Updated Manual 3

This table summarizes changes of Manual 3 as of 5/21/2026

Section in Manual 3	Description of Changes in Manual
9.1 Introduction, pg. 46 9.1.1.4 Hospital Discharge Index pg. 48 & pg. 51 9.2.2 Procedures for Hospital Events pg. 57 9.2.3 Summary of Cohort Investigations, pg. 58	• Clarifications were added to sections of the manual to reflect that, as of May 2026, creatinine is collected only for CHD, HF, and Stroke eligible events.
Appendix x., pg. 113	• Clarifications were added to the Naming Convention for Hospital Records section.

ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

Manual 3

Surveillance Component Procedures Manual of Operations

Version 6.9
05/21/2026

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FOREWORD

This manual, entitled Surveillance Component Procedures, is one of a series of protocols and manuals of operation for the Atherosclerosis Risk in Communities (ARIC) Study. The complexity of the ARIC Study requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the ARIC Study. Manual 2 describes the operation of the Cohort component. This edition of Manual 3 (Version 6.7) describes Cohort and Community surveillance methods. Detailed Manuals of Operation for specific procedures, including those of reading centers and central laboratories, make up Manuals 4 through 11 and 13 through 16. Manual 12 on Quality Assurance contains a general description of the study's approach to quality assurance as well as the details for quality control for the different study procedures.

Note: Even though community surveillance of coronary heart disease and heart failure in the ARIC communities ended with event year 2014, methods used in community surveillance are included in this manual for historical purposes. However, surveillance and event ascertainment and classification of coronary heart disease, heart failure and stroke among cohort participants continues. Methods used for cohort surveillance are also included in this manual. Also note that the Surveillance Inventory (SXI) and the Confidential Data (CFD) forms, used primarily for community surveillance purpose are no longer needed and were discontinued in 2015 and 2018, respectively.

Manual 3. Surveillance Component Procedures

Table of Contents

1.0 INTRODUCTION

Through community surveillance (1987-2014), the ARIC study enumerated and validated cases (events) of hospitalized myocardial infarction (MI) and coronary heart disease (CHD) deaths occurring after January 1, 1987 in 35 through 74 year old male and female residents of the four ARIC study communities: Forsyth County, North Carolina; Jackson, Mississippi; suburbs of Minneapolis, Minnesota; and Washington County, Maryland. The eligible age range was expanded to 84 beginning in 2005.

ARIC surveillance also includes monitoring and validating events among cohort participants. In addition to the CHD endpoints above, clinically recognized strokes among cohort participants are also identified and validated through surveillance procedures. Hospitalized events of heart failure in the four ARIC communities and among cohort participants are also identified starting January 1, 2005. Details of the procedures for ascertainment of heart failure are outlined in Manual 3A and not discussed further in this manual.

This manual details the procedures used in ARIC community surveillance as well as those in use for identification and validation of selected events among the ARIC cohort. Section 2 describes the procedures by which potential events in the community were identified (i.e., death registries, hospital discharge indexes). Section 3 details procedures for collecting the additional information needed once an event was 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. Sections 9 and 10 detail the surveillance procedures for identifying CHD events (Section 9) and clinical stroke (Section 10) among the ARIC cohort. Section 11 describes how the Mortality and Morbidity Classification Committee (MMCC) functions and Section 12 outlines the quality control measures used in ARIC surveillance.

The methods used to identify and classify CHD events among cohort participants are modified from those used in community surveillance. These modifications are outlined in Section 9 of this manual. CHD events occurring among ARIC cohort participants are ascertained through cohort follow-up as well as through the on-going monitoring of discharge lists from hospitals within the ARIC communities.

2.0 IDENTIFICATION OF EVENTS IN COMMUNITY SURVEILLANCE

2.1 Introduction

The basic features of the coronary heart disease community surveillance design are summarized in Table 2.1. Events surveyed in each of the four communities include fatal CHD and hospitalized MI (see Appendix I), beginning January, 1987.

Table 2.1 ARIC Community Surveillance Eligibility Criteria

Criteria	Eligibility
Age	Between 35 and 74 years, inclusive, for events between January 1, 1987 and December 31, 2004. Between 35 and 84 years, inclusive, for events on and after January 1, 2005
Race	All races
Place of residence	Within the defined boundaries of the ARIC Communities
Date of discharge or death	January 1, 1987 or later
ICD-9 Codes for identification of CHD death (years 1987-1998)	250, 401, 402, 410-414, 427-429, 440, 518.4, 798, 799
ICD-10 Codes for identification of CHD death (years 1999 and after)	E10-14, I10-11, I21-25, I46-51, I70, I97, J81, J96, R96, R98-99
ICD-9 Codes for identification of hospitalized MI	402, 410-414, 427, 428, 518.4
ICD-10 Codes for identification of hospitalized MI	I11.x, I20.x, I21.x, I22.x, I24.x, I25.x, I46.x, I47.x, I48.x, I49.x, I50.x, J81.0, R00.1

Events meeting the eligibility criteria given in Table 2.1 were investigated for conformity with ARIC surveillance diagnostic criteria. Identification of hospitalized events was limited to acute care hospitals in the catchment area (Section 2.2.3); no systematic attempt was made to obtain events from records of nursing homes, psychiatric hospitals, private physicians, or hospitals out of the catchment area, except for Washington County where transfers to outlying hospitals from catchment area hospitals were targeted for surveillance (see section 3.2.1).

Hospitalized MIs were verified and classified by means of pain, cardiac biomarkers (CPK, CPKMB, LDH1, LDH2, tropinin I, and troponin T) as well as ECG evidence documented using the Minnesota Code.

Out-of-hospital deaths (as defined in Section 3.1.2) were documented by means of informant interviews and family physician questionnaires. Coroner/medical examiner records were abstracted when available. Since Maryland laws prohibit the use of information found in death certificates as a means to contact relatives, validation of out-of-hospital deaths in Washington County was not carried out for the years 1987-1994. With approval of the Maryland State Health Department, investigation of out-of-hospital deaths was initiated for events occurring in 1995 and thereafter. Deaths occurring in acute care hospitals were documented by abstracting the medical record, as with all nonfatal events.

The elements of the diagnostic criteria for the various events are abstracted onto standardized computer screens. For hospitalized events, the occurrence of MI was determined when

possible by computer analysis of the recorded diagnostic elements; for fatal events, cause of death is assigned by computer or by the Mortality and Morbidity Classification Committee, according to criteria described in Section 4.

Quality control procedures were in place to assess reliability of abstracting medical records, both the reliability and validity of coding ECGs, and the reliability of MMCC procedures.

Two sources of identification of events were used: death certificates and hospital discharge indexes.

2.2 Identification of Hospitalized MI

2.2.1 Obtaining Access to Hospital Medical Records

A critical feature of community surveillance was obtaining information from medical records. Without complete cooperation of hospitals, the usefulness of event rates in any community is limited. Cooperation was sought through hospital administration, medical records directors, hospital ethics committees, and influential medical staff.

It was sometimes necessary to compromise with the hospital review committees and house staff. Again, the major consideration is confidentiality. Some hospitals did not permit the abstraction of a patient's name. It was important to obtain the name because this is the surest method to reduce redundancy in the records and determine case fatality after discharge. However, less optimal procedures are available. The first was to seek permission to code the name and record addresses, social security numbers, and birth dates. If these were available, the likelihood of redundancy can be reduced by sorting lists of individuals by birth dates or social security numbers. For events occurring in 2005 and later, electronic files containing name, address, and date of birth information were not available for the Minnesota VA hospital. The eligibility of events for this site was determined locally by the Field Center Staff.

2.2.2 HOSPITAL DISCHARGE INDEX

Eligible hospitalized MIs were identified from the discharge index of each hospital surveyed. Discharge indices were obtained directly from the hospital or from an indexing service such as Healthcare Knowledge Resources.

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). Most hospitals subscribe to a service that takes these diagnostic codes and produces an index of discharges classified by code.

The ICD was originally constructed to provide comparable international data on causes of death. It is now extended by many countries for use in coding hospital discharge diagnoses. Effective October 1, 2015 the extension of the ICD used by hospitals is called ICD10-CM (Clinical

Modification). The hospital or "CM" modifications provide additional codes so that diagnoses may be classified with more detail.

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

1) Age. ARIC examines cases only at ages 35 through 74. For events occurring on or after January 1, 2005, the age criteria are expanded to 35-84.

2) Place of Residence. Patients **must have lived** within the boundaries of the ARIC community. The discharge index may give only 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 were counted. If the patient died and it is an eligible death for abstraction, the death certificate was considered the source document, therefore the address on the death certificate takes precedence over the hospital record**.**

3) Date. Time eligibility was determined from the date of discharge. Only cases discharged after January 1, 1987 were eligible.

4) Codes. The following cases with primary or secondary diagnoses with ICD9-CM codes 402, 410-414, 427, 428, 518.4 or `I11.x, I20.x, I21.x, I22.x, I24.x, I25.x, I46.x, I47.x, I48.x, I49.x, I50.x, J81.0, R00.1` were selected for documentation of hospitalized MI.

The number of cases meeting these four eligibility criteria was reduced by applying various sampling fractions to different classes of ICD9-CM codes. The following sampling strategy was employed for hospitalizations occurring from 1987-1993. Note that each hospitalization may have multiple ICD discharge diagnoses, and all were considered in a hierarchical manner for determination of eligibility to abstract and of sampling fraction.

i) Code 410. 100% sample.

ii) Code 411 without a 410 code. 50% sample. The 50% sample was selected by choosing only the events with discharges occurring on even days of the month, i.e., days 2, 4, 6, etc.

iii) Codes 412-414 without codes 410-411. 25% sample. The 25% sample was selected by choosing only the events with discharges occurring on days of the month divisible by 4, i.e., days 4, 8, 12, 16, 20, 24 and 28.

iv) Codes 402, 427, 428 and 518.4 (without codes 410-414). 10% sample. The 10% sample was selected by choosing only the events with discharges occurring on days of the month divisible by 8, i.e., days 8, 16, and 24.

These sampling fractions were reassessed periodically. New sampling fractions were introduced for hospitalized events occurring in 1994 and afterwards. The following data outlines the sampling of events beginning in 1994. Each of the potentially eligible discharge codes were evaluated sequentially. For example, suppose a case discharged on the 5th of the month has a 411 and a 414 hospital discharge diagnosis code but no 410. This case was not "eligible" based on the 411 code (not evenly divisible by 3) but was "eligible" due to its 414 code and date (evenly divisible by 5). However, because this case had a 411, its eligibility is determined at that point. Therefore, this case was not eligible and was not abstracted.

1) Codes 410 and gender equals Male. 84% sample, all events except those days divisible by 6.

2) Codes 410 and gender equals Female. 100% sample.

3) Codes 411 without a 410 code (gender equals male or female). 33% sample, events on days evenly divisible by 3.

4) Codes 412-414, 402, 427, 428, and 518.4 and no 410-411 codes (gender equals male or female). 20% sample, events on days evenly divisible by 5.

In 2003, it became apparent that Forsyth County was abstracting substantially more hospitalized events using this sampling protocol than the other centers. Therefore, it was decided to reduce the number of cases that Forsyth County abstracted for 2002 cases onwards. The following outlines the sampling of events for **Forsyth County only** starting in 2002.

1) Codes 410 and gender equals Male. 61% sample, all events except those days divisible by 3 or 8.

2) Codes 410 and gender equals Female. 67% sample, all events except those days divisible by 3.

3) Codes 411 without a 410 code (gender equals male or female). 23% sample, events on days evenly divisible by 4.

4) Codes 412-414 without codes 410-411 (gender equals female). 16% sample, events on days evenly distributed by 6.

5) Codes 412-414 without codes 410-411 (gender equals males) 402, 427, 428, and 518.4 (gender equals male or female). 13% sample, events on days evenly divisible by 7.

Starting with January 1, 2005, an older age decade, 75-84 was added and the effective hospitalization sampling fractions were allowed to vary by field center, sex, age (35-74 or 75-84), and race (in Forsyth County and Jackson only), in order to achieve a greater balance in the numbers of incident events between field center, sex, and race groups, so that precision of event rate estimates would be similar across these groups. There are 4 ICD-9 code strata. With sex and age (35-74 or 75-84) considered, there were a total of 16 sampling strata for Minneapolis and Washington County; with race added as well, there were 32 sampling strata for Forsyth County and Jackson. For event year 2005, the sampling fractions were chosen in terms of numbers of days per month being sampled (1/30, 2/30, etc.) as in prior years. Appendix VII shows how this was implemented.

The total number of abstractions per field center came from contract negotiations for abstracting beginning in 2005, as given in the following table.

Table 2.3 Estimated number of CHD hospital abstractions per year from final proposal

Center	35-74	75-84
Forsyth	982	477
Jackson	858	433
Minnesota	690	280
Washington	682	285
All	3212	1475

ICD codes listed on the hospital discharge index may not exactly correspond with those found in the corresponding hospital chart. Eligibility for selection uses both sources. However, the index information is used first. Beginning with 2005, the electronic hospital discharge lists - were sent to the Coordinating Center (CC) for selection of hospitalizations eligible for community surveillance abstraction. (The selection 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.

The sampling criterion for selecting hospitalizations for CHD and HF abstraction was simplified in 2006. The new method will randomly select hospitalizations from each stratum using a specific sampling fraction. The strata was defined by Month of Discharge, CHD group (or HF group), Age group, Race, and Sex. The sampling fractions for each stratum for 2005 and subsequent years are listed in Appendix VI. The selection for each field center was done as follows:

a) Count the number of CHD (or HF) events in each stratum defined by Month of discharge, Age group, CHD group (or HF groups), race, sex.

b) Determine the number of events (N) that need to be selected in each stratum by multiplying the number of events by the sampling fraction for that stratum and round up to the nearest integer.

c) Select the N observations randomly in each stratum. These are the hospitalizations that will be abstracted.

In event year 2007 the Forsyth field center was significantly delayed in abstraction efforts at hospital #12 (Forsyth Medical Center). In order to allow this field center to catch-up on abstraction and prevent a delay in beginning the next years abstraction a one-time cut in the sampling fraction was made in order to reduce the total number of abstraction necessary for event year 2007 at this hospital. See Appendix V1 for details of the sampling fraction used for Forsyth in event year 2007.

The number of abstractions required for event year 2012 exceeded the contracted number in Forsyth in both age groups. Thus, the CC proposed to reduce the abstractions in Forsyth to approximately contracted levels in 2013 by applying a reduction factor based on 2013 projections to the sampling fraction in each stratum. See the Appendix VI for details of changes.

The coordinating center monitored the number of events that are eligible and selected for abstraction on a yearly basis. If any field center was abstracting 10% more or less than their contracted number of events, the sampling fraction was altered in order to bring the field center back to its contracted number of abstractions.

2.2.3 MIS OCCURRING OUTSIDE THE STUDY COMMUNITY

Community residents with MI may have been hospitalized out of the study area for the following reasons:

1) A major hospital catchment area for the region exists outside of the study area (e.g., tertiary care hospital referral centers).

2) Residents who work outside of the geographic area may be admitted to an out-of-area hospital if they have a MI at work.

3) A resident may have an event while in transit outside of the geographic area for recreation or social activities.

In order to select hospitals outside of the study area to include in surveillance, each Field Center first identified those hospitals that were located in the surrounding areas. Second, the center determined by checking with local physicians, cardiologists, hospital administrators and others whether or not patients with acute MI were usually hospitalized locally prior to admission to a tertiary care facility outside the study area. Third, 1984 and 1985 death certificates for study area residents were reviewed. Surveillance was carried out in any hospital outside of the geographic area that contributed at least six eligible in-hospital MI deaths (ICD9-CM 410-414) in the 1984-1985 period. Major medical centers or tertiary referral facilities some distance from the study area were not included in surveillance unless there was evidence that patients with acute MI from the study area were directly admitted to such hospitals without treatment at a within-area hospital. Selection of hospitals included in community surveillance was reassessed after completion of 1987-1993 surveillance. No new hospitals were added as a result of that investigation. Based on review of data from 1994-1998, one hospital (River Oaks)

was added to community surveillance in Jackson. Surveillance at River Oaks was established for events occurring in 1998 and after. Investigation of potential new hospitals for community surveillance was conducted periodically after 1999.

Community residents hospitalized with acute MI while outside both the study area and the surrounding counties were 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

Hospitalized MI patients were identified by review of records only at acute care hospitals. Nursing homes, rehabilitation hospitals, long-term chronic disease hospitals, and psychiatric hospitals were excluded. A small number of MI patients hospitalized at these chronic care facilities for another disease, e.g., multiple sclerosis, peripheral vascular disease, diabetes, etc., may have an acute MI while in the chronic care facility and not be referred to an acute care facility or may die before referral. These individuals were lost to the surveillance system. Such an event is probably rare and would be difficult to identify from review of chronic care facility records. Community surveillance did not identify nonfatal MI occurring outside of a hospital and for which the individual is not hospitalized (unrecognized MI). These "unrecognized" or "silent" MIs are identified, however, in cohort surveillance (see Section 9).

2.2.5 GENERAL PROCEDURES IN THE ABSTRACTION OF HOSPITAL RECORDS

Instructions for filling out individual forms are given in the “Question by Question” instructions for each form, which are listed in the Appendix to this manual. With the implementation of a computerized abstraction system in the Data Management System (DMS) in November of 2007, there are some changes in the data collection methods for community and cohort surveillance. The entire list of hospitalizations needing community surveillance or cohort abstraction for CHD and HF are installed into the central database. Creation of these “HLIST” (hospital list) files is done after selection 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 was furnished to the Coordinating Center by the field center. The HLIST files were used to implement a management system for the field centers to track abstraction. This computerized process gave the complete list of community surveillance and cohort hospitalizations that needed to be abstracted for each specific hospital where the hospitalizations were identified by medical record number and discharge date combination. Information available from the hospital lists were auto filled into the abstraction forms. Prior to 2014 creation of H-List cohort hospitalizations for Minnesota were done by the field center.

2.2.6 ORDER OF COMPLETION OF SURVEILLANCE FORMS

The specified order for completion of surveillance forms was as follows: CEL (cohort eligibility form, used only for cohort members); CFD (confidentiality form); CHI (common hospital information). The following forms could be implemented in any order: HRA (for hospitalized MI), HFA (for hospitalized HF), STR (for hospitalized stroke, cohort only). Note that if the hospital chart cannot be found, this was registered in the CEL for cohort members and in the CFD for non-cohort, and no further abstraction was done. For event years 2005-2009 the Minneapolis field center was indicating charts that could not be found on the NOF form in

questions 2 (for CHD) or 3 (for HF) with a response of “E. Other reason/s.” If the computerized address check did not resolve whether the address is in or out of catchment area, the abstractor was asked to suspend abstracting (for a non-cohort participant) pending further investigations. If the address proves eligible, the CFD form was to be completed. However, if eligibility could not be determined, the abstractor proceeded to abstract into the required forms.

Each of the CFD, CHI, HRA, HFA, and STR started with identifying the hospital, medical record number, and discharge date if the data entry session starting from the hospital selection list or Annual Follow-up (AFU) Form is interrupted before the entire set is completed, to assure that when abstraction is restarted the right chart is associated to the already assigned hospitalization ID number. If there have been no interruptions, these fields were auto filled and then scrambled, since they are already available in the database, from the hospital selection list or from the CEL.

The CHI is the form data that both HRA and HFA would otherwise need were entered, and the form was created to save entering the data twice when abstraction for both HF and CHD is required. The data entered into CHI was mainly administrative, and there remained a few items common to HRA and HF that was entered in both forms. When abstracting for multiple surveillance events for a given hospitalization, i.e., CHD, HF and Stroke, the event ID was to be the same across all forms (HRA, HFS, STR, CEL, CFD, CHI and NOF).

2.3 IDENTIFICATION OF CHD DEATHS

2.3.1 Death Certificates

All deaths in the United States must be recorded on a death certificate that is filled out by a physician, medical examiner, or coroner. The death certificate is a legally mandated, public document that is filed in the county of the decedent's residence. A copy is filed with the state. If a person dies away from his usual residence, a copy of the death certificate is (eventually) returned to the decedent's county of residence for filing and is also filed at the state health department. In each state, health department trained nosologists code the causes of death given on the death certificate according to the ICD. For deaths occurring in 1999 and beyond, the tenth revision of the ICD codes was used to identify CHD deaths (see Table 2.4, replacing the ninth revision that was used for all previous years of ARIC surveillance.

Each of the four states containing the ARIC communities assigns the specific "underlying cause of death" from the nosologist's coding of the death certificate using the Automated Classification of Medical Entities (ACME) system. Computer files, which include the date of death, underlying cause, decedent's age and residence, are available. Each center obtained a monthly printout (or electronic copy) of potentially eligible cases based on the criteria listed below. Washington County obtains death certificates from the county health department and relied on listings provided annually by the State to assure completeness. The monthly printouts generally contain in-state deaths that occurred three to five months previously. In addition, three out of the four centers annually obtain a final computer tape of eligible deaths to verify that ascertainment is complete and to provide numerators for rate calculations. Prior to 2005

access to electronic files of annual deaths with sufficient information to determine eligibility was not available for Jackson.

2.3.2 Selection of Fatal Events:

Fatal events were selected according to the following eligibility criteria.

1) Age. ARIC examines deaths only at ages 35 to 74 (expanded to age 84 beginning in 2005).

2) Place of Residence. The decedent must have lived within the boundaries of the ARIC community. The residence at death determines eligibility. However, if it is found in event investigation that the decedent was only visiting the area, or had two residences, for example, a nursing home and permanent address, the place where the person lived at least six months out of the year is considered the residence for ARIC purposes. Anonymous "John Doe" deaths are not counted. However, deaths of people residing in a local jail at the time of death are counted. If the address listed on the hospital record is different from the one listed on the death certificate, the address on the death certificate takes precedence, as it is the source document.

3) Date. Only deaths occurring after January 1, 1987 are eligible.

4) ICD9 Codes. Deaths whose underlying cause is coded: 250, 401, 402, 410-414, 427-429, 440, 518.4, 798 and 799.

5) ICD10 codes: Deaths whose underlying cause is coded: E10-14, I10-11, I20-25, I46-51, I70, I97 (except I97.2), J81, J96, R96, R98, or R99. See Table 2.4 for comparison of ICD9 and ICD10 target codes.

Table 2.4 Comparison of Underlying Cause of Death Codes between ICD-9 and ICD-10

ICD-9 Codes	ICD-9 Terms	ICD-10 Codes	ICD-10 Terms
250(.0-.9)	Diabetes	E10(.0-.9) E11(.0-.9) E12(.0-.9) E13(.0-.9) E14(.0-.9)	Insulin dependent DM NIDDM Malnutrition DM Other specified DM Unspecified DM
401 (.1,.9)	Hypertension	I10	Essential hypertension
402 (.0x,.1x,.9x)	Hypertensive heart disease	I11 (.0,.9)	Hypertensive heart disease
410(.0-.9)	Acute MI	I21 (.0-.4, .9), I22 (.0,.1, .8, .9) I23(.0-.6, .8)	AMI within 4 weeks Subsequent AMI Certain complications following AMI
411(.0,.1,.8)	Other acute IHD	I24 (.0,.1,.8,.9) I20.0	Other acute IHD Unstable angina
412 414 (.0,.1x,.8,.9)	Old MI Chronic CHD	I25(.0-.9)	Chronic IHD (including Old MI)
413(.0,.1,.9)	Angina pectoris	I20 (.1,.8,. 9)	Angina pectoris
427 (.0,.1,.2,.3x,	Cardiac	I46 (.0,.1, .9),	Cardiac arrest
.4x,.5,.6x,.8x,.9)	dysrhythmias	I47 (.0,.1, .2,.9), I48 I49 (.0-.5, .8-.9)	Paroxysmal Tachycardia Atrial fibrillation/flutter Other cardiac arrhythmias
428 (.0,.1,.9)	Heart Failure	I50 (.0,.1, .9)	Heart Failure
429 (.0,.1,.3,.4,.5, .6,.8x, .9) (exclude 429.2)	Ill defined heart disease	I51 (.0-.5, .7-.9) exclude I51.6 I97 (.0,.1, .8,.9) exclude I97.2	Complications and ill-defined heart disease Post-procedural disorders of circulatory system, not else classified.
429.2	Unspecified CVD	I51.6	CVD unspecified
440 (.0-.2,.8,.9)	Atherosclerosis	I70 (.0, .1, .2,.8,.9)	Atherosclerosis
518.4	Acute edema of the lung	J81	Pulmonary edema
798 (.0,.1,.2,.9)	Sudden death	R98 R96(.0,.1)	Unattended death Other sudden death, cause unknown
799 (.0-.4,.8,.9)	Ill-defined mortality	R99 (no decimal)	Other ill-defined causes of mortality
		J96 (.0, .1, .9)	Respiratory failure

Copies of death certificates for the potential fatal events identified on the monthly printouts were obtained from the respective State Departments of Health. Abstractors reviewed each certificate to confirm the death meets age, residency, date, gender, and ICD code criteria. ARIC cohort members are identified by comparison with the cohort clinic roster. The remaining fatal cases were reduced in number by applying various sampling fractions to different classes of ICD codes. These constitute the deaths to be investigated. The following were sampling fractions used for fatal event investigation for cases occurring between 1987 and 1994 using ICD9 codes.

1) Codes 410-414 and 429.2. 100% sample.

2) Codes 250, 401, 402, 427-429 (except 429.2), 440, 518.4, 798 and 799, and no 410-414 or 429.2. 25% sample. For a 25% sample of cases, only deaths occurring on days of the month divisible by 4 are selected for further investigation.

For fatal events occurring from January 1, 1995 to December 31, 1998, new sampling fractions were used. These are outlined as follows:

1) Codes 410-414, 429.2 and gender equals Male. 84% sample, all events except those on days divisible by 6.

2) Codes 410-414, 429.2 and gender equals Female. 100% sample.

3) Codes 250, 401, 402, 427-429 (except 429.2) 440, 518.4, 798 and 799, and no 410-414 or 429.2 codes (gender equals male or female). 66% sample, events or days not divisible by 3.

For fatal events occurring on January 1, 1999 and beyond, same sampling fractions were applied to ICD-10 codes. See also table 2.5 below.

1) ICD-10 codes I20-I25, I51.6 and gender equals Male. 84% sample, all events except those on days divisible by 6.

2) ICD-10 codes I20-I25, I51.6 and gender equals Female. 100% sample.

3) ICD-10 codes E10-E14, I10-I11, I46-I51 (except I51.6), I70, I97 (except I97.2), J81, J96, R96, R98, R99 (gender equals male or female), and no I20-I25, I51.6 codes. 66% sample, events or days not divisible by 3.

