ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

Manual 3A

Surveillance of Heart Failure Manual of Operations

Version 2.1

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Foreword

This manual, entitled Surveillance Component of Heart Failure Procedures is one of a series of protocols and manuals of operation for the Atherosclerosis Risk in Communities (ARIC) Study. Manual 1 provides the background, organization, and general objectives of the ARIC Study. Manual 2 describes the operation of the cohort follow-up component. Manual 3 describes cohort and community coronary heart disease (CHD) surveillance methods and Manual 3A (version 1.0) describes cohort and community heart failure (HF) surveillance methods.

ARIC Study Protocols and Manuals of Operation

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1	General Description and Study Management
2	Cohort Component Procedures
3	Cohort and Community Surveillance for CHD
3A	Cohort and Community Surveillance for HF

Manual 3A. Heart Failure Surveillance Component Procedures

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1.0 INTRODUCTION

ARIC heart failure (HF) surveillance includes monitoring and validating hospitalized heart failure events among community and cohort participants, and monitoring out-of-hospital heart failure events among cohort participants.

Through community surveillance of heart failure, the ARIC study enumerates and validates cases (events) of hospitalized heart failure occurring after January 1, 2005 in men and women, age 55 and above, among residents of the four ARIC study communities: Forsyth County, North Carolina; Jackson, Mississippi; selected suburbs of Minneapolis, Minnesota; and Washington County, Maryland.

This manual details the procedures for ARIC community and cohort surveillance of heart failure. Section 2 describes the procedures by which potential hospitalized events in the community are identified (i.e. hospital discharge indexes). Section 3 details procedures for collecting the additional information needed once an event has been identified. Diagnostic criteria are documented in Section 4, and review and classification procedures are described in Section 5. The procedures for obtaining information on certain indicators of medical care are described in Section 6. Procedures for linkage of multiple events are described in Section 7. Section 8 briefly discusses the reliability of record abstraction. Section 9 details the surveillance procedures for identifying heart failure events among the ARIC cohort. Section 10 describes how the Mortality and Morbidity Classification Committee (MMCC) functions and Section 11 outlines the quality control measures used in ARIC surveillance. Section 12 outlines the heart failure abstraction certification system. Section 13 summarizes the use of Medicare data to estimate outpatient heart failure events in community surveillance. Section 14 describes the web-based data entry system that will be used for case identification and data entry.

1.1 Useful Definitions

Heart Failure

In general terms, heart failure is the inability of the heart to pump blood at a rate adequate to fill tissue metabolic requirements or the ability to do so only at an elevated filling pressure; defined clinically as a syndrome of ventricular dysfunction with reduced exercise capacity and other characteristic hemodynamic, renal, neural, and hormonal responses. Clinical practice guidelines define heart failure as a syndrome or condition characterized by: 1) signs and symptoms of intravascular and interstitial volume overload, including shortness of breath, rales, and edema or 2) manifestations of inadequate tissue perfusion, such as fatigue or poor exercise tolerance. Heart failure is often categorized as either systolic or diastolic.

Congestive Heart Failure (CHF)

CHF is characterized by breathlessness and abnormal sodium and water retention, resulting in edema, with congestion of the lungs or peripheral circulation, or both. Often the terms “heart failure” and “congestive heart failure” are used to describe the same condition.

Systolic heart failure or Systolic dysfunction

Systolic dysfunction is due to poor left ventricular contraction, usually expressed as ejection fraction (EF). In other words, systolic heart failure is heart failure due to a defect in the expulsion of blood that is caused by an abnormality in systolic function.

Diastolic heart failure or diastolic dysfunction

Heart failure patients with diastolic dysfunction (more common in the elderly) have normal left ventricular ejection fraction, the defect seem to lie in relaxation of the left ventricle and is associated with delayed filling.

Progression of heart failure symptoms

In the abstraction of the medical record using the Heart Failure Abstraction (HFA) form, section one is concerned with identifying patients with progression, decompensation, or new onset of symptoms. Progression or progressive heart failure is defined as the development of new symptoms or the worsening of existing symptoms of heart failure (e.g. pulmonary edema, shortness of breath, etc.). Progressive heart failure may be either incident or prevalent (See below). These patients may be treated with new therapy or with the escalation of existing therapy for heart failure.

Decompensation of heart failure symptoms

In general terms, decompensation means the inability of the heart to maintain adequate circulation, marked by dyspnea, venous engorgement, and edema. Patients with decompensated heart failure are those with progressive heart failure who received treatment with intravenous medical therapy during the course of the hospitalization, including intravenous inotropic agents and intravenous vasodilators. Patients receiving intravenous diuretics are considered to have decompensated heart failure if the therapy was administered for the progression of heart failure (i.e. worsening of symptoms). Persons receiving post-operative or prophylactic intravenous diuretic therapy in the absence of progressive heart failure are not considered to have decompensated heart failure.

Event

For the purposes of completing the HFA, an "event" is the occurrence of progression of heart failure symptoms or of decompensation. Of interest for the HFA is the specific date of the event (i.e. what date did the progression or new onset of symptoms begin? See HFA item 5). In some cases the "event" date is the date of presentation to the hospital. In other cases, the "event" may have started before or after the patient was admitted. Both first (incident) events and recurrent events are abstracted.

Incident Heart Failure

An incident event is a person's first (ever) diagnosis of heart failure.

Prevalent Heart Failure

A prevalent case is a patient with a history of heart failure prior to this event.

2.0 IDENTIFICATION OF EVENTS IN COMMUNITY SURVEILLANCE

2.1 Introduction

The basic features of the community surveillance of hospitalized heart failure design are summarized in Table 2.1. Heart failure community surveillance began with events occurring on or after January 1, 2005 in each of the four communities.

Table 2.1. ARIC Community Surveillance Hospitalized Heart Failure Eligibility Criteria

Criteria	Eligibility
Time period	Discharges occurring on January 1, 2005 and beyond
Age	55 years of age and above at time of hospital discharge
Gender	Men and women
Race	All races
Place of residence	Home address within defined boundaries of the ARIC communities
ICD9-CM Codes for case identification*	398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 415.0, 416.9, 425.4, 428.x, 518.4, 786.0x

x= any number
* See also table 2.2 for description of each diagnosis code

Events meeting the eligibility criteria given in Table 2.1 are investigated for conformity with ARIC surveillance diagnostic criteria. Identification of hospitalized events is limited to acute care hospitals in the catchment area (Section 2.2.3). No systematic attempt is made to obtain events from records of nursing homes, psychiatric hospitals, private physicians, or hospitals out of the catchment area.

Hospitalized heart failure events are investigated by means of review of hospital medical records. The elements of several heart failure diagnostic criteria are abstracted onto standardized computer screens representing the hospitalized HFA form. The occurrence of heart failure is determined when possible by computer analysis of the recorded diagnostic elements. However, hospitalization meeting certain criteria will be reviewed by members of the Mortality and Morbidity Classification Committee (MMCC), according to criteria described in Section 4.

Quality control procedures are in place to assess reliability of abstracting medical records and the reliability of MMCC procedures.

Out-of-hospital deaths, although investigated to validate a coronary heart disease as a cause of death via informant interview, physician questionnaire, and coroner/medical examiner questionnaire (See Manual 3), are not specifically investigated to validate heart failure as a cause of death. Out-of-hospital deaths receive a final CHD death diagnosis through review by the MMCC in accordance to procedures outlined in Manual 3. No attempt is made to determine whether the cause of death was specifically due to heart failure for either in-hospital or out-of-hospital deaths. The only death classification created for deaths in the ARIC communities is that described in Manual 3 for coronary heart disease.

Table 2.2. Heart Failure Target ICD-9-CM Discharge Diagnosis Codes

ICD-9-CM	Disease classification
398.91	Rheumatic heart disease
402.01	Hypertensive heart disease-malignant with congestive heart failure
402.11	Hypertensive heart disease-benign with congestive heart failure
402.91	Unspecified hypertensive heart disease with congestive heart failure
404.01	Hypertensive heart disease and renal failure-malignant with congestive heart failure
404.03	Hypertensive heart disease and renal failure-malignant with congestive heart and renal failure
404.11	Hypertensive heart disease and renal failure-benign with congestive heart failure
404.13	Hypertensive heart disease and renal failure-benign with congestive heart and renal failure
404.91	Hypertensive heart disease and renal failure-unspecified with congestive heart failure
404.93	Hypertensive heart disease and renal failure-unspecified with congestive heart and renal failure
415.0	Acute cor pulmonale
416.9	Chronic pulmonary heart disease, unspecified
425.4	Other primary cardiomyopathies
428.x	Congestive heart failure
518.4	Acute edema of lung, unspecified
786.0x	Dyspnea and respiratory abnormalities

x = any number

2.2 Identification of Hospitalized Heart Failure

2.2.1 Obtaining Access to Hospital Medical Records

A critical feature of ARIC community surveillance is obtaining complete and accurate information from hospital medical records. Without complete cooperation of hospitals in identifying a complete sampling frame of cases and unrestricted access to eligible medical charts, the usefulness of event rates generated in any community is limited. Cooperation is sought through hospital administration, medical records directors, hospital ethics committees, and influential medical staff.

It is sometimes necessary to compromise with the hospital review committees and house staff. A major consideration may be confidentiality and authorized consent to access patient's charts. Each ARIC field center works closely with its community hospitals to establish a working relationship that maximizes access to the full spectrum of eligible occurrences of heart failure that are seen at each hospital.

2.2.2 Hospital Discharge Index

Eligible hospitalized heart failure occurrences are identified from the discharge index of each hospital surveyed. Discharge indices are obtained directly from the hospital. When a person is discharged from a hospital, the physician must indicate the major illness from which the patient suffers. Usually one such diagnosis accounts for the hospitalization. This is the primary discharge diagnosis. Other old or new diagnoses may be listed as secondary discharge diagnoses. Discharge diagnoses are coded by the hospital medical records personnel according to the International Classification of Diseases (ICD). (See Manual 3 Section 2.2.2 for more information on ICD classification.)

Using the discharge index for each hospital, community surveillance hospitalized events are selected according to the following eligibility criteria.

1. Age. ARIC examines cases only at ages 55 and above at time of discharge.

2. Place of Residence. Patients must live within the boundaries of the ARIC community. The discharge index may give limited information regarding the patients place of residence (e.g. only a zip code), in which case a determination of residence eligibility may require checking the address in the hospital records. If a review of the medical record indicates the person was only visiting the area or had two residences, the address where the person lived at least six months of the year is considered the place of residence for ARIC purposes. People residing in a local jail at the time of hospitalization are counted.

3. Date. Time eligibility is determined from the date of discharge. Only cases discharged on or after January 1, 2005 are eligible.

4. ICD-9-CM code. 398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 415.0, 416.9, 425.4, 428.x, 518.4, 786.0x (x= any number)

The number of cases meeting these four eligibility criteria and that are to be abstracted is reduced by applying various sampling fractions to different classes of ICD9-CM codes. These sampling fractions are reassessed periodically. Two sampling strata are defined from eligible heart failure ICD-9-CM discharge diagnosis codes.

1. ICD-9-CM code 428.x: Any code with digits 428 to the left of the decimal.

2. Other ICD-9-CM codes: Hospitalization without a discharge diagnosis code of 428, but with one of the following discharge codes: 398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 415.0, 416.9, 425.4, 518.4, 786.0x.

The hospitalization sampling fractions for these code groups are allowed to vary by field center, sex, and race (by race in Forsyth County and Jackson only). This procedure of non-uniform sample probabilities is established in order to achieve a balance in the numbers of incident events between field center, sex, and race groups, so that precision of event rate estimates will be

similar across these groups. With the two ICD-9-CM code strata shown above and sex, there are a total of 4 sampling strata for Minneapolis and Washington County. The addition of race in Forsyth County and Jackson results in 8 sampling strata in those two communities.

The total number of abstractions per field center came from contract negotiations for abstracting beginning in event year 2005, are as follows: Forsyth County 1107, Jackson 885, Minneapolis 410, and Washington County 675. Therefore for all field centers combined the total number of HF hospitalizations to be abstracted annual is not to exceed 3077.

Another element of the sampling fraction creation is that the ratio of number of abstractions in the ICD-9-CM 428 code group is set to be twice that of the "other" ICD-9-CM code group (i.e. 398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 415.0, 416.9, 425.4, 518.4, 786.0x). This 2:1 ratio will be re-evaluated after one year of abstraction and may be increased for event years beyond 2005. For event year 2005 the 2:1 ratio will be sufficient to assess the rate of validated incident heart failure among cases occurring in this code group. The sampling fractions were chosen in terms of numbers of days per month being sampled (e.g. 1/30, 2/30). To implement these sampling fractions, one must select IDs from the hospital index based on rules for selecting specific discharge days of the month. A listing of the specific days to be sampled has been established. The sampling fractions for heart failure and the sampling implementation rules are shown in Table 2.3a and Table 2.3b. See Manual 3 Section 2 for a description of how CHD and death sampling fractions can be implemented.

