidence study 52 + 16 + 3650 + 8 + 60 + 984 = 4770

Total Population 5306:

|  |  |
| --- | --- |
| Category | Number of Subjects |
| Individuals that had prevalent HF before first AFU | 126 (AFUCat = 1) |
| Individuals that did not have prevalent HF before first AFU, but developed HF before 01/01/2005 | 68 |
| *first AFU "No", “Yes” at one AFU and no “No” answer afterward* | *52 (AFUCat = 2)* |
| *first AFU "No", and “Yes” at one AFU after first AFU and at least one “No” answer afterward* | *16 (AFUCat = 3)* |
| Individuals that did not report HF at any AFU before 01/01/2005 | 3872 |
| *Individuals that did not report HF at any AFU before 01/01/2005 and “No” at the first AFU after 01/01/2005* | *3650 (AFUCat = 4)* |
| *Individuals that did not report HF at any AFU before 01/01/2005 and “Yes” at the first AFU after 01/01/2005* | *68* |
| *adjudicated events identified between 01/01/2005 and first AFU after 01/01/2005, event time specified as first adjudicated event time after 01/01/2005* | *8 (AFUCat = 5)* |
| *adjudicated events not identified between 01/01/2005 and first AFU after 01/01/2005, event time specified as middle point of last AFU before 01/01/2005 and 01/01/2005* | *60 (AFUCat = 6)* |
| *Individuals that did not report HF at any AFU before 01/01/2005 and Missing HF question answer at all AFU after 01/01/2005* | *154 (AFUCat = 7)* |
| Individuals missing HF question answer for all AFUs before 01/01/2005 | 1240 |
| *Individuals missing HF question answer for all AFUs before 01/01/2005 and “No” at the first AFU after 01/01/2005* | *1109* |
| *subjects did not report HF status at any AFU before 01/01/2005 and “No” at the first AFU after 01/01/2005 with Form A Question 7b (can be used to generate incidence data set)* | *984 (AFUCat = 8)* |
| *subjects did not report HF status at any AFU before 01/01/2005 and “No” at the first AFU after 01/01/2005 with Form C Question 9 (can not be used to generate incidence data set)* | *125 (AFUCat = 9)* |
| *Individuals missing HF question answer for all AFUs before 01/01/2005 and “Yes” at the first AFU after 01/01/2005* | *25 (AFUCat = 10)* |
| *Individuals missing HF question answer for all AFUs before 01/01/2005 and Missing at all the AFUs after 01/01/2005* | *106 (AFUCat = 11)* |

To summarize, the sensitivity analysis incident HF Hospitalization variable (AFUHF, AFUExamdate, AFUDate, AFUYear, AFUYears and AFUDays) was assessed from V1 to 12/31/2012, and HF Hospitalization Events from V1 to 01/01/2005 came from AFU, and HF Hospitalization Events from 01/01/2005 to 12/31/2012 are adjudicated.