Table 2.5. ICD-10 Codes Sampling Fractions for ages 35-74 and Deaths on or after January 1, 1999

ICD-10 Code	Gender	Fraction	Sampling Directions
I20-25 or I51.6	Men	0.84	All except those on days divisible by 6 (deaths on 6th, 12th, 18th, 24th , and 30th of each month ineligible)
I20-25 or I51.6	Women	1.0	All eligible regardless of day
Other eligible codes * , and no I20-I25, I51.6	Men	0.66	All except those on days divisible by 3 (deaths on 3rd, 6th, 9th, 12th , 15th, 18th, 21st, 24th, 27th, and 30th of each month ineligible)
Other eligible codes *, and no I20-I25, I51.6	Women	0.66	All except those on days divisible by 3 (deaths on 3rd, 6th, 9th, 12th , 15th, 18th, 21st, 24th, 27th, and 30th of each month ineligible)

* E10-14, I10–11, I46–51(not I51.6), I70, I97 (not I97.2), J81, J96, R96, R98, R99

For fatal events through 2004, the death sampling fractions follows Table 2.5 above. Deaths occurring on or after January 1, 2005, (an older age decade), 75-84, is included. The sampling fraction for this age group differed by field center. The death sampling fraction for the younger age group 35-74 has not changed. Death sampling fractions for deaths occurring on or after January 1, 2005 are given in Appendix VIII.

A Surveillance Event Eligibility Form was used by centers to help with inventory and sample selection. An ID number was assigned to each event, a Death Certificate Form (DTH) is completed (see Section 3.1), and the death certificate was filed locally.

2.3.3 CHD Deaths Occurring Outside the Study Community

For fatal hospitalized events, the address on the death certificate takes precedence over the address in the hospital record for determining eligibility.

Deaths outside of the study area, but within the state, are included on State Health Department monthly printouts, but some delay between the death and the transfer of the certificate to the place of residence file is expected. If the death certificate file was reviewed for ARIC prior to receipt of out-of-area certificates, subsequent review was undertaken to identify in-transfer deaths.

Deaths that occurred in other states were relatively few in the ARIC study areas that did not closely border another state. The out-of-state deaths could not be identified in a timely fashion but were identified on the annual mortality computer tapes provided by the State Health

Departments. Access to identifiers for out-of-state deaths was restricted. For these reasons, CHD eligible out-of-state deaths was only be enumerated from vital records and did not require abstraction or further investigation.

3.0 EVENT INVESTIGATION

For hospitalized MI, event investigation entailed review of the hospital record. Investigation of fatal CHD includes review of the death certificate and hospital record where available, and, for out-of-hospital deaths in Forsyth County, Jackson, Minneapolis, and Washington County (after 1995), physician questionnaires, interviews with next-of-kin, and collection of other information. In Washington County, the medical examiner adds relevant questions to his routine inquiry, but other out-of-hospital investigations were prohibited for events occurring between 1987 and 1994.

Procedures for the identification and investigation of hospitalized and fatal 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 in Section 9 are identified where appropriate.

3.1 Procedures for Fatal CHD

The DTH is completed for all eligible fatal events. A worksheet and the Surveillance Event Inventory/Linkage Summary (SXI) Form were used locally to monitor selection and completion of investigation forms. One or more of the following data forms may have been also completed: Hospital Record Abstraction (HRA) Form, Stroke (STR) Form (for cohort members only), Informant Interview (IFI) Form, Physician Questionnaire (PHQ), and the Coroner/Medical Examiner Report (COR) Form. Autopsy reports for cohort members are copied. All forms were provided on desktop and laptop computers and available for direct data entry. A list of all forms and instructions are located in Appendix IX

Some proportion of fatal events, either in-hospital or out-of-hospital, are coroner/medical examiner cases. This means that the county coroner or state medical examiner has performed an investigation of the circumstances of death in order to ascertain that the causes were natural. In this case, the coroner/medical examiner signs the death certificate. In general, the coroner/medical examiner takes cases of unexpected death where no physician was in attendance during the 24 hours prior to death. During his investigation, the coroner/medical examiner may or may not perform an autopsy. Any death where a legal question is likely to arise (e.g., after surgery, during an automobile accident, etc.) will probably be a coroner/medical examiner case. If the death is certified by a coroner or medical examiner, the Coroner/Medical Examiner Report Form was completed; the data was entered into the database at the field center, and later transferred to the CC.

Medical examiner and coroner reports are generally stored in their offices. The entirety of the documents generally requires full review in order to complete the Coroner/Medical Examiner

Report Form. Whatever could be retrieved from the records of these inquiries was used to answer questions on the Coroner/Medical Examiner Form as to whether the document is called a report, an investigation, findings, or a summary.

Procedures for the investigation of fatal events in cohort members are described in Section 9. Briefly, a Cohort Eligibility Form and Death Certificate Form are completed for a fatal event occurring in a cohort member. A Coroner's Form was completed if the death is certified by a coroner/medical examiner, and the autopsy report copied and sent to the Coordinating Center if an autopsy was performed.

3.1.1 In-Hospital CHD Deaths

In-hospital deaths, which include deaths on the wards, in the ICU, CCU, or operating room, were identified by screening either the hospital discharges or the death certificates. Both the Hospital Record Abstraction Form (HRA), and the Death Certificate Form were completed if the in-hospital death is eligible for study, either as a hospitalized CHD event (according to the CHD eligible discharge codes and sampling fractions specified in Section 2.2.2) or as a CHD eligible fatal event (according to the cause of death codes and sampling fractions specified in Section 2.3.1).

If the in-hospital death was initially identified from the death index, the hospital may occasionally lie outside the catchment area for the ARIC community. In this was the case, this fact was recorded on the Death Certificate Form and no attempt was made to obtain the hospital record.

Persons who, upon record abstraction were found to have been admitted without vital signs are treated as out-of-hospital deaths (as defined in Section 3.1.2). Only the administrative data of the Hospital Record Abstraction Form, along with information on discharge diagnoses, chest pain, and history of CHD were recorded in such cases. If the death was first identified from the death index and the death certificate indicated "dead on arrival", an attempt was made to find the hospital record to verify this information.

As of October 2010, clarification to the rule was established. It was decided that for all in-hospital eligible CHD deaths both the HRA and DTH are required, even if the hospitalization is less than 24 hours. Previous to this decision there were some sites that were not abstracting deaths less than 24 hours.

If the hospital record indicated that the person was transferred within the study area directly from another acute care hospital, the record for the other hospitalization was found and abstracted onto another Hospital Record Abstraction Form, provided the hospital discharge index contains an eligible ICD-9 discharge code regardless of day of discharge.

3.1.2 Out-of-Hospital CHD Deaths

CHD deaths occurring outside of regular acute care hospitals were categorized as "out-of-hospital CHD deaths". This includes deaths in nursing homes and other chronic care facilities. It also includes persons dead on arrival at acute care hospitals, dying in outpatient departments or emergency rooms, or admitted without vital signs. For purposes of defining out-of-hospital death, "no vital signs" means no pulse rate or no systolic blood pressure. A person admitted on a respirator who never had a pulse rate or a systolic blood pressure off the respirator was also considered an out-of-hospital death.

For out-of-hospital deaths (except in Washington County prior to 1995) information was sought from the decedent's family and physician(s); ideally this was completed one year after death. Prior to contacting the informant or the physician, it was ascertained whether the deceased was a member of the ARIC cohort. If the deceased was a cohort member, the cohort procedures for investigating deaths described in Section 9 were followed instead of the community surveillance procedures.

The family member was contacted for an interview, and the physician was sent a questionnaire. Whenever possible, the informant was the spouse or another family member of the decedent. Also, the informant may be someone else who witnessed the death. Some death certificates contain the names of the spouse and a witness.

First an attempt was made to contact and interview the spouse or a first-degree relative (i.e., son, daughter, or sibling) of the decedent, or someone else who lived with the decedent. If another person witnessed the death, this person was interviewed as well. Using name and address information from the death certificate, an attempt was made to find the informant's telephone number in either the regular or the reverse ("criss-cross") telephone directory. If the telephone number was available, a Format 1 letter (Appendix II) was sent.

If a telephone number could not be found, a Format 2 letter (Appendix II) was sent asking the informant to return a telephone number on an enclosed form in a self-addressed, stamped envelope (Format 3: Appendix II) to the Surveillance Supervisor at the Field Center. These letters included a request to the U.S. Post Office for address correction and were sent with both the interviewer and Field Center Principal Investigator's signatures.

After enough time passed for the Format 1 letter to arrive or a reply form to be received, the interview was conducted over the telephone or in person, using the Informant Interview Form. If a Format 2 (Appendix II) letter was sent and no reply was received in two weeks, another such letter was sent by registered mail. If no reply was received, a Format 4 letter (Appendix II) was sent to next-door neighbor(s) (identified through the reverse telephone directory) to request information on the whereabouts of the potential informants. A reply was requested on a self-addressed, stamped postcard (Format 5: Appendix II) to the Surveillance Supervisor at the Field Center. Format 2 and Format 4 letters were also sent when a telephone number was

initially available, but attempts at telephone contacts with informants were unsuccessful. If no reply is received from the neighbors, no further effort was attempted.

When the death was witnessed by someone other than a member of the decedent's family, both a family member and the witness were interviewed. In such a case, the information from both interviews was recorded on separate Informant Interview Forms. Up to three (the three best) Informant Interview Forms may have been completed for a given event.

A successful informant interview included the following information: description of general health, prior history of CHD, description of symptoms, presence of anyone nearby when death occurred, and timing from symptom onset to collapse. Age and risk factors (such as smoking, diabetic) need not be included in the informant interview narrative as this information could bias the MMCC judgment for event classification.

Information was sought from physicians by sending the Physician Questionnaire. One questionnaire was sent to the physician who signed the death certificate, if he/she was not the medical examiner. From the informant interview, an attempt was made to identify the decedent's usual physician and/or a physician who attended the decedent for heart disease during the four weeks prior to death. A questionnaire was sent to these physicians (if any, and if different from the one signing the death certificate). Sample cover letters were provided in Appendix II for each of these physician contacts (Formats 7 and 8, respectively). Up to two (the two most complete) Physician Questionnaires may have been entered into the ARIC database for a given event.

If there was no response after four weeks of the initial mailing to a physician, a follow-up letter and another copy of the Physician Questionnaire was sent. If there is no response after eight weeks of the initial mailing, the physician was contacted by telephone. On occasion, prior to returning the Physician Questionnaire (or prior to answering questions over the telephone), the physician requests a release form signed by the informant, which can be modeled after the Release-of-Information Form for physicians (Format 9: Appendix II) or for nursing homes (Format 6: Appendix II).

If the patient had no physician or no knowledgeable physician can be identified, and the patient's medical record or emergency room record was accessible, then it was permissible for an ARIC abstractor to complete the physician questionnaire using the record.

If the fatal event was a coroner's or medical examiner's case, his/her report is abstracted onto the Coroner Form. The medical examiner/ coroner may require a Release of Information Form. If the decedent died in a nursing home, nursing home personnel are asked to complete a Physician Questionnaire based on the nursing home record. Centers may offer to assist with abstraction if this would be helpful. The nursing home may require the family informant to provide a Release-of-Information Form.

If information provided by the informants or physicians indicates that a person who died out-of-hospital was admitted to a catchment area hospital within 28 days prior to death for MI or heart surgery, an attempt is made to locate the hospital record. If the discharge diagnoses include an ARIC screening code, regardless of day of discharge, the chart is abstracted onto the Hospital Record Abstraction Form.

If neither an Informant Interview nor a Physician Questionnaire form can be completed, then the Hospital Discharge Indices from eligible hospitals were checked for the period covering 28 days before death. If an ICD code eligible hospitalization was found, a HRA was abstracted, regardless of discharge day.

Procedures for the investigation of out-of-hospital deaths occurring in cohort members are described in Section 9. Procedures for contacting informants are similar to those described above, except that the letters refer to the decedent's participation in the ARIC Study.

3.2 Procedure for Hospitalized MI

The Hospital Record Abstraction Form was used to abstract events meeting ARIC eligibility criteria for age residence, date, hospital discharge code, and sampling fraction (Section 2.2.2). If a patient was discharged alive without an ICD-9 410 or 411 or ICD-10 I20.x, I21.x, I24.x discharge codes and with no more than one ECG taken and no abnormal cardiac enzymes, only the administrative information on the Hospital Record Abstraction Form is completed. Otherwise, the entire form is completed.

If 12-lead ECGs were taken during the admission, up to three ECGs are copied, scanned and sent to the ECG Reading Center on a regular basis (approximately monthly). Instructions on preparing and sending ECGs can be found in Appendix IV. The ECG Reading Center transmits the coded ECG results to the Coordinating Center on a regular basis (approximately monthly).

There are a few cases in which the ICD code was recorded incorrectly, so that a code on the diagnostic index meets the ARIC criteria but none of the diagnoses recorded on the discharge summary of the medical record meet the study criteria. The HRA Form was still completed in such a case, but is not considered eligible.

Prior to abstracting a record from a hospital for ARIC, information was collected on the normal ranges used for each of the cardiac enzymes abstracted. Many hospitals report use of more than one upper limit of normal for a particular enzyme, for example, when a different laboratory is used for determinations at night or on weekends.

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.

3.2.1 Clarifications to protocols for abstracting transfers

In 2006, the following clarification to the protocol for abstracting transfers was established. The outline below for identifying community surveillance eligible hospitalizations is an extension of the existing protocol of selecting transfers and hospitalizations already in place. This clarification is a supplement to the surveillance protocol in order to capture hospitalizations at outlying hospitals that accept Emergency Department transfers from Washington County Hospital that are currently missed because the transfers were not from inpatient admissions.

- The new protocol was initiated in 2006 and retroactive to event year 2000.

  Lists of Emergency Department discharges (without inpatient admission and discharge) from Washington County Hospital to other acute care facilities will be reviewed. Eligibility will be determined using the algorithm for inpatient admissions using the emergency department discharge ICD-9-CM codes of 402, 410-414, 427, 428, 518.4 OR ICD-10-CM codes of I11.x, I20.x, I21.x, I22.x, I24.x, I25.x, I46.x, I47.x, I48.x, I49.x, I50.x, J81.0, R00.1 sampling fraction.

- The acute care facilities of interest will be hospitals accepting more than 3 (≥ 4) eligible transfers a year or hospitals where inpatient transfer abstraction is already in place. Currently these include Johns Hopkins Hospital, Saint Joseph's Hospital, Sinai Hospital, Union Memorial Hospital, Washington Adventist, and Washington Hospital Center. Ongoing event identification and investigation of inpatient admissions at University of Maryland Hospital and Martinsburg Veterans Administration Hospital is already in place and is not affected by this protocol clarification.

- The sampling of Emergency Department transfers is based on and consistent with current procedures from identifying and investigating inpatient transfers. Selection of patients discharged from the Emergency Department to be investigated will be determined by their Emergency Department discharge ICD-CM code, gender, residence, and Emergency Department discharge/transfer date. Emergency Department discharges that do not have an eligible inpatient hospital discharge ICD-CM code (ICD-9: 402, 410-414, 427, 428, 518.4, OR ICD-10: I11.x, I20.x, I21.x, I22.x, I24.x, I25.x, I46.x, I47.x, I48.x, I49.x, I50.x, J81.0, R00) at the receiving hospital should not be abstracted and are deemed not eligible. However, if the case does have an eligible inpatient discharge code, it should be abstracted regardless of date of discharge from the hospital. The Emergency Department discharge date determines the date eligibility for the cases.

- Medical records from the accepting hospital for selected Washington County Hospital Emergency Department patients will be requested and abstracted using existing hospital record abstraction forms. Information from the Emergency Department visit that initiated this investigation should be reviewed and abstracted using the HRA form similar to an initial inpatient hospitalization. Because of the relatively short duration of Emergency Department stays, the abstractors need only to select the first and last electrocardiogram for coding. An additional third electrocardiogram (normally selected for inpatient admissions on the third day) is not needed.

- Because the existing protocol dictates that all hospitalizations reported by cohort participants are to be pursued, regardless of location, it is unlikely that transfers from Emergency Department admissions without inpatient stays will present a major problem. If in reviewing lists of Emergency Department admissions (without inpatient stays) at Washington County Hospital it is apparent that there are cohort participants that transferred to another inpatient facility but that inpatient stay was not abstracted, the records for that inpatient stay should be obtained and abstracted. The Emergency Department record from Washington County Hospital for cohort participants does not need to be abstracted since all inpatient stays are abstracted.

3.3 Summary of CHD Event Investigations

The following scheme summarizes the forms completed for eligible surveillance events:

1) Out-of-hospital CHD death, as defined in Section 3.1.2 (died in outpatient department, includes DOA, ER admitted without vital signs)
    a) Death Certificate Form, Surveillance Event Eligibility Form (optional).
    b) Up to two Physician Questionnaires and three Informant Interview Forms.
    c) Coroner Form on all coroner/medical examiner's cases and Hospital Record Abstraction Form on cases admitted to a catchment area hospital in past 28 days with heart conditions meeting ARIC screening codes regardless of day of discharge.

2) *Hospital CHD deaths, no vital signs in-hospital
    a) DTH, SEL (optional).
    b) First part of HRA, CFD, CHI, CEL (if cohort see Section 9 for more information)
    c) PHQ, IFI, COR.

3) *Hospital CHD death, vital signs sometime in hospital
    a) DTH, HRA (full) (CFD, CHI, CEL (if cohort, see section 9 for more information).

4) *Hospitalized CHD case, discharged alive
    a) HRA (full) CFD, CHI, CEL (if cohort, see section 9 for more information).

*If a patient also transferred to or from a catchment area hospital, complete an additional Hospital Record Abstraction form.

3.4 Corrections of Erroneous Event Investigation Procedures

A fatal or hospitalized CHD event may be identified by surveillance procedures (death certificates or hospital discharge indices) and investigated as a surveillance event, then discovered at a later time to have occurred in a cohort member. In the case of a hospitalized event, a second Hospital Record Abstraction Form is completed independently by a second abstractor (see Section 8). Twelve-lead ECGs have to be copied and sent to the Minnesota ECG Reading Center for coding. In addition, certain surveillance forms have to be replaced by cohort forms, certain items on other forms changed, and possibly additional forms appropriate for cohort members completed. Specifically, the Cohort Eligibility Form must be completed. Additional forms required for cohort members have to be indicated on the Death Certificate Form if the death occurred in an out-of-catchment area hospital. The Physician Questionnaire and Informant Interview Form remain unchanged. If an eligible event has been investigated erroneously as a cohort event, the Cohort Eligibility Form must be deleted. If the event investigated was a stroke, the Stroke Form must be deleted.

3.5 Procedures for Sending Duplicate Material for MMCC Review

Hospital discharge summary, history and physical and cardiac consultation, if available, are sent to the MMCC for event review. The CC assembles review packets for MMCC members.

For the following type of events, abstractors at each site will send the duplicated material to the CC without request:

- All hospitalized cohorts that are non-skip-outs (a skip-out case is defined as a case where the patient was discharged alive without an ICD-9 410, 411 OR ICD-10 code I20.x, I21.x, I24.x discharge code and with no more than one ECG taken and no abnormal cardiac enzymes)
- All who transferred with ICD-9 Code 410 , 411, OR ICD-10 code I20.x, I21.x, I24.x
- All CHD-related deaths in Community or in Cohort Surveillance

CC will make special request for duplicate material for other events.

For each of these events a PDF is prepared. Included in the PDF file is one of the following, ranked in priority:

- ✓ Discharge summary (EXCEPT items like discharge instructions, hospital/doctor follow-up, when to call the doctor, go to the ER or when to be concerned)
- ✓ Progress note of last physician and cardiac consultation
- ✓ Progress note of last physician and history and physical

For hospitals where only paper copies of records are available, the field centers scan these materials with the completed "Checklist for Hospital Event Materials" included as the first page and transmit an electronic version to the coordinating center. Please refer to the "Instructions for Sending Hospital Records to the CC (Duplicate Materials)" (Appendix X) document for step-by-step details. Note that death certificates are no longer sent because the DTH Form has been entered into the data entry system.

When a significant number of medical records have been prepared, they are put in numeric order and sent to the CC via Liquid Files.

If CC requires hospital records for materials not sent for a particular patient's event, such as cases of hospitalizations to determine possible linkages, these are also prepared and sent in a similar fashion, as soon as possible.

4.0 DIAGNOSTIC CRITERIA

4.1 Fatal Coronary Heart Disease (CHD)

4.1.1 Definite Fatal Myocardial Infarction (MI)

Must meet BOTH criteria below:

1) No known non-atherosclerotic or non-cardiac atherosclerotic process or event that was probably lethal.

2) Definite hospitalized MI within four weeks of death; use criteria in Section 4.2.2 for Definite Hospitalized MI.

4.1.2 Definite Fatal CHD

Must meet ALL of the following criteria:

1) Lack of sufficient evidence to diagnose Definite Fatal MI according to the criteria given in Section 4.1.1.
2) No known non-atherosclerotic or non-cardiac atherosclerotic process or event that was probably lethal.

3) Presence of one or both of the following findings:
   a) A history of chest pain within 72 hours of death;
   b) A history of ever having had chronic ischemic heart disease such as coronary insufficiency or angina pectoris.

4.1.3 Possible Fatal CHD

Must meet ALL of the following criteria:

1) Lack of sufficient evidence to diagnose Definite Fatal MI or Definite Fatal CHD according to the criteria in Sections 4.1.1 and 4.1.2.

2) No known non-atherosclerotic or non-cardiac atherosclerotic process or event that was probably lethal.

3) Death certificate with consistent underlying cause of death, i.e., ICD9 codes: 410-414, 427.5, 429.2, and 799.

4.1.4 Non-CHD Death

All deaths that do not meet the above criteria for Definite Fatal MI, Definite Fatal CHD, or Possible Fatal CHD.

4.1.5 Chronology of Death

The time interval from onset of acute symptoms to time of death is recorded, where possible, for all CHD deaths. For out-of-hospital deaths, their time interval is ascertained by their MMCC reviewer and recorded on the final diagnosis form.

4.1.6 Limitation of Activity

For out-of-hospital CHD deaths it is noted whether the decedent's activity was limited in the month before death because of sickness or illness.

4.2 Hospitalized Myocardial Infarction (MI)

4.2.1 Introduction

The aim of the ARIC Study is to establish a well-standardized process for the identification of hospitalized coronary disease of an acute nature, allowing for valid inter-community and longitudinal comparisons. Mild and chronic manifestations of ischemic heart disease, such as angina pectoris, congestive heart failure, and arrhythmias are not identified as target diagnoses in community surveillance but are included in the screening process to aid in the identification of acute MI. So-called silent infarctions are excluded in community surveillance.

The criteria presented are based on two source documents: the findings of the CCSP Pilot Study and the results of the Minnesota Heart Survey, as well as other surveillance studies. The diagnostic criteria presented here approximate those contained in the above-mentioned documents. The differences in diagnostic criteria are the lack of a duration requirement for cardiac pain, and the use of the more sensitive and specific CK-MB and LDH isoenzymes and inclusion of troponin proteins. The description of diagnostic criteria to follow includes troponins in the category of “cardiac enzymes” even though they are technically structural proteins and not enzymes. The combinations of pain, ECG and enzyme categories required for each diagnosis below are approximately the same as those contained in the above-mentioned documents.

It is recognized that aggressive treatment of early signs and symptoms of acute coronary events, such as coronary artery bypass graft or thrombolytic therapy, may prevent the development of the full diagnostic syndrome. In such cases, it may be difficult to diagnose the event accurately. The use of such modalities is recorded and subject to data analysis, but not employed in the criteria for diagnosis.

4.2.2 Definite Hospitalized MI

Must meet one or more of the following criteria:

1) Evolving diagnostic ECG pattern (ED1 - ED7, defined below);
   OR
2) Diagnostic ECG pattern (D1 or D2) and abnormal enzymes (both defined below);
   OR
3) Cardiac pain (defined below) and abnormal enzymes;
   AND
   a) Evolving ST-T pattern (EV1 through EV8)
   OR
   b) Equivocal ECG pattern (E1 through E4)

4.2.3 Probable Hospitalized MI

Must meet one or more of the following criteria in the absence of sufficient evidence for Definite Hospitalized MI:

1) Cardiac pain and abnormal enzymes
   OR
2) Cardiac pain and equivocal enzymes and either:
   a) Evolving ST-T pattern
   b) Diagnostic ECG pattern
   OR
3) Abnormal enzymes and evolving ST-T pattern

4.2.4 Suspect hospitalized MI

Must meet one or more of the following criteria in the absence of sufficient evidence for Definite or Probable Hospitalized MI:

1) Abnormal enzymes
   OR
2) Cardiac pain and incomplete enzymes and either
   a) Diagnostic ECG pattern
   b) Evolving ST-T pattern

OR

3) Cardiac pain and equivocal enzymes

OR

4) Equivocal enzymes and either
   a) Diagnostic ECG pattern
   b) Evolving ST-T pattern
   c) Equivocal ECG pattern

The criteria for Definite, Probable, Suspect, and No Hospitalized MI are summarized in Table 4.1.

4.2.5 Definition of Cardiac Pain

Pain having both the following characteristics:

1) It occurs anywhere in the anterior chest, left arm or jaw

AND

2) Absence of a definite non-cardiac cause of pain. (If there is evidence of a non-cardiac cause, the pain diagnosis is downgraded by computer to "not present".)

Table 4.1 Summary of ARIC Diagnostic Criteria for Hospitalized MI

Cardiac Pain	ECG Finding	Enzymes	Diagnosis
Present	Evolving Diagnostic ECG Pattern	Abnormal	Definite MI
		Equivocal	Definite MI
		Incomplete	Definite MI
		Normal	Definite MI
	Diagnostic ECG Pattern	Abnormal	Definite MI
		Equivocal	Probable MI
		Incomplete	Suspect MI
		Normal	No MI
	Evolving ST-T Pattern	Abnormal	Definite MI
		Equivocal	Probable MI
		Incomplete	Suspect MI
		Normal	No MI
	Equivocal	Abnormal	Definite MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
	Absent, Uncodable, or Other	Abnormal	Probable MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
Not Present, Unknown or Missing	Evolving Diagnostic ECG Pattern	Abnormal	Definite MI
		Equivocal	Definite MI
		Incomplete	Definite MI
		Normal	Definite MI
	Diagnostic ECG Pattern	Abnormal	Definite MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
	Evolving ST-T Pattern	Abnormal	Probable MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
	Equivocal ECG Pattern	Abnormal	Suspect MI
		Equivocal	Suspect MI
		Incomplete	No MI
		Normal	No MI
	Absent, Uncodable, Or other	Abnormal	Suspect MI
		Equivocal	No MI
		Incomplete	No MI
		Normal	No MI

4.2.6 Definitions of Electrocardiographic Criteria

The ECG series is assigned the highest category for which criteria are met, i.e., evolving diagnostic is greater than diagnostic is greater than evolving ST-T patterns are greater than equivocal is greater than other. The ECGs are coded using Minnesota Code (Manual 5, Electrocardiography, Appendix E).

4.2.6.1 Evolving Diagnostic Q Waves

An evolving Diagnostic Q Wave pattern is defined as an evolving pattern on serial ECGs of ECG changes within lead groups, i.e., anterior (V1 - V5); lateral (I, aVL, V6); or inferior (II, III, aVF). Two or more ECG recordings during the hospitalization are needed for this classification.

4.2.6.2 Evolving Diagnostic ECG (Judged within lead group)

ED1 through ED7 cannot be assigned if a 7-1-1 code is present. ED2 through ED7 cannot be assigned if a 7-2-1 or 7-4 code is present.

ED1. If the following condition is met for any lead group, then ED1 is positive. Either no Q-code or a 1-2-6 code in reference ECG followed by a record with a Diagnostic Q-code in the same lead group OR any code 1-3-x or 1-2-8 in reference ECG followed by a record with any code 1-1-x in the same lead group and there is no 7-1-1 code in either ECG, then ED1 is positive.