To increase the overlap between CHD and HF abstraction, we further divided those IDs in the hospital index that are age eligible for HF abstraction and have ICD code 428 in their discharge code, into 9 groups based on their age and ICD discharge code as follows:

Group 1: has any ICD code 410, and age<75
Group 2: **not in 1** and has any ICD code 411 and age<75
Group 3. **not in 1,2** and has any ICD code 412,413,414 and age<75
Group 4. **not in 1,2,3** and age<75
Group 5: has any ICD code 410 and 74<age<85
Group 6: **not in 5** and has any ICD code 411 and 74<age<85
Group 7: **not in 5,6** and has any ICD code 412,413,414 and 74<age<85
Group 8: **not in 5,6,7** and 74<age<85
Group 9: age out of range for CHD selection (i.e., age>=85)

The sampling frame implemented for year 2005 is described in Appendix X1. The sampling frame implemented for year 2006 is described in Appendix X2.

ICD-9-CM codes listed on the hospital discharge index may not exactly match those found in the corresponding hospital chart. If the targeted ICD codes were in the hospital discharge index but not found in the medical record, abstraction still should be completed and considered as eligible. Beginning with 2005, the electronic hospital discharge lists are sent to the Coordinating Center for selection of hospitalizations eligible for community surveillance abstraction. (The abstraction in Minnesota is still done by the field center, from electronic lists.) The need for abstraction for

non-cohort hospitalizations is totally determined by the hospital lists, and the list of selected hospitalizations becomes a part of the ARIC database.

2.2.3 HF Hospitalizations Occurring Outside the Study Community

Community residents hospitalized with heart failure while outside both the study area and the surrounding counties are not identified by routine surveillance. An estimate of the effect of this procedure is available from the surveillance for hospitalized events in cohort members.

2.2.4 Range of Facilities Covered in Surveillance

See Manual 3 Section 2.2.4 for a full discussion of this the criteria for a facility to be included in community surveillance. Manual 3 also describes the procedures implemented annually to assess whether new hospitals are to be included in community surveillance.

2.2.5 General procedures in the abstraction of hospital records for heart failure

Instructions for filling out individual forms are given in the "Question by Question" instructions for each form, and are in the Appendices to this Manual. A web-based platform is used to enter information regarding heart failure hospitalizations into the data base. Instructions on the use of the web-based data entry system (DES) are given in Section 14. The entire list of hospitalizations needing community surveillance abstraction for heart failure will be installed into the central database. This will generally be done by the Coordinating Center after being selected from the hospital discharge lists supplied to the field centers by the hospitals. Where for any reason this procedure is not feasible, an equivalent list will be furnished to the Coordinating Center by the field center. The central database files will be used to implement a computer management system for the field centers to track abstraction. This computer management system will give the complete list of community surveillance hospitalization abstractions needed, and can be used to furnish abstractor-specific work lists. Hospitalization ID numbers can be assigned from this system for each specific hospital by medical record number and discharge date combination. Information available from the hospital lists will be auto-filled into the abstraction forms.

There are several new forms for use in community surveillance, and a specified order for use of these forms is as follows: CEL (cohort eligibility form, used only for cohort members); CFD (confidentiality form); CHI (common hospital information); HFA (for hospitalized HF). Note that, if the hospital chart cannot be found, this is registered in the CEL for cohort members and in the CFD for non-cohort, and no further abstraction need be done. A computerized address check takes place in process of completing the CFD, and if it leads to ineligibility, no further abstraction need be done. If the computerized address check does not resolve whether the address is in or out of catchment area, the abstractor is asked to suspend abstracting (for a non-cohort participant) after completion of the CFD form pending further investigations. If the address proves eligible or continues as indeterminate, abstraction continues for required forms.

Each form related to a heart failure abstraction (i.e. CFD, CHI, HFA) will start with identifying the hospital identifying code, medical record number, and discharge date. This will help insure that if the data entry session starting is interrupted for any reason before the entire set is completed, the right chart is associated to the already assigned hospitalization ID number. If

there have been no interruptions, these 3 fields (hospital identifying code, medical record number, and discharge date) will be auto-filled onto the computer screens. These data are later scrambled to ensure confidentiality protection.

The common hospital information (CHI) was created to save entering the same data twice when a hospitalization is both HF and CHD eligible. The data entered into CHI is mainly administrative, and there remain a few items common to Hospital Record Abstraction (HRA) and HFA that will be entered in both forms.

When abstracting for multiple surveillance events for a given hospitalization, i.e., CHD, HF and Stroke, the event ID must be the same across all forms (HRA, HFS, STR, CEL, CFD, CHI and NOF).

3.0 EVENT INVESTIGATION

For hospitalized heart failure, event investigation centers on review of the hospital medical record. Procedures for the identification of hospitalized events in members of the ARIC cohort differ from community surveillance procedures at certain stages and are described in detail in Section 9. In the following paragraphs, general differences between surveillance and the investigation of cohort events are noted. References to specific procedures for cohort surveillance are identified in Section 9 where appropriate.

3.1 Procedure for Hospitalized Heart Failure

The HFA Form is used to abstract events meeting ARIC hospitalized heart failure eligibility criteria for age, residence, date, and hospital discharge code and sampling fraction (Section 2.2.2).

There are a few cases in which the ICD-9-CM code is recorded incorrectly, so that a code on the diagnostic index (used as the primary means of identifying eligible hospitalizations to abstract) meets the ARIC criteria but none of the diagnoses recorded on the discharge summary of the medical record meet the study criteria. The HFA Form is completed in such a case and still considered eligible.

If an eligible hospital record indicates that the patient was transferred directly from another acute care hospital in the catchment area, or that the patient upon discharge is being transferred directly to another acute care hospital in the catchment area, the record for the other hospitalization is found and abstracted if it has ARIC screening codes regardless of day of discharge. Clearly designated extended care facilities that are physically located within an acute care hospital are not considered as another acute care hospital. This procedure of processing transfers is the same as for community surveillance of hospitalize myocardial infarction.

Capturing hospitalizations for heart failure at outlying hospitals that accept emergency department transfers from Washington County Hospital follow the protocol established for myocardial infarction surveillance (Manual 3, Section 3.2.1). Therefore, the list of heart failure target codes (Manual 3A, Section 2.2.2) are added to the list of emergency department discharges from Washington County Hospital that are reviewed and pursued at outlying

hospitals. The transfer practice of heart failure patients from the emergency department at Washington County Hospital will be monitored periodically and the protocol modified if needed.

3.2 Fatal Heart Failure

In-hospital deaths include deaths occurring on the hospital wards, in the intensive care units or operating room. For community surveillance, a Heart Failure Abstraction (HFA) form is completed for hospitalizations indentified on the HFA eligibility listing provided to the field centers. Completion of an HFA form for a hospitalization that concluded with the patient's death prior to discharge (in-hospital death) does not trigger the completion of a DTH form that would not be otherwise completed as per CHD surveillance protocol.

Death certificates are not abstracted for HF. The number of deaths occurring in the community with an underlying cause of death of heart failure (ICD-10 code I-50) or with heart failure listed as a contributing cause on the death certificate are determined from electronic death certificate files. However, these fatal events are not investigated and validated for heart failure.

3.3 Summary of Heart Failure Event Investigation

3.3.1 Hospital heart failure events

The following steps summarize the forms to be completed when investigating community surveillance hospitalized HF.

Step 1: A hospitalization is identified as eligible from computerized discharge list obtained from community surveillance hospitals and loaded into a database available to field center staff.

Step 2: The medical record of the hospitalizations identified in Step 1 are obtained from the medical records department at each hospital.

Step 3: Abstractors verify that the hospitalization is eligible (e.g. verifies address is within catchment area) if instructed to by the computerized case selection program. Abstractor is instructed by case selection program if case is also eligible for abstraction using HRA form.

Step 4: Abstractors completes the confidentiality (CFD) on their laptop computer.

Step 5: Abstractor completes the common hospital information (CHI) on their laptop computer.

Step 6: Abstractor completes the heart failure abstraction (HFA) form on their laptop computer. Abstractor also completes HRA form if appropriate. Abstractor also locates and copies the following materials from the medical record: echocardiogram, nuclear reports, discharge summary, first ECG, catheterization report, and three chest X-ray reports starting after heart failure decompensation. The History and Physical Form (H & P), should be copied if, in the abstractor's opinion, the discharge summary is inadequate, or if the discharge summary says to go to the H & P. The abstractor should consult with the local HF committee physician if there are questions as to the need.

Step 7: Abstractor completes a surveillance event inventory/linkage (SXI) form.

Step 8: Abstractors obtains access to the web and down loads data to coordinating center site.

3.4 Correction of Erroneous Event Investigation Procedures

A hospitalized heart failure event may be identified by surveillance procedures (hospital discharge indices) and investigated as a surveillance event, then discovered at a later time to have occurred in a cohort member. In these cases, a Cohort Eligibility Form (CEL) must be completed. Instruction for completing other forms as indicated by the CEL should be followed.

3.5 Procedures for Sending Duplicate Material for MMCC Review

As indicated in Section 3.3.1, abstractors are to locate and copy materials from the medical record (e.g. echocardiogram, nuclear reports, discharge summary, first ECG, catheterization report, and three chest X-ray reports starting after heart failure decompensation). Items from the discharge summary such as discharge instructions, hospital/doctor follow-up, when to call the doctor, go to the ER or when to be concerned do not need to be included. However, discharge medications should be sent. History and physical part of the hospital record is not required. The History and Physical Form (H & P), should be copied if, in the abstractor's opinion, the discharge summary is inadequate, or if the discharge summary says to go to the H & P. The abstractor should consult with the local HF committee physician if there are questions as to the need.

4.0 DIAGNOSTIC CRITERIA

4.1 Hospitalized Heart Failure

Diagnostic data abstracted from the medical record of heart failure eligible hospitalized occurrences using the HFA form include elements of four established diagnostic criteria for HF (i.e. Framingham, Modified Boston, Gothenburg, and NHANES I). The diagnostic criteria and scoring algorithms are summarized in Table 4.1. Data elements collected from the HFA form will be used to create four diagnostic classifications for each eligible hospitalized occurrence (Table 4.2-5). In addition, selected hospitalization will also be reviewed by the Heart Failure Mortality and Morbidity Classification Committee (HF MMCC) to establish a fifth diagnostic classification based on clinical judgment. The HF MMCC review will involve completion of a HF Diagnosis (HDX) form (Figure 5.1). Based on clinical judgment of two independent HF MMCC reviewers (disagreement adjudicated by chair of the HF MMCC), an ARIC classification of **definite** decompensated heart failure, **possible** decompensated heart failure, **chronic** stable heart failure, heart failure **unlikely**, or **unclassifiable** will be established for each hospitalization.

4.2 Criteria For Selecting Cases for Heart Failure MMCC Review

All hospitalizations occurring in 2005 that meet heart failure abstraction eligibility (i.e. sampled in community surveillance events or cohorts meeting CEL criteria) receive an independent review by two members of the heart failure MMCC. Each reviewer completes a Heart Failure Diagnosis form (HDX) where the hospitalization is classified based on clinical judgment as described in Section 4.1. Heart failure MMCC reviewers do not have access to the results of the

computer classifications based on the scoring algorithms applied to abstracted data for their use in completing the HDX form (i.e. Framingham criteria, Modified Boston criteria, NHANES criteria or Gothenburg criteria). However, the heart failure MMCC members are provided a summary of the HFA abstraction on the Heart Failure Event summary form (Appendix I). Disagreements between the two reviewer's classifications are identified by the coordinating center and sent to the Chair of the HF-MMCC for final adjudication. Hospitalizations where abstraction of the medical record results in a skip out of the HFA form at question 3 are not reviewed by the heart failure MMCC and are automatically classified as "heart failure unlikely".

For community surveillance eligible heart failure hospitalizations occurring in 2006 and beyond, criteria for selecting cases for heart failure MMCC review are as follows:

1. All hospitalizations are reviewed by a single member of the heart failure MMCC with the classification determined by the MMCC reviewer becoming the event's final ARIC classification with the following exception.

a. If the Framingham, NHANES, and Modified Boston computer classification scoring algorithms meet the formula below* AND the heart failure MMCC classification is either "chronic stable heart failure" or "no heart failure", the case is sent to the Chair of the heart failure MMCC for adjudication. The Chair's adjudicated classification becomes the event's final ARIC classification.

