**Heart Failure Validation Guidelines**

**November 13, 2013**

**Background**:

Congestive Heart failure (HF) is a complex syndrome characterized by the inability of the heart to supply sufficient blood flow to the body. HF is diagnosed clinically and further dichotomized by left ventricular ejection fraction (i.e. reduced or preserved). Symptoms of HF include shortness of breath (dyspnea) when you exert yourself or when you lie down; fatigue and weakness, swelling (edema) in your legs, ankles and feet; rapid or irregular heartbeat; reduced ability to exercise; persistent cough or wheezing with white or pink blood-tinged phlegm; swelling of your abdomen (ascites); sudden weight gain from fluid retention; lack of appetite and nausea; difficulty concentrating or decreased alertness.

**Definitions of Case/Control Status**

**Heart Failure Cases:**

For chart validation, a case is defined as any person with heart failure diagnosed by a health care provider who meets Framingham Criteria for Congestive Heart Failure.

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| **\*Framingham Criteria for Congestive Heart Failure:** Diagnosis of HF requires the simultaneous presence of at least 2 major criteria or 1 major criterion in conjunction with 2 minor criteria. |
| Major criteria:   * Paroxysmal nocturnal dyspnea * Neck vein distention * Rales * Radiographic cardiomegaly (increasing heart size on chest radiography) * Acute pulmonary edema * S3 gallop * Increased central venous pressure (>16 cm H2O at right atrium) * Hepatojugular reflux * Weight loss >4.5 kg in 5 days in response to treatment |
| Minor criteria:   * Bilateral ankle edema * Nocturnal cough * Dyspnea on ordinary exertion * Hepatomegaly * Pleural effusion * Decrease in vital capacity by one third from maximum recorded * Tachycardia (heart rate>120 beats/min.)   Minor criteria are acceptable only if they cannot be attributed to another medical condition (such as pulmonary hypertension, chronic lung disease, cirrhosis, ascites, or the nephrotic syndrome). |

**Controls:**

For chart validation, a control is defined as a patient without a documented history of physician diagnosed heart failure.

**Sample Selection:**

Chart review validation of HF status for 50 cases and 50 controls identified from an automated EMR algorithm. Selection of cases and controls for review will be at random. However, for the cases there should be equal number of cases with preserved (≥ 50%) and reduced (< 50%) EF.

**Instructions:**

The review will encompass the entire medical record. The reviewer will be blind to case/control status as determined by the EMR algorithm. The reviewer will be given a patient identifier and validation spreadsheet to record validation results.

1. Is there evidence of HF diagnosed by health care provider?
   1. No – stop (Control)
   2. Yes – proceed to #2
2. Does this patient meet Framingham Heart Failure Criteria?
   1. No (validated case = No ) - stop
   2. Yes (validated case = Yes) – proceed to #3 & 4
3. Record earliest HF diagnosis date.
4. Record the type of HF using the lowest EF measured 0-182 (approximately a 6-month period) days **after** the HF date. If missing, then use the lowest EF measured 0-182 days **prior** to the HF date. If missing, then use the lowest EF measured 183-365 days **after** the HF date. If missing, then use the lowest EF measured 183-365 days **prior** to HF date. If missing, set HF type to “unable to determine”.
   1. HF with reduced EF = ejection fraction < 50% (HF Type = reduced)
   2. HF with preserved EF = ejection fraction ≥ 50% (HF Type = preserved)

\*The Framingham Heart Study criteria are 100% sensitive and 78% specific for identifying persons with definite congestive heart failure (McKee PA, Castelli WP, McNamara PM, Kannel WB. The natural history of congestive heart failure: the Framingham study. N Engl J Med. 1971 Dec 23;285(26):1441-6.)