ED2. If an Equivocal Q-code in some lead group of reference ECG is followed by a record with a Diagnostic Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major ST-segment Depression in reference ECG, but followed by a record with a Major ST-segment Depression in that same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED2 is positive.

ED3. If an Equivocal Q-code in some lead group of reference ECG is followed by a record with a Diagnostic Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major T-wave Inversion in reference ECG, but followed by a record with a Major T-wave Inversion in the same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED3 is positive.

ED4. If an Equivocal Q-code in some lead group of reference ECG is followed by a record with a Diagnostic Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no ST-segment Elevation in reference ECG, but followed by a record with the ST-segment Elevation in that same lead group, and there are not 7-1-1, 7-2-1 or 7-4 codes in either ECG, the ED4 is positive.

ED5. If there is no Q-code or a 1-2-6 code in some lead group of reference ECG is followed by a record with an Equivocal Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major ST-segment Depression in reference ECG, but followed by a record with a Major ST-

segment Depression in that same lead group, and there are not 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED5 is positive.

ED6. If there is no Q-code or a 1-2-6 code in some lead group of reference ECG is followed by a record with an Equivocal Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no Major T-wave Inversion in reference ECG, but followed by a record with a Major T-wave Inversion in that same lead group, and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED6 is positive.

ED7. If there is no Q-code or a 1-2-6 code in some lead group of reference ECG is followed by a record with an Equivocal Q-code in the same lead group, AND if there is also a lead group not necessarily the same as for the Q-code change, in which there is no ST-segment Elevation in reference ECG, but followed by a record with an ST-segment Elevation in that same lead group and there are no 7-1-1, 7-2-1, or 7-4 codes in either ECG, then ED7 is positive.

4.2.6.3 Evolving ST-T Pattern (Judged within lead group)

This diagnosis cannot be assigned if a 7-1-1 or 7-2-1 or 7-4 code is present.

EV1 Either 4-0 (no 4-code), 4-4 or 4-3 in reference ECG followed by a record with 4-2 or 4-1-2 or 4-1-1; OR 4-2 in reference ECG followed by a record with 4-1-2; OR 4-2, 4-1-2 or 4-1-1 in reference ECG followed by a record with 4-0, 4-4 or 4-3; OR 4-1-2 in reference ECG followed by a record with 4-2,

PLUS

no Q-code in both the reference ECG and the follow-up ECG.

EV2 Either 4-2 or 4-1-2 in reference ECG followed by a record with 4-1-1 OR 4-1-1 in reference ECG followed by a record with 4-2 or 4-1-2,

PLUS

no Q-code in both the reference ECG and the follow-up ECG.

EV3 Either 5-0, 5-4 or 5-3 in reference ECG followed by a record with 5-2 or 5-1 OR 5-2 or 5-1 in reference ECG followed by a record with 5-0, 5-4 or 5-3,

PLUS

no Q-code in both the reference ECG and the follow-up ECG.

EV4 Code 5-2 in reference ECG followed by a record with 5-1 OR 5-1 in reference ECG followed by a record with 5-2,

PLUS

no Q-code in both the reference ECG and the follow-up ECG.

EV5 Code 9-0 in reference ECG followed by a record with 9-2 OR 9-2 in reference ECG followed by a record with 9-0,

PLUS

no Q-code in both the reference ECG and the follow-up ECG.

EV6 Code 4-1-1 in reference ECG followed by a record with 4-1-1 OR 4-1-1 in reference ECG followed by a record with 4-1-1,

PLUS

no Q-code in both the reference ECG and the follow-up ECG.

EV7 Code 5-1 in reference ECG followed by a record with 5-1 OR 5-1 in reference ECG followed by a record with 5-1,

PLUS

no Q-code in both the reference ECG and the follow-up ECG.

EV8 Code 5-2 in reference ECG followed by a record with 5-2 OR 5-2 in reference ECG followed by a record with 5-2,

PLUS

no Q-code in both the reference ECG and the follow-up ECG.

Note: EV6-8 do not apply to community surveillance.

4.2.6.4 Diagnostic ECG

D1 (Diagnostic Q wave)
An ECG record with any Diagnostic Q-code (Minn. code 1-1-1 through 1-2-5 plus 1-2-7).

D2 An ECG record with ST-segment elevation code 9-2 PLUS (T-wave inversion code 5-1 or 5-2 in the absence of 7-2-1 or 7-4).

4.2.6.5 Equivocal ECG

E1 (Equivocal Q wave)
An ECG record with an Equivocal Q-code [(Minn. code 1-2-8 in the absence of 7-2-1 or 7-3) or (any 1-3 code)].

E2 An ECG record with ST-segment depression (code 4-1-X or 4-2 or 4-3 in the absence of 7-2-1 or 7-4).

E3 An ECG record with T-wave inversion (code 5-1 or 5-2 or 5-3 in the absence of 7-2-1 or 7-4).

E4 An ECG record with ST-segment elevation code 9-2 (in the absence of 7-2-1 or 7-4).

4.2.6.6 Other ECG

Reference ECG coded 7-1-1.
Any ECG coded 7-1-1.
OTHERWISE Normal ECG(s), defined as 1.0 in "clear" field of all ECGs.
Other findings including 1-2-6.

4.2.6.7 Uncodable ECG

U1 Technical errors coded 9-8-1 by Minnesota Code.

4.2.6.8 Absent ECG

A1 No ECG available for coding.

4.2.6.9 Minnesota Coding Procedures

The following ECG tracings are identified:

1) The first codable ECG after admission;
2) The last codable ECG recorded before discharge; and
3) The last codable ECG recorded on day 3 (or the first ECG thereafter) following admission or an in-hospital event.

Photocopies of the hospital ECGs are sent electronically to the Minnesota Coding Center in Minneapolis for Minnesota Coding, using the Minnesota Coding for hospitalized ECGs shown in Appendix O of Manual 5. Each ECG is read one time blinded. Unlike for cohort, serial change rules are not applied. Minnesota Code criteria are in Appendix E of Manual 5.

In 2013-2014, the Minnesota Coding Center created a new computer processing system for coding ECGs using REDCap and SAS. The new system was successfully validated by comparing a random sample of ECG records newly entered into REDCap/SAS with the same records that had been processed on the old computer system. As of December 1, 2014, the Coding Center has been transmitting via secure FTP production data from this new REDCap/SAS system to the Coordinating Center for automatic upload data management-system (DMS).

Starting in 2016, Wake Forest ECG reading center (EPICARE) took over the reading of ECGs from the Minnesota ECG Reading Center. Efforts were made to ensure comparability between the two systems. EPICARE employed the same coding procedures as used previously by the Minnesota Coding Center.

4.2.7 Definitions of Cardiac Biomarker Criteria

All pertinent biomarker results (as defined below) recorded on days 1 through 4 after hospital admission of an in-hospital CHD event are abstracted. Information on non-ischemic cause for

elevated biomarkers is abstracted exclusively from the discharge summary on the medical chart.

4.2.7.1 Abnormal Cardiac Biomarkers

Biomarkers are classed as "abnormal" if any biomarker values recorded meet any of these four criteria:

1. a) CK-MB is "present" (if laboratory uses the criterion of "present" or "absent" without reporting a more specific value) or CK-MB is at least twice the upper limits of normal (if the laboratory gives a normal range) or, if no normal range is given, the CK-MB (heart fraction) is greater than or equal to 10% of the total CK value or, if the upper limits of normal is zero and the CK-MB is positive,

   AND

   b) There is no known non-ischemic cause (cardiac surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value.

2. a) The ratio LDH1 : LDH2 **>** 1, or if LDH2 is missing and LDH1 is at least twice the upper limit of normal,

   AND

   b) There is no evidence of hemolytic disease.

3. a) Total CK and total LDH are both at least twice the upper limit of normal. (These increases do not have to occur on the same day.)

   AND

   b) There is no known non-ischemic cause (surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value and no evidence of hemolytic disease.

4. a) Troponin is "present" (if laboratory uses the criterion of "present" or "absent" without reporting a more specific value) or is at least twice the upper limits of normal,

   AND

   b) There is no known non-ischemic cause (surgery, severe muscle trauma, rhabdomyolysis) for the elevated enzyme value and no evidence of hemolytic disease.

4.2.7.2 Equivocal Cardiac Biomarkers

Biomarkers are classed as "equivocal" if the criteria for abnormal biomarkers are not met and if:

1. Either total CK or total LDH are at least twice the upper limits of normal.

   OR

2. Both total CK and total LDH are between the upper limits of normal and twice the upper limits of normal. (These increases do not have to occur on the same day.)

   OR

3. CK-MB is "weakly present" or between the upper limits of normal and twice the upper limits of normal or 5% ≤ CK-MB < 10%.

OR

4. If LDH1 is present and LDH2 is missing, and LDH1 is between the upper limits of normal and twice the upper limits of normal.

OR

5. Troponin is "weakly present", or troponin levels are between the upper limits of normal and twice the upper limits of normal.

4.2.7.3 Spurious Biomarkers

If biomarkers met one of the following criteria, the "abnormal" biomarkers were considered spurious, and were downgraded to "equivocal".

1. If the first abnormal CK-MB is at or after the date of trauma, cardiac procedure or rhabdomyolysis.

2. If LDH1/LDH2 is abnormal and there is evidence of hemolytic disease.

3. If both total CK and total LDH are abnormal, and there is evidence of hemolytic disease, or the first abnormal total CK/total LDH is at or after the date of trauma, cardiac procedure or rhabdomyolysis.

4. If the first abnormal troponin is at or after the date of trauma, cardiac procedure or rhabdomyolysis.

5.0 EVENT CLASSIFICATION-DETERMINING WHICH EVENTS GET MMCC REVIEW

5.1 Hospitalized Events

Hospitalized events are classified using a computer algorithm based on criteria given in Section 4.2. Most non-linked hospital events and some linked events have an automatic computer classification for MI that is considered final. Linked and non-linked hospitalized events that require MMCC review before final hospitalized MI diagnosis (Section 5.1.1) include the following:

Hospitalized events (linked to at least one other eligible hospitalization within 28 days or non-linked) if:

a) The final computer diagnosis is "Definite MI" but discharge codes from hospitalizations for the event do not include ICD-9 codes 410 , 411 OR ICD-10 I20.x, I21.x, I24.x. (Note: Computer "Definite MI" + ICD-9 410-411 OR ICD-10 I20.x, I21.x, I24.x discharge codes lead to automatic classification of Definite MI.)

b) The computer diagnosis is "No MI" and hospital discharge ICD-CM codes from at least one of the hospitalizations for the event include ICD-9 410 OR ICD-10 I20.x, I21.x. (Note: Computer "No MI" + No 410 OR I20.x, I21.x discharge code from any hospitalization in the event lead to automatic classification of "No MI.")

This review of linked and non-linked hospitalizations is done, when needed, by one MMCC member for hospitalized MI diagnosis.

Special Automatically Classified Cases (No MMCC Review required):
a) If no chart can be located for all hospitalizations for the event, an automatic classification of "Unclassifiable" is given.

b) No discharge codes for any hospitalizations for the event contains 410-411, I20.x, I21.x, I24.x codes, there is no mention of acute MI in discharge summary, there is no more than one ECG, and there is no Cardiac Enzyme above the normal limits, an automatic classification of "No MI" is given. (Note: These are the cases that skip out of the HRA form at question 20.)

c) For cohort participants, events occurring in year 2019 and afterwards, all non-fatal, non-linked events where the computer diagnosis is either 'NO-MI' or 'SUSPMI" and there is no MI ICD-10 discharge code (I20.x, I21.x), the event's final classification is determined by the computer classification algorithm and such cases do not go for MMCC review. This rule went into effect May 2020.

5.2 In-Hospital Deaths (MI and Death Classification)

Non-linked in-hospital deaths are reviewed for death diagnosis by two MMCC reviewers (after final MI classification by computer algorithm) and adjudicated by a third reviewer if needed. Linked in-hospital deaths (including >28 day linked deaths) are reviewed for death and MI if needed by one MMCC reviewer. The following cases, however, need no MMCC review.

1) Those with ICD codes for underlying cause of death 410-414 or 427.5 or 429.2 or 799, and a final computer diagnosis of "Definite MI," and the date of death and date of MI are within 28 days. The corresponding ICD-10 underlying cause of death codes are (I20-25, I46-49, I51.6, R99, J96) (Note: These cases are classified directly as "Definite Fatal MI" (Section 4.1.1).)

2) Those with ICD codes for underlying cause of death 410-411 or 427.5 or 429.2 , 799, I20-25, I46-49, I51.6, R99, J96 for which the final computer diagnosis of "Definite MI" could not be made according to ARIC criteria but who had pain of cardiac origin or a history of MI, angina pectoris, or coronary insufficiency. (Note: These cases are classified directly as "Definite Fatal CHD"
(Sections 4.1.2 and 4.1.3).)

3) Those with ICD-9 codes for underlying cause of death not including 410-414 or 427.5 or 429.2 or 799 or I20-25, I46-49, I51.6, R99, J96 for which the diagnosis of a Definite MI could not be made according to ARIC Criteria and
    1. No pain of cardiac origin, and
    2. No history of previous MI, angina pectoris or coronary insufficiency.

   (Note: These cases are classified directly as "Non-CHD death" (Section 4.1.4).)

5.3 Out-of-Hospital Deaths

All out-of-hospital deaths are reviewed by two members of the MMCC for death diagnosis except those with death certificate ICD-9 codes for underlying cause of death 410-414 or 427.5 or 429.2 or 799 (corresponding ICD-10 underlying cause of death codes are I20-25, I46-49, I51.6, R99, J96) and a catchment area hospital admission within 28 days with a final diagnosis of "Definite MI".

(Note: These cases are classified as "Definite Fatal MI.")

This review for death diagnosis is done after final MI classification, in case there is an eligible linked hospital admission within 28 days of death, and is done by two MMCC reviewers, then adjudicated by a third reviewer if there is no agreement between the two reviewers.

"Definite" and "Possible" CHD deaths are classified as to time from first symptoms to death.

5.4 Case Law Used by MMCC

An important function of the MMCC is to maintain complete records of any clarifications of ARIC diagnostic criteria required to reach diagnostic decisions. Such "case law" is systematized for convenient reference purposes and, when appropriate, incorporated into the ARIC diagnostic protocol. New case law is developed as a result of discussions with the MMCC and is approved by the Chair of the MMCC before adoption.

The following are general community and cohort surveillance rules established as case law.

Final Classification Rules:

1) When the death certificate is the only available document, and the ICD code is compatible with CHD (410-414, 427.5, 429.2, 799 or I20-25, I46-49, I51.6, R99, J96), then final ARIC classification of cause of death is usually “Possible CHD,” unless there is (I) a demonstrable coding error, or (II) an explicit non-CHD probable cause of death (such as malignant hypertension with renal failure). Analogously, for other ICD codes the classification of cause of death is usually “Non-CHD”.

2) The classification “Diagnosis Unclassifiable” will be reserved for cases not meeting ARIC criteria for CHD diagnosis, but in whom a specific non-atherosclerotic or non-cardiac atherosclerotic process cannot be identified.

3) In the case of conflicting information, the more inclusive cause of death (e.g., Definite CHD rather that Definite MI) is preferred.

4) Stroke qualifies as a "yes" answer to "a non-atherosclerotic or non-cardiac atherosclerotic process," if judged to be the probably cause of death.

5) If the decedent was debilitated from a potentially lethal non-atherosclerotic or non-cardiac process and had a related downhill course, with no symptomatic evidence of a recent coronary event, the death is classified a non-CHD.

6) In cases of "Definite" or "Probable MI," treated or aborted with tissue plasminogen activator (TPA) or similar clot-dissolving therapy, in which the patient dies of a direct complication or adverse effect of this therapy (i.e., hemorrhage), a final death classification of "Definite fatal CHD" should usually be assigned.

7) If a patient having an elective coronary artery bypass graft (CABG) dies as a complication of surgery, a final death classification of "Definite fatal CHD" should usually be assigned.

8) Generally, "hypertensive heart disease" will not be considered a "nonatherosclerotic cause of death".

<u>Chronology</u>

9) Death is assumed to have occurred at the time the patient stops breathing on his/her own and does not recover.

10) Symptoms are assumed to begin when the patient changes his/her activity. If symptoms come and go, the onset of symptoms is the time when they crescendo, leading to death.

11) In cases where timing of symptoms or death is unknown, the best estimate of the chronology is to be made.

12) . Symptoms of CHD leading to a hospital admission for CHD are usually considered to be related to a subsequent death from CHD, which occurs either before discharge or within 28 days of admission, whichever occurs first. Deaths of doubtful chronology admitted for the investigation or treatment of CHD are classified as deaths occurring in > 24 hours if admitted for at least 24 hours.

13) Unknown chronology of death of an institutionalized patient is usually considered to be < 24 hours.

Evidence

14) The relative credibility of conflicting witnesses is established from all the available evidence, i.e., there is no fixed hierarchy of credibility (such as physician overriding a lay informant). However, as a general rule:
    (i) A knowledgeable physician takes priority for medical history.
    (ii) A witness takes priority for events around death and timing of death.

15) A clinical history of arteriosclerotic heart disease (ASHD) or CHD counts as evidence of previous manifestations of CHD. If the event under consideration is the first manifestation of CHD, it does not qualify as a "history" of CHD.

16) A history of CABG or coronary angioplasty at any time prior to death is equivalent to a positive history of CHD.

17) For community surveillance events, a coroner's listing of causes of death (e.g. arteriosclerotic cardiovascular disease (ASCVD)) is interpreted only as findings at death and is not sufficient evidence, by itself, of past history. Other non-autopsy information, however, such as reported previous MI, may suffice as evidence of past history.

18) Autopsy evidence of old MI or other chronic CHD may not be used as evidence of a history of CHD in community surveillance events.

19) Angiographic evidence of coronary artery disease (CAD) mentioned on the chart as documented previously, is regarded as equivalent to recorded history of CHD when evaluating whether there was a past history of ischemic heart disease. However, evidence of CAD on catheterization at the time of the event under consideration is not a "history of CHD".

The following are case laws developed and approved by the MMCC specifically for use with cohort reviews.

1) For cohort surveillance events only, autopsy or unequivocal angiographic evidence of old MI or other chronic CHD counts as evidence of a history of CHD.

2) For cohort surveillance events only, autopsy reports may be used to judge cause of death and in most cases take precedence. Autopsy evidence of an acute MI or MI within 4 weeks may be used to answer "Yes" to "Was there a definite MI within 4 weeks of death." Such evidence includes acute coronary arterial thrombosis deemed sufficient to produce acute MI, even in the absence of evidence for acute myocardial tissue necrosis.

3) The diagnosis of "Definite MI" based upon "Evolving Diagnostic" ECG may be downgraded to the algorithm diagnosis which would be obtained if the ECG were

"Diagnostic," and the diagnosis of "Probably MI," based upon "Evolving ST-T" ECG may be downgraded to the algorithm diagnosis which would be obtained if the ECG were "Equivocal," but only if:

a. the clinical history is compatible with the downgraded diagnosis, and
b. the "Evolving Diagnostic" or "Evolving ST-T" ECG is suspicious because
(i) a non-MI cause of the ECG abnormality is identified, or
(ii) a hospital ECG interpretation contradicts it.

4) Changes in hospital pain or enzyme classification are permitted only in restricted circumstances based on strong clinical judgment. When a change in classification is made by a reviewer, the change should be reflected in the reviewer's answer to Item 7b (physician "preferred diagnosis"), not in the answers to Items 3, 5 or 6.

The ARIC protocol, not individual hospital physician's judgment, determines what exact enzyme level qualified as "elevated."

Reviewers may downgrade enzyme classification on the basis of an identified non-cardiac or non-ischemic cause, but only if enzyme review has not already occurred.

Reviewers may downgrade the pain classification on the basis of an identified non-cardiac or non-ischemic cause, but only if pain review has not already occurred.

Changes in pain or enzyme classification are permitted when the narrative summary clearly contradicts the pain, enzyme, or ECG information abstracted and an ARIC abstractor's error appear probable. If the discharge summary clearly says there was ECG evidence of st-segment elevation, you may use this in your preferred diagnosis.

An anginal equivalent (e.g. pulmonary edema, exhaustion, syncope) may be considered similar to chest pain in recording a "preferred diagnosis**."**

5) Upgrading the MI diagnosis in hospital deaths, e.g., from "No MI" to "Suspect" or "Definite MI," is not permitted on the basis of the judgment that had the patient lived, the enzymes or ECG would have provided sufficient evidence for the upgraded diagnosis.

6) Upgrading the MI diagnosis in cases of delayed hospitalization is not permitted on the basis of the judgment that had the patient been hospitalized earlier the enzymes or ECG would have provided sufficient evidence for the upgraded diagnosis.

7) When the discharge summary clearly indicates a perioperative MI and ARIC chest pain are "absent," a diagnosis of "Probable" (but not "Definite") "MI," may be assigned if the algorithm criteria for "probable" or "Definite MI" would have been met had chest pain been "present."

8) If a reviewer believes the ECG DX and the discharge summary were so discrepant as to suggest a missing ECG that might change the MI DX, the reviewer should not review the case and notify the Coordinating Center of the problem. The CC will check at the coding center as to whether the appropriate tracings were in the system. If this were done, and if the tracings were appropriately included and coded, then the procedures should mandate acceptance of the ECG criteria. On the other hand, if a request for a check should reveal missing ECG or a programming error, such could then be corrected as needed.

9) When considering whether a death event had a history of angina (Cohort Diagnosis Form (CDX) item 11), do not rely solely on report of Rose angina from the ARIC visit (as found on the ESF).

5.5 MMCC Final Diagnosis Forms

When a member of the MMCC reviews a case, he/she completes a MMCC Final Diagnosis Form (MDX/CDX) and returns it to the Coordinating Center for processing. The MDX form was used for community eligible events and the CDX form is used for evaluating events among cohort participants.

6.0 MEDICAL CARE ASSESSMENT

This section describes the assessment of medical care in community-wide surveillance. Medical care elements which are recorded only in cohort members include the participant's access to and use of providers for routine and special care, use of all prescription and over-the-counter medications, records of all hospitalizations for all reasons, records of all cardiovascular procedures and all cardiovascular diagnoses received, and detailed information on hospitalizations for CHD and stroke.

In community surveillance, medical care data collected includes information for out-of-hospital deaths, information abstracted from hospital records and information about the services provided in the community's acute care hospitals.

For out-of-hospital deaths, the Physician Questionnaire and Informant Interview Form allow collection of information about physician visits prior to the acute event, utilization of physician and emergency services during the acute event, history of hospital admission within one month prior to death, receipt of cardiopulmonary resuscitation, delay in receiving definitive care, use of nitrates and digitalis shortly before death, and history of coronary bypass surgery. The potential for cardiopulmonary resuscitation is assessed by the information on whether death was witnessed and the location of death.

For events that include abstraction of the full hospital record, additional data on medical care are obtained. These data include information on transportation to the hospital, time of arrival, receipt of cardiopulmonary resuscitation, use of a number of procedures, and medications for

treatment of the cardiovascular event (such as angioplasty and Beta blocking agents), and the use of diagnostic procedures (such as cardiac catheterization and echocardiography).

7.0 LINKAGE OF MULTIPLE EVENTS

Since many deaths are listed on both the hospital discharge index and the state death index, survey personnel must compare these lists carefully to avoid duplicating the investigation of in-hospital deaths. If an eligible in-hospital death is found first from the death certificate lists, the case is flagged and it is linked with the hospital chart when that record is found. The linked forms are given the same event ID number. An in-hospital chart is abstracted, and the death certificate obtained as soon as possible. Again, only one event ID number is assigned to these forms.

If an eligible hospital record indicates that a patient was transferred directly from another acute care hospital, or that the patient upon discharge is being transferred directly to another acute care hospital, the record for the other hospitalization is abstracted onto another HRA Form, if it meets ARIC screening codes regardless of discharge day. The two forms initially have different hospitalization ID numbers.

On occasion, it is difficult to differentiate between two or more successive admissions for the same event and two or more different events in the same person. As it is often difficult to make this distinction on the basis of ECG, enzyme or pain characteristics, a simple rule is followed: a CHD death or a hospital admission for MI occurring within 28 days of a previous admission for MI is regarded as the same event, for purposes of calculating rates.

Over the duration of the ARIC surveillance, increasing numbers of community residents are hospitalized for cardiovascular conditions more than once. Others are hospitalized and subsequently die of CHD. Although not used routinely in surveillance investigation, these events can be linked for future use. Sufficient information for correct identification of these patients is collected, where hospitals permit, and matching procedures based on these identification variables are conducted. Patients' initials, last name, SSN, sex, race, and date of birth of all community surveillance participants are compared. If the similarity is beyond a threshold level, these cases are sent out to the field center in the form of a data check for investigation. The field center then determines if these events belong to the same participant and records their findings on all SXI forms for this participant. The Coordinating Center also produces a listing of possible linkages suggested from community surveillance forms. Various forms (HRA, IFI, COR) contain questions as to whether the person had been hospitalized within 4 weeks prior to this event. The field center uses this listing to find linked hospitalizations that have not yet been abstracted. Any positive findings from this investigation are also recorded on the SXI form.

8.0 RELIABILITY AND VALIDITY OF COMMUNITY SURVEILLANCE PROCEDURES

For cohort members, it is possible to validate information on selected variables obtained by community surveillance procedures, by using the more accurate information obtained by

cohort procedures. An example of a variable for which the validity of surveillance approaches is assessed by using information available for cohort members is MI order (new vs. recurrent). Although community surveillance defines a MI as new when there is no mention in the medical chart of a past episode, additional information is available for cohort participants, including the clinic interview and a baseline ECG. Thus, the more accurate definitions of "new" and "recurrent" available for the cohort are used as a "gold standard" to determine sensitivity and specificity of surveillance procedures. Specifically, ECG findings at baseline are used to determine in cohort members to which extent a diagnostic Q wave, as classified in community surveillance, can be assumed to be either a "new" or an "old" Q wave.

"Ecologic" validation is also undertaken, by comparing event rates derived from community surveillance with those obtained from cohort follow-up. In addition to examining surveillance rates in population subgroups, the similarity of patterns of associations of rates with demographic variables between cohort and community surveillance is evaluated.

9.0 COHORT SURVEILLANCE FOR CHD

Identification and classification of events among cohort participants follows 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 events occurring among cohort participants are highlighted below.

9.1 Introduction

The aim of cohort surveillance is to identify and record hospital discharge diagnoses and procedure codes for all hospitalizations for each cohort participant. Selected hospitalizations are further investigated in order to validate the diagnosis of myocardial infarction, heart failure and stroke events. Ascertainment and validation of all out-of-hospital fatal events that are potentially cardiac-related are also completed. Beginning October 2014, cohort surveillance was expanded to identify and record diagnosis and procedure codes for hospital stays, observation unit visits, or ambulatory surgery episodes lasting less than 24 hours involving coronary revascularization only. Hospitalizations lasting less than 24 hours were previously not investigated as part of cohort surveillance. In October 2014, cohort surveillance was also modified to capture serum creatinine measurements taken as part of hospitalizations lasting 24 hours or more that were not otherwise investigated as potential myocardial infarction, heart failure, or stroke events. As of May 2026, the Steering Committee has approved a modification of the creatinine protocol: creatinine will only be collected for events eligible for abstraction as potential myocardial infarction, heart failure, or stroke events. Details of these changes are presented in the appropriate sections to follow.