> * Framingham criteria equal "heart failure present", and NHANES criteria equals "heart failure present", and Modified Boston criteria equal "definite or possible heart failure".

For events occurring in 2006 and beyond among cohort participants, all hospitalizations are reviewed by two heart failure MMCC members. Differences between these reviews are adjudicated by the Chair of the heart failure MMCC. The adjudicated classification becomes the event's final ARIC classification.

Table 4.1 Criteria for classifying hospitalized heart failure in ARIC Study Surveillance

Criteria name (reference)	**Classification Criteria**
Framingham Criteria (Ho et al, 1993)	HF **present** with 2 major or 1 major plus 2 minor criteria: Major: Paroxysmal nocturnal dyspnea or oorthopnea, neck vein distension, rales, cardiomegaly, acute pulmonary edema, S3 gallop, increase venous pressure (≥ 16 cm H_20), circulation time ≥ seconds, hepatojugular reflux) Minor: ankle edema, night cough, dyspnea on exertion, hepatomagaly, pleural effusion, vital capacity decreased one third from maximum, tachycardial rate ≥ 120/min. Weight loss ≥ 4.5 kg in 5 days in response to treatment, major criterion if weight loss occurred during therapy, otherwise minor.
Modified Boston (Carlson et al, 1985)	Point system (8-12 points **definite HF**, 5-7 points **possible HF**, < 5 **HF unlikely**) Category I: History No dyspnea (0 pts), leg fatigue on walking on level (1 pt), dyspnea walking on level (2 pts), paroxysmal nocturnal dyspnea (3 pts), orthopnea (4 pts), dyspnea at rest (4 pts). Category II: Physical findings: Heart rate < 90 (0 pts), 91-110 (1 pt), > 110 (2 pts) Jugular venous pressure: < 6 cm H_20 (0 pts), > 6 cm H_20 (2 pts), > 6 mm H_20 plus liver enlargement or pitting edema (3 pts) Pulmonary rales: No (0 pts), at the bases only (1pt), more than basilar (2 pts) Wheezes: No (0 pts), yes (3 pts) S3 gallop: No (0 pts), yes (3 pts) Category III: Chest X-ray - normal (0 pts), upper flow redistribution (2 pts), cardiac enlargement (relative heart volume>540 $ml.m^{-2}$ in men and > 490 ml m^{-2} in women) (3 pt), interstitial pulmonary edema (3 pts), bilateral pleural effusion (3 pts), alveolar pulmonary edema (4 pts) No more that 4 points allowed for each of three categories

Table 4.1 Criteria for classifying hospitalized heart failure (continued)	
NHANES (Schocken et al, 1992)	Point system (**HF present** if score ≥ 3): History: Shortness of breath when hurrying on the level or up slight hill (1 pt), shortness of breath when walking at ordinary pace on the level (1pt), stops for breath when walking at own pace (2 pts), stops for breath after 100 yards on the level (2 pts) Physical exam: Heart rate 91-110 (1pt), > 110 (2 pts), basal rales (1pt), > basal rates (2 pts), neck vein distension (1pt), neck vein distention and edema or hepatomegaly (2 pts) Chest x-ray: cephalization of pulmonary veins (1pt), interstitial edema (2pts), alveolar fluid and pleural fluid (3 pts), interstitial edema and pleural fluid (3pts)
Gothenburg Criteria (Eriksson et al, 1987)	Takes into account history and physical findings to calculate a score considered with drug treatment to assign HF stage. Grade 0 (**absent**) if all 3 scores are 0. Grade 1 (**latent**) if cardiac score > 0 and pulmonary and therapy score = 0. Grade 2 (**manifest HF**) if cardiac score > and either pulmonary or therapy score > 0. **Grade 3 heart failure** if cardiac score > 0 and both pulmonary and therapy score > 0. **Grade 4** if the person died in HF. Cardiac score: Coronary heart disease present in past (1 pt), present within last year (2 pts); angina pectoris present in the past (1 pt), present within last year (2 pts); swollen legs at end of day (1 pt); pulmonary rales at physical exam (1 pt); atrial fibrillation on ECG (1 pt). Note heart disease and angina can only contribute 2 points together. Pulmonary disease score: History of chronic bronchitis (1 pt), history of chronic bronchitis within last year (2 pts); history of asthma (1 pt), history of asthma within last year (2 pts); history of coughing, phlegm or wheezing (1 pt), presence of rhonchi at physical examination (1 pt). Therapy score: History of digitalis administration (1 pt), history of diuretic administration (1 pt).
ARIC Review Criteria-Hospitalized Heart Failure	Hospitalizations with any disagreement between the above four criteria are reviewed. Two independent reviewers base classification of HF on clinical judgment. A third reviewer adjudicates differences. The resulting clinical judgment classification: **Definite HF, Possible HF, HF unlikely, or unclassifiable HF**. See Heart Failure Diagnosis (HDX) form (Appendix I). Reviewers have access to how each event meet criteria for Framingham, Modified Boston, NHANES I, and Gothenburg criteria, key data elements from the HFA, and copies of the echocardiogram report, nuclear studies,

	discharge summary, catheterization report, and chest radiography report for each hospitalization.

Table 4.2. Framingham Criteria for Diagnosis of Heart Failure and ARIC Hospitalized Heart Failure Abstraction (HFA) Data Elements

Classification	Criteria	Points	HFA form section (page number)	HFA variable number *
Framingham Criteria Algorithm: Heart failure present with 2 major or 1 major plus 2 minor criteria	Paroxysmal nocturnal dyspnea	Major	Section V: Physical Exam-Findings (9)	23.h
	Orthopnea	Major	Section V: Physical Exam-Findings (9)	23.i
	Jugular venous distension	Major	Section V: Physical Exam-Findings (9)	22.b
	Pulmonary rales (basilar and more than basilar)	Major	Section V: Physical Exam-Findings (9)	23.j, 23.k
	Cardiomegaly	Major	Section VI: Diagnostic tests (11)	28.d
	Acute pulmonary edema (alveloar/interstitial)	Major	Section VI: Diagnostic tests (11)	28.b, 28.c
	S3 gallop	Major	Section V: Physical Exam-Findings (10)	24.a
	Circulation time ≥ 25 seconds	Major	--	--
	Hepatojugular reflux	Major	Section V: Physical Exam-Findings (9)	22.c
	Lower extremity edema	Minor	Section V: Physical Exam-Findings (9)	22.a
	Dyspnea on climbing or exertion	Minor	Section V: Physical Exam-Findings (9)	23.d
	Hepatomegaly	Minor	Section V: Physical Exam-Findings (9)	22.d
	Pleural effusion (bilateral/unilateral)	Minor	Section VI: Diagnostic tests (11)	28.g, 28.h
	Vital capacity decreased one third from maximum	Minor	Section V: Physical Exam-Findings (9)	23.m
	Weight loss ≥ 4.5 kg in 5 days in response to treatment	Minor	Section IV: Physical Exam-Vital signs (8)	20.a, 20.b

* HFA data item numbers refer to version B 11/21/07
-- data item not included on HFA form

Table 4.3. Modified Boston Criteria for Diagnosis of Heart Failure and ARIC Hospitalized Heart Failure Abstraction (HFA) Data Elements

Classification	Criteria	Points	Heart Failure Abstraction (HFA) form section (page number)	HFA variable number *
Modified Boston Criteria Algorithm (pts): 8-12 = definite HF 5-7 = possible HF < 5 = HF unlikely Note: No more that 4 points allowed for each of three categories	Category I:			
	No dyspnea	0	Section V: Physical Exam-Findings (9)	23.b-23.d
	Leg fatigue on walking on level	1	Section V: Physical Exam-Findings (9)	22.e
	Dyspnea walking on level	2	Section V: Physical Exam-Findings (9)	23.c
	Paroxysmal nocturnal dyspnea	3	Section V: Physical Exam-Findings (9)	23.h
	Orthopnea	4	Section V: Physical Exam-Findings (9)	23.i
	Dyspnea at rest	4	Section V: Physical Exam-Findings (9)	23.b
	Category II:			
	Heart rate < 90	0	Section IV: Physical Exam- Vital Signs (8)	18a
	Heart rate 91-110	1	Section IV: Physical Exam- Vital Signs (8)	18a
	Heart rate > 110	2	Section IV: Physical Exam- Vital Signs (8)	18a
	Pulmonary Rales-bases only	1	Section V: Physical Exam-Findings (9)	23.j
	Pulmonary Rales more than basilar	2	Section V: Physical Exam-Findings (9)	23.k
	Wheezes	3	Section V: Physical Exam-Findings (10)	23.i
	S3 gallop	3	Section V: Physical Exam-Findings (9)	24.a
	Category III:			
	Upper flow redistribution	2	Section VI: Diagnostic tests (11)	28.e
	Cardiomegaly (relative heart volume)	3	Section VI: Diagnostic tests (11)	28.d
	Interstitial pulmonary edema	3	Section VI: Diagnostic tests (11)	28.c
	Bilateral pleural effusion	3	Section VI: Diagnostic tests (11)	28.g
	Alveolar pulmonary edema	4	Section VI: Diagnostic tests (11)	28.b

* HFA data item numbers refer to version B 11/21/07 or HFS version A 11/21/07

Table 4.4. NHANES Criteria for Diagnosis of Heart Failure and ARIC Hospitalized Heart Failure Abstraction (HFA) Data Elements

Classification	Criteria	Points	Heart Failure Abstraction (HFA) form section (page number)	HFA variable number *
NHANES Criteria Algorithm (pts): heart failure present if score ≥ 3	History:			
	Shortness of breath when hurrying on the level or up slight hill	1	Section V: Physical Exam-Findings (9)	23.d
	Shortness of breath when walking at ordinary pace on the level	1	Section V: Physical Exam-Findings (9)	23.c
	Stops for breath when walking at own pace	2	Section V: Physical Exam-Findings (9)	23.e
	Stops for breath after 100 yards on the level	2	Section V: Physical Exam-Findings (9)	23.f
	Physical Exam:			
	Heart rate 91-110	1	Section IV: Physical Exam-Vital Signs (8)	18.a
	Heart rate > 110	2	Section IV: Physical Exam-Vital Signs (8)	18.a
	Basal rales	1	Section V: Physical Exam-Findings (9)	23.j
	More than basal rates	2	Section V: Physical Exam-Findings (9)	23.k
	Neck vein distension	1	Section V: Physical Exam-Findings (9)	22.a, 22.b, 22.d
	Neck vein distention and edema or hepatomegaly	2	Section V: Physical Exam-Findings (9)	22.b, 22.d, 22.a
	Chest X-ray:			
	Upper zone redistribution/ cephalization	1	Section VI: Diagnostic Tests (11)	28.e
	Interstitial edema	2	Section VI: Diagnostic Tests (11)	28.c
	Alveolar fluid and pleural fluid	3	Section VI: Diagnostic Tests (11)	28.b, 28.g, 28.h
	Interstitial edema and pleural fluid	3	Section VI: Diagnostic Tests (11)	28.c, 28.h, 28.g

* HFA data item numbers refer to version B 11/21/07 or HFS version A 11/21/07

Table 4.5. Gothenburg Criteria for Diagnosis of Heart Failure and ARIC Hospitalized Heart Failure Abstraction (HFA) Data Elements

Classification	Criteria	Points	Heart Failure Abstraction (HFA) form section (page number)	HFA variable number *
Gothenburg Criteria Algorithm (pts): **Grade 0** (absent) if all 3 scores are 0. **Grade 1** (latent) if cardiac score > 0 and pulmonary and therapy score = 0. **Grade 2** (manifest heart failure) if cardiac score > and either pulmonary or therapy score > 0. **Grade 3** if cardiac score > 0 and both pulmonary and therapy score > 0. **Grade 4** if the person died in heart failure. **Grade 5** (unspecified) if: (cardiac score=0 and pulmonary score=0 and therapy score>0) or (cardiac score=0 and pulmonary score>0 and therapy score=0) or (cardiac score=0 and pulmonary score>0 and therapy score>0)	Cardiac score **:			
	Coronary heart disease present in past	1	Section III: Medical History (6)	11.h
	Coronary heart disease present within last year	2	Section III: Medical History (6)	11.g
	Angina pectoris present in the past	1	Section III: Medical History (5)	11.a
	Angina pectoris present within last year	2	--	--
	Dyspnoea at night	1	Section V: Physical Exam-Findings (9)	23.h
	Pulmonary rales	1	Section V: Physical Exam-Findings (9)	23.j, 23.k
	Atrial fibrillation on ECG	1	Section VI: Diagnostic tests (11)	26.c
	Pulmonary score:			
	History of chronic bronchitis	1	Section III: Medical History (5)	10.b
	History of chronic bronchitis within last year	2	--	--
	History of asthma	1	Section III: Medical History (5)	10.a
	History of asthma within last year	2	--	--
	History of coughing, phlegm or wheezing	1	Section III: Medical History (5)	10.e
	Presence of rhonchi at physical examination	1	Section V: Physical Exam-Findings (9)	23.g
	Therapy score:			
	History of digitalis administration	1	Section IX: Medications (18)	67
	History of diuretic administration	1	Section IX: Medications (18)	68

* HFA data item numbers refer to version B 11/21/07 or HFS version A 11/21/07
** Note: heart disease and angina can only contribute 2 points together.
-- data item not included on HFA form

5.0 EVENT CLASSIFICATION

5.1 Introduction

The aim of heart failure investigation in the ARIC study is to establish a well-standardized process for the identification of hospitalized heart failure in the four study communities. Identification and classification of HF outside of the hospital (i.e., out-patient heart failure) is pursued only among cohort participants.

