1.a. Full Title: Trends in accuracy of hospital discharge diagnosis codes for acute myocardial infarction in the primary and secondary positions, and relation to mortality and coronary revascularization rates

b. Abbreviated Title (Length 26 characters): Trends in validity of diagnostic codes for AMI.

2. Writing