9.1.1 Identification of events

In addition to the procedures for identification of potentially eligible events used in community surveillance, cohort surveillance also uses information obtained from the follow-up telephone interviews (both annual and semi-annual follow up). When the cohort follow-up interview

indicates that the participant has either died or been admitted to a hospital (for any reason), the medical record or death certificate is obtained, and information abstracted into a computer data base system. The ARIC Study records the occurrence of all hospitalizations (including those lasting less than 24 hours beginning in October 2014) but only investigates for validation selected kinds of medical events for cohort participants in hospitalizations lasting 24 hours or longer. These include: 1) hospitalized MI, stroke or heart failure, and 2) death from CHD,. Identifying and validating cases of venous thromboembolism and cancer are conducted through ARIC ancillary studies and will not be covered in this manual. The identification and classification of clinical stroke is covered separately in Section 10, and identification and classification of heart failure is covered separately in Manual 3A. This section (Section 9) describes the identification, investigation and diagnosis of cardiac related hospitalized and fatal events. ARIC also records the occurrence of a number of non-hospitalized, non-fatal events, events identified through the routine operations of the ARIC clinics and follow up interviews, such as angina pectoris and peripheral vascular disease, including intermittent claudication. These are generally defined using standard instruments, such as the Rose Questionnaire, and their identification and diagnosis are described elsewhere.

9.1.1.2 Identification of Hospitalized CHD 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) occurrence must be after the participant's baseline (visit 1) examination; and 3) an eligible CHD discharge code and/or a CHD key word in the discharge summary. Hospital admissions may be identified initially through review of hospital discharge indexes or information elicited during the cohort follow-up interviews. Hospital chart abstraction is carried out whenever needed to identify MI. All events discharged with specified diagnostic codes are abstracted onto the Hospital Record Abstraction Form (HRA). In order to assure completeness of ascertainment, the discharge summary information is reviewed for events discharged with certain screening codes more remotely related to MI. If an MI is suggested, the chart is abstracted. In addition, all discharge diagnoses for all hospitalizations are recorded. 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.

9.1.1.3 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.

9.1.1.4 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 (including those lasting less than 24 hours beginning in October 2014) occurring in ARIC cohort members within the area identified. However, only special diagnoses require full hospital chart abstraction, as described below. Hospitalizations (regardless of time spent in the hospital) not eligible for full chart abstraction due to absence of special diagnosis codes require an abbreviated chart review where only discharge codes and procedures codes are recorded. Between 2014 and May 2026 serum creatinine measures were also recorded. With the implementation of a web-based data entry system (DMS) in the fall of 2006, there were some changes in the data collection methods for community and cohort surveillance.

Instructions for filling out individual forms are given in the "Question by Question" instructions for each form, which are listed in the Appendix to this manual. With the implementation of a computerized abstraction system in the Data Management System (DMS) in November of 2007, there were some changes in the data collection methods for cohort surveillance. This computerized process gives the complete list of cohort hospitalizations that need to be abstracted for each specific hospital where the hospitalizations are identified by medical record number and discharge date combination. Information available from the hospital lists are auto filled into the abstraction forms. Prior to 2014 creation of H-List, cohort hospitalizations for Minnesota were done 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 a list of cohort hospitalizations from area hospitals, and can be used to furnish abstractor-specific work lists. However, hospitalizations occurring out of area hospitals will not be on the list. Because the hospital index list might be restricted to certain zip code numbers, hospitalizations of cohort members who moved out of catchment area may not be in the list either. Furthermore, some eligibility of hospitalizations for cohort members is decided by key words in medical records when a required ICD code is not in the medical record. Under these circumstances, the field centers will not rely on hospital discharge indices to identify the cohort hospitalization. Hospitalization ID numbers can be assigned from this system for each specific hospital by a combination of medical record number and discharge date. 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. 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 company of the tracking system. If a suggested cohort match is verified as not a cohort member, the abstractor should proceed to complete the required forms as indicated by the community surveillance protocol.

The specified order for completion of surveillance forms is as follows: CEL (cohort eligibility form, used only for cohort members); CFD (confidentiality form); CHI (common hospital information). The last three forms can be implemented in any order: HRA (for hospitalized MI), HFA (for hospitalized HF), and STR (for hospitalized stroke, cohort only). 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 suspend abstracting (for a non-cohort participant) pending further investigations. If the address proves eligible, the CFD form is to be completed. However, if eligibility cannot be determined, the abstractor proceeds to abstract into the required forms.

Hospital Record Abstraction (HRA) Form is completed for all of the hospitalizations with the following ICD-CM primary or secondary discharge diagnosis codes:

1. MI: ICD codes: 402, 410-414, 427, 428 and 518.4 OR
   I11.x, I20.x, I21.x, I22.x, I24.x, I25.x, I46.x, I47.x, I48.x, I49.x, I50.x, J81.0, R00.1

A list of diseases included in these ICD-CM rubrics is presented in Appendix I.

Hospital chart discharge summaries are reviewed for the following screening codes:

Disease	**ICD-9**	**ICD-10**
Diabetes:	250	E10.x, E11.x, E12.x, E13.x, E14.x
Diseases of the circulatory system (including pulmonary embolism and hypertensive heart disease):	390-459	G45.x, I00, I01.x, I02.x, I05.x, I06.x, I07.x, I08.x, I09.x, I10, I11.x, I12.x, I13.x, I15.x, I20.x, I21.x, I22.x, I23.x, I24.x, I25.x, I26.x. I27.x, I28.x, I30.x, I31.x, I32, I33.x, I34.x, I35.x, I36.x, I37.x, I38, I39, I40.x, I41, I42.x, I43, I44.x, I45.x, I46.x, I47.x, I48.x, I49.x, I50.x, I51.x, I52, I60.x, I61.x, I62.x, I63.x, I65.x, I66.x, I67.x, I68.x, I69.x, I70.x I71.x, I72.x, I73.x, I74.x, I75.x, I76, I77.x, I78.x, I79.x, I80.x, I81, I82.x, I83.x, I85.x, I86.x, I87.x, I89.x, I95.x, I97.x, I99.x

Disease	ICD-9	ICD-10
Cardiac surgery:	35-39	02x, 02Nx, 02Rx, 02Qx , 027x, 028x, 02Bx, 02Ux, 021x, 02Lx, 02Vx, 02Sx, 02Cx, 3E0x, 0W9x, 0WCx, 02x, 4A0x, 02Kx, B24x, 02JA3ZZ, 0WJx, 4A02x, 4A12x, B2x, 3E05x 3E06X, 3E07X, 3E08X, 0WJDx, 02x , 02Tx, 025x, 02Yx, 02Hx, 02Wx, 02Px, 5A0x, 5A1x , 0JWx, 0JHx, 0JPx, 06Cx, 04Cx , 04Hx, 06Hx , 03Cx, 02QAx, 039x, 03Bx, 049x, 04Bx, 059x, 05Bx, 069x, 06Bx, 03Jx, 04Jx, 8E023DZ, B22x, B32x, B42x, B52x, 05Jx, 06Jx, 8E02x, 03Rx, 04Rx, 05Rx, 06Rx, 05Dx, 06Dx, 035x, 055x, 065x, 045x, 06Lx, 06Vx, 055x , 03Lx, 04Lx, 05Lx, 03Hx, 05Hx, B51x, B54x, 031x, 061x, 051x, 06Hx, 041x, 02Qx, 03Qx, 04Qx, 05Qx, 06Qx, 0W3x, 03Px, 05Cx, 03PYx, 03CYx, 03QYx, 04CYx, 04QYx,05CYx, 05QYx, 06CYx, 06QYx, 037x, 047x, 057x, 067x, 03Vx, 04Vx, 05Vx, 04Sx, 06Sx, 03Ux, 04Ux, 05Ux, 06Ux, 03Sx, 05Sx, 04Cx, 5A12x, 5A15x, 03Wx, 0G5x, 0G9x, 0GBx, 0GJx, 0GNx, 0GQx, 0GTx, 03Nx, 04Nx, 05Nx, 06Nx, 0X3x, 0Y3x,
Cardiac angiography:	88.5	B2000ZZ, B2001ZZ, B200YZZ, B2060ZZ, B2061ZZ, B206YZZ, B2100ZZ, B2101ZZ, B210YZZ, B2110ZZ, B2111ZZ, B211YZZ, B2120ZZ, B2121ZZ, B212YZZ, B2130ZZ, B2131ZZ, B213YZZ, B2160ZZ, B2161ZZ, B216YZZ, B2170ZZ, B2171ZZ, B217YZZ, B2180ZZ, B2181ZZ, B218YZZ, B21F0ZZ, B21F1ZZ, B21FYZZ, B5080ZZ, B5081ZZ, B508YZZ, B5090ZZ, B5091ZZ, B509YZZ, B5180ZZ, B5181ZZ, B518YZZ, B5190ZZ, B5191ZZ, B519YZZ, B2040ZZ, B2041ZZ, B204YZZ, B2140ZZ, B2141ZZ, B214YZZ, B2050ZZ, B2051ZZ, B205YZZ, B2150ZZ B2151ZZ, B215YZZ, B2010ZZ, B2011ZZ, B201YZZ, B201YZZ, B210010, B210110, B210Y10, B211010, B211110, B211Y10, B212010, B212110, B212Y10, B213010, B213110, B213Y10,
Congenital abnormalities of the heart:	745-747	Q23.x, Q24.x, Q25.x, Q26.x, Q27.x, Q28.x
Cardiovascular symptoms, signs and ill-defined conditions:		
(Abnormal function study);	794.3	R94.x
(Sudden death, cause unknown);	798	R99, B33.x, B97.x, B34.x
and (other)	799	R09.x, R45.x, R53.81, R64, R41.x, R68.82,

Disease	ICD-9	ICD-10
		R69, B97.89, R99

Should any mention of MI on the present admission (or synonyms for these conditions) be uncovered by the review of discharge summaries for the above conditions, full hospital chart abstraction onto the Hospital Record Abstraction Form is undertaken. For all other ICD-CM codes associated with hospital stays lasting ≥ 24 hours, the discharge diagnoses and procedure codes are obtained from hospital discharge lists and recorded on the Cohort Eligibility Form (CEL) and the discharge summary is obtained and submitted to the Coordinating Center via secure Liquid Files. Before May 2026, this process also included abstraction of serum creatinine measurements. See protocol for investigating stroke and heart failure in the cohort for important exceptions to their general rules for MI. The Cohort Eligibility Form is used to help determine eligibility.

A number of hospitalized events for cohort members are fatal. Abstraction of hospital records for these events is the same as for non-fatal events, regardless of whether the ICD code for underlying cause of death from the death certificate satisfies the eligibility criteria for fatal events.

9.1.1.5 Hospitalized Events Occurring Outside the Study Community

Review of death certificates or annual follow-up interviews may reveal that the cohort member was hospitalized outside the study area. Hospitalization may occur outside the study area for the following reasons:

A major hospital catchment area for the region exists outside of the area (e.g., tertiary care hospital referral centers).

Residents who work outside of the geographic area may be admitted to an out-of-area hospital if they have an event requiring admission on an emergency basis.

A resident may have an event while in transit outside of the geographic area for recreation or social activities.

A cohort member may have moved from the study community.

Every effort is made to identify discharge diagnoses for such events and, if applicable, review the hospital chart. In soliciting access to discharge indexes and, occasionally, medical charts, a letter briefly describing the ARIC cohort study is sent to the hospital administrator as well as the director of medical records, along with a copy of the ARIC hospital record release form, signed by the participant at the time of the first exam. In some situations, it is also useful to send an abbreviated protocol. Additional contacts, including telephone conversations, with the hospital administrator or the head of the proper department (cardiology, neurology, etc.) may be necessary. Cohort participants who deny access to medical records are not investigated.

9.1.1.6 Range of Facilities Covered for Hospitalized Events

Events occurring to cohort members in acute care hospitals are investigated, regardless of where the hospital is located. Events in other institutions providing medical care (such as nursing homes, rehabilitation hospitals, long term chronic disease hospitals, hospice care facilities, and psychiatric hospitals) are not investigated. Cohort events in hospitals in the study community are identified by review of the discharge indexes from these hospitals and by the cohort follow-up interview. The cohort follow-up interview also allows identification of events occurring in or leading to admission to acute care hospitals out of the study community. Events in out-of-area hospitals will generally have to be investigated by requesting a complete copy of the medical record to be mailed to the Field Center.

9.1.2 Identification of Deaths

9.1.2.1 Death Certificates

Each ARIC center obtains a monthly printout of deaths in the community, from which cohort deaths are identified. Deaths occurring in cohort members are also identified if the member has moved out of the study community. Methods include systematic review of death certificates, annual follow-up interview, hospital chart review, use of obituary notices and other means. The corresponding death certificate is located and abstracted onto the ARIC Death Certificate Form (DTH). For cohort deaths that are found via the National Death Index (NDI) and are five or more years old, a DTH form is not needed. The coordinating center will obtain the information in these cohort deaths directly from the NDI.

9.1.2.2 Deaths Occurring Outside the Study Community

Deaths outside of the study area but within the state are included on State Health Department monthly printouts, but some delay between the death and death registration is expected. The delay for out-of-state deaths is even greater, and they may appear only on final death files at the State Health Department. If the death certificate file is reviewed for the ARIC Study prior to receipt of the out-of-area certificates, a subsequent review is undertaken to identify these deaths. If the location of an out-of-area death is learned through the annual interview with a participant's proxy, a copy of the death certificate can be obtained directly.

Deaths occurring outside the study community are also identified through the National Death Index and, in some centers, by monitoring of obituaries.

9.1.2.3 Identification of Deaths Requiring Special Investigation

Deaths in cohort members that occur out-of-hospital (as defined in Section 9.2.1.2) require a special investigation to determine whether or not they died of CHD if their death certificates have any of the following ICD-9 codes for the underlying cause:

250, 401, 402, 410-414, 427-429, 440, 518.4, 798 and 799,

or any of the following ICD-10 codes (for fatal events after January 1, 1999) for the underlying cause:

E10-E14, I10-I11, I20-I25, I46-I51, I70, I97 (except I97.2), J81, J96, R96, R98 and R99.

For a listing of disease categories see Appendix I.

Deaths in hospitalized cohort members which occur before an ECG or a complete set of enzymes is obtained also require special investigation, if the death certificate has one of the death certificate codes as shown.

The special investigation required for these deaths is described in Section 9.2.1.2.

9.2 Event Investigation

For the hospitalized event of MI, investigation entails review of the hospital record. Investigation of the fatal events occurring in cohort members (Section 3.1) includes review of the death certificate and hospital record where available. For out-of-hospital deaths and some inadequately diagnosed in-hospital events (defined in Section 3.1.2), investigations include physician questionnaires, interviews with next-of-kin and collection of other information.

9.2.1 Procedures for Fatal Events

The Cohort Eligibility Form and the Death Certificate Form are completed for all fatal events occurring in cohort members. One or more of the following forms may also have to be completed: 1) Hospital Record Abstraction Form, 2) Informant Interview Form, 3) Physician Questionnaire, and 4) Coroner/Medical Examiner Report Form.

The Death Certificate Form is completed and submitted to the Coordinating Center prior to or concurrent with submission of other forms. Occasionally it is necessary to obtain certificates for deaths occurring out-of-state to study area residents by writing to the state in which the death occurred.

Some proportion of fatal events -- either in-hospital or out-of-hospital -- are coroner or medical examiner's cases. This means that the county coroner or state medical examiner has performed an investigation of the circumstances of death in order to ascertain whether the causes were natural. In this case, the coroner/medical examiner signs the death certificate. In general, the coroner/medical examiner takes cases of unexpected death where no physician was in attendance during the 24 hours prior to death. During this investigation, the coroner/medical examiner may or may not order an autopsy. Any death where a legal question is likely to arise (e.g., after surgery, during an automobile accident, etc.) will probably be a coroner/medical examiner case. If a death is certified by a coroner/medical examiner, the

Coroner/Medical Examiner Form is completed and submitted to the Coordinating Center. If an autopsy is performed, a copy of that report is sent to the Coordinating Center.

Specific procedures for investigating in-hospital and out-of-hospital deaths and requirements for completion of the other forms listed above are given in the next two sections.

9.2.1.1 In-Hospital Deaths

In-hospital deaths may be identified initially from death certificates or hospital discharge indexes. Hospital records for these events are abstracted if eligible as hospitalized events according to the rules described in Section 9.1.1.2. The Death Certificate Form is also completed and sent to the Coordinating Center for all deaths.

If the in-hospital death is initially identified from the hospital discharge index, the death certificate printout must be crosschecked to avoid duplication. If the in-hospital death is initially identified from the death index, the hospital discharge index must be crosschecked. Occasionally the hospital lies outside the catchment area for the ARIC Study community. In this case, this fact is noted on the Death Certificate Form and an attempt is made to find and, if eligible, abstract the hospital record.

Cohort members who die in the emergency room, are pronounced dead on arrival at the hospital, or are admitted without vital signs are reclassified as out-of-hospital deaths (as defined in Section 9.2.1.2). Only the administrative data of the Hospitalized Event Form are recorded for patients without vital signs. If the death is first identified from the death index and if the death certificate indicates "dead on arrival," an attempt is made to find the hospital record in order to verify this information.

If the hospital record indicates that the cohort member has been transferred directly from another acute care hospital or is transferring directly to another such hospital, the record for the other hospitalization is found and reviewed according to the rules given in Section 9.1.1.2.

9.2.1.2 Out-of-Hospital Deaths

Out-of-hospital deaths with one of the eligibility codes given in Section 9.1.2.3 require a special investigation into the cause of death. For this purpose out-of-hospital death is defined to include:

1. Deaths occurring outside of regular acute care hospitals.
2. Deaths occurring in hospital emergency rooms or outpatient departments.
3. Persons who were either dead on arrival or were admitted without vital signs. For purposes of defining out-of-hospital death "no vital signs" means no pulse rate and systolic blood pressure (or admitted on a respirator with no pulse rate or systolic blood pressure at any time off the respirator).

When the special investigation for out-of-hospital deaths is required, the information from the decedent's family and physician must be obtained within 3-12 months after death if feasible. The former is contacted for an interview, the latter by questionnaire. Often the informant is the spouse or other family member of the decedent. On other occasions the informant is someone else who witnessed the death or someone whose name is mentioned on the death certificate.

First an attempt is made to contact and interview the spouse or a first-degree relative (i.e., son, daughter, or sibling) of the decedent, or someone else who lived with the decedent. If another person witnessed the death, this person is interviewed as well. Using the information provided by the participant at the time of the clinic interview, the informant's telephone number can be identified, and a "Format 1" letter sent (Appendix II). If a number cannot be found when reviewing information in the clinic interview, a reverse ("criss-cross") directory is used. If the informant's telephone number is still unavailable, a "Format 2" letter is sent asking the informant to provide a telephone number on the enclosed, self-addressed stamped post card. A copy of the participant's consent form is attached to the letter to the informant. These letters are sent with both the interviewer and the Field Center Principal Investigator's signatures. After enough time elapses for the "Format 1" letter to arrive, or after receiving the reply post card to the "Format 2" letter, the interview is conducted using the Informant Interview Form. This interview may be conducted over the telephone, or if necessary, in person. If no reply is received, a "Format 4" letter is sent to next-door neighbors (identified by the reverse telephone directory) to request information on the whereabouts of the potential informant. A "Format 4" letter is also sent to the neighbor(s) when an informant's telephone number is initially available, but attempts at telephone contacts are unsuccessful. If no reply is received from the neighbor(s), no further effort is needed.

When the death is witnessed by someone other than a member of the decedent's family, both the family member whose name was given by the participant, and the witness recorded on the death certificate are interviewed. In such a case, the information from both interviews is recorded on separate Informant Interview Forms. Up to three (the three most complete) Informant Interview. Forms may be completed for a given event.

Information is sought from physicians by sending the Physician Questionnaire (PHQ). From both the clinic and informant interviews an attempt is made to identify the physician(s) who attended the decedent during the four weeks period prior to death. One questionnaire is sent to the physician who signed the death certificate. Another questionnaire is sent to the physician (if any, and if different from the first) who saw the patient for heart disease during the 28 days prior to death. Another questionnaire could be sent to the physician to whom ARIC sent the most recent ARIC visit result letter (if different from the first two). The most current consent form signed by the participant at the visits could be sent along to help authorize completion of the PHQ. Release-of-Information Forms signed by the deceased cohort participant are attached to these letters. If there is no response after four weeks of the initial mailing to the physician, a follow-up letter and another copy of the Physician Questionnaire are sent. If there is no response after eight weeks of the initial mailing, the physician is contacted

by telephone. Up to two (the two most complete) Physician Questionnaires may be completed for a given event.

If the decedent died in a nursing home or hospice, personnel are asked to attempt to complete a Physician Questionnaire based on the nursing home or hospice record. Centers may offer to assist with abstraction if this would be helpful. A Release of Information Form may be needed.

If information provided by the informants or physicians indicates that a person who died out-of-hospital was hospitalized within 28 days prior to death for MI or heart surgery, an attempt is made to ascertain the discharge diagnoses and, if applicable, review and abstract the hospital record. Requests to hospitals include copies of the ARIC release forms. If using the medical record for completing the medical history portion of the PHQ, a 6-month look back is sufficient.

9.2.2 Procedures for Hospitalized Events

Hospitalized events with one of the discharge diagnosis codes suggestive of an MI (ICD codes 420,410-414, 427, 428, 518.4, I11.x, I20.x, I21.x, I22.x, I24.x, I25.x, I46.x, I47.x, I48.x, I49.x, I50.x, J81.0, R00.1 receive full abstraction using the Hospital Record Abstraction form. For the special case of MI, for events with discharge codes other than 410, 411, I20.x, I21.x, I24.x , if the patient was discharged alive with no ECGs taken and no cardiac biomarkers measured, only the administrative information on the Hospital Record Abstraction Form is completed.

For certain ICD procedure and diagnosis codes which are more remotely related to MI, the medical record is obtained and its discharge summary reviewed. Any evidence in the discharge summary of the occurrence of MI (see key words listed on item 11.a.2 on the CEL form), requires the full use of the Hospital Record Abstraction Form. (ICD codes: 00.50-00.54, 00.61-00.66, 35-39, 88.5, 250, 390-459, 745-747, 794.3, 798, 799 OR ICD-10: 021x, 025x, 027x, 028x, 02Bx, 02Cx, 02Hx, 02JA3ZZ, 02JY3ZZ, 02Kx, 02Lx, 02Nx, 02Px, 02Qx, , 02Rx, 02Sx, 02Tx, 02Ux, 02Vx, 02Wx, 02Yx, 031x, 035x, 037x, 039x, 03Bx, 03Cx, 03Hx, 03Jx, 03Lx, 03Nx, 03Px, 03Qx, 03Rx, 03Sx, 03Ux, 03Vx, 03Wx, 041x, 045x, 047x, 049x, 04Bx, 04Cx, 04Hx, 04Jx, 04Lx, 04Nx, 04Qx, 04Rx, 04Sx, 04Ux, 04Vx, 051x, 055x, 057x, 059x, 05Bx, 05Cx, 05Dx, 05Hx, 05Jx, 05Lx, 05Nx, 05Qx, 05Rx, 05Sx, 05Ux, 05Vx, 061x, 065x, 067x, 069x, 06Bx, 06Cx, 06Dx, 06Hx, 06Jx, 06Lx, 06Nx, 06Qx, 06Rx, 06Sx, 06Ux, 06Vx, 0G5x, 0G9x, 0GBx, 0GNx, 0GQx, 0GTx, 0JH6x, 0JH7x, 0JH8x, 0JHDx, 0JHFx, 0JHGx, 0JHHx, 0JHLx, 0JHMx, 0JHNx, 0JHPx, 0JPx, 0JWx, 0W3x, 0W9x, 0WCx, 0WJx, 0X,3x, 0Y3x, 3E0x, 4A0x, 4B02X,TZ 5A0x, 5A1x, 8E023DZ, B20x, B21x, B24x, B32x, B42x, B50x, B51x, B52x, B54x, B33.x, B34.x, B97.x, E10.x, E11.x, E12.x, E13.x, E14.x, G45.x, I00 I01.x, I02.x, I05.x, I06.x, I07.x, I08.x, I09.x, I10 I11.x, I12.x, I13.x, I15.x, I20.x, I21.x, I22.x, I23.x, I24.x, I25.x, I26.x, I27.x, I28.x, I30.x, I31.x, I32 I33.x, I34.x, I35.x, I36.x, I37.x, I38, I39 I40.x, I41 I42.x, I43 I44.x, I45.x, I46.x, I47.x, I48.x, I49.x, I50.x, I51.x, I52, I60.x, I61.x, I62.x, I63.x, I65.x, I66.x, I67.x, I68.x, I69.x, I70.x, I71.x, I72.x, I73.x, I74.x, I75.x, I76 I77.x, I78.x, I79.x, I80.x, I81, I82.x, I83.x, I85.x, I86.x, I87.x, I89.x, I95.x, I97.x, I99.x, K64.x, M30.x, M31.x, Q20.x, Q21.x, Q22.x, Q23.x, Q24.x, Q25.x, Q26.x, Q27.x, Q28.x, R00.x, R09.x, R41.x, R45.x, R53.81 R58 R64 R68.82 R69 R94.x, R96.x, R98, R99)

For all remaining ICD codes, the discharge lists are perused and the discharge diagnoses and procedure codes are recorded. These latter codes do not lead to full hospital record abstraction.

Abstracting of cardiac biomarker levels and ranges, copying of ECGs and treatment of transfer status follow guidelines specified for community surveillance in Section 3 of this manual.