The criteria for classifying hospitalized heart failure presented here are adapted from other heart failure surveillance studies. Because diagnostic criteria used vary across studies and no consensus diagnosis strategy is currently available, the ARIC study's classification system allows for the application of several different classification rubrics. Data collected on hospitalized events is sufficient to apply four different classification algorithms. In addition, the HF MMCC will classify most hospitalized events on the basis of a "clinical judgment" diagnosis through review. The final ARIC classification of hospitalized heart failure is "unlikely" if all four criteria indicate no heart failure, "definite heart failure" if all criteria indicate the presence of heart failure, and the result of the Heart Failure MMCC review for all other events. If the investigation of an eligible discharge finds that a chart can not be located and a completed HFA form is not available the event is classified as "unclassifiable". Eligible discharges that skip out of the HFA form at item 3 (no indication of decompensation, progression or new onset of symptoms, no evidence in the doctor's note of heart failure and the patient is not a cohort participant), the event is automatically classified as "heart failure unlikely".

5.2 MMCC Review for Heart Failure

Cases are sent to the Heart Failure MMCC members for review if they meet criteria detailed in Section 4.0. Materials made available for reviewers include a summary of key information collected from the HRA form, and an indication of how the event meet each of the four diagnostic criteria. These data are provided on a heart failure event summary form (HF-ESF) (see Appendix I.). Cases where a medical chart is not found, the ARIC heart failure classification is "unclassifiable" and the case is not reviewed by committee.

5.3 Case Law Used by the MMCC

An important function of the Heart Failure MMCC is to maintain a complete record of any classification rules to be adhered to in assigning a diagnosis based on clinical judgment. These rules or guidelines for clinical judgment are stated as case laws. The heart failure Review committee approves case laws by consensus. Case laws are reviewed annually and new case law is developed as a result of discussions with the full committee.

5.4 MMCC Final Diagnosis Forms

The HF MMCC final diagnosis form (HDX) is completed independently by two reviewers (Appendix II..). The chair of the heart failure Review committee adjudicates disagreements. Disagreement is defined on the basis of the original reviewers answer to item 7 (i.e. clinical

judgment classification as definite, possible, unlikely or unclassifiable HF). Any disagreement between reviewers for item 7 is adjudicated. For cases requiring both a MMCC review for CHD and for heart failure, the CHD review is completed first.

See Appendix II. Heart Failure Diagnosis (HDX) Form

6.0 MEDICAL CARE ASSESSMENT

An additional goal of ARIC community surveillance of heart failure is the assessment of medical care. Detailed characterization of the type of and trends in diagnostic and therapeutic care heart failure patients receive is an important feature of the surveillance protocol. Many key quality of care indicators are included in the HFA form. The HFA form is reviewed annually to determine if changes in practice patterns warrant the addition of items for new procedures, medications, or therapies.

7.0 LINKAGE OF MULTIPLE EVENTS

A characteristic of the natural history of heart failure is that it leads to multiple hospitalizations over an extended period of time. The exact onset of HF is often difficult to pinpoint, thus it may be difficult to disentangle successive admissions for the same "event" and to distinguish two or more different events in the same person. In ARIC heart failure surveillance, each hospitalization is treated as an independent occurrence for the purposes of medical record abstraction and review (e.g. each hospitalization receives a unique identification number, each hospitalization receives a computer diagnosis and in most cases an ARIC review classification as well). Heart failure diagnostic criteria across multiple hospitalizations within 28 days are not grouped together for the purpose of applying the four established diagnostic criteria (i.e. Framingham, Modified Boston, Gothenburg, and NHANES I) (Table 4.1). The Heart failure MMCC review process treats each hospitalization as separate and does not consider linkage in its review process. Any linkage created for persons with multiple hospitalizations for heart failure are accomplished in analysis after classification.

8.0 RELIABILITY AND VALIDITY OF COMMUNITY SURVEILLANCE PROCEDURES

9.0 COHORT SURVEILLANCE OF HEART FAILURE

9.1 Introduction

Identification and classification of hospitalized events among cohort participants follow many of the same procedures as the classification of community surveillance events previously described in this manual (Sections 1-8), but with some important differences. Surveillance procedures for heart failure events occurring among cohort participants are highlighted below. The aim of cohort heart failure surveillance is to identify all heart failure hospitalizations for each cohort participant and validate the diagnosis. Out-of-hospital heart failure events are also ascertained

and validated by obtaining information from information obtained during the annual follow up call and data collected from the treating physician.

9.2 Identification of Events

In addition to the procedures for identification of potentially eligible heart failure events used in community surveillance, cohort surveillance also uses information obtained from the annual follow-up interviews. This section describes the identification, investigation and diagnosis of hospitalized heart failure events.

9.2.1 Identification of Hospitalized Heart Failure Events

All hospitalized events occurring in cohort members are identified. Cohort events are not subject to the sampling methods used for community surveillance and are instead deemed eligible based on the following criteria: 1) a valid cohort ID; 2) discharge on or after January 1, 2005; and 3) an eligible heart failure discharge ICD-9-CM code and/or a heart failure key word in the discharge summary. Hospital admissions may be identified initially (automatically by computer selection program) or through review of hospital discharge indexes or information elicited during the annual follow-up interview. Hospitalizations that are eligible based on selection criteria (i.e. discharge codes, discharge date, age, race, sex) but are found upon inspection to have been hospitalized for less that 24 hours should not be abstracted. If such cases appear on abstraction selection lists, a NOF form should be completed and the reason for not abstracting the case should be noted (NOF item 1c or 2c). Hospital chart abstraction is carried out to identify heart failure whenever appropriate. All events discharged with specified diagnostic codes are abstracted onto the HFA form. In order to assure completeness of ascertainment, the discharge summary information is reviewed for events discharged with certain screening codes (ICD-9-CM discharge and procedure codes) more remotely related to heart failure. If a heart failure is suggested, the chart is eligible for abstraction. In addition, all discharge diagnoses for all cohort hospitalizations are recorded on the CEL form. The community surveillance database is also searched for possible events occurring among cohort participants that are not reported at the annual follow-up or may be otherwise missed.

9.2.2 Obtaining Access to Hospital Medical Records

A critical feature of the process of hospitalized event identification among cohort members is obtaining information from medical records. Hospital cooperation is sought for the cohort and community surveillance components of the ARIC Study simultaneously. However, the protocol sent to hospital administrators emphasizes the fact that, for cohort members, ARIC obtains signed hospital record release forms. A detailed description of an approach for obtaining hospital cooperation for community surveillance is found in Section 2.2.1. On occasion, there may be a need to carry out special negotiations with out-of-area hospitals where an ARIC Study cohort member was hospitalized.

9.2.3 Hospital Discharge Index

Eligible hospitalized events are identified from the discharge index of each hospital surveyed. Discharge indices are obtained directly from the hospital or from an indexing service.

Using the discharge index for each hospital, all hospitalized events occurring in ARIC cohort members are identified. However, only special diagnoses require hospital chart abstraction, as described below. Instructions on the use of the web-based data entry system (DES) are given in Section 14. The entire list of cohort member hospitalizations identified from area hospitals will be installed into the central database. This will generally be done by the Coordinating Center after identification of likely cohort participants by the Coordinating Center from the hospital discharge lists supplied to the field centers by the hospitals. Where for any reason this procedure is not feasible, an equivalent list will be furnished to the Coordinating Center by the field center. The central database files will be used to implement a management system for the field centers to track abstraction. This management system will give the complete list of identified cohort hospitalizations from area hospitals, and can be used to furnish abstractor-specific work lists. Hospitalization ID numbers can be assigned from this system for each specific hospital by medical record number and discharge date combination. Information available from the hospital lists will be auto-filled into the abstraction forms.

The first task in use of this database for cohort abstraction is to verify at the field center whether the Coordinating Center's algorithm has correctly identified a cohort participant. The algorithm uses information available about the patient to assign a score related to how closely the information matches a cohort participant, and will classify hospitalizations as likely cohort matches and possible cohort matches, but in either case the field center should use information from the hospital chart and information about the cohort participant to verify the identification. The Coordinating Center algorithm is designed to more often falsely suggest a match than falsely to miss a match, though may still occasionally miss a match with a cohort member, which then can be identified only as a result of AFU data. If a suggested cohort match is verified as a cohort member the abstractor should proceed to abstract the required forms as indicated by the cohort component of the tracking system. If a suggested cohort match is verified as not a cohort member the abstractor should proceed to abstract the required forms as indicated by the community surveillance component of the tracking system, which in many case will be none.

The specific order of completion of hospitalized occurrence forms is as follows: CEL (cohort eligibility form, used only for cohort members); CFD (confidentiality form); CHI (common hospital information), and the HFA (hospitalized HF). Note that if the hospital chart cannot be found, this is registered in the CEL for cohort members, and no further abstraction would be done. An address check takes place in the CFD, and, for verified cohort matches, has no effect on whether abstraction is done. Nevertheless, it is important for cohort members, in the determination of whether the hospitalization should be included in community surveillance on the basis of the patient's address. If the computerized address check does not resolve whether the address is in or out of catchment area, the abstractor is asked to further investigate the address and document if it is in or out of the catchment area.

Hospital chart abstraction onto the heart failure Abstraction (HFA) Form is carried out for all hospitalizations with the following ICD-9-CM primary or secondary discharge diagnosis codes: 428.x, 398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 415.0,

416.9, 425.4, 518.4, and 786.0x (where x is any number). A list of diseases included in these ICD-9-CM rubrics is presented in Table 2.2.

Should any mention of heart failure on the present admission (or synonyms for these conditions) be uncovered by the review of discharge summaries for the above conditions, hospital chart abstraction onto the HFA Form is undertaken. For all other ICD-9-CM codes, the discharge diagnoses are obtained from hospital discharge lists and recorded on the Cohort Eligibility Form (CEL), but hospital records are not obtained or abstracted. The Cohort Eligibility Form (Appendix II) is used to help determine eligibility. A number of hospitalized events for cohort members are fatal. Hospital abstracting for these events is the same as for non-fatal events.

9.2.4 Hospitalized Events Occurring Outside the Study Community

See the corresponding section in Manual 3.

9.2.5 Range of Facilities Covered for Hospitalized Events

See the corresponding section in Manual 3.

9.3 Diagnostic Criteria

The diagnostic criteria for hospitalized heart failure among cohort participants are the same as events identified from community surveillance (See section 4.0 of this manual). However, unlike community surveillance, events occurring in the outpatient setting are investigated for cohort members. For more information about the use of Medicare data to estimate the occurrence of outpatient HF see Section 13 of this manual.

9.3.1 Out-patient heart failure diagnostic criteria (draft)

Data on symptoms, medical history and treatment collected from the annual follow up call and the PHF form are combined and applied to Gothenburg criteria (Table 9.1). Table 9.1 summarizes the data items from annual follow up and the PHF that are used to derived a diagnostic classification for out-patient events based on Gothenburg criteria. In addition, the PHF form asks the physician of reported out-patient events whether the patient ever had heart failure or cardiomyopathy of any type (PHF question 1). Out-patient heart failure is classified as: "Definite out-patient heart failure" (Gothenburg score 3 and physician diagnosis (PHF 1= yes), or self report of HF from AFU and PHF1=yes and PHF 5 = diuretic or digitalis; "Possible out-patient heart failure" (Gothenburg score 2 or 3, and no physician diagnosis (PHF = no), or physician diagnosis (PHF 1= yes) and Gothenburg score <3.; else "Unlikely out-patient heart failure" (Gothenburg score 0 or 1); else Unclassifiable out-patient heart failure.

Table 9.1 Gothenburg Criteria for Diagnosis of Heart Failure and ARIC Out-of-hospital Data Elements from AFU and PHF

Classification	Criteria	Points	AFU (L) or PHF (A) Data Elements	Data element
Gothenburg Criteria Algorithm (pts): **Grade 0** (absent) if all 3 scores are 0. **Grade 1** (latent) if cardiac score > 0 and pulmonary and therapy score = 0. **Grade 2** (manifest heart failure) if cardiac score > and either pulmonary or therapy score > 0. **Grade 3** if cardiac score > 0 and both pulmonary and therapy score > 0. **Grade 4** if the person died in heart failure.	Cardiac score **:			
	Coronary heart disease present in past	1	PHF question 3 and AFU(L) 11.a	(PHF): Has pt ever had previous MI? Has pt ever had other CHD? (AFU): Has a doctor ever said that you had a heart attack?
	Coronary heart disease present within last year	2	--	--
	angina pectoris present in the past	1	PHF question 3 or AFU(L) Question 11.b	(PHF): Has pt ever had angina pectoris? (AFU): Has a doctor ever said that you had angina, angina pectoris or chest pain due to heart disease?
	angina pectoris present within last year	2	--	--
	swollen legs at end of day	1	AFU(L) question 13.a	Do you often have swelling in your feet or ankles at the end of the day?
	Dyspnoea at night	1	AFU(L) 19.a	Are there times when you wake up at night because of difficulty breathing?
	pulmonary rales	1	PHF question 3	Has pt ever had pulmonary rales on a PE?
	atrial fibrillation on ECG	1	PHF question 3 or AFU(L) question 12	(PHF): Has pt ever had atrial fibrillation on ECG? (AFU): Has a doctor ever said that you had an irregular heart beat called atrial fibrillation, or atrial fibrillation on a heart scan or ECG tracing?
	Pulmonary score:			
	History of chronic bronchitis	1	AFU(L) question 18.a	Has a doctor ever told you that you had chronic lung disease, such as bronchitis, or emphysema?
	history of chronic bronchitis within last year	2	AFU(L) question 18.b	Were you told by the physician that you had chronic lung disease since we last contacted you on mm/dd/yyyy?
	history of asthma	1	AFU(L) 20	Has a doctor ever said you had asthma?
	history of asthma within last year	2	AFU(L) 20.a	Did the doctor say that you have asthma since we last contacted you on mm/dd/yyyy?
	history of coughing, phlegm or wheezing	1	AFU(L) 19.g	Do you usually have some cough or wheezing?
	presence of rhonchi at PE	1	PHF question 3	Has pt ever had rhonchi on a PE?
	Therapy score:			
	History of digitalis administration	1	PHF question 5	Was this pt prescribed digitalis in the past year?
	history of diuretic administration	1	PHF question 5	Was this pt prescribed diuretics in the past year?

** Note: heart disease and angina can only contribute 2 points together. -- data item not included on either AFU or PHF form. PE=physical exam

9.4 Diagnosis of Prevalent HF at Baseline

Prevalent heart failure at baseline is determined by the following criteria from data obtained during ARIC cohort visit: 1) those answering "yes" to the following question: "Were any of the medications you took during the last two weeks for HF?" (N = 83), or 2) those with stage 3 or 'manifest HF' by Gothenburg criteria (N = 699).

9.5 Out-of-hospital HF events

Out of hospital heart failure among cohort participants is ascertained with use of the annual follow up phone call.. When a cohort participant indicates (from annual follow up call) that they have had heart failure diagnosed in a physician's office and have not been hospitalized for this diagnosis, ARIC will obtain information about the diagnosis directly from the physician's office if the participant permits physician contact. A Physician Heart Failure (PHF) form is sent to the physician's office to obtain relevant information regarding the self-reported out-patient visit (Appendix II).

Specifically, the PHF form is completed by the physician when a participant reports that a physician has diagnosed heart failure during an outpatient visit within the last year (from date of AFU interview). The interviewer initiates the process that enables ARIC to send that physician a request to complete the PHF (e.g. obtains the name and address of the physician). The PHF form is sent to each physician for whom the participant submits an authorization for access to information from the physician's records. Completed PHF forms received by ARIC Field Center staff are entered into the data entry system.

No attempt is made to identify outpatient physician visits for heart failure from community surveillance.

10.0 MORTALITY AND MORBIDITY CLASSIFICATION COMMITTEE

10.1 HF Reviews Specific to Community Surveillance

The CSCC generates the MMCC Event Summary Forms in the ARIC Data Management Program (MGP). The steps taken at CSCC in processing Community Surveillance MMCC materials are to:

A. **Organize ID Listings and Event Summary Forms:**
Upon notification that the MGP is ready, print out the ESFs and listings in job 05.

B. **Collect All Needed ID Medical Records:** ID-labeled file folders containing the discharge summary, echocardiogram, nuclear report, catheterization report and chest x-ray report for each event are obtained from the secured CSCC file cabinets or requested from the field centers (F, J, M, W).

C. **Collate and Copy Materials for Each Event for Review:** Community cases are single reviewed. Job 05 must be copied once. The original set is placed in the event folder behind any medical records. The medical records, received in duplicate from the field centers are copied once and the ESFs are stapled to the specific record.

D. **Prepare Events for Reviewers:** The IDs to be sent to a reviewer are tracked by the Batch Number from the MGP and the Sequence Number for the Reviewer. Each available reviewer is usually sent a set of 25 to 50 cases to review. The packet shipped, usually by Federal Express, contains a memo describing the cases and a list of IDs. The memo states the date that the reviews are expected to be returned to CSCC, usually a period of 3 to 4 weeks.

An HDX Form is prepared for each Event ID in the DMS. The CSCC prefills the batch number, type of event and reviewer ID for each ID. The Reviewer then completes the electronic form and notifies the CSCC when his batch is fully entered.

10.2 HF Reviews Specific to Cohort Surveillance

The CSCC generates the MMCC Event Summary Forms in the Data Management Program. The steps taken at CSCC in processing Cohort Surveillance MMCC materials, similar to those for the Community Surveillance, are to:

A. **Organize ID Listings and Event Summary Forms:**
Upon notification that the MGP is ready, print out the ESFs and listings in job 05.

B. **Collect All Needed ID Medical Records:** ID-labeled file folders containing the discharge summary, echocardiogram, nuclear report, catheterization report and chest x-ray report for each event are obtained from the secured CSCC file cabinets or requested from the field centers (F, J, M, W).

C. **Collate and Copy Materials for Each Event for Review:** Cohort cases are double reviewed. Job 05 must be copied twice. The original set is placed in the event folder behind any medical records. The medical records, received in duplicate from the field centers are copied twice and the ESFs are stapled to the specific record.

D. **Prepare Events for Reviewers:** The IDs to be sent to a reviewer are tracked by the Batch Number from the MGP and the Sequence Number for the Reviewer. Each available reviewer is usually sent a set of 25 to 50 cases to review. The packet shipped, usually by Federal Express, contains a memo describing the cases and a list of IDs. The memo states the date that the reviews are expected to be returned to CSCC, usually a period of 3 to 4 weeks

An HDX Form is prepared for each Event ID in the DMS. The CSCC prefills the batch number, type of event and reviewer ID for each ID. The Reviewer then completes the electronic form and notifies the CSCC when his batch is fully entered.

10.3 Adjudication of HF Reviews

Adjudication is required if the classification in Question 6 (The overall heart failure diagnosis) disagrees between two reviewers for Cohort Surveillance. In Community Surveillance, adjudication is necessary if the Framingham, NHANES, and Modified Boston computer classification scoring algorithms meet the formula below* AND the heart failure MMCC classification is either "chronic stable heart failure" or "no heart failure", the case is sent to the Chair of the heart failure MMCC for adjudication. The Chair's adjudicated classification becomes the event's final ARIC classification.

***** Framingham criteria equal "heart failure present", and NHANES criteria equals "heart failure present", and Modified Boston criteria equal "definite or possible heart failure".

10.4 Monitoring Return of HDX Forms

Reviewers who do not meet expected deadlines are reminded of their tardiness. If forms are found to be incomplete, the reviewer is asked to complete the form.

10.5 Monitoring Consistencies of New Reviewers

When new reviewers have been certified and are ready to begin reviewing cases, the number of HF events is kept low. As original reviewers, they are paired with experienced reviewers. Feedback to the new reviewers on the cases needing adjudication is helpful. New reviewers are also highly encouraged to attend all of the quarterly Case Review Calls headed by the adjudicator.

11.0 QUALITY CONTROL MEASURES

11.1 Quality Control for Heart Failure record abstraction

The process to obtain an ongoing measure of inter-abstractor reliability of the completion of the HFA form is modeled after that conducted for surveillance of hospitalized myocardial infarction (see Manual 3 section 12). For hospitalized heart failure surveillance a sample of hospitalizations is re-abstracted by a different abstractor within the same field center. Each abstractor re-abstracts 2 records each month that were originally abstracted by another abstractor at their same field center. One of these hospitalizations each month should be selected from those hospitalizations with a 428.x discharge code. The other record should come from hospitalizations without a 428.x code that meet eligibility by virtue on one of the following

discharge codes (398.1, 402.1, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 415.0, 416.9, 425.4, 518.4, or 786.0x). Hospitalizations for re-abstraction will be selected by the field center from their list of eligible cohort hospitalization. Should the number of available cohort hospitalization be insufficient to meet the needs for re-abstraction in a given month, a hospitalization from the community surveillance selection list is selected. The sampling procedure will be re-evaluated after 6 months of abstraction, with consideration to reducing the selection to 1 case per abstractor per month targeted for re-abstraction. Beginning with the 2010 event year, the number of re-abstraction cases for heart failure is reduced from 2 cases per abstractor to 1 case per abstractor, effective July 1, 2011.

11.2 Quality Control for MMCC Reviews

For all cohort events and community events in year 2005 two original reviews are required to determine their heart failure classification. For those events where the two original reviewers disagree on the event classification a third review by an adjudicator is required and this review becomes the final classification for the event. For quality control purposes agreement rates between the two original reviewers, as well as between the original reviewers and the adjudicator are computed and distributed to the MMCC and Surveillance Committees semi-annually.

For community events in 2006 and 2007 only a single review is required for events where the first review is classifies an event as definite or probable heart failure or the Framingham, NHANES, or modified Boston criteria indicate heat failure is not present. Also, for these two year events where the first original reviewer indicates chronic heart failure, not heart failure, or unclassifiable while the Framingham, NHANES, and modified Boston criteria indicate HF is present then these events go straight to the adjudicator for final classification. For events with two original reviews agreement rates between the reviewers are calculated. For events sent to adjudication agreement between the original reviewer(s) and the adjudicator are computed and distributed to the MMCC and Surveillance Committees semi-annually.

Beginning with event year 2008 a computer algorithm was developed to automatically classify some community events without needing any MMCC reviews. Although not used in the final classification, the computer algorithm diagnosis is also determined for cohort events. To maintain quality control of the computer algorithm classification agreement between the computer classification and the MMCC review classification will be calculated for cohort events. Quality control of all other community events will be similar procedures used in event year 2006 and 2007.

• MMCC QC Summary
- agreement rates for HF classification between 2 original reviewers, by year
- % of original reviews that agree with adjudicator for HF classification, by reviewer
- % agreement between computer classification algorithm and final MMCC classification

12.0 CERTIFICATION FOR HEART FAILURE ABSTRACTIONS

12.1 Introduction

ARIC Study staff involved in medical record abstraction must be certified before they begin record abstraction in the field. The certification process involves participation in a week long centralized training workshop held at the ARIC coordinating center as well as satisfactory performance on a certification exam. The following describes the certification process.

12. 2 Training

Expectation
In order to be certified for HF abstraction, staff must participate in an initial week long centralized training workshop. Participation in the workshop also includes review and completion of a pre-training workbook. The pre-training workbook includes important background information about the clinical presentation and treatment of HF, detailed question by question instructions for completing the HFA form, practice exercises in completing the diagnostic test evaluation section of the HFA, and two full medical record abstraction exercises complete with answer keys. Staff is expected to review these materials and gain experience with reviewing medical documents and completing the HFA form prior to the central training.

During the central training, abstractor staff will be expected to participate in the group discussions and abstraction practice opportunities. During the central training, abstractors will also be instructed on navigation of the data entry system.