Similarly, hospitalizations lasting at least 24 hours with discharge diagnosis codes suggestive of stroke (430-436 or G45.x, I60.x, I61.x, I62.x, I63.x, I65.x, I66.x, I67.x) received full medical record abstraction using the Stroke Abstraction (STR) form. For certain ICD procedure and diagnosis codes which refer to procedures or conditions, which may be related to stroke, the medical record is obtained and its discharge summary reviewed. Any evidence in the discharge summary of the occurrence of stroke (see key words listed on item 11.b.2 on the CEL form) requires the full use of the Stroke Abstraction Form. (ICD codes: 00.50-00.54, 00.61-00.66, 35-39, 88.5, 250, 390-459, 745-747, 794.3, 798, 799 or ICD-10: 021x, 025x, 027x, 028x, 02Bx, 02Cx, 02Hx, 02JA3ZZ, 02JY3ZZ, 02Kx, 02Lx, 02Nx, 02Px, 02Qx, , 02Rx, 02Sx, 02Tx, 02Ux, 02Vx, 02Wx, 02Yx, 031x, 035x, 037x, 039x, 03Bx, 03Cx, 03Hx, 03Jx, 03Lx, 03Nx, 03Px, 03Qx, 03Rx, 03Sx, 03Ux, 03Vx, 03Wx, 041x, 045x, 047x, 049x, 04Bx, 04Cx, 04Hx, 04Jx, 04Lx, 04Nx, 04Qx, 04Rx, 04Sx, 04Ux, 04Vx, 051x, 055x, 057x, 059x, 05Bx, 05Cx, 05Dx, 05Hx, 05Jx, 05Lx, 05Nx, 05Qx, 05Rx, 05Sx, 05Ux, 05Vx, 061x, 065x, 067x, 069x, 06Bx, 06Cx, 06Dx, 06Hx, 06Jx, 06Lx, 06Nx, 06Qx, 06Rx, 06Sx, 06Ux, 06Vx, 0G5x, 0G9x, 0GBx, 0GNx, 0GQx, 0GTx, 0JH6x, 0JH7x, 0JH8x, 0JHDx, 0JHFx, 0JHGx, 0JHHx, 0JHLx, 0JHMx, 0JHNx, 0JHPx, 0JPx, 0JWx, 0W3x, 0W9x, 0WCx, 0WJx, 0X,3x, 0Y3x, 3E0x, 4A0x, 4B02X,TZ 5A0x, 5A1x, 8E023DZ, B20x, B21x, B24x, B32x, B42x, B50x, B51x, B52x, B54x, B33.x, B34.x, B97.x, E10.x, E11.x, E12.x, E13.x, E14.x, G45.x, I00 I01.x, I02.x, I05.x, I06.x, I07.x, I08.x, I09.x, I10 I11.x, I12.x, I13.x, I15.x, I20.x, I21.x, I22.x, I23.x, I24.x, I25.x, I26.x, I27.x, I28.x, I30.x, I31.x, I32 I33.x, I34.x, I35.x, I36.x, I37.x, I38, I39 I40.x, I41 I42.x, I43 I44.x, I45.x, I46.x, I47.x, I48.x, I49.x, I50.x, I51.x, I52, I60.x, I61.x, I62.x, I63.x, I65.x, I66.x, I67.x, I68.x, I69.x, I70.x, I71.x, I72.x, I73.x, I74.x, I75.x, I76 I77.x, I78.x, I79.x, I80.x, I81, I82.x, I83.x, I85.x, I86.x, I87.x, I89.x, I95.x, I97.x, I99.x, K64.x, M30.x, M31.x, Q20.x, Q21.x, Q22.x, Q23.x, Q24.x, Q25.x, Q26.x, Q27.x, Q28.x, R00.x, R09.x, R41.x, R45.x, R53.81 R58 R64 R68.82 R69 R94.x, R96.x, R98 R99),

Hospitalizations lasting at least 24 hours that are not otherwise eligible for full medical record abstraction (as noted above using the HRA, HFA, or STR form) will have discharge summaries obtained, scanned, and sent to the coordinating center for archiving. Prior to May 2026, these hospitalizations were also reviewed for serum creatinine measurements, and this information was used to complete the serum creatinine section of the CEL form.

9.2.2.1 Procedures for less than 24 hour stays in hospitals or other medical facilities

Beginning in October 2014, the cohort surveillance protocol was modified to include capture of information on cardiovascular revascularization procedures performed in medical facilities and out-patient settings not involving a hospital stay lasting greater than 24 hours. The purpose of

this modification was to account for evolving medical care practice that has changed how cardiovascular revascularization procedures are performed. Stays in hospitals or other medical facilities such as outpatient clinics lasting less than 24 hours are identified through cohort follow up phone interviews (annual or semi-annual). This information is made available to the surveillance staff at each field center. When field center surveillance staff become aware of a cohort stay in hospital, outpatient clinic or other medical facility lasting less than 24 hours, the staff acquires the medical records and completes a CEL form. The CEL form has been modified to allow field center staff to record the diagnosis and cardiovascular revascularization procedure codes for these events. Recording of serum creatinine values or scanning of discharge summaries is not required for these events lasting less than 24 hours.

9.2.3 Summary of Cohort Investigations

Table 9.1 – Forms for Event Type

	Event Type	Forms Required for Abstraction of Event Type										
		CEL	CFD	CHI	DTH	NOF	PHQ	IFI	COR	HRA (Full)	HRA (Part)	SXI♦
A	**Out-of-Hospital Death (CHD eligible)**	Y			Y		Y	Y	Y			Y
B	**Hospital Death (no vital signs at arrival, CHD eligible)**	Y			Y		Y	Y	Y*		Y	Y
C	**Hospital Death (vital signs at arrival, CHD eligible)**	Y			Y				Y*	Y		Y
D	**Death (not CHD eligible)**	Y			Y							Y
E	**Hospitalized Case greater than 24 hours stay (discharged alive, CHD eligible)**	Y	Y	Y						Y		Y
F	**Hospitalized Case greater than 24 hours stay, discharged alive (not CHD eligible)**	Y+										
G	**Hospital stay less than 24 hours (discharged alive, CHD eligible with coronary revascularization procedures)**	Y&										

* If a death is certified by a coroner/medical examiner, the Coroner/Medical Examiner Form is completed and submitted to the Coordinating Center. If an autopsy is performed, a copy of that report is sent to the Coordinating Center.

+Hospitalizations (regardless of time spent in the hospital) not eligible for full chart abstraction due to absence of special diagnosis codes require an abbreviated chart review where only discharge codes and procedures codes are recorded. Between 2014 and May 2026, serum creatinine measures were additionally collected.

& See Procedures for less than 24 hour Observation Unit Stay Events, Section 9.2.2.1. The CEL form was modified to allow field center staff to record the diagnosis and cardiovascular revascularization procedure codes for these events.

9.3 Diagnostic Criteria

Events occurring among cohort participants receive a computer derived diagnosis classification into fatal diagnostic categories (definite fatal myocardial infarction, definite fatal CHD, possible fatal CHD, non-CHD death) and MI categories (definite, probable, suspect, and no). However, for cohort events the final diagnosis classification is determined by MMCC review. The only exceptions are those outlined in Section 9.4.1.1. In these cases a computer-derived classification is sufficient. Criteria for these classifications are identical to that described for community surveillance (Section 4).

9.3.1 Hospitalized Myocardial Infarction (MI)

As described in Section 9.1.1, all hospitalized events occurring in cohort members are identified; detailed chart abstraction is carried out only when acute MI is suspected. In addition, hospitalization for mild and chronic manifestations of ischemic heart disease, such as angina pectoris and congestive heart failure, are included in the screening process, only to aid in the identification of acute MI. (So-called silent infarctions are not identified from the hospital records, but from ECG changes occurring to cohort members between their baseline and follow-up examinations.) Both Q-wave (transmural) and non-Q-wave (non-transmural) infarctions are sought in all hospital records abstracted.

As with community surveillance, it is recognized that aggressive treatment of signs and symptoms of impending myocardial infarction, such as angioplasty, coronary artery bypass graft or thrombolyic therapy, may prevent the development of the full diagnostic syndrome. In such cases, it may be difficult to diagnose the event accurately. The use of such modalities is recorded and subject to data analysis, but is not employed in the criteria for diagnosis. A computer derived diagnostic classification is created for all eligible cohort events. These categories (definite MI, probable MI, suspect MI and No MI) follow the same criteria outlined in the community surveillance section 4.2.2 to 4.2.4.

9.3.1.1 Definition of Cardiac Pain

Cardiac pain is defined as pain occurring anywhere in the anterior chest, left arm or jaw; and an absence of a definite non-cardiac cause of chest pain.

9.3.1.2 Definitions of Electrocardiographic Criteria:

The ECG series is assigned the highest category for which criteria are met, i.e., evolving diagnostic ECG patterns are higher than diagnostic ECG patterns, which are higher than evolving ST-T patterns, which are higher than equivocal ECG patterns, which are higher than other, which are higher than uncodable.

To fit an evolving ECG Pattern (Evolving Diagnostic and Evolving ST-T) two or more recordings are needed. Changes must occur within lead groups, i.e., lateral (I, aVL, V6), inferior (II, III, aVF), or anterior (V1-V5) and be confirmed for all codes by Serial ECG comparison.

Example

Reference ECG codes:	1-3-4	4-0	5-0	9-0
Follow-up ECG codes:	1-2-4	4-0	5-2	9-0

To be considered Evolving Diagnostic (pattern ED3) both the 1-2-4 and the 5-2 must be determined to be Significant Increase by Serial Change rules. If the 1-2-4 change is not Significant Increase and the 5-2 change is Significant Increase, then the change would fit Evolving ST-T (pattern EV3). If the 5-2 change is not Significant Increase, then the pattern would be Diagnostic ECG (pattern D1) because of the 1-2-4, regardless of whether or not the 1-2-4 change is Significant Increase.

Minnesota Coding Procedures

The following ECG tracings are identified:

The first codable ECG after admission;

The last codable ECG recorded before discharge; and

The last codable ECG recorded on day 3 (or the first ECG thereafter) following admission or an in-hospital event.

Photocopies of the cohort hospital ECGs were sent to the Minnesota Coding Center in Minneapolis for Minnesota Coding, using the Cohort Hospital ECG Form (ECG) shown in Appendix P of Manual 5. ECGs are read three times, blinded; the final codes are adjudicated by a senior coder. Minnesota code criteria are in Appendix E of Manual 5.ECGs are now sent electronically to the EPICARE group at Wake Forest as described before.

The data from the ECG form is entered and a determination is made at the CC by computer algorithm as to whether or not the Minnesota Code change criteria are met. A list of those IDs that fit the change criteria (i.e., any pattern ED1 through ED7 or EV1 through EV5, defined above) is sent to the ECG Coding Center. ECGs for these IDs are examined side by side for Serial ECG change.

Simultaneous ECG comparison is performed on the final Minnesota codes using the first codable ECG of the hospitalization as the reference. Serial ECG changes are determined three times, blinded. Serial change categories are 1) significant increase, 2) decrease (4-, 5-, and 9-2 codes, but not for Q-codes), 3) no change (this implies no increase for Q-codes) or 4) technical problem. The final categories are adjudicated by a senior coder and added to the EKG Form. Serial Change criteria are in Appendix L of Manual 5.

As an example, the ARIC protocol defines a new Minnesota code 1-2-7 as a potential ischemic event. Persons with this severity of ECG change will have simultaneous ECG comparison. The ECG comparison procedure (for this case) requires a ≥ 1 mm R-wave amplitude decrease between corresponding leads of the reference and comparison ECGs. The criteria for 1-2-7 are QS patterns in V1, V2, and V3. If the reference ECG has R-waves that are ≥ 1 mm tall in V1 or V2 or V3, when comparing these ECGs side by side, and the R-waves in the reference ECG appear to decrease the appropriate amount (at least 1 mm), then a "significant increase" is noted on the Appendix O form. If the reference ECG has R-waves < 1 mm tall, it cannot fulfill the change criteria and no change (or no increase) is noted. See Appendix X of Manual 5.

9.4 Event Determination

Final assignment of diagnostic categories for all cohort events of interest in the ARIC Study is made by the Morbidity and Mortality Classification Committee (MMCC), after initial assignment to diagnostic categories is carried out by computer algorithm. The final classification of a cohort event is that preferred by the MMCC review process. In some selected cases beginning in event year 2019, the computer classification is used as the final event determination and do not require MMCC review (See Section 11.2.e and/or Section 5.1.c for details. This section describes the procedures by which these determinations are made.

Computer-generated summaries of all relevant coded information from the data collection forms are provided to the MMCC in summary form (Event Summary Form (ESF)) for review. In addition, the MMCC considers remarks by family interviewers, hospital record abstractors, or clinic examiners or other uncoded information recorded on the data collection forms. These are recorded in the form of note logs in the database and made available for use by the committee. All cohort events (with some exception noted below) are reviewed by two members of the MMCC. The final diagnosis decision made by the MMCC reviewer is recorded on the CDX form.

For types of events which often are not classifiable by computer algorithm, e.g., out-of-hospital deaths, the diagnostic criteria given in Section 3.3 may not be specific enough to permit unequivocal classification of each event by the MMCC. If the MMCC discovers a rule which helps standardize this process, it either 1) makes a recommendation to the ARIC Steering Committee for further specification of the ARIC Study diagnostic criteria or 2) records the rule as a part of the "case law" for its own use in classifying similar events.

In addition to diagnosing all cohort clinical events, the MMCC provides other information about these events. Examples include clinical judgments required prior to making diagnoses and resolution of conflicting evidence regarding the time interval between onset of symptoms and death. These are discussed in the appropriate sections below.

9.4.1 Diagnosis of Coronary Heart Disease

9.4.1.1 Hospitalized MI

The following cohort cases are automatically classified (do not require MMCC review). These account for 10-15% of the total number of cohort events.

The computer assigns a diagnosis to cohort events that skip out of the HRA form and no 410-discharge code is present. These events are automatically classified as NO_MI by the ARIC diagnostic algorithm. The computer also assigns a final diagnosis of NO_MI for cohort events with no 410 codes, no pain, normal or incomplete enzymes, and ECG finding that is absent, uncodeable, or other.

Starting in event year 1995, an additional type of cohort case will be automatically classified by the ARIC diagnostic algorithm and will not require MMCC review. All non-linked, non-fatal hospitalized CHD events where discharge codes do not include 410, chest pain is absent or present, enzymes are normal or incomplete, and ECG findings are equivocal, absent, or uncodable will automatically be assigned a final diagnosis of NO_MI by the computer.

Also starting in event year 1995, all non-linked, non-fatal cohort cases that are not automatically classified by the computer will only be reviewed by one MMCC reviewer (instead of 2) and the computer. A second MMCC reviewer will adjudicate disagreements between the reviewer and the computer.

All other events including linked non-fatal hospitalizations, fatal hospitalization (linked and non-linked), and out-of-hospital death (linked and non-linked) are reviewed by two MMCC reviewers and an adjudicator if necessary. The only exception is for linked greater than 28-day deaths. These special reviews are sent to one MMCC reviewer with no adjudications.

9.4.1.2 CHD Death

Narratives recorded by family interviewers and other uncoded information is important in diagnosing deaths that occurred out-of-hospital. For many out-of-hospital events, the MMCC must resolve conflicting information collected from several informants. In-hospital deaths meeting the criteria for "Definite MI" require MMCC review for a possible Non-CHD cause of death before being classified as "Definite Fatal MI".

A computer diagnosis of "Definite Fatal MI", "Definite Fatal CHD" or "Non-CHD Death" is provided for those events for which all the necessary coded information is available and unequivocal. Except for a sample of unequivocal computer diagnosed Non-CHD Deaths, all cohort deaths require MMCC review and classification.

All out-of-hospital deaths classified as "Definite Fatal CHD" or "Possible Fatal CHD" requires an MMCC determination of the interval between the onset of symptoms and death. Differences between reviewers in time interval are not adjudicated.

9.4.2 Event Summary Forms (ESF)

Event summary forms for cohorts differ slightly from community in that they include additional information that is taken from various cohort forms (AFU and clinic visit forms). The additional information includes visit exam reports, annual follow-up information, previous cohort diagnosis for MI, and previous diagnosis for stroke. Autopsy reports, if available, can also be included for cohorts. Another area on the ESF that differs between community and cohort is enzyme diagnosis. Community events that have “spurious” enzymes as defined by ARIC protocol automatically have the enzymes downgraded. For cohorts, it is the reviewer's decision whether to downgrade the "spurious" enzymes. The reviewer is given the downgraded enzyme values, original enzyme values, and 2 pages of additional enzyme data.

9.4.3 Additional Cohort Forms

In addition to regular surveillance forms, cohorts have a few additional forms that are used. The Cohort Eligibility Form (CEL) is used to determine if a cohort event is eligible for surveillance. Data from the CEL is run through various data and code checks against other surveillance forms such as the DTH and HRA. The Annual Follow-up Form data pertaining to Rose angina are printed out on the cohort ESF (Rose angina was removed from the AFU interview after version F) and is also used to locate any possibly missing cohort events that are surveillance eligible.

9.5 Diagnosis of Prevalent MI at Baseline and Interim MI between Clinic Visits

9.5.1 Procedures

9.5.1.1 Minnesota Coding

Cohort 12-lead ECGs were taken during Field Center visits. One ECG was taken at the baseline exam and a second ECG was taken at the follow-up exam three years later.

Abnormal ECGs and a 10% selection of normal ECGs were transmitted from the Epicare Computer Center to the Minnesota Coding Center in Minneapolis. These ECGs were coded visually by the Minnesota Code on the coding form shown in Appendix K of Manual 5. ECGs were read three times, blinded; the final codes are adjudicated by a senior coder.

9.5.1.2 Adjudication

The visual Minnesota Codes were sent to the Coordinating Center for comparison with the computer-generated codes. Adjudication between the visual code and the computer code was performed by two electrocardiographers only on ECGs that have a discrepancy involving any Q-code, or any 4-2, 4-1-2, 4-1-1, 5-2, 5-1 or 9-2. The Coordinating Center determined the IDs that have any of these discrepancies and sent a report form to the Minnesota Coding Center listing the ID, acrostic, date and time of ECG, the visual codes and the computer codes. These ECGs

were examined and the adjudicated codes were recorded on the report form, which was returned to the Coordinating Center.

9.5.1.3 Serial ECG Coding

The Coordinating Center adds the adjudicated codes to the database as the definitive Minnesota Codes for the ID involved.

When two ECGs from different Field Center visits are available, a determination is made at the Coordinating Center as to whether or not Minnesota Code change criteria are met. A list of those IDs that fit the change criteria (i.e. any pattern ED1 through ED7) is sent to the ECG Coding Center. ECGs for these IDs are examined side by side for Serial ECG change.

Simultaneous ECG comparison is based on the final Minnesota Codes. Serial ECG changes (significant increase, no increase or technical problem) are determined three times; the final categories are adjudicated by a senior coder and added to the Appendix O form, Manual 5. The simultaneous ECG evaluation procedure uses the ECG of the first clinic visit as the reference ECG for comparison.

ARIC requires Minnesota Code change plus agreement by simultaneous ECG comparison before declaring the ECG pattern change meets ARIC criteria for an interim MI.

9.5.2 Definitions

A determination that an ARIC participant has had an MI, either prior to the initial clinic visit or between visits, can be made on ECG evidence alone, using the following criteria:

9.5.2.1 Prevalent MI at Baseline

Baseline ECG (initial cohort visit) coded:

a) any 1-1-X code.
OR
b) any 1-2-X PLUS 4-1-1 or 4-1-2 or 4-2 or 5-1 or 5-2.

9.5.2.2 Interim MI between Cohort Visits

An Evolving Diagnostic ECG Pattern (ED1 through ED7) between the baseline ECG (initial cohort visit) and an ECG from a later cohort visit.

An “unrecognized MI” or “silent MI” can be said to have occurred in the interval between visits if such ECG evidence of MI was found and there was no clinically recognized MI event picked up by hospital surveillance during follow-up. More information on the determination of unrecognized MI can be found in Boland (2002).

10.0 COHORT SURVEILLANCE FOR STROKE

For cohort surveillance of stroke, see Manual 3c 'Cohort Surveillance Procedures - Stroke'

11.0 CC PROCEDURES FOR PREPARING MORBIDITY AND MORTALITY CLASSIFICATION COMMITTEE (MMCC) MATERIALS

11.1 CHD Reviews Specific to Community Surveillance

The CC generated the MMCC Event Summary Forms and any other related materials, such as the >28-day listing, in the ARIC Data Management Program (MGP). The steps taken at CC in processing Community Surveillance MMCC materials were:

A. **Separate and Organize ID Listings and Event Summary Forms:**
Upon notification that the MGP is ready, print out the listings in 5 jobs. Job 04: Events of one patient that occur over a period longer than 28 days that require a determination of possible linkage(s). Job 32: Linked Out-of Hospital Deaths (OHD-L). Job 33: Linked Non-Fatal Hospitalizations (NFH-L), In-Hospital Deaths (IHD), and Linked In-Hospital Deaths (IHD-L). Job 34: Out-of-Hospital Deaths (OHD). Job 37: Events for special review that include Linked Non-Fatal Hospitalizations (NFH-L), In-Hospital Deaths (IHD), and Linked In-Hospital Deaths (IHD-L). The number of events in Jobs 32, 33, 34, and 37 are recorded in a table, "Current Status of ARIC Surveillance Reviews", for monitoring purposes.

B. **Collect All Needed ID Medical Records:** ID-labeled file folders containing the discharge summary, progress note, cardiac consult, and/or history and physical for each event are obtained from the secured CC file cabinets or requested from the field centers (F, J, M, W). The listing in the variable, "Material", on the ESFs indicates whether the field center has already shipped each record for the event, or it needs to be requested. There will be no materials for Job 34 and the summary listing variable "Chart" will indicate whether there is a hospital record for an event. If the event has been reviewed previously, a folder will be on file at CC.

C. **Collate and Copy Materials for Each Event for Review:** Jobs 04 and 37 must be copied once; Jobs 32, 33, and 34 two times. 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 for Jobs 32, 33, and 34. The ESFs are stapled to the specific record: OHD events have none are stapled together. Each event is clipped together with a prepared MDX Form on top.

D. **Prepare Events for Reviewers:** The IDs to be sent to a reviewer are tracked by the Batch Number from the MGP, Sequence Number for the Reviewer, and

Dates for the steps in the process are recorded for Jobs 32, 33, 34, and 37 and 04. Each available reviewer is usually sent a set of 30 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 CC, usually a period of 3 to 4 weeks, and requests that the reviewer notify CC if the reviewer will be unable to complete reviews for an extended time in the future.

A MDX Form is prepared for each Event ID: the 7-digit Event ID is written in the set of boxes under which any linkages are also listed in reverse chronological order; the Sequence and Batch Numbers come from the MGP; the Code Number of the intended reviewer is noted (Sequence 0X represents the first time for review; 1X, the second, 2X, the third, *etc.*). For non-linked events, each MDX Form is clipped to the ESF stapled to the record, if there is one. For linked events, each MDX Form is clipped to the separately stapled events, with the Event ID first, followed by the linked events in reverse chronological order. The ESF prints the required parts of the form that need completing.

1. Linked Non-fatal Hospitalizations (NFH-L): (Job 37) The Community Surveillance MDX Form is prepared for a special reviewer using the Sequence Number X4 and Parts A and B of the Form with the Type of Review in Question 1.b. as “S” and Code Number of the intended special reviewer.

2. Special In-hospital Deaths (IHD and IHD-L): (Job 37) The MDX Form is prepared for a special reviewer using Sequence Number X5 for IHD and X4 or X5 for IHD-L; the Sequence Number is listed on the ESF for the Event ID. The events that are IHD require Parts A and C completed, and IHD-L require Parts A, B, and C completed by the reviewer. The Type of Review is “S” for Sequence x4 and “G” for Sequence X5.

3. In-hospital Deaths, Non-linked and Linked (IHD and IHD-L): (Job 33) Two MDX Forms are prepared for two reviewers using Sequence Numbers X1 and X2, as “Original” Reviews, with Type of Review also marked in Question lb as “O”. These events require Parts A and C completed. For linked events, the MGP prints out an additional sheet, “Overall Hospital Diagnoses Sheet” that goes on top of the Event ID materials, followed by the separately stapled set(s) of linked event(s).

4. Non-linked Out-of-hospital Deaths (OHD): (Job 34) Two MDX Forms are prepared for two reviewers using Sequence Numbers X1 and X2, as “Original” Reviews, with Type of Review also marked in Question lb as “O”. There are no records for these events and the ESFs have a different format. These events require Parts A and C completed; cross out Part B.

5. Linked Out-of-hospital Deaths (OHD-L): (Job 32) Two MDX Forms are prepared for two reviewers as for OHD, with addition of the linkages listed under the Event ID. The linked events, stapled together separately with any records available, are clipped to the Event ID in the usual fashion. These events usually require Parts A and C to be completed; cross out Part B. In rare cases, the MGP will generate a review that requires that Part B be completed and an "Overall Diagnoses Sheet" will be printed.

6. Determination of Possible Linkage(s) for Events Occurring >28 Days Apart: (Job 04) The MGP generates a composite listing of possibly linked events for a number of patients. The packet for determination of linkage(s) by a special reviewer contains the pages of the each set of ESFs stapled to the medical **r**ecords for each event, clipped together for each patient (Note: If no abstractions have been done and there is no material, then no linkages can be determined.). The prepared reviews are sent to a special reviewer to determine any greater than 28-day linkage(s). Determinations of any linkages are submitted to be incorporated into the next MGP.

11.2 CHD Reviews Specific to Cohort Surveillance

The CC generates the MMCC Event Summary Forms in the Data Management Program as well as Annual Follow-up Events. The steps taken at CC in processing Cohort Surveillance MMCC materials, similar to those for the Community Surveillance, are to:

A. **Separate and Organize ID Listings and Event Summary Forms:** Job 20: Each Cohort AFU, usually one page, must be placed first when all the materials are collated with the ESFs of that event. Job 16: Linked Non-Fatal Hospitalizations (NFH-L), In-Hospital Deaths (IHD), and Linked In-Hospital Deaths (IHD-L). Job 17: Non- Linked Non-Fatal Hospitalizations (NFH). Job 18: Out-of Hospital Deaths (OHD). Job 19: Linked Out-of-Hospital Deaths (OHD-L). The number of events in Jobs 16, 17, 18, and 19 are recorded in a table, "Current Status of ARIC Surveillance Reviews", for monitoring purposes.

B. **Collect All Needed ID Medical Records:** Procedures for obtaining materials are the same as for Community Events. There will be no materials at the field Centers for Job 18.

C. **Collate and Copy Materials for Each Event for Review:** The pages of all events to be reviewed must have the AFU sheet(s) first with the EFSs next, in the same manner as Community reviews; linked events follow, in reverse chronological order. Job 17 must be copied once. Unless events go to special view, Jobs 16, 18, and 19 need to be copied twice. The original set is placed in the event folder behind the medical record. The medical records, received in duplicate from the field centers, are copied once for Job 16, 18, and 19. The

AFUs and ESFs are stapled to the event for review and the linked events are stapled with the ESFs and record; OHD events have none, as will others, and are stapled together. Each event is clipped together with a prepared CDX Form on top.

D. **Prepare the Events for Reviewers:** The IDs to be sent to a reviewer are tracked by Batch Number from the MGP, Sequence Number for the Reviewer, and Dates for the steps in the process are recorded for Jobs 16, 17, 18, and 19. Each packet is prepared in the same manner as described for Community Surveillance.

1. Non-fatal Hospitalizations (NFH): (Job 17) The Cohort Surveillance CDX Form is prepared for a single reviewer using the Sequence Number X1 and Parts A and B of the Form with the Type of Review in Question 1.b. as "O" and the Code Number of the intended reviewer (Prior to 1995, two reviewers diagnosed the non-linked NFH events.).

2. Linked Non-fatal Hospitalizations (NFH-L) and In-hospital Deaths, Non-linked and Linked (IHD and IHD-L): (Job 16) The CDX Form is usually prepared for two reviewers using Sequence Numbers X1 and X2 with the Type of Review in Question 1.b. as "O" and the Code Numbers of the intended reviewers. The events that are NFH-L require Parts A and B completed and IHD and IHD-L require Parts A, B, and C completed by both reviewers.

3. Special Linked Non-fatal Hospitalizations (NFH-L) and In-hospital Deaths, Non-linked and Linked (IHD and IHD-L): (Job 16) The Sequence Number is listed on the ESF for the event with X5, as spanning >28 days. The CDX Form is prepared for a special reviewer with the Type of Review in Question 1.b. as "G" and the Code Number of the special reviewer. The events that are NFH-L require Parts A and B completed and IHD and IHD-L require Parts A, B, and C completed.