Performance measure
Successful completion of the training phase of certification will be measured by participation in the abstraction exercises and involvement in the group discussion of the HF abstraction protocols and instructions as well as completion of practice exercises assessed by field center supervisor.

12.3 Certification Exam

Expectation
After successful completion of the training phase, an abstractor will be eligible to sit for the certification exam. The exam will consist of abstracting two medical charts using the HFA form. The abstraction of the exam charts may be completed using the electronic data entry system or paper forms if preferable. Abstractors wishing to be certified in HF records may take the exam at a time of their choosing within two weeks of completing the training phase. Exam charts must be completed independently.

Performance measure
The two completed exam HFA forms will be scored relative to a key created by consensus of two members of the HF Surveillance Committee, one of which will be the Chair of the Committee. Scoring of the exam charts will be weighted to give more weight to those items on the HFA form deemed to be most critical (e.g., Section I: Screening for decomposition or new onset of symptoms, and components of the various diagnostic classification algorithms in the

sections III, IV, V, and VI). An overall abstraction quality score assigned by the Chair of the HF Committee will also be factored in to the final score. In order to qualify for Certification, abstractors must pass both medical charts per criteria set by the Chair of the HF Committee. If they fail in either one of the charts, they will need to retake the certification exam to be certified.

Abstractor may retake the certification exam a maximum of two separate times. Retaking the certification exam will involve review of a different set of two medical records, not a reexamination of the same medical records. A two day interval is required before a reexamination will be provided. Staff have up to one month after their first exam to retake the exam. Staff not successfully completing the certificate exam after three attempts will not be certified.

Appeals of the abstractors score will be considered. Decisions of the Chair of the HF Surveillance Committee are final.

12.4. Re-certification and training future abstractors

Annual required re-certification training for HF abstractors will be conducted at the coordinating center. Re-certification training for HF abstraction will be organized similar to CHD re-certification. In this process, abstractors will be required to complete abstraction of a set of four medical records prior to the face-to-face re-certification training. All abstractors will review the same four medical records. Question by question agreement amongst all abstractors will be reviewed and discusses at the re-certification training. Participation in re-certification training is required for staff to retain their certification for HF abstractor status.

In the future, new hires will be trained centrally at the coordinating center on an as needed basis. Training will consist of a 3-day program covering background clinical information about HF, training in reviewing diagnostic tests, data entry system training, and practice abstracting medical records. The training will be conducted by the coordinating center staff in conjunction with the chair of the HF Committee.

Appendices

Appendix X1. Sampling Frame for 2005
Appendix X2. Sampling Frame for 2006
Appendix I. Heart Failure Event Summary Form (ESF)
Appendix II. Heart Failure Diagnosis Form and Instructions (HDX)
Appendix III. Heart Failure Physician Heart Failure Form (PHF)
Appendix IV. Physician Heart Failure Form (PHF) instructions

Appendix X1. Sampling Frame for 2005

The following sample frame is implemented for year 2005:

Table 2.3a. and Table 2.3b. Implementation rules for hospitalization selection for heart failure. Event year 2005

Table 2.3a. For Hospital Index IDs with ICD code 428:

Center	Gender	Race	New category (based on ICD group and age)	Sample fraction	Selection Rule (day of month) (based on hospital discharge date)
F	F	B	1	0.22793	1, 5,10,15,19,24,29
F	F	B	2	0.22998	1, 4, 7,10,11,14,17
F	F	B	3	0.22998	4, 8,12,16,20,24,28
F	F	B	4	0.22998	4, 8,12,16,20,24,28
F	F	B	5	0.22998	1, 5, 9,13,17,21,25
F	F	B	6	0.22793	2, 7,11,16,20,25,29
F	F	B	7	0.22998	1, 3, 6, 9,12,15,18
F	F	B	8	0.22998	3, 6, 9,12,15,18,21
F	F	B	9	0.19439	Days divisible by 5
F	M	B	1	0.26283	1,4,8,11,15,18,22,25
F	M	B	2	0.26283	2,4,8,10,12,14,16,18
F	M	B	3	0.26283	4,8,12,16,20,24,28, 1
F	M	B	4	0.26078	1, 5, 9,13,17,21,25,29
F	M	B	5	0.26078	1, 5, 9,13,17,21,25,29
F	M	B	6	0.26078	1, 5, 9,13,17,21,25,29
F	M	B	7	0.26283	1, 4, 7,10,13,16,19,21
F	M	B	8	0.26283	1, 4, 8,12,16,19,23,27
F	M	B	9	0.22998	Days divisible by 4
F	F	W	1	0.09856	1,13,25
F	F	W	2	0.09856	5,15,25
F	F	W	3	0.09856	8,16,24
F	F	W	4	0.09582	15,30, 1
F	F	W	5	0.09856	2,14,24
F	F	W	6	0.09856	7,14,21
F	F	W	7	0.09582	15,30, 1
F	F	W	8	0.09582	15,30, 1
F	F	W	9	0.06297	The 15th and the 30th of the month
F	M	W	1	0.09856	2,12,22
F	M	W	2	0.09856	7,14,21
F	M	W	3	0.09582	15,30, 1
F	M	W	4	0.09582	15,30, 1
F	M	W	5	0.09856	3,12,21
F	M	W	6	0.09856	7,14,21
F	M	W	7	0.09582	15,30, 1

Center	Gender	Race	New category (based on ICD group and age)	Sample fraction	Selection Rule (day of month) (based on hospital discharge date)
F	M	W	8	0.09582	15,30, 1
F	M	W	9	0.09856	Days divisible by 8
J	F	B	1	0.09856	1,11,21
J	F	B	2	0.09856	4,12,20
J	F	B	3	0.09856	7,14,21
J	F	B	4	0.09856	7,14,21
J	F	B	5	0.09856	2,13,23
J	F	B	6	0.09856	1, 9,17
J	F	B	7	0.09856	6,12,18
J	F	B	8	0.09856	6,12,18
J	F	B	9	0.09856	Days divisible by 8
J	M	B	1	0.16427	2, 8,12,16,20
J	M	B	2	0.16427	4, 8,12,16,20
J	M	B	3	0.16427	7,14,21,28, 1
J	M	B	4	0.16153	6,12,18,24,30
J	M	B	5	0.16427	1, 7,13,19,25
J	M	B	6	N/A	N/A
J	M	B	7	0.16427	2, 5, 8,12,15
J	M	B	8	0.16427	1, 6,12,18,24
J	M	B	9	0.16153	Days divisible by 6
J	F	W	1	0.19713	1, 6,11,16,21,26
J	F	W	2	0.22998	1, 5, 9,13,17,21,25
J	F	W	3	0.19439	5,10,15,20,25,30
J	F	W	4	0.19439	5,10,15,20,25,30
J	F	W	5	0.19713	1, 6,11,16,21,26
J	F	W	6	0.19713	1, 5,10,14,19,23
J	F	W	7	0.19713	1, 3, 6, 9,12,15
J	F	W	8	0.19713	2, 5, 8,12,15,18
J	F	W	9	0.19439	Days divisible by 5
J	M	W	1	0.26078	1, 5, 9,13,17,21,25,29
J	M	W	2	0.26078	1, 5, 9,13,17,21,25,29
J	M	W	3	0.2601	5,10,15,20,25,30, 1,27
J	M	W	4	0.2601	5,10,15,20,25,30, 1,27
J	M	W	5	0.26078	1, 5, 9,13,17,21,25,29
J	M	W	6	0.26283	2, 4, 8,10,12,14,16,18
J	M	W	7	0.2601	5,10,15,20,25,30, 1,27
J	M	W	8	0.26283	4,8,12,16,20,24,28, 1
J	M	W	9	0.22998	Days divisible by 4
W	F		1	0.09856	1,14,27
W	F		2	0.09856	2,14,24

Center	Gender	Race	New category (based on ICD group and age)	Sample fraction	Selection Rule (day of month) (based on hospital discharge date)
W	F		3	0.09856	5,15,25
W	F		4	0.09856	5,15,25
W	F		5	0.09856	1,14,27
W	F		6	0.09856	5,15,25
W	F		7	0.09856	8,16,24
W	F		8	0.09856	8,16,24
W	F		9	0.06297	The 15th and the 30th of the month
W	M		1	0.09856	1,12,23
W	M		2	0.09856	1,11,21
W	M		3	0.09856	6,12,18
W	M		4	0.09856	4,12,20
W	M		5	0.09856	1,11,22
W	M		6	0.09856	4,12,20
W	M		7	0.09856	8,16,24
W	M		8	0.09856	7,14,21
W	M		9	0.09856	Days divisible by 8
M	F		1	0.065708	1,25
M	F		2	0.065708	3,24
M	F		3	0.065708	7,28
M	F		4	0.065708	6,24
M	F		5	0.065708	2,22
M	F		6	0.065708	6,24
M	F		7	0.062971	15,30
M	F		8	0.062971	15,30
M	F		9	0.032854	15
M	M		1	0.065708	1,21
M	M		2	0.065708	6,24
M	M		3	0.062971	15,30
M	M		4	0.065708	8,16
M	M		5	0.065708	1,20
M	M		6	0.065708	6,24
M	M		7	0.062971	15,30
M	M		8	0.065708	8,16
M	M		9	0.062971	15,30

Table 2.3b. For Hospital Index IDs without ICD code 428 but with other eligible HF Code*:

Center	Sex/Race	Sample fraction	Selection Rule (day of month) (based on hospital discharge date)
Forsyth	Black Female	0.29569	Days not ending with 2, 5 or 8
	Black male	0.73922	Days where the reminder is not 1 when divided by 4
	White Female	0.35866	Days divisible by 3 and the first day of the month
	White male	0.35866	Days divisible by 3 and the first day of the month
Jackson	Black Female	0.42437	Even numbered days except for the 6th and 26th
	Black male	0.60849	All days except for those ending with 1,4,7,0
	White Female	0.80561	Days not divisible by 5
	White male	1	Everyday
Washington	Female	0.57563	Odd numbered days plus the 6th and the 26th
	Male	0.70431	Days not ending with 2, 5 or 8
Minneapolis	Female	0.16153	Days divisible by 6
	Male	0.16153	Days divisible by 6

* Hospitalization without a 428 code but with any of the following codes: 398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 415.0, 416.9, 425.4, 518.4, 786.0x

Appendix X2. Sampling Frame for 2006.

The HF sampling fractions for 2006 are ¾ of optimal fractions. (These fractions are 1.5 times the SF for 2005, which was ½ of optimal fractions).

Sampling fractions for HF: Jackson County, 2006					
HF_AGE: (HF_Age Strata =1 if 55≤age≤74 =2 if 75≤age≤84 3 = if age≥85)	RACE: (B=Black, W=White)	SEX: (F=Female , M=Male)	HF_GRP: (HF group)	HFNUM (1=ICD9 428.x, 2=other ICD9 HF)	HF_SF: (HF Sampling Fraction)
1	B	F	ICD9_428	1	0.149
2	B	F	ICD9_428	1	0.149
3	B	F	ICD9_428	1	0.149
1, 2, or 3	B	F	Other_HF	2	0.636
1	B	M	ICD9_428	1	0.246
2	B	M	ICD9_428	1	0.246
3	B	M	ICD9_428	1	0.246
1, 2, or 3	B	M	Other_HF	2	0.912
1	W	F	ICD9_428	1	0.296
2	W	F	ICD9_428	1	0.296
3	W	F	ICD9_428	1	0.296
1, 2, or 3	W	F	Other_HF	2	1.0
1	W	M	ICD9_428	1	0.392
2	W	M	ICD9_428	1	0.392
3	W	M	ICD9_428	1	0.392
1, 2, or 3	W	M	Other_HF	2	1.000

Sampling fractions for HF: Forsyth County, 2006				
HF_AGE: (HF_Age Strata =1 if 55≤age≤74 =2 if 75≤age≤84 = 3 if age≥85)	SEX: (F=Female, M=Male)	RACE: (B=Black, W=White)	HFNUM: (1=ICD9 428.x, 2=other ICD9 HF)	HF_SF: (HF Sampling Fraction)
1	F	B	1	0.345
2	F	B	1	0.345
3	F	B	1	0.345
1,2, or 3	F	B	2	0.444
1	M	B	1	0.391
2	M	B	1	0.391
3	M	B	1	0.391

Sampling fractions for HF: Forsyth County, 2006				
HF_AGE: (HF_Age Strata =1 if 55≤age≤74 =2 if 75≤age≤84 = 3 if age≥85)	SEX: (F=Female, M=Male)	RACE: (B=Black, W=White)	HFNUM: (1=ICD9 428.x, 2=other ICD9 HF)	HF_SF: (HF Sampling Fraction)
1, 2, or 3	M	B	2	1.00
1	F	W	1	0.148
2	F	W	1	0.148
3	F	W	1	0.148
1,2, or 3	F	W	2	0.538
1	M	W	1	0.148
2	M	W	1	0.148
3	M	W	1	0.148
1,2, or 3	M	W	2	0.538

HF sampling fractions for Washington County, 2006			
HF_AGE: (HF_Age Strata =1 if 55≤age≤74 =2 if 75≤age≤84 = 3 if age>85)	SEX: (F=Female, M=Male)	HFNUM: (1=ICD9 428.x, 2=other ICD9 HF)	HF_SF: (HF Sampling Fraction)
1	F	1	0.148
2	F	1	0.148
3	F	1	0.148
1, 2, or 3	F	2	0.863
1	M	1	0.148
2	M	1	0.148
3	M	1	0.148
1, 2 or 3	M	2	1.000

HF sampling fractions for Minnesota, 2006			
HF_AGE: (HF Age Group =1 if 55≤age≤74, =2 if 75≤age≤84, 3 = if age≥85)	SEX: (F=Female, M=Male)	HFNUM [1] (1=ICD9 428.x, 2=other ICD9 HF)	HF_SF
1,2,3	F	1	0.0986
1,2,3	F	2	0.242
1,2,3	M	1	0.0986
1,2,3	M	2	0.242

A

Appendix I. Heart Failure Summary Form

Heart Failure Event Summary Form

A. ARIC Identifiers

Surveillance ID	Cohort ID	Gender	Age at Discharge	Date of Event	Admission Date	Discharge Date	Primary Discharge Code

List of all ICD Discharge Codes:

B. *Section B deleted*.

C. Selected data elements from hospital record.

l. EVIDENCE OF MEETING SCREENING CRITERIA:

Increasing or new onset SOB:	Yes	No/NR
Increasing or new onset edema:	Yes	No/NR
Increasing or new onset paroxysmal nocturnal dyspnea	Yes	No/NR
Increasing or new onset orthopnea	Yes	No/NR
Increasing or new onset hypoxia	Yes	No/NR
MD note indicates reason for hospitalization was heart failure	Yes	No/NR
Cohort member	Yes	No/NR

ll. HISTORY OF HEART FAILURE(HF):

Previous diagnosis	Yes	No/NR	Unsure
Previous hospitalization	Yes	No/NR	Unsure
Previous treatment	Yes	No/NR	Unsure
History of MI	Yes	No/NR	
History of hypertension	Yes	No/NR	
Discharge status	Deceased	Alive	

lll. IN-HOSPITAL HEART FAILURE

New onset or progression/exacerbation of HF

At the time of admission	Yes	No/NR
During this hospitalization	Yes	No/NR

A

IV. EJECTION FRACTION(EF):

Pre-hospital	EF%
Lowest Ejection Fraction(LVEF)	____
LV Function-Qualitative Description	Normal, Decreased Mildly, Decreased Moderately, Decreased Severely, None of the above

In-hospital	EF%
Transthoracic Echocardiogram	____
Transesophageal Echocardiogram	____
Radionuclide Ventriculogram	____
Coronary angiography	____

V. BNP LEVELS:	Worst	Last	ULN*
BNP	_____	_____	_____
ProBNP	_____	_____	_____

*ULN = Upper Limit

VI. PERTINENT CHEST X-RAY FINDINGS:

Alveolar/pulmonary edema	Yes	No/Unknown
Interstitial pulmonary edema	Yes	No/Unknown
Alveolar infiltrates	Yes	No/Unknown
Unilateral pleural effusion	Yes	No/Unknown
Bilateral pleural effusion	Yes	No/Unknown
Cardiomegaly	Yes	No/Unknown
Upper zone flow redistribution/cephalization	Yes	No/Unknown
Congestive heart failure	Yes	No/Unknown
Pulmonary vascular congestion	Yes	No/Unknown

ARIC

Atherosclerosis Risk in Communities

HEART FAILURE DIAGNOSIS FORM

EVENT_ID NUMBER : | | | | | | | | CONTACT NUMBER: | | | FORM CODE: H D X VERSION: A DATE: 11/7/07

Instructions: Please complete the Heart Failure Diagnosis Form using the attached Event Summary Form and the medical reports provided to assign a heart failure diagnosis. If you mark an answer in error, mark an "X" through the incorrect answer and circle the appropriate response.

PART A: ADMINISTRATIVE INFORMATION

1.a. Batch Number: | | | | -- | H

b. Type of Review: Original …….…… O

Adjudication ……..……. A

Special review ……. S

c. Date of HDX completion: | | / | | | / | | | | |

Month Day Year

2. Code number of person completing this form: | | | |

PART B: REVIEW OF COMPUTER'S HF DIAGNOSIS

	Yes	No	Unknown
3. Does this event meet criteria for complete chart abstraction?	Y	N	U
4. Is there evidence of:			
a. Abnormal LV systolic function?	Y	N	U
b. Abnormal RV systolic function?	Y	N	U
c. LV diastolic dysfunction?	Y	N	U

5. Estimated LVEF (worst): a. ≥50% ☐ b. 35-49% ☐ c. < 35% ☐ d. Unknown ☐

6. Assign an overall heart failure diagnosis based on your clinical judgment (select only one)

Definite decompensated heart failure …… .A

Possible decompensated heart failure……B

Chronic stable heart failure……C → Skip to Item 8

Heart failure unlikely…… ….D → Skip to Item 8

Unclassifiable……..E → Skip to Item 8

	Yes	No	Unknown
a. Was definite or possible decompensated heart failure present at admission?	Y	N	U

	Yes	No	
7. Was this event fatal?	Y	N →	Skip to Item 8

	Yes	No	Unknown
a. Was decompensated heart failure the primary cause of death?	Y	N	U

8. Comments: _____

_____

QUESTION-BY-QUESTION INSTRUCTIONS FOR MMCC HEART FAILURE FINAL DIAGNOSIS FORM (HDX)

HDX, Version A, QxQ, 02-12-2008

An MMCC Heart Failure Diagnosis Form (HDX) is completed for each ARIC Heart Failure hospitalization that is sent to you as a MMCC Heart Failure (HF) reviewer. The goal of this review is to be **specific** rather than too sensitive. Please refer, as needed, to the MMCC Case Law Document (Section 5.3 Manual 3a) when completing this form.

When you get your case materials, check to see that all available information is included. Events will be hospital events only. The HDX form will be accompanied by an Event Summary Form (ESF) and copies of specific documents from the medical record. Medical record documents may include a discharge summary, echocardiogram reports, nuclear imaging reports, and catheterization reports as available.

Complete only one HDX for each event.

There are two sections to the HDX form. **Part A** contains administrative information and the Coordinating Center (CC) will provide some of the information for this section. **Part B** is to be completed by a MMCC reviewer based on the information provided. All cases will be reviewed by 2 MMCC members independently, with disagreements adjudicated by a third reviewer (events occurring in 2005).

The EVENT_ID NUMBER listed at the top of the HDX form is also included in the upper left hand side of the ESF, Section A, "ARIC Identifiers" and should also appear on the second item, and on the accompanying documents from the medical record.

The CC will provide a memo with a list of the EVENT_ID NUMBERS representing the cases that are sent to reviewers. The memo will also include the CONTACT NUMBER related to each EVENT_ID NUMBER.

The CC will specify the time period for completion and/or making changes to HDX.

Instructions for Data Entry Key Field Screen
The web Data Management System (DMS) ID screen will require the EVENT_ID NUMBER as ID, "HDX" as form, and a CONTACT NUMBER. Specific instructions for using the web DMS are detailed in the DMS User Manual.

Instructions for Part A. Administrative Information

1.a. The Batch Number and letter for this case will be assigned by the CC. Refer to the CC memo sent with the cases being reviewed for this number and letter. 'H' indicates a Heart Failure event.

b. The CC will indicate the type of review. See memo accompanying your set of cases. The letter "O" indicates an original review, the letter "A" indicates an adjudication, and the letter "S" indicates a special review.

c. Fill in the date of HDX completion.

2. Record the assigned code number of this reviewer. Your reviewer code number will be printed on the cover memo

Instructions for Part B. Review of HF Diagnosis

Items 3-8 are to be completed on your review of the ESF and medical record documents. For each, enter the letter that correctly characterizes the case under review.

3. Does this event meet criteria for complete chart abstraction? Review information provided on the ESF and materials copied from the medical record to determine if this event meets criteria for complete abstraction of the Heart Failure Record Abstraction Form (HFA). Refer to Item 1, Section C of the ESF and the medical record documents. These criteria include evidence of the presence of new or decompensated/exacerbated heart failure (HFA items 1 through 2). Evidence of symptoms and signs that may indicate new or decompensated heart failure include evidence of increasing or new onset shortness of breath, increasing or new onset edema, increasing or new onset paroxysmal nocturnal dyspnea, increasing or new onset orthopnea, increasing or new onset hypoxia; evidence in the doctor's notes that the reason for this hospitalization was heart failure. Select "Y"(Yes), "N" (No), or "U"(Unknown). If this is a cohort member but no other items suggesting decompensation (HFA items 1 through 2), then select "N" (No).

4a-4c. Is there evidence of (a.) Abnormal LV systolic function? (b.) Abnormal RV systolic function? (c.) LV diastolic dysfunction? Based on your review of the ESF and the medical record documents provided, indicate either "Y"(Yes) if documentation indicates less than normal, "N" (No) if documentation indicates normal, or "U"(Unknown) if no data is available (i.e., not recorded). In general, use medical record documents related to that hospitalization as the first reference; however, records included by the abstractor that pre-date the hospitalization can be used to answer these items if there are no current related documents for that hospitalization.

4a. A dilated left ventricle alone is not sufficient to select "Y"(YES)". An estimated LVEF of $\leq 50\%$ is sufficient to define LV systolic dysfunction. However, if the abstractor has recorded a specific LV ejection fraction (LVEF) on the ESF, but there are no supporting documents, then record "U"(Unknown); the rationale for this is that confirmation for LV systolic dysfunction should be documented by an official report to

differentiate a historical diagnosis versus an objectively documented diagnosis (both types will be captured on the ESF).

4b. A dilated right ventricle alone is not sufficient to select "Y"(YES)".

4c. Diastolic dysfunction must be explicitly described or documented in order to select "Y"(YES)". Synonyms include "diastolic LV dysfunction", "impaired LV relaxation", "impaired LV compliance", "impaired LV diastolic filling", "reversed E-A ratio", "late diastolic filling", "stiff ventricle", "abnormal mitral annulus tissue Doppler signal", "pseudonormalization of transmitral Doppler flow", "restrictive filling pattern", "Grade 1 diastolic dysfunction", "Grade 2 diastolic dysfunction", and "Grade 3 diastolic dysfunction". If left ventricular compliance or relaxation is normal, code "N (No)" for diastolic dysfunction (4c).

5. Estimated LVEF (worst): Review the data for Ejection Fraction in Item 3, Section C of the ESF and the accompanying medical record documents. If there is a discrepancy within the available documentation, use clinical judgment to determine which is most accurate (e.g., description of abnormal LVEF (<50%) by history which is not confirmed by objective testing but an echocardiogram report documents normal LVEF (≥50%) in a patient with no symptoms of heart failure, most likely LVEF is ≥50%). However, if there are records documenting different estimates of LVEF, take the most recent lowest LVEF (e.g., if old LVEF prior to that hospitalization is 10% but *current* hospitalization describes *lowest* LVEF is 40%, record the *lowest current* LVEF = 40%). However, if the abstractor has recorded a specific LV ejection fraction (LVEF) on the ESF, e.g., from the notes (patient with history of LVEF x%), but there are no supporting documents, then record "d"(Unknown). The rationale for this is that confirmation for an estimated LVEF should be documented by an official report to differentiate a historical LVEF versus an objectively documented LVEF (both types will be captured on the ESF).

Indicate either A (≥ 50 %), B (35-49%), C (<35%) or D (Unknown). If LVEF is described as "normal", and no percentage is given, record A (≥50%).

6. Assign an overall heart failure diagnosis based on your clinical judgment (select only one). Review carefully the medical record documents provided and the event summary form pertinent to this event and select a diagnosis based on your clinical judgment. Provided in Section B of the ESF for your consideration are algorithm-based diagnostic classifications using Boston, Framingham, Gothenburg and NHANES criteria. Your answer to item 6 may or may not agree with classifications indicated in Section B of the ESF. Note that all 4 classifications do not distinguish between chronic stable HF and decompensated HF. Refer to Manual 3a, Section 5.0 for a guide to ARIC HF diagnosis. Select only one of the following letters:

"A" (definite decompensated heart failure), i.e., decompensation clearly present based on available data (satisfies criteria for decompensation).