4. Non-linked Out-of-hospital Deaths (OHD): (Job 18) Two CDX Forms are prepared in a similar fashion to the MDX Forms in Job 34.

5. Linked Out-of-hospital Deaths (OHD-L): (Job 19) The CDX Form is usually prepared for two reviewers using Sequence Numbers X1 and X2 with the Type of Review in Question 1.b. as "O" and the Code Numbers of the intended reviewers. These Cohort events require Parts A, B, and C to be completed by both reviewers. Rarely is there a special review generated for an event with Sequence X5, spanning >28 days; the CDX Form prepared for the special reviewer has the Type of Review in Question 1.b. as "G".

E. For cohort participants, events occurring in year 2019 and afterwards, all non-fatal, non-linked events where the computer diagnosis is either 'NO-MI' or

'SUSPMI" and there is no MI ICD-10 discharge code (I20.x, I21.x), the event's final classification is determined by the computer classification algorithm and such cases do not go for MMCC review. This rule went into effect May 2020.

11.3 Adjudication of CHD Reviews

Adjudication was required if the algorithm classification in Question 13 (determined from MDX Questions 8 - 12) disagrees between two reviewers for Community Surveillance. In Cohort Surveillance, adjudication is necessary when the preferred classification (CDX Questions 7b, 14B) or the algorithm classification (Questions 6, 13), if there is no preferred classification, disagrees between two reviewers. For Non-fatal Hospitalizations in Job 17, if the one reviewer disagrees with the ARIC algorithm (Question 7a is "No"), then adjudication is necessary for Question 7b. Special reviews (Sequences X4 and X5) do not require adjudication. Adjudication is required only for the most current data if there were data changes initiating a new review.

Copy the completed MDX/CDX Forms that were returned by the original reviewers and the ESFs with the medical records that were sent to the original reviewers. The MDX/CDX Forms are prepared for the adjudicator using Sequence Number X3, as "Adjudication", with Type of Review marked in Question lb as "A". These events require the same Parts completed as the original review and have the same IDs and Batch Number as the original reviews. Clip the adjudicator's new MDX/CDX Form on top of the packet of each event to adjudicate. Community events for adjudication are tracked by Batch Number from the MGP, Sequence Number for the Reviewer, and Dates for the steps in the process are recorded. Follow the same procedures for shipping the adjudications as those for original reviews.

11.4 Monitoring Return of MDX/CDX Forms

Reviewers who do not meet expected deadlines are reminded of their tardiness. If forms are found to be incomplete, they are returned to the reviewer prior to data entry. The DMS and MGP also check for incompleteness of forms with inconsistent answers; forms with these problems are returned to the original reviewers for resolution.

11.5 Monitoring Consistencies of New Reviewers

When new reviewers have been certified and are ready to begin reviewing cases, the number of CHD events is kept low; the type of reviews best suited to them are OHD, then IHD, and later linked events. As original reviewers, they are paired with experienced reviewers. Feedback to the new reviewers on the cases needing adjudication is helpful. A new reviewer, still requiring training, can be given the same set of events to review as two original reviewers with Sequence Numbers 0X or 1X, which are checked by hand, until the accuracy on the MDX or CDX Forms is acceptable for events to be entered into the DMS

11.6 Filing and Storing Completed CHD Reviews in Event ID Labeled Folders

Verified MDX and CDX Forms are placed in the front of the Event ID folder and filed in numeric order in secured CC file cabinets; any linked IDs are filed independently in numeric order at the same time.

Folders with CHD events *over 5 years old*, as determined from the MGP, can be removed from the secured ARIC CHD file cabinets to secured offsite storage.

11.8 Summary of the ARIC MMCC Processing Procedures♣

Table 11.1

COHORT CHD: COMPLETION OF CDX FORM (Job 16-20)						
Type MGP	**Job #**	**Seq #**	**MI DX[a] (part B)**	**Death DX[a] (part C)**	**Reviewer**	**Items to check for Adjudications**
NH[a], Unlinked, >=1995	17,20	*1♦	Yes	No	Anyone	Q7a
NH[a], Linked	16,20	*1,*2	Yes	No	Anyone	Q7b vs Q7b if both Q7b not blank Q7b vs Q6 if one Q7b is blank Q6 vs Q6 if both Q7b are blank
IHD[a], Linked & Unlinked	16,20	*1,*2	Yes	Yes	Anyone	MI: Q7b vs Q7b if both Q7b not blank Q7b vs Q6 if one Q7b is blank Q6 vs Q6 if both Q7b are blank Death: Q14b vs Q14b if both Q14b not blank Q14b vs Q13 if one Q14b is blank Q13 vs Q13 if both Q14b are blank
OHD[a], Unlinked	18,20	*1,*2	No	Yes	Anyone	Q14b vs Q14b if both Q14b not blank Q14b vs Q13 if one Q14b is blank Q13 vs Q13 if both Q14b are blank
OHD[a], Linked	19,20	*1,*2	Yes	Yes	Anyone	MI: Q7b vs Q7b if both Q7b not blank Q7b vs Q6 if one Q7b is blank Q6 vs Q6 if both Q7b are blank Death: Q14b vs Q14b if both Q14b not blank Q14b vs Q13 if one Q14b is blank Q13 vs Q13 if both Q14b are blank
Special Deaths	**16**	***5**	**Yes**	**Yes**	**Folsom**	
Adjudication		***3**	**Same as Originals**	**Same as Originals**	MMCC Chair	

Table 11.2

COMMUNITY CHD: COMPLETION OF MDX FORM (Job 32-34,37, 04[d])						
NH[a], Linked	37	*4	Yes	No	Folsom	
IHD[a], Unlinked	33	*1,*2	No[e]	Yes	Anyone	Derived[b] Q6
IHD[a], Linked	33	*1,*2	No[f]	Yes	Anyone	Derived[b] Q6 & Q13
IHD[a], Linked (Special[f])	37	*4	Yes	Yes	Folsom	
OHD[a], Unlinked	34	*1,*2	No	Yes	Anyone	Derived[b] Q13
OHD[a], Linked	32	*1,*2	Mostly, No[g]	Yes	Anyone	Dervied[b] Q13
Special Deaths	37	*5	Yes if L-IHD	Yes	Folsom	
Adjudication		*3	Same as Originals	Same as Originals	MMCC Chair	

Table 11.3

COHORT STROKE: COMPLETION OF SDX FORM						
Type MGP	**Job #**	**Seq #**	**Stroke DX[a] (part B)**	**Stroke CL[a] (part C)**	**Reviewer**	**Items to check for Adjudications**
Original	06	01	Yes	If Q5=C or G	Shahar Gottesman	Computer DX
Adjudication		03	Yes	If Q5=C or G	Shahar Gottesman	

♣ Determination of possible linkages for events occurring > 28 days (from MGP Job 04) is not included in this summary table.

♦ * =0, 1, 2, ... depending on the number of times that an event was reviewed. If an event is reviewed for the first time, *=0. If an event is reviewed for the second time due to data changes, *=1, etc.

a) Abbreviations:

CL	= Classification	DX	= Diagnosis
NH	= Non-fatal Hospitalizations	IHD	= In-Hospital Deaths
OHD	= Out-of-Hospital Deaths	L-IHD	= Linked IHD

b) Criteria for adjudication:
Cohort with 1 review: compare preferred DX with computer DX (if Q7a is 'N', need adjudication).

Cohort with 2 reviews: compare preferred DX between reviewers. That is, compare Q7b vs Q7b if both Q7b are not blank, Q7b vs Q6 if one Q7b is blank, Q6 vs Q6 if both Q7b are blank. Similarly for Death Dx (Q13 & Q14b).

NOTE: the comparison listed above is under the assumption that the CDX form is complete (no incomplete items), and Q6 (determined by Q3-Q5. See Table 2 in the next page) and Q13 (determined by Q8-12 of the CDX form) are answered correctly. If Q6 and/or Q13 are answered incorrectly, data checks will be generated and the review is considered incomplete.

Community with 2 reviews: compare derived ARIC DX in Q6 & Q13 between reviewers. Note that Q6 is determined by Q3-Q5. See Table 2 in the next page. Q13 is determined by Q8-12 of the MDX form. If Q6 and/or Q13 are answered incorrectly, data checks will be generated and the review is considered incomplete.

Reviews with sequence numbers *4 or *5 do not require adjudication.

Cases needing adjudication should be processed right after receiving the reviews from reviewers. MGP Job 19 (comm surv) & Job 05 (cohort surv) check the cases still needing adjudication.

c) Before 1995, Unlinked Non-fatal Hospitalizations in cohort surveillance were reviewed by 2 reviewers with sequence number *1 & *2.

d) Community Surveillance MGP job 04.OUT is to be sent to Folsom for > 28 days linkage review. Feedback will be passed to the Statistician for the next MGP.

e) MI diagnosis for unlinked Non-fatal Hospitalizations and linked out-of-hospital deaths are automatically classified by computers.

f) Linked IHD cases: if MI is computer-classified, but not death, will require 2 reviewers (unless it's >28 death event). If both MI & Death require a manual review, a special review with seq # *4 will be assigned.

g) MI diagnosis for linked out-of-hospital deaths are mostly automatically classified by computers. However, a portion of events which linked to >=2 hospitalizations require 2 reviews.

11.9 Procedures for Hospital Record Sent to CC

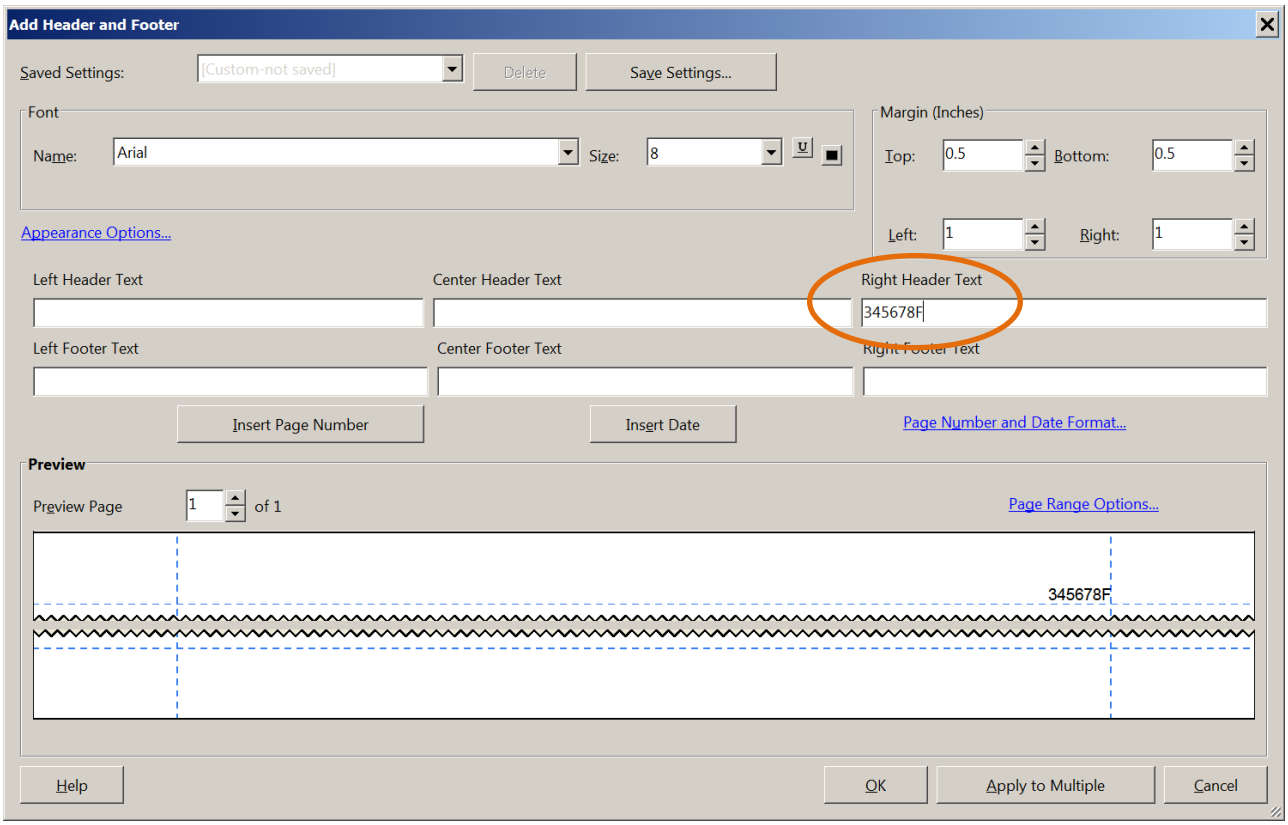
For the following type of events, field centers should send the electronic materials to the CC via Liquid Files on a regular basis (without CC's request):

All hospitalized cohorts that are non-skip-outs
All who transferred with ICD-9 code 410 or 411 or ICD-10 code I20-24
All deaths in Cohort or Community

For each of these events, a PDF is prepared. Included in the PDF file is one of the following, ranked in priority:

- ✓ Discharge summary
- ✓ Progress note of last physician and cardiac consultation
- ✓ Progress note of last physician and history and physical

Each document should be blinded using a black china marker or the redacting tool (see appendix X). Use the "Checklist for Hospital Event Materials" as the first page of the PDF document. Cut and paste the event id from the Hlist to the electronic version of the checklist or, if using a paper version, hand write the id. The event IDs should be added to each page of the document using a 'header' in the PDF.



.

When a significant number of medical records have been prepared, they are put in numeric order and sent to the CC via a secure website.

If CC requires hospital records for materials not sent for a particular patient's event, such as cases of hospitalizations to determine possible linkages, these are also prepared and sent in a similar fashion.

12.0 QUALITY CONTROL OF MMCC REVIEW PROCESS

Each year, the CC generated a set of Surveillance QC reports. QC Charts are now available on the ARIC secure website view system that uses current data (see https://views.cscc.unc.edu/#/login). In addition, monitoring visits from the CC to each site, and central training for abstractors and MMCC reviewers are held once every 1-3 years to assure data quality.

12.1 Quality Control for Medical Record Abstractions

In ARIC Surveillance, hospital medical records for cohort participants with discharge ICD-9 code 410 or 411 were re-abstracted for events in 1987-1997. Starting from late 1997 (event year), the number of re-abstractions was decreased to 12 per abstractor per calendar year and event

year. Therefore, each abstractor is expected to re-abstract one of their colleague's abstractions each month. Each year, items in the re-abstracted HRA were compared to their original abstraction to compute the percentage of disagreement. Additionally, "side-by-side tables" which detail every disagreement within an HRA form between the original and the phantom abstraction are provided to the surveillance supervisors at each field center. The disagreement tables and side-by-side tables are generated on a quarterly basis and distributed to supervisors prior to each quarters abstractors conference call. Other quality control reports generated related to abstraction include:

- % of missing data or unknown responses for HRA items, by year and center
- % of unlocatable charts, % of MI/death unclassifiable events, by year and center

12.2 Quality Control for Out-of-Hospital Death Investigation

For OHD events, information from informants, patient's physicians and coroner/medical examiner need to be abstracted. Up to three Informant interviews and two physician questionnaires may be collected. Each year, the percentage of completeness of the abstractions for OHD is computed. A report detailing the time from an eligible death date until OHD death investigation has been completed is also generated on an annual basis.

12.3 Quality Control for MMCC Reviews

Quality control of MMCC reviewers is conducted via calculation of disagreement rates for both cohort and community events that require review by two MMCC members. Further for those events where the MMCC reviewers disagree the event is sent to the adjudicator and disagreement rates between the reviewers and adjudicator are calculated. This process is done for both MI events and fatal events and displayed graphically on the ARIC website view system.

12.4 Summary of the Annual Surveillance QC Report

Each year, the CC generates a QC report includes the following items:

HRA QC

- disagreement rates in repeat abstraction, by year and center;
- % of unlocatable charts, % of MI/death unclassifiable events, by year and center

OHD investigation

- Completeness of event investigation
- Time to completion of investigation

MMCC QC

- disagreement rates for MI/Death classification between 2 original reviewers, by year
- % of original reviews disagreed with Adjudicators for MI classification, by reviewers

- % of original reviews disagreed with Adjudicators for Death classification, by reviewers
- % of dirty data (inconsistent answers among Q3-Q6) for MI classification, by year & reviewers
- % of dirty data (inconsistent answers among Q8-Q13) for Death classification, by year & reviewers

12.5 Certification Procedures

12.5.1 Certification for Medical Records Abstraction

Medical record abstractors are re-certified annually during a central (face to face) training session or a webinar. Generally, these training sessions are conducted over a period of 2 days. The agenda of the training sessions include detail discussions of changes or updates to the data entry systems, updates to question by question instructions for each data collection form, review of ongoing quality control reports. A key feature of the training is the recertification process. As a part of that process, each abstractor receives a packet of 4 medical records (one from each center). Each abstractor completes a full hospital record abstraction for each record and enters it into the certification data management system at https://cdart2.cscc.unc.edu/CDART2/ using their 'certification login' (their usual id with _cert at the end). Answers from each abstractor for every item on the HRA form are compared and a printout generated. This is reviewed in detail during the training session, with discussion lead by the senior abstractor supervisor. Discrepancies between abstractors on any items are discussed in detail. Items with significant disagreement are identified and the appropriate sections of the question-by-question instructions and protocols discussed. In addition, each center prepares and presents four cases for review and discussion by the group. An abstractor must successfully complete these exercises in order to be re-certified. The senior abstractor supervisor in consultation with the Chair of the Surveillance Committee makes the decision of re-certification.

12.5.1.1 Certification of Stroke Medical Records Abstraction

Beginning in April 2015 certification of medical records for stroke was implemented, as two new stroke abstractors were trained and certified in stroke abstractions at the Minnesota field center. These procedures were approved by the ARIC Surveillance Committee March 2015. Training for certification is conducted by the stroke clinician and lead stroke abstractor**.**

Training materials developed by Dr. Shahar are used. Training includes the following:

- Studying the form and the QxQ, learning about stroke (types, pathology, etc)
- Abstracting records (about 20)
- Abstracting various diagnostic reports (about 50)

The trainees work is reviewed and discussed together as a group and questions are answered over multiple sessions with the Lead Stroke Abstractor and lead stroke clinician

Abstractors are certified on the basis of their abstraction of two certification charts. There is a no *a-priori* rules for passing established (such as 90% of items). Instead the results are reviewed to determine competency. A correct answer to most of the items is expected, but is not sufficient for to be considered certified. For example, 95% correct responses while missing a major deficit and an MR diagnosis would not be considered certified.

To maintain certification in stroke, an abstractor is required to abstract one stroke event per week for the first 4 months, and then one per month after that. The lead stroke abstractor in Minnesota would select 3 cases for the annual recertification training.

12.5.2 Certification for Informants Interview

Staff responsible for conducting informant interviews are also re-certified annually at the central training. During the training session, the protocol and question-by-question instructions for completing the informant interview form are reviewed in detail. A main focus of the informant interview re-certification is review of the informant narrative. Examples (n=40) of informant narratives from all field centers are read out loud during the session and critiqued by the interviewers and surveillance supervisors. Successful completion of these exercises is required to be re-certified as an informant interviewer.

12.5.3 Certification for MMCC review

On an annual basis (starting in 1999) the Mortality and Morbidity Classification Committee meets either in person or by conference call to conduct its training sessions. Topics for discussion during these training sessions include update on changes in ICD coding rules, innovations in diagnostic testing (e.g. incorporation of cardiac troponins), review of quality control data, update on form changes, group discussion of informant interviews and detailed discussion of changes to case law. A main feature of the training session is the re-certification process. As a part of recertification, a standard set of cases (a variety of types including linked and non-linked non-fatal hospitalizations, in-hospital deaths, out-of-hospital deaths) from community and cohort surveillance are distributed to all members prior to the meeting. Committee members are asked to complete the appropriate CDX or MDX form as they normally would do and send them to the coordinating center. The data from the CDX and MDX forms are summarized in table form and distributed for discussion during the re-certification process. Each case is reviewed in detail with special discussion among the group on any disagreement in diagnosis. This session is led by the chair of the MMCC. In addition, special cases selected by the chair of the MMCC are presented and discussed in detail. Successful completion of these exercises, as determined by the chair of the MMCC is required for individuals to be re-certified.

13.0 CONFIDENTIALITY

Several procedures are in place to protect the security of the personal identifying information obtained from medical records. Personal identifiers (name, social security number, date of birth, gender, race) are abstracted from the medical record for the purpose linkage to the

National Death Index. This information is used to determine vital status of Cohort participants who are lost to follow-up. For community surveillance cases, personal identifiers are used to determine long-term case-fatality of validated myocardial infarction events by either linkage with death certificate data provided by the state health departments or with the National Death Index (Jackson only). Except for the purposes of this linkage, all personal identifiers are removed from distributed datasets. Raw data files residing at the CC are password protected. Personal identifiers are "blacked out" on any paper copy of medical records sent to the CC and these copies are stored in locked secure rooms. Study personnel involved in medical record abstraction and handling of these data have been trained on the protection of human subjects in research.

14.0 SUGGESTED READINGS

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APPENDICES
APPENDIX I. ICD-9 AND 10 CODES FOR IDENTIFYING SURVEILLANCE EVENTS

ICD-9 Codes for the Identification of Fatal CHD

(January 1, 1987 and December 31, 1998)

Code	Title
250	Diabetes Mellitus
401	Essential Hypertension
402	Hypertensive Heart Disease
410	Acute Myocardial Infarction
411	Other Acute and Subacute Ischemic Heart Disease
412	Old Myocardial Infarction
413	Angina Pectoris
414	Other Chronic Ischemic Heart Disease
427	Cardiac Dysrhythmias
428	Heart Failure
429	Ill-Defined Descriptions and Complications of Heart Disease
440	Atherosclerosis
518.4	Acute Edema of Lung
798	Sudden Death, Cause Unknown
799	Other Ill-Defined and Unknown Causes of Morbidity and Mortality

ICD-10 Codes for the Identification of Fatal CHD

(January 1, 1999 and beyond)

Code	Title
E10-14	Diabetes Mellitus
I10	Essential Hypertension
I11	Hypertensive Heart Disease
I20	Unstable Angina, angina pectoris
I21-23	Acute Myocardial Infarction
I24	Other Acute IHD
I25	Chronic IHD (including old MI)
I46	Cardiac Arrest
I47	Paroxysmal Tachycardia
I48	Atrial Fibrillation
I49	Other cardiac arrhythmias
I50	Heart Failure
I51	Ill-defined heart disease
I70	Atherosclerosis
I97 (not I97.2)	Postprocedural disorder of circulatory system
J81	Pulmonary Edema
J96	Respiratory Failure
R96	Other Sudden Death
R98	Unattended Death
R99	Other ill-defined cause

ICD Codes for the Identification of Hospitalized Myocardial Infarction

ICD-9	Title	ICD-10
402	Hypertensive Heart Disease	I11.x
410	Acute Myocardial Infarction	I21.x,
411	Other Acute and Subacute Ischemic Heart Disease	I24.x
412	Old Myocardial Infarction	I25.x
413	Angina Pectoris	I20.x
414	Other Chronic Ischemic Heart Disease	I25.x
427	Cardiac Dysrhythmias	I47.x, 149.x, R00.1
428	Heart Failure	I50.x,
518.4	Acute Edema of Lung, Unspecified	J81.0

APPENDIX II. FORM LETTERS

Format 1: Sample Letter to Informant: Known Telephone Number

Dear _____,

I am writing on behalf of the National Heart, Lung, and Blood Institute's Atherosclerosis Risk in Communities study, a project of (name of institution) designed to measure the rates of heart disease in (name of state or area), to ask for your help. Your name is listed on the death certificate of (name) who passed away on (date). In a few days (name), a member of my staff, will be calling to explain further about the project and seek your permission to ask a few medical questions. Of course, your participation is entirely voluntary.

The information we need will be used for statistical purposes only, and will remain strictly confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Thank you very much in advance for your help in this important study.

Sincerely,

ARIC Principal Investigator
(Name of Institution)

Format 2: Sample Letter to Informant: Unknown Telephone Number

Dear _____,

I am writing on behalf of the National Heart, Lung, and Blood Institute's Atherosclerosis Risk in Communities study, a project of (name of institution), designed to measure the rates of heart disease in (name of state or area), to ask for your help. Your name is listed on the death certificate of (name) who passed away on (date). We would like to call you to explain more about the project and to ask a few medical questions, but have been unable to find your telephone number.

Could you take a few moments to fill out and mail the enclosed postcard? The information we will be calling about will be used for statistical purposes only, and will remain strictly confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Of course, your assistance in our research is entirely voluntary. Thank you very much in advance for your help in the important study.

Sincerely,

ARIC Principal Investigator
(Name of Institution)

(ENCLOSE POSTCARD, RETURN ADDRESSED AND STAMPED. SEE FORMAT 3.)

Format 3: Reply Postcard From Informant With Telephone Number

FORMS SHOULD BE RETURN-ADDRESSED TO LOCAL SURVEILLANCE CENTER AND STAMPED.

Dear (Name of Surveillance Supervisor):

I will be able to help with you Atherosclerosis Risk in Communities study.

I do have a telephone number which is (___)_____. The best times to reach me are or _____.

An alternative telephone number is: (___)_____. The best times to reach me at this number are or _____.

I do not have a telephone number, but I agree to be interviewed in person, and will be calling your staff to set up a time and a place for the interview.

Sincerely,

Print Name of Informant

Format 4: Sample Letter to a Neighbor RE: Location of Informant

Dear _____,

I am writing on behalf of the National Heart, Lung, and Blood Institute's Atherosclerosis Risk in Communities study, a project of (name of institution) designed to measure the rates of heart disease in (name of state or area), to ask for your help. As you may know, (name of decedent) passed away on (date). As part of the study, we are systematically attempting to contact a next-of-kin or another person who lived with the decedent, in order to obtain some medical information that would help us to find out whether (name of decedent) died from a heart attack. Since we have not been able to locate such a person and since you were (name of decedent's) neighbor, we believe that you may be able to help us.

Could you take a few moments to fill out and mail the enclosed postcard? The information we wish to obtain from a next-of-kin or another person who lived with (name of decedent) will be used for research purposes only, and will remain strictly confidential. It will contribute to our efforts to better understand heart disease and prevent its occurrence in the future. Of course, your assistance in our research is entirely voluntary.

If you have any questions, please feel free to call me collect at (___)_____, or our local Surveillance Supervisor, (name) at (___)_____. Thank you very much in advance for your help in this important study.

Sincerely,

ARIC Principal Investigator
(Name of Field Center)

(ENCLOSE POSTCARD, RETURN-ADDRESSED AND STAMPED. SEE FORMAT 5.)

Format 5: Reply Form on the Location of Informant

POSTCARD SHOULD BE RETURN-ADDRESSED TO LOCAL SURVEILLANCE CENTER AND STAMPED.

Dear (Name of Surveillance Supervisor):

The following individual(s) was (were) living with (name of decedent) at the time of his/her death:

Name	Relationship to Deceased	Present Address	Present Telephone Number
_____	_____	_____	
_____	_____	_____	
_____	_____	_____	
_____	_____	_____	

I do not have any information on persons who were living with (name of the decedent) at the time of his/her death.

Sincerely,

(Print Name of Neighbor)

Format 6: Informant Release of Information Form: Nursing Home

I hereby authorize and request _____ to furnish to the Atherosclerosis Risk in Communities study the medical records on (name of the decedent). These records will be reviewed only for research purposes and none of the information will be released to any individual other than the research team. Any costs for reproduction of records will be covered by the study.

Date: _____ Signed:

(Relationship to the Deceased)

Witness:

Format 7: Letter to Physician Signing Death Certificate

Dear Doctor _____,

I am writing on behalf of the Atherosclerosis Risk in Communities study, an epidemiologic project of (name of institution) along with three other centers in the United States. The survey is assessing incidence of myocardial infarctions and coronary death in four communities throughout the country. We need some information concerning (name of the decedent), whose death certificate you signed on (date). The information is needed to supplement the death certificate in assigning a cause of death. Could your nurse or you take a few moments to provide the answers to the questions on the enclosed form from your records?

This information will be used for statistical purposes only, and will remain strictly confidential. If you have any questions, please feel free to call me collect at (___)_____, or our local Surveillance Supervisor, (name) at (___)_____. Thank you very much in advance for your kind assistance and consideration of this request.

Sincerely,

ARIC Principal Investigator
(Name of Field Center)

Enclosure: Physician Questionnaire

Format 8: Letter to Attending Physician of Decedent

Dear Doctor _____,

I am writing on behalf of the Atherosclerosis Risk in Communities study, an epidemiologic project of (name of institution) along with three other centers in the United States. The survey is assessing incidence of myocardial infarctions and coronary death in four communities throughout the country. We need some information concerning (name of decedent), who, according to the family, was your patient. The information is needed to supplement the death certificate in assigning a cause of death. Could your nurse or you take a few moments to provide the answers to the questions on the enclosed form from your records?

This information will be used for statistical purposes only, and will remain strictly confidential. If you have any questions, please feel free to call me collect at (___)_____, or our local Surveillance Supervisor, (name) at (___)_____. Thank you very much in advance for your kind assistance and consideration of this request.

Sincerely,

ARIC Principal Investigator
(Name of Field Center)

Enclosure: Physician Questionnaire

Format 9: Informant Release of Information: Physician

Physician:

The above named physician has my permission to release medical information to the Atherosclerosis Risk in Communities study. This information will be used for statistical purposes only, and will remain strictly confidential.

Decedent's name:

My name:

Address:

Relationship to Decedent:

Date: _____ Signed:

Witness:

Format 10: Informant Release of Information: Out-of-Area Hospital

TO:

(Name of Hospital)

The above named hospital has my permission to release medical information to the Atherosclerosis Risk in Communities study. This information will be used for statistical purposes only, and will remain strictly confidential.

Decedent's Name:

My Name:

Address:

Relationship to Decedent:

Date: _____ Signed:

Relationship to Decedent:

Witness:

APPENDIX III. COMPUTERIZED STROKE CLASSIFICATION ALGORITHM

I. Subarachnoid Hemorrhage (SAH)

ARIC Definition of Definite SAH:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the four below:

1. Meets criteria (a) and (b) below:
   a. Angiographic identification of a saccular aneurysm as the source of bleeding (e.g. demonstration of a clot adjacent to aneurysm or reduced caliber of otherwise normal vessels) AND
   b. Bloody (not traumatic) tap or xanthochromic spinal fluid, OR
2. Demonstration by CT or MRI of a blood clot in Fissure of Sylvius, between the frontal lobes, in basal cisterns or within a ventricle with no associated intraparenchymal hematoma, OR
3. Demonstration at surgery of bleeding saccular aneurysm, OR
4. Demonstration at autopsy of recent bleeding of a saccular aneurysm

ARIC Definition of Probable SAH:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet either criterion (1) or criteria (2) and (3) below:

1. a. Angiographic identification of a saccular aneurysm as the source of bleeding (e.g. demonstration of a clot adjacent to aneurysm or reduced caliber of otherwise normal vessels) AND
   b. Spinal tap was either not done or was traumatic, or missing, OR
2. One or more of the following symptoms or signs occurred within minutes or a few hours after onset:
   a. Severe headache at onset, or severe headache when first conscious after hospital admission;
   b. Depression of state of consciousness;
   c. Evidence of meningeal irritation;
   d. Retinal (subhyaloid) hemorrhages; AND
3. Bloody (not traumatic) tap or xanthochromic spinal fluid.

II. Brain Hemorrhage (IPH)

ARIC Definition of Definite IPH:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the three below:

1. Demonstration of definite intracerebral hematoma by CT or MRI, e.g. an area of increased density, such as seen with blood, OR
2. Demonstration at autopsy or surgery of intracerebral hemorrhage, OR
3. Evidence in the patient's clinical record that meet criteria (a), (b), (c), and (d) below:
   a. One major or two minor neurological signs or symptoms from the following list that lasted at least 24 hours or until the patient died:

      Major:

      - hemiparesis involving two or more body parts
      - homonymous hemianopia
      - aphasia

Minor:

- diplopia
- vertigo or gait disturbance
- dysarthria or dysphagia or dysphonia
- unilateral numbness involving two or more body parts, AND

b. Bloody (not traumatic tap) or xanthochromic spinal fluid, AND
c. Cerebral angiography demonstrates an avascular mass effect and no evidence of aneurysm or arteriovenous malformation, AND
d. No CT / MRI was performed or the CT / MRI was technically inadequate.

ARIC Definition of Probable IPH: Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet all the criteria below:

1. One major or two minor neurological signs or symptoms listed above under definite #3 that lasted at least 24 hours or until the patient died, AND
2. Decreased level of consciousness or coma that lasted at least 24 hours or until the patient died, AND
3. Bloody (not traumatic tap) or xanthochromic spinal fluid, AND

3. No CT / MRI was performed or the CT / MRI was technically inadequate.

III. Thrombotic Brain Infarction (TIB)

ARIC Definition of Definite TIB:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the two below:

1. Demonstration at autopsy of nonhemorrhagic infarct in brain, OR
2. Evidence in the patient's clinical record that meet criteria (a) and (b) below:
   a. One major or two minor neurological signs or symptoms from the following list that lasted at least 24 hours or until the patient died:

      Major:

      - hemiparesis involving two or more body parts
      - homonymous hemianopia
      - aphasia

      Minor:

      - diplopia
      - vertigo or gait disturbance
      - dysarthria or dysphagia or dysphonia
      - unilateral numbness involving two or more body parts, AND

   b. CT or MRI shows "infarct" or an area of decreased density which may indicate edema or ischemia, with no evidence of hemorrhage.

ARIC Definition of Probable TIB:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet all the criteria below:

1. One major or two minor neurological signs or symptoms listed above under definite #2a that lasted at least 24 hours or until the patient died, AND

2. Demonstration of negative or nonspecific findings and no evidence of hemorrhage by CT or MRI performed in the first 48 hours after the onset of symptoms or signs, AND
3. A spinal tap was either not done, or was a traumatic tap, or yielded clear, colorless spinal fluid.

IV. Noncarotid Embolic Brain Infarction (EIB)

ARIC Definition of Definite EIB:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet the criteria specified under at least one of the two below:

1. Demonstration at autopsy of:
   a. An infarcted area (bland or hemorrhagic) in the brain, AND
   b. A source of emboli in a vessel of any organ, or an embolus in the brain, OR
2. Evidence in the patient's clinical record that meet criteria (a), (b), and (c) below:
   a. One major or two minor neurological signs or symptoms from the following list that lasted at least 24 hours or until the patient died:

      Major:
      - hemiparesis involving two or more body parts
      - homonymous hemianopia
      - aphasia

      Minor:
      - diplopia
      - vertigo or gait disturbance
      - dysarthria or dysphagia or dysphonia
      - unilateral numbness involving two or more body parts, AND

   b. Establishment of a likely source for cerebral embolus, e.g.: valvular heart disease (including prosthetic heart valve), atrial fibrillation or flutter, MI, cardiac or arterial operation or procedure, cardiac myxoma, bacterial endocarditis, AND

   c. CT or MRI shows an area of decreased density which may indicate edema or ischemia, with no evidence of hemorrhage

ARIC Definition of Probable EIB:

Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus must meet all the criteria below:

1. One major or two minor neurological signs or symptoms listed above under definite #2a that lasted at least 24 hours or until the patient died, AND
2. An identifiable source for the cerebral embolus as specified in definite #2b, AND
3. Demonstration of negative or nonspecific findings and no evidence of hemorrhage by CT or MRI performed in the first 48 hours after the onset of symptoms or signs, AND
4. A spinal tap was either not done, or was a traumatic tap, or yielded clear, colorless spinal fluid.

V. Possible Stroke of Undetermined Type

ARIC Definition:
Evidence in the patient's clinical record of sudden or rapid onset of neurologic symptoms lasting for more than 24 hours or leading to death, plus one major or two minor neurological signs listed below:

Major:

- hemiparesis involving two or more body parts
- homonymous hemianopia
- aphasia

Minor:

- diplopia
- vertigo or gait disturbance
- dysarthria or dysphagia or dysphonia
- unilateral numbness involving two or more body parts
- severe headache at onset or severe headache when first conscious after hospital admit
- depression of state of consciousness
- evidence of meningeal irritation
- retinal (subhyaloid) hemorrhages
- palsy of the iii cranial nerve, AND

Clinical history, signs, symptoms, and findings from diagnostic tests and / or autopsy are not sufficient to meet the criteria for classifying the case as a “definite” or “probable” case of one of the four specific diagnostic categories of stroke.

APPENDIX IV. INSTRUCTIONS FOR SENDING ECGS TO THE WAKE FOREST UNIVERSITY ECG READING CENTER

Starting November of 2016 the ARIC study changed ECG reading centers to Wake Forest University. Sites will continue to send, via a secure web portal, scanned ECG copies in PDF format, however now they are now sent to the Wake Forest ECG Reading Center.

The following are the Field Center procedures for (i) preparation and scanning the ECGs into PDF document, (ii) creating the PDF document, and (iii) uploading the PDFs to the secure CC Liquid File Center website.

1. Preparation and Scanning the ECGs

- It is imperative to have high quality PDFs of ECGs, as a distorted copy of an ECG cannot be read accurately.

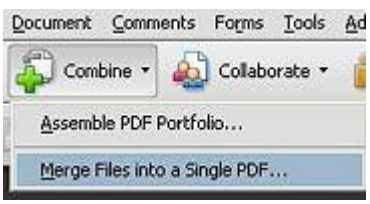
- It is preferable to save a PDF copy of digitally stored ECGs without producing a paper copy. Save an electronic copy at your site until the appropriate time to destroy that year's event documents.

- When it is necessary to make a PDF of a photocopied scanned ECG, the paper copy should not be enlarged or shrunken. To achieve the best possible copy quality, check that the copier/scanner used is not changing image sizes. This can be discerned by comparing the length of the calibration mark or intervals with those expected from a normal ECG. To avoid distorting the image, scan the paper copy top to bottom rather than side to side.

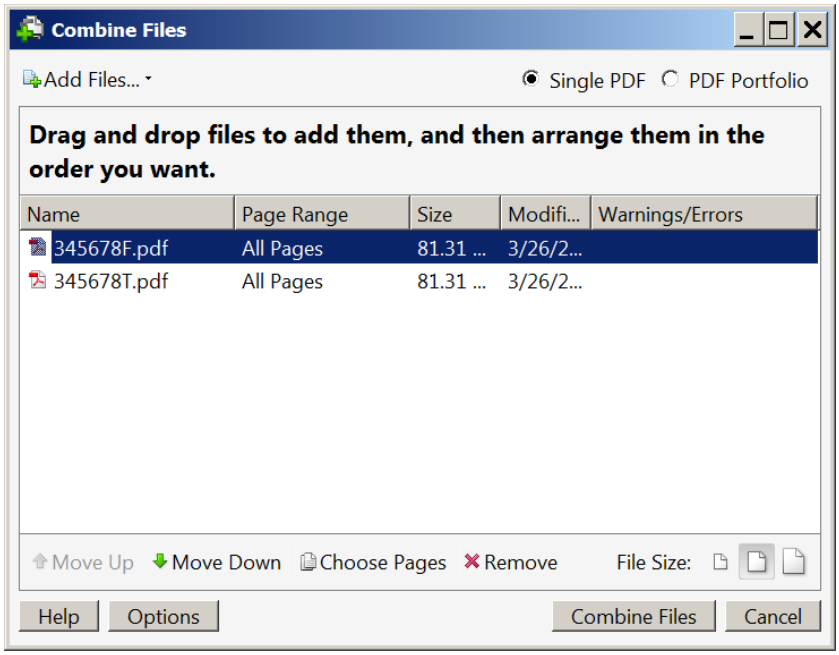
- The ECG PDF document should be in landscape view. Do not make the original FIT the landscape view as that would distort the ECG.

- Each ECG needs to be labeled in the top right corner with, ID number and what sequence of ECG it is (i.e., first, third, or last). Please ensure the ID is placed within the printable space. Depending on how you get the ECG from the hospital, you can write the ID and sequence on the paper ECG before scanning, or you can type in the ID if scanning directly into Adobe Acrobat. Do not use PaperPort to type in the ID numbers as the IDs do not show up when printing from Adobe Acrobat. Use the typewriter feature also known as 'add or edit text box' in Adobe. **Tools > Typewriter** When typing an ID leave at least a ½ inch margin from the top of the page. It will get cut off it it's too close to the top edge. This may result in some IDs being more toward the middle of the page and not the right side (see example below).

- Combine all the ECGs for that event ID into 1 pdf using the 'combine' feature to 'merge files into a single pdf'. Open one of the pdf documents and select **Combine > Merge Files into a Single PDF.**



- Click Add Files or 'drag and drop' the pdf documents for that event ID that you want to add.



- Use '**Move Up'** or '**Move Down'** to reorder the pages. When finished arranging the files, click '**Combine Files'**.

- Save the document that has all the ECGs for that event and name the final PDF '3456789FTL'. This indicates that the pdf includes the first, third and last ECG. If perhaps they only have the first and last, the name would be '3456789FL'.

- Name the final PDF file "Your Site Initial ID #", (i.e. F_3456789FTL.PDF).

3. <u>Uploading the ECGs to the ECG Reading Center</u>

ECGs will be sent to the RC using a similar system used to send pdfs of the event materials to the CC. However, ECGs will be uploaded via the web link:

https://csccex.cscc.unc.edu/filedrop/wakereading

- For more information on using LiquidFiles refer to the User Guide: https://csccex.cscc.unc.edu/help

- Please put the year of the event AND your site in the subject line for the RC; example : "ECGs for Forsyth 2015"

NOTE: The Wake ECG Reading Center has requested that we **not** send more than 1 batch (upload) a day, and the batch should contain **at least 5 ECGs** minimum (Except with special request from CC for data checks/clean-up).

The 1 batch per day is PER PERSON, not per site. So it is okay for **a** person to send a batch(upload) every day.

APPENDIX V. DUPLICATE MATERIALS SHIPPING FORMS

ARIC SURVEILLANCE SHIPPING INVENTORY
DUPLICATED MATERIALS FOR MMCC REVIEWERS

CENTER ____ BATCH _____ DATE _____ TYPE _____

Event ID #	Event ID #
1.	**16.**
2.	**17.**
3.	**18.**
4.	**19.**
5.	**20.**
6.	**21.**
7.	**22.**
8.	**23.**
9.	**24.**
10.	**25.**
11.	**26.**
12.	**27.**
13.	**28.**
14.	**29.**
15.	**30.**

REMARKS: _____

CHD Checklist for Hospital Event Materials
MMCC Committee for ARIC

Event ID

Material

☐ Discharge Summary ☐Not available

☐ H & P or Cardiac Consult ☐Not available

☐ Autopsy Report (Cohort Only)

☐*Other
*if available (need not be noted as missing if they do not exist)

Comments on materials

Status of Case Materials

☐ First Sending, material is complete

☐ First Sending, material is NOT complete

☐ Update, material is complete

☐ Update, material is NOT complete

Notification of Missing Materials:

Missing Material	

Reason material is missing:	

Date prepared:	

APPENDIX VI. CHD HOSPITALIZATIONS SAMPLING FRACTIONS

CHD sampling fractions for ages 35-74 for CHD: Forsyth County

RACE	SEX	CODEGRP	2006, 2008-2012 SAMFRAC	2007 SAMFRAC	2013 SAMFRAC
Black	Female	410	0.867	0.303	0.713
Black	Female	411 not 410	0.400	0.14	0.329
Black	Female	412-414 not 410-411	0.233	0.082	0.192
Black	Female	Others not 410-414	0.233	0.082	0.192

RACE	SEX	CODEGRP	2006, 2008-2012 SAMFRAC	2007 SAMFRAC	2013 SAMFRAC
Black	Male	410	0.867	0.303	0.713
Black	Male	411 not 410	0.433	0.152	0.356
Black	Male	412-414 not 410-411	0.233	0.082	0.192
Black	Male	Others not 410-414	0.267	.093	0.219

RACE	SEX	CODEGRP	2006, 2008-2012 SAMFRAC	2007 SAMFRAC	2013 SAMFRAC
White	Female	410	0.500	0.175	0.411
White	Female	411 not 410	0.200	0.07	0.164
White	Female	412-414 not 410-411	0.100	0.035	0.082
White	Female	Others not 410-414	0.067	0.023	0.055

RACE	SEX	CODEGRP	2006, 2008-2012 SAMFRAC	2007 SAMFRAC	2013 SAMFRAC
White	Male	410	0.300	0.105	0.247
White	Male	411 not 410	0.133	0.047	0.109
White	Male	412-414 not 410-411	0.067	0.023	0.055
White	Male	Others not 410-414	0.067	0.023	0.055

CHD sampling fractions for ages 75-84 for CHD: Forsyth County

RACE	SEX	CODEGRP	2006, 2008-2012 SAMFRAC	2007 SAMFRAC	2013 SAMFRAC
Black	Female	410	1.000	0.35	0.822
Black	Female	411 not 410	0.633	0.222	0.520
Black	Female	412-414 not 410-411	0.367	0.128	0.302
Black	Female	Others not 410-414	0.333	0.116	0.274

RACE	SEX	CODEGRP	2006, 2008-2012 SAMFRAC	2007 SAMFRAC	2013 SAMFRAC
Black	Male	410	1.000	0.35	0.822
Black	Male	411 not 410	1.000	0.35	0.822
Black	Male	412-414 not 410-411	0.700	0.245	0.575
Black	Male	Others not 410-414	0.800	0.28	0.658

RACE	SEX	CODEGRP	2006, 2008-2012 SAMFRAC	2007 SAMFRAC	2013 SAMFRAC
White	Female	410	0.433	0.152	0.356
White	Female	411 not 410	0.133	0.047	0.109
White	Female	412-414 not 410-411	0.067	0.023	0.055
White	Female	Others not 410-414	0.067	0.023	0.055

RACE	SEX	CODEGRP	2006, 2008-2012 SAMFRAC	2007 SAMFRAC	2013 SAMFRAC
White	Male	410	0.333	0.117	0.274
White	Male	411 not 410	0.133	0.047	0.109
White	Male	412-414 not 410-411	0.067	0.023	0.055
White	Male	Others not 410-414	0.067	0.023	0.055

CHD sampling fractions for ages 35-74 for CHD: Jackson

RACE	SEX	CODEGRP	2006-13 SAMFRAC
Black	Female	410	0.500
Black	Female	411 not 410	0.233
Black	Female	412-414 not 410-411	0.133
Black	Female	Others not 410-414	0.133

RACE	SEX	CODEGRP	2006-13 SAMFRAC
Black	Male	410	0.433
Black	Male	411 not 410	0.233
Black	Male	412-414 not 410-411	0.133
Black	Male	Others not 410-414	0.167

RACE	SEX	CODEGRP	2006-13 SAMFRAC
White	Female	410	1.000
White	Female	411 not 410	0.500
White	Female	412-414 not 410-411	0.200
White	Female	Others not 410-414	0.200

RACE	SEX	CODEGRP	2006-13 SAMFRAC
White	Male	410	1.000
White	Male	411 not 410	0.500
White	Male	412-414 not 410-411	0.200
White	Male	Others not 410-414	0.200

CHD sampling fractions for ages 75-84 for CHD: Jackson

RACE	SEX	CODEGRP	2006-13 SAMFRAC
Black	Female	410	0.633
Black	Female	411 not 410	0.267
Black	Female	412-414 not 410-411	0.167
Black	Female	Others not 410-414	0.167

RACE	SEX	CODEGRP	2006-13 SAMFRAC
Black	Male	410	1.000
Black	Male	411 not 410	0.533
Black	Male	412-414 not 410-411	0.300
Black	Male	Others not 410-414	0.367

RACE	SEX	CODEGRP	2006-13 SAMFRAC
White	Female	410	1.000
White	Female	411 not 410	0.667
White	Female	412-414 not 410-411	0.367
White	Female	Others not 410-414	0.300

RACE	SEX	CODEGRP	2006-13 SAMFRAC
White	Male	410	1.000
White	Male	411 not 410	0.433
White	Male	412-414 not 410-411	0.200
White	Male	Others not 410-414	0.233

CHD sampling fractions for ages 35-74 for CHD: Minneapolis

SEX	CODEGRP	2006-13 SAMFRAC
Female	410	0.767
Female	411 not 410	0.333
Female	412-414 not 410-411	0.133
Female	Others not 410-414	0.167

SEX	CODEGRP	2006-13 SAMFRAC
Male	410	0.367
Male	411 not 410	0.167
Male	412-414 not 410-411	0.067
Male	Others not 410-414	0.100

CHD sampling fractions for ages 75-84 for CHD: Minneapolis

SEX	CODEGRP	2006-13 SAMFRAC
Female	410	0.433
Female	411 not 410	0.167
Female	412-414 not 410-411	0.067
Female	Others not 410-414	0.067

SEX	CODEGRP	2006-13 SAMFRAC
Male	410	0.400
Male	411 not 410	0.167
Male	412-414 not 410-411	0.067
Male	Others not 410-414	0.100

CHD sampling fractions for ages 35-74 for CHD: Washington County

SEX	CODEGRP	2006-13 SAMFRAC
Female	410	0.750
Female	411 not 410	0.325
Female	412-414 not 410-411	0.150
Female	Others not 410-4140.150	

SEX	CODEGRP	2006-13 SAMFRAC
Male	410	0.750
Male	411 not 410	0.300
Male	412-414 not 410-411	0.125
Male	Others not 410-414	0.175

CHD sampling fractions for ages 75-84 for CHD: Washington County

SEX	CODEGRP	2006-13 SAMFRAC
Female	410	0.750
Female	411 not 410	0.150
Female	412-414 not 410-411	0.075
Female	Others not 410-4140.075	

SEX	CODEGRP	2006-13 SAMFRAC
Male	410	0.700
Male	411 not 410	0.175
Male	412-414 not 410-411	0.075
Male	Others not 410-414	0.100

APPENDIX VII. CHD HOSPITALIZATIONS SAMPLING FRACTIONS FOR EVENT YEAR 2005

Table 2.2 Implementation of the Sampling Fractions

Nominal fraction		Discharge date days chosen	Real fraction	Difference between real fraction and nominal fraction	Rule
1 /30	0.033	15	0.03285	0.0004791	The 15th of the month
2 /30	0.067	15,30	0.06297	0.0036961	The 15th and the 30th of the month
3 /30	0.100	8,16,24	0.09856	0.0014374	Days divisible by 8
4 /30	0.133	7,14,21,28	0.13142	0.0019165	Days divisible by 7
5 /30	0.167	6,12,18,24,30	0.16153	0.0051335	Days divisible by 6
6 /30	0.200	5,10,15,20,25,30	0.19439	0.0056126	Days divisible by 5
7 /30	0.233	4,8,12,16,20,24,28	0.22998	0.0033539	Days divisible by 4
8 /30	0.267	1,5,9,13,17,21,25,29	0.26078	0.0058864	Days where the remainder is 1 when divided by 4
9 /30	0.300	2,5,8,12,15,18,22,25,28	0.29569	0.0043121	Days ending with 2, 5 or 8
10/30	0.333	3,6,9,12,15,18,21,24,27,30	0.3258	0.0075291	Days divisible by 3
11/30	0.367	1,3,6,9,12,15,18,21,24,27,30	0.35866	0.0080082	Days divisible by 3 and the first day of the month
12/30	0.400	1,4,7,10,11,14,17,20,21,24, 27,30	0.39151	0.0084873	Days ending with 1,4, 7 or 0
13/30	0.433	2,4,8,10,12,14,16,18,20,22, 24,28,30	0.42437	0.0089665	Even numbered days except for the 6th and 26th
14/30	0.467	2,4,6,8,10,13,15,17,19,22,24,26, 28,30	0.45722	0.0094456	Even numbered days before the 11th or after the 21st, and odd numbered days between the 12th and 20th
15/30	0.500	1,3,5,7,9,11,13,15,17,19,21, 23,25,27,29,31	0.50992	-0.0099247	All odd numbered days
16/30	0.533	1,3,5,7,9,11,12,14,16,18,20, 21,23,25,27,29,31	0.54278	-0.0094456	Odd numbered days between the 1st and the 11th, between the 21st and 31st and even numbered days between the 12th and the 20th
17/30	0.567	1,3,5,6,7,9,11,13,15,17,19,21,23 ,25,26,27,29,31	0.57563	-0.0089665	Odd numbered days plus the 6th and the 26th
18/30	0.600	2,3,5,6,8,9,12,13,15,16,18,19,22 ,23,25,26,28,29,31	0.60849	-0.0084873	All days except for those ending with 1,4,7,0
19/30	0.633	2,4,5,7,8,10,11,13,14,16,17, 19,20,22,23,25,26,28,29,31	0.64134	-0.0080082	Days not divisible by 3, excluding the first day of the month
20/30	0.667	1,2,4,5,7,8,10,11,13,14,16,17,19 ,20,22,23,25,26,28,29,31	0.6742	-0.0075291	All days except those divisible by 3

Nominal fraction		Discharge date days chosen	Real fraction	Difference between real fraction and nominal fraction	Rule
21/30	0.700	1,3,4,6,7,9,10,11,13,14,16,17,19,20,21,23,24,26,27,29,30,31	0.70431	-0.0043121	Days not ending with 2, 5 or 8
22/30	0.733	2,3,4,6,7,8,10,11,12,14,15,16,18,19,20,22,23,24,26,27,28,30,31	0.73922	-0.0058864	Days where the remainder is not 1 when divided by 4
23/30	0.767	1,2,3,5,6,7,9,10,11,13,14,15,17,18,19,21,22,23,25,26,27,29,30,31	0.77002	-0.0033539	Days not divisible by 4
24/30	0.800	1,2,3,4,6,7,8,9,11,12,13,14,16,17,18,19,21,22,23,24,26,27,28,29,31	0.80561	-0.0056126	Days not divisible by 5
25/30	0.833	1,2,3,4,5,7,8,9,10,11,13,14,15,16,17,19,20,21,22,23,25,26,27,28,29,31	0.83847	-0.0051335	Days not divisible by 6
26/30	0.867	1,2,3,4,5,6,8,9,10,11,12,13,15,16,17,18,19,20,22,23,24,25,26,27,29,30,31	0.86858	-0.0019165	Days not divisible by 7
27/30	0.900	1,2,3,4,5,6,7,9,10,11,12,13,14,15,17,18,19,20,21,22,23,25,26,27,28,29,30,31	0.90144	-0.0014374	Days not divisible by 8
28/30	0.933	1,2,3,4,5,6,7,8,9,10,11,12,13,14,16,17,18,19,20,21,22,23,24,25,26,27,28,29,31	0.93703	-0.0036961	All days except the 15th and 30th
29/30	0.967	1,2,3,4,5,6,7,8,9,10,11,12,13,14,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31	0.96715	-0.0004791	All days except the 15th

APPENDIX VIII. DEATH SAMPLING FRACTIONS FOR DEATHS OCCURING ON OR AFTER JANUARY 1, 2005.

Forsyth County Cases Eligible for Death Abstraction for Deaths occurring on or after January 1, 2005

Center	Age Group	Sex	Death group[1]	Rule	Days	Sampling Fraction
F	35-74	Male	1	All events except those on days divisible by 6	1,2,3,4,5, 7,8,9,10,11 13,14,15,16,17, 19,20,21,22,23 25,26,27,28,29, 31	0.83847
F	35-74	Female	1	100% sample (all days)	All days in month	1
F	35-74	Male	2	All days except for those divisible by 3	1, 2,4,5,7,8,10,11,13,14,16,17, 19,20,22,23,25,26,28,29,31	0.6742
F	35-74	Female	2	All days except for those divisible by 3	1, 2,4,5,7,8,10,11,13,14,16,17, 19,20,22,23,25,26,28,29,31	0.6742
F	75-84	Male or Female	1	All days except for those divisible by 5	1,2,3,4, 6,7,8,9, 11,12,13,14, 16,17,18,19, 21,22,23,24, 26,27,28,29, 31	0.80561
F	75-84	Male or Female	2	All days except for those divisible by 5	1,2,3,4, 6,7,8,9, 11,12,13,14, 16,17,18,19, 21,22,23,24, 26,27,28,29, 31	0.80561

[1]ICD-10 codes used for classifying deaths: I20.x-I25.x (where x is any digit, see Table 2.4 Manual 3), I51.6 is defined as Death Group=1 and the other eligible death ICD codes are defined as Death Group = 2.

Jackson Cases Eligible for Death Abstraction for Deaths occurring on or after January 1, 2005

Center	Age Group	Sex	Death group[1]	Rule	Days	Sampling Fraction
J	35-74	Male	1	All events except those on days divisible by 6	1,2,3,4,5, 7,8,9,10,11 13,14,15,16,17, 19,20,21,22,23 25,26,27,28,29, 31	0.83847
J	35-74	Female	1	100% sample (all days)	All days in month	1
J	35-74	Male	2	All days except for those divisible by 3	1, 2,4,5,7,8,10,11,13,14,16,17, 19,20,22,23,25,26,28,29,31	0.6742
J	35-74	Female	2	All days except for those divisible by 3	1, 2,4,5,7,8,10,11,13,14,16,17, 19,20,22,23,25,26,28,29,31	0.6742
J	75-84	Male or Female	1	100% sample (all days)	All days in month	1
J	75-84	Female or Female	2	All events on odd numbered days or the 6th or the 26th of the month.	1,3,5,6,7,9,11,13,15,17, 19,21,23,25,26,27,29,31	0.57563

* Jackson death sampling fractions for 2005 are the same as for 2004. In 2005, Jackson applied the rules for the younger age group 35-74 to the older age group 75-84.

[1]ICD-10 codes used for classifying deaths: I20.x-I25.x (where x is any digit, see Table 2.4 Manual 3), I51.6 is defined as Death Group=1 and the other eligible death ICD codes are defined as Death Group = 2.

From 2006, we applied different rules for the 75-84 age group and the goal is to abstract 57 out-of- hospital deaths for the Jackson city site. The rule is as the following:
For those underlying cause of death is ICD10 code I20-I25.x or I51.6, we selected all of them;
For those underlying cause of death is ICD10 code E10-14.x, I10-11.x, I46-51.x (except for I51.6), I70.x, I97.x (except for I97.2), J81.x, J96.x, R96.x, R98.x or R99.x: if the date of death is an odd numbered day or it is the 6th or the 26th of the month, then select.

Minnesota Cases Eligible for Death Abstraction for Deaths Occurring on or after January 1, 2005

Center	Age Group	Sex	Death group[1]	Rule	Days	Samp
M	35-74	Male	1	All events except those on days divisible by 6	1,2,3,4,5, 7,8,9,10,11 13,14,15,16,17, 19,20,21,22,23 25,26,27,28,29, 31	0.83847
M	35-74	Female	1	100% sample (all days)	All days in month	1
M	35-74	Male	2	All days except for those divisible by 3	1, 2,4,5,7,8,10,11,13,14,16,17, 19,20,22,23,25,26,28,29,31	0.6742
M	35-74	Female	2	All days except for those divisible by 3	1, 2,4,5,7,8,10,11,13,14,16,17, 19,20,22,23,25,26,28,29,31	0.6742
M	75-84	Male or Female	1	All days except for those divisible by 3	1, 2,4,5,7,8,10,11,13,14,16,17, 19,20,22,23,25,26,28,29,31	0.6742
M	75-84	Male or Female	2	Days divisible by 4	4,8,12,16,20,24,28	0.22998

[1]ICD-10 codes used for classifying deaths: I20.x-I25.x (where x is any digit, see Table 2.4 Manual 3), I51.6 is defined as Death Group=1 and the other eligible death ICD codes are defined as Death Group = 2.

Washington County Cases Eligible for Death Abstraction for Deaths Occurring on or after January 1, 2005

Center	Age Group	Sex	Death group[1]	Rule	Days	Sampling Fraction
W	35-74	Male	1	All events except those on days divisible by 6	1,2,3,4,5, 7,8,9,10,11 13,14,15,16,17, 19,20,21,22,23 25,26,27,28,29, 31	0.83847
W	35-74	Female	1	100% sample (all days)	All days in month	1
W	35-74	Male	2	All days except for those divisible by 3	1, 2,4,5,7,8,10,11,13,14,16,17, 19,20,22,23,25,26,28,29,31	0.6742
W	35-74	Female	2	All days except for those divisible by 3	1, 2,4,5,7,8,10,11,13,14,16,17, 19,20,22,23,25,26,28,29,31	0.6742
W	75-84	Male or Female	1	All days except for those divisible by 3	1, 2,4,5,7,8,10,11,13,14,16,17, 19,20,22,23,25,26,28,29,31	0.6742
W	75-84	Male or Female	2	Days that are odd numbers	1,3,5,7,9,11,13,15,17,19,21,23,25,27,29,31	0.50992

[1]ICD-10 codes used for classifying deaths: I20.x-I25.x (where x is any digit, see Table 2.4 Manual 3), I51.6 is defined as Death Group=1 and the other eligible death ICD codes are defined as Death Group = 2.

APPENDIX IX. LIST OF FORMS AND INSTRUCTIONS

1a. Cohort Event Eligibility (CEL) Form
1b. CEL Form Instructions
2a. Confidential Data (CFD) Form
2b. CFD Form Instructions
3a. Common Hospital Information (CHI) Form
3b. CHI Form Instructions
4a. Hospital Record Abstraction (HRA) Form
4b. HRA Form Instructions
5a. Death Certificate (DTH) Form
5b. DTH Form Instructions
6a. Informant Interview (IFI) Form
6b. IFI Form Instructions
7. Physician Questionnaire (PHQ) Form
8a. Coroner/Medical Examiner (COR) Form
8b. COR Form Instructions
9a. Cohort Stroke Abstraction (STR) Form
9b. STR Form Instructions
10. Stroke Diagnosis (SDX) Form
11a. Surveillance Event Inventory/Linkage (SXI) Form
11b. SXI Form Instructions
12a. Phantom (PTM) Form
12b. PTM Form Instructions
13a. Cohort Final Diagnosis (CDX) Form
13b. CDX Form Instructions
14a. Community Final Diagnosis (MDX) Form
14b. MDX Form Instructions

APPENDIX X. INSTRUCTIONS FOR SENDING DUPLICATE HOSPITAL RECORDS TO THE CC

PDF files are prepared per procedures in Section 11.9.

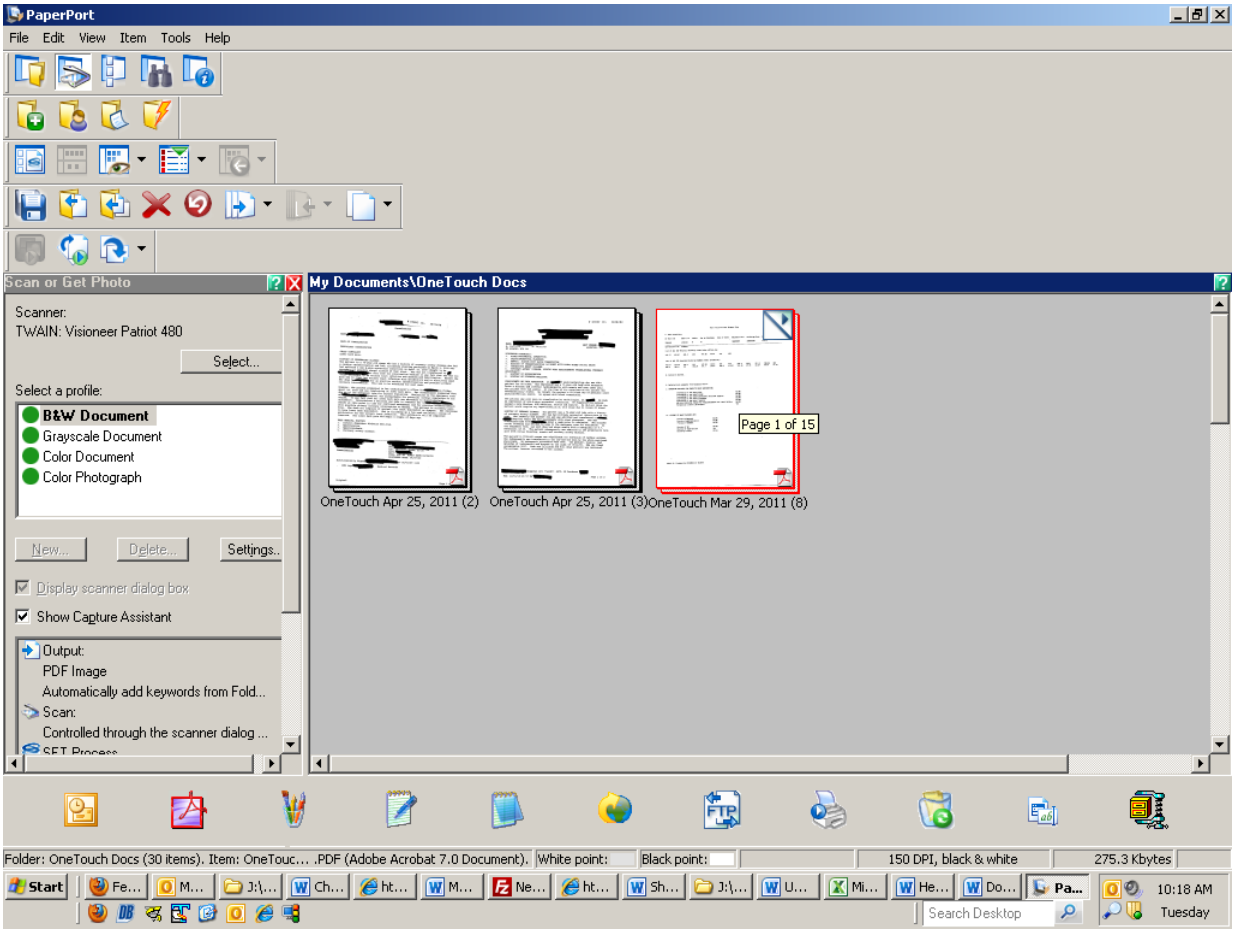
When a significant number of medical records have been prepared, they are put in numeric order and sent to the CC File Center via a secure Liquid Files account. If CC requires hospital records for materials not sent for a particular patient's event these are also prepared and transferred in a similar fashion.

Naming Convention for Hospital Records
CHD: Surveillance ID followed by "C"
Stroke: Surveillance ID followed by "S"
Heart Failure: Surveillance ID followed by "H"
Ineligible for Abstraction: Surveillance ID followed by "N"
Discharge Summary Only ("Skipouts"): Surveillance ID followed by "N"
Serum Creatinine (no longer used as of May 2026): Surveillance ID followed by "K"

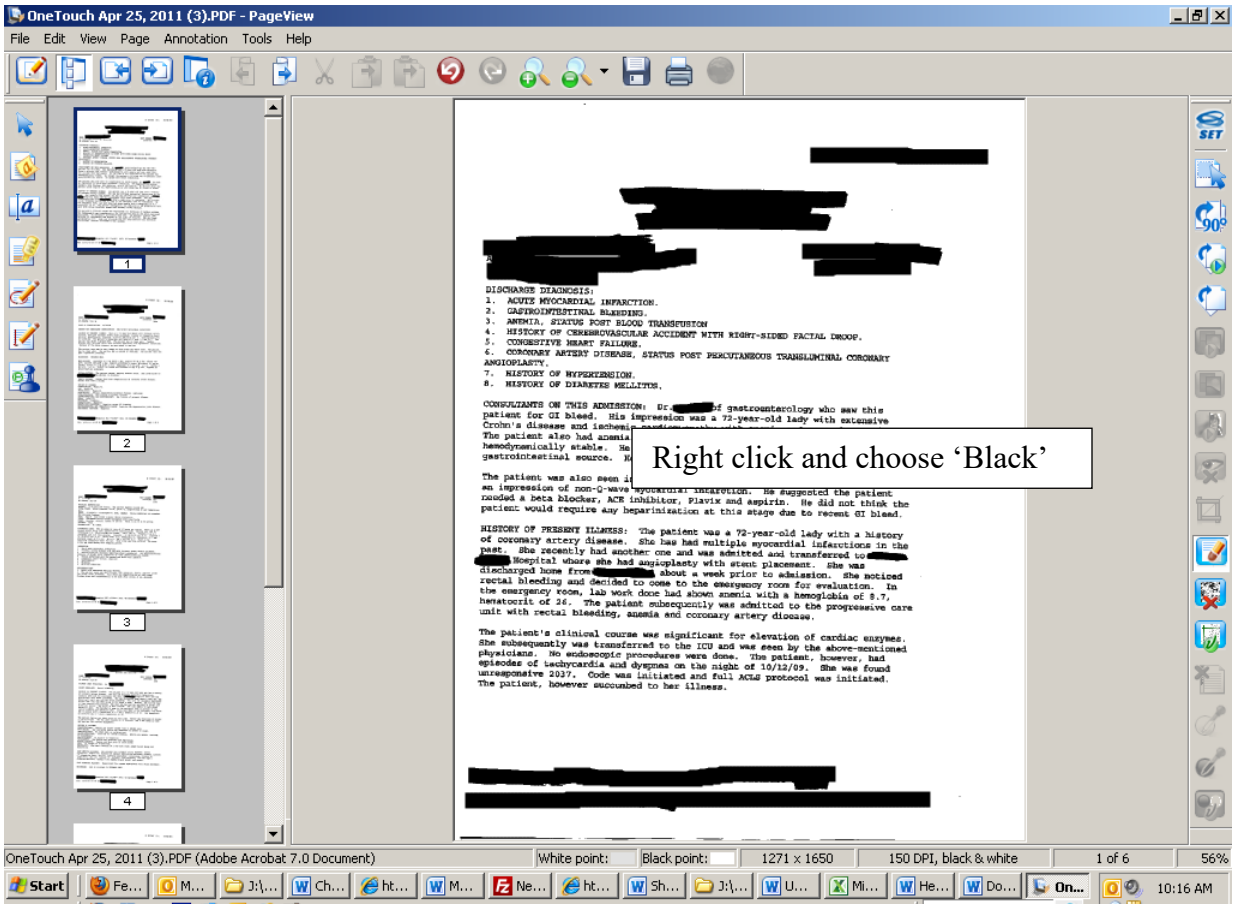
Preparing Paper Files to send to the CC
Scan all the appropriate materials for each event using your scanner set to black and white document. Include the completed "Checklist for Hospital Event Materials" as a cover page. Cut and paste the event id from the Hlist report from the DMS onto the electronic version of the checklist. If using a paper version of the checklist, write the event id in by hand. Before uploading the documents you will need to blind the documents of PHI using a redacting tool; like the one in Adobe.

List of Items for Blinding
The following items should be blinded for all duplicate materials sent to the CC.

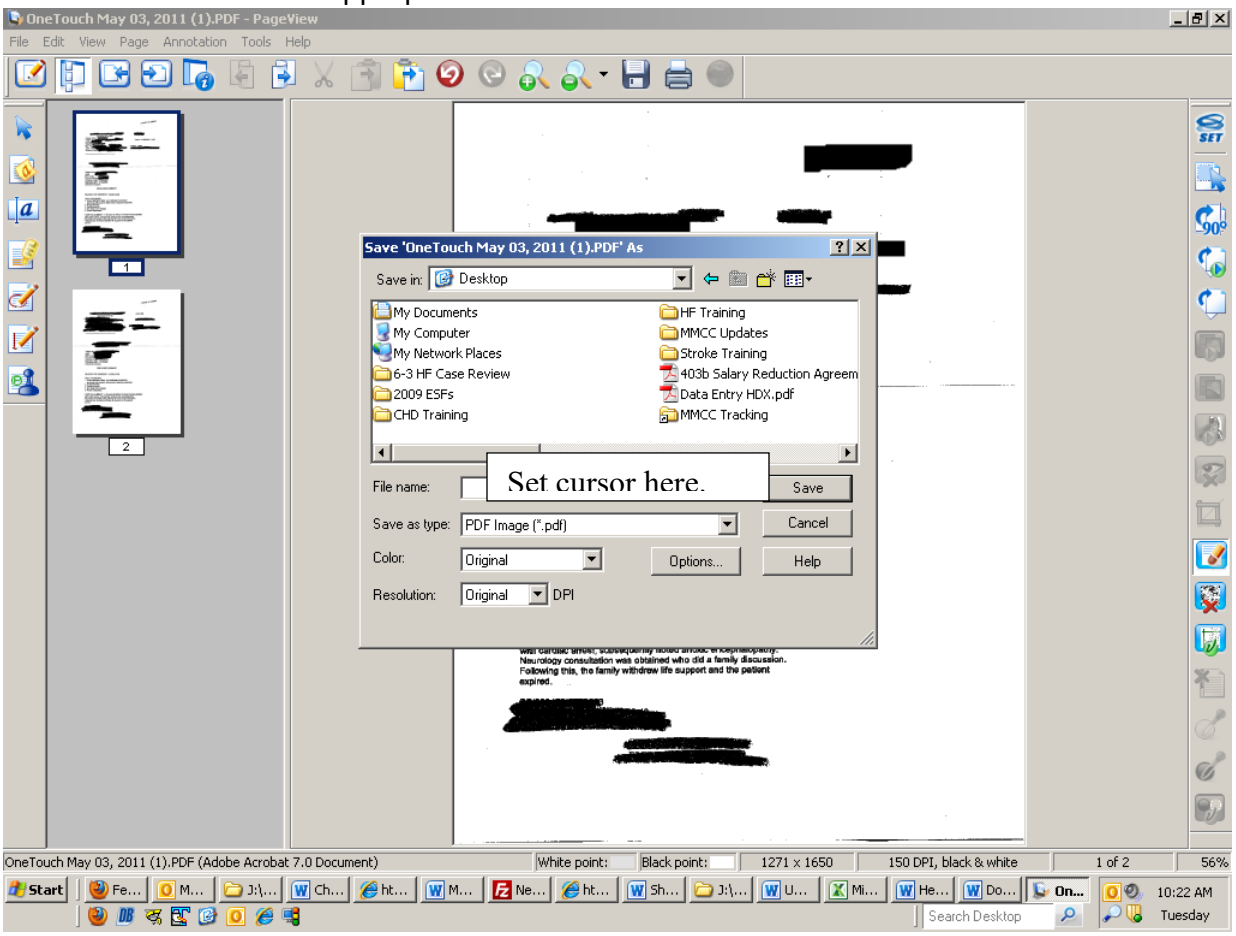
- Names of the Patient or of the Patient's Relatives, Employers, or Household Members. (Their initials need NOT be redacted. Names/Initials of hospital/medical care personnel do NOT need to be redacted.)
- Social Security number
- Date of Birth
- Street address, city county, precinct, zip code, and equivalent geocodes
- Telephone, Fax, Drivers License or plate numbers
- Email addresses
- ~~Hospital name~~
- Medical record number
- Health plan ID numbers
- Account numbers



Blind the documents using the eraser tool (set to black) found in the PaperPort software.



Save the materials as a PDF in a secure location. Choose File/Save As/Place curser in the File Name box and enter the appropriate event ID.



Preparing Electronic Files to send to the CC

The Coordinating Center recommends using Adobe Acrobat Professional Version 8 or higher to create PDFs of your electronic files.

Each field center may receive their materials in a number of different formats. Follow this link for guidance on how to convert many common file types to PDF.
http://helpx.adobe.com/en/acrobat.html

This software package also includes a redacting tool. Follow this link for instructions.
http://helpx.adobe.com/acrobat.html?content=WS5E28D332-9FF7-4569-AFAD-79AD60092D4D.html

Scan the completed “Checklist for Hospital Event Materials” as a cover page and combine with the duplicated materials into a single PDF. Add a top right header to the PDF document that contains the event id.

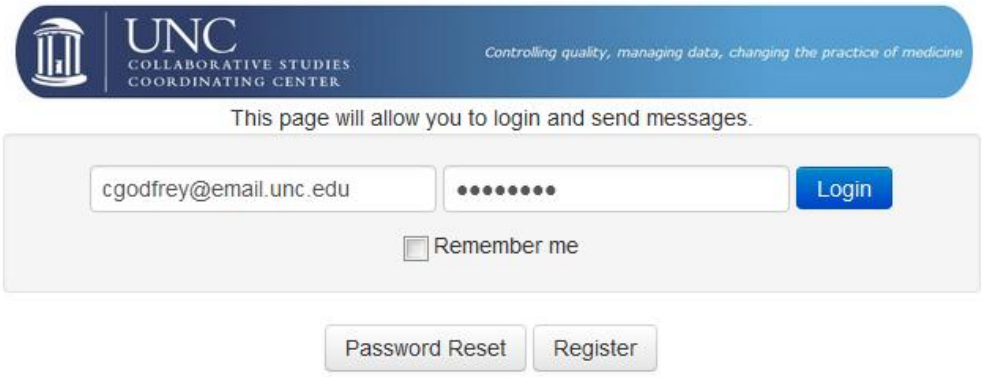
Follow this link for instructions on using adobe.
http://helpx.adobe.com/en/acrobat.html

After creating and blinding the PDF choose File/Save As and place the curser in the File Name box. Choose the appropriate folder in the Save In drop down and scan the bar code for that ID.

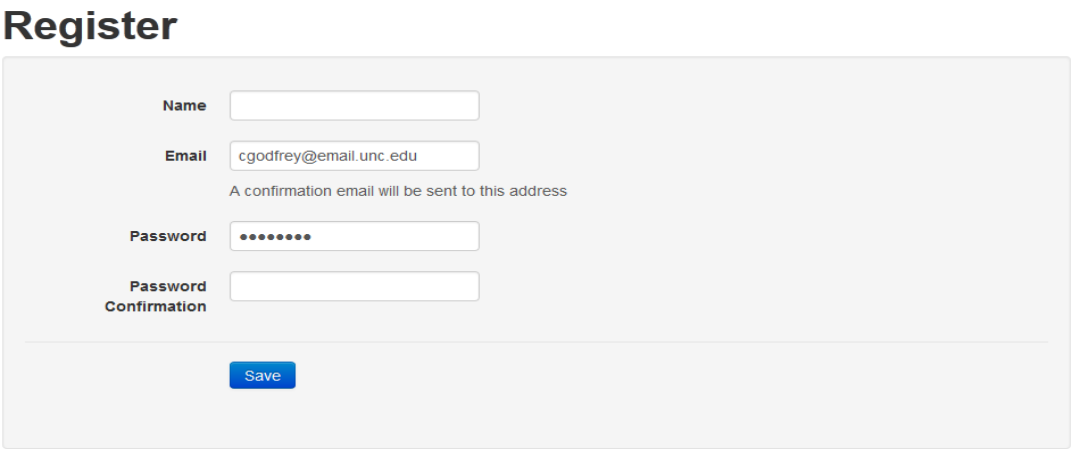
Utilizing the CC File Center to send documents to the CC

Creating a Liquid Files Account

Go to the website:
https://csccex.cscc.unc.edu/

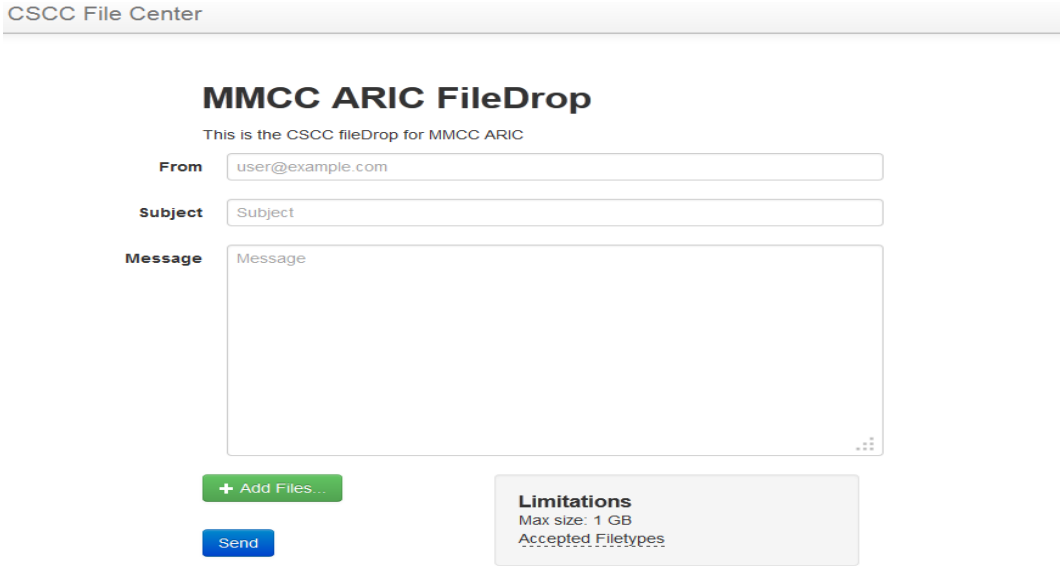


Click on Register and to create a new account. Once your account has been created you will receive a confirmation email.



Fill in name, email address and password.

Once the account has been created, hospital records in PDF format can be sent to the CC through this weblink: https://csccex.cscc.unc.edu/filedrop/MMCCARIC



Click the '+Add Files' to add files to be sent. You can review the files you are sending by looking at the attached files list before you send. When you have completed uploading all of the files click 'send'.