"B" (possible decompensated heart failure), i.e., decompensation possibly but not definitively present. A typical case of "possible" rather than "definite" would be due to the presence of co-morbidity that could account for the acute symptoms (COPD exacerbation, for example). In some cases of chronic CHF, it may be difficult to tell whether the patient's status matches the baseline CHF status or indicates some deterioration. If in doubt, record "possible decompensated HF". In general, prefer "possible" whenever the evidence for decompensation (symptoms, signs, imaging) is subtle. Also, take the *totality* of the evidence provided. For example, a case of possible decompensated HF may be one that has a known history of CHF who has chest x-rays showing "active CHF", description of diuretic therapy, and an ICD-9 codes of 428, but there is no statement about decompensated heart failure in the discharge summary. (However, if a patient has such documentation with no known history of CHF, then the patient most likely has "definite decompensated heart failure" ["A"]). If there is scant documentation and you are choosing between "A" and "B", rely more on the ESF than the provided records; e.g., records do not confirm definite decompensated heart failure but "MD notes suggest reason for hospitalization is HF = yes", then choose "A".

"C" (chronic stable heart failure) i.e., no decompensation but patient has chronic heart failure. "Stable" also denotes "compensated" heart failure (not necessarily asymptomatic, but that patient's chronic HF symptoms are controlled with therapy and there is no evidence in augmentation of therapy for worsening HF during the hospitalization.) Note: This includes patients with asymptomatic heart failure (evidence of LV systolic dysfunction, i.e., EF < 50%, and no heart failure symptoms). Do NOT include: a history of transient LV/RV dysfunction if heart function is currently normal; or asymptomatic diastolic dysfunction alone.

"D" (heart failure unlikely**),** i.e., there is no HF, heart function is normal based on available documentation. Ideally, there should be some mention of normal heart function, but "heart failure unlikely" may be selected if there is sufficient data to make that inference in the absence of clear documentation.

"E" (unclassifiable), i.e., medical record documentation is missing; or there is no decompensated HF AND cannot differentiate between "chronic stable heart failure" and "heart failure unlikely".

Note: If there are symptoms of heart failure only in the setting of a fatal cardiac arrest not due to an acute myocardial infarction, and the patient otherwise was not hospitalized for a heart failure exacerbation, do not count as "decompensated heart failure" ("A" or "B"). Instead, classify the case as "chronic stable heart failure" ("C") *if* the patient had known history of heart failure but was not hospitalized with decompensated heart failure except at time of arrest (e.g., patient with metastatic cancer who had known LVEF 15% from ischemic cardiomyopathy, but had an arrest while being evaluated for failure to thrive because of the cancer). If the patient has no history of heart failure, consider classifying the case as "D" or "E".

Some general guidelines:

(1) If debating between the following answers -

- If choosing between “B” (possible decompensated HF) and “C” (chronic stable HF), favor “B”.
- If choosing between “A” (definite decompensated HF) and “B”, favor B.
- If choosing between “B” and “E” (unclassifiable), favor “E”.
- If choosing between “B” and “D”, favor “E”.
- If choosing between “C” and “D” (HF unlikely) [and “E”], favor “E”.

(2) Not all disagreements are equally important.

- Disagreement between “D” and “E” is not that important.
- Disagreement between “C” and “B” is very important.
- Disagreement between “C” and “A” is very important.
- Disagreement between “A” and “B” is very important.

(3) The distinction between “C” and “D” (or “C” and “E”) is important only for the Cohort (since "chronic stable HF" will not be counted in community analysis). Therefore, do not agonize about this choice unless the case is a cohort member.

If “A” or “B”, is selected, answer item 6.a. If “C”, “D” or “E” is selected, skip to item 8.

a. Was definite or possible decompensated heart failure present at admission? After review of the medical record documents pertinent to this event, indicate if there was decompensated heart failure at admission. Indicate either “Y”(Yes), “N” (No) or “U”(Unknown).

7. Was this event fatal? After review of the medical record documents provided, indicate either “Y”(Yes), or “N” (No). If “Y” is selected, answer Item 7a. If “N” (no) is selected skip to Item 8.

a. Was decompensated heart failure the primary cause of death? After review of the medical record documents provided, indicate either “Y”(Yes), “N” (No) or “U”(Unknown). Note that “primary” in this context is not synonymous with underlying cause from a nosologist’s point of view. Primary cause of death for the purpose of item 7a is a decision based on your clinical review of the provided materials that heart failure was the most important, or the principal, chief, crucial, or primary factor leading to death. To answer “Yes” (decompensated HF was the primary cause of death), you need to have the following idea in mind: the patient would not have died if decompensated HF were absent. If so, record “Y” (Yes) to item 7a. If it is clear that the person died and also had heart failure but heart failure was not a principal or primary factor in causing death record “N” (No). If not sure, record “U” (Unknown).

8. Comments. Add any brief comment(s) about this review. These comments will be made available to the adjudicator.

Appendix III. Physician Heart Failure Survey

ARIC

Physician Heart Failure Survey

O.M.B 0925-0281
Exp. 05/31/2010

ID NUMBER: | | | | | | | |

FORM NAME: | P | H | F |

VERSION: | A | DATE: 05/22/2007

CONTACT YEAR NUMBER: | | |

FORM SEQUENCE NUMBER: | | |

General Instructions:

The Heart Failure Form is completed when a participant reports that a physician has diagnosed heart failure (HF) during an outpatient visit, and during the time frame specified in the AFU. The interview initiates the process that enables ARIC to send that physician a request to complete the Physician Heart Failure Form (PHF). The PHF form is sent to each physician for whom the participant submits an authorization for access to information from the physician's records. When the physician returns the PHF to the ARIC Field Center, the data is entered in the data entry system. Refer to the instructions for this form for data entry.

Note: Sections I and II will not appear on the data entry screen.

Section I: Instructions to Physicians:

Dear < Dr >,

Your patient, < Ms/Mr. > who is a long time participant in the ARIC Study, has indicated to ARIC study personnel that < s/he > has been diagnosed with heart failure. We have your patient's authorization to ask you to provide this information for our study records. We appreciate your response to the following questions and request that you return this form in the enclosed envelope at your earliest convenience (ideally within 2 weeks).

Thank you.

Sincerely,
< Field center medical director > Date < Date letter is sent >

Section II: Patient Confidential Information:

Patient Name: _____

Patient Date of Birth: _____

Section III: Data Reported by Physician:

0. Name of medical doctor to whom inquiry sent:

1. Has this patient ever had heart failure or cardiomyopathy of any type?

Yes……..Y
Unsure……U
No……N — If no, skip to question 3.

2. If the patient has or ever had heart failure or cardiomyopathy:
   (a) Is this patient's condition characterized as predominantly:

Systolic dysfunction…….. S
Diastolic dysfunction……..D
Mixed……M
Not determined…….. N

(b) Estimated LVEF (worst): | | | | %

(b.1.) If LVEF is not specifically available, estimate LV function:

Normal…….. … N
Decreased mildly……. L

Decreased moderately ……D
Decreased severely……..S

(c) Estimated date of onset or diagnosis (month/year): | | | / | | | | |

3. Has this patient ever had (check all that apply):

	Yes	No
a. Atrial fibrillation on an ECG?	Y	N
b. Angina pectoris?	Y	N
c. Pulmonary rales on a physical examination?	Y	N
d. Previous MI?	Y	N
e. Rhonchi on a physical examination?	Y	N
f. Other coronary heart disease?	Y	N
g. None of the above.	Y	N

4. Was s/he prescribed treatment specifically for heart failure during the past year?

Yes……... Y
No……. N
Not known …….. …..……. U

5. Was this patient prescribed any of the following during the past year? (check all that apply)

	Yes	No
a. ACE inhibitors	Y	N
b. Aldosterone blocker	Y	N
c. Alpha blockers	Y	N
d. Amiodarone / Antiarrhythmics	Y	N
e. Angiotensin II receptor blockers	Y	N
f. Anticoagulants	Y	N
g. Aspirin / Antiplatelets	Y	N
h. Beta blockers	Y	N
i. Calcium channel blockers	Y	N
j. Digitalis	Y	N
k. Diuretics	Y	N
l. Hydralazine	Y	N
m. Lipid-lowering agents	Y	N
n. Nitrates	Y	N
o. Other antihypertensives	Y	N

6. Form completed by:

MD ……... M
Other …….. O

7. Date (mm-dd-yyyy): | | | – | | | – | | | | |

Section IV: Administrative:

8. Data entered by: | | | |

9. Date data entry completed (mm-dd-yyyy): | | | – | | | – | | | | |

INSTRUCTIONS FOR COMPLETING PHYSICIAN HEART FAILURE FORM
PHF VERSION A, 02/12/2008

I. GENERAL INSTRUCTIONS

The Physician Heart Failure (PHF) Form is completed by the physician when a participant reports that a physician has diagnosed heart failure (HF) during an outpatient visit within the last 3 years (from date of AFU interview). The interviewer initiates the process that enables ARIC to send that physician a request to complete the PHF. The PHF form is sent to each physician for whom the participant submits an authorization for access to information from the physician's records. When the physician returns the PHF to the ARIC Field Center, the data is entered in the data entry system. The itemized questions (items 1- 7) on the questionnaire that was sent to the physician are in Section III of the PHF Form. Record the data as indicated on the returned PHF questionnaire.

Note that the Physician Heart failure Survey (PHF) form specifies two time frames: "ever" for certain diagnoses and signs/symptoms and "last year" for information on medical treatment. If persons filling out the PHF wish to interpret "ever" as restricted to the previous three years, this is acceptable.

If for some reason the PHF is unobtainable after a participant has given consent, please code the PHF form as permanently missing (using the menu item on menu bar called "perm.miss").

II.DATA ENTRY SCREEN

Contact Year: The specific year is determined by the contact year on the AFU interview that initiated this PHF. For example, if the current year of interview for the participant is "19", then enter "19" in the field provided for "Contact Year" on the PHF.

Form Sequence Number: This number corresponds directly to questions 8, 9, and 10 of the AFU. For example, if the PHF questionnaire that was sent to the physician was initiated by question 8 of the AFU, then enter 08 for "Form Sequence Number" on the PHF. If the PHF questionnaire that was sent to the physician was initiated by question 9 of the AFU, then enter 09 for "Form Sequence Number" on the PHF. In the event that the name of the physician was the same for AFU questions 8 and 9, or 8 and 10, or 9 and 10 enter the number of the question at which the physician's name first occurred.

lll. DATA REPORTED BY PHYSICIAN

0. Name of medical doctor to whom inquiry sent.
   Record the name of the physician as indicated in the salutation on the returned questionnaire.

2. Has this patient ever had heart failure or cardiomyopathy of any type?
   Record Y (Yes), U (Unsure), or N (No). If the response is "no", skip to item 3.

2. If the patient has or ever had heart failure or cardiomyopathy.
Record the data for items 2a-2c, if the response to item 1. was either Y (Yes) or U (Unsure).

2.a. Is this patient's condition characterized as predominantly:
Record either (S) Systolic dysfunction, (D) Diastolic dysfunction, (M) Mixed, or (N) Not determined as indicated by the physician.

2.b. Estimated LVEF (worst).
Record the percentage indicated. The acceptable range is of values is 00-85.

2.b.1. If LVEF is not specifically available, estimate LV function.
Record physician's answer: N (Normal), L (Decreased mildly), D (Decreased moderately) or S(Decreased severely).

2.c. Estimated date of onset or diagnosis (month/year).
Record the month and year. as indicated by the physician.

3. Has this patient ever had (check all that apply).
Record Y (Yes), or N (No), to items 3a-3g as indicated by the physician.

4. Was s/he prescribed treatment specifically for heart failure during the past year?
Record Y (Yes), or N (No), or U (Unknown) as indicated by the physician.

5. Was this patient prescribed any of the following during the past year? (check all that apply)
Record Y (Yes), or N (No), to items 5a-5o as indicated by the physician.

10. Form completed by:
This corresponds directly to the item on the returned PHF questionnaire that asks for the signature or stamp of the person who completed the questionnaire. From the information provided for this item, determine whether the person was an MD or other and record either M (MD) or O (Other).

11. Date (mm-dd-yyyy).
Record the month, day, and year that the PHF questionnaire was completed from the paper form.

Section IV: Administrative:

12. Data entered by:
Code the number of the person who completed the data entry process for this form.

9. Date data entry completed:
Record the month, day and year on which the date entry was completed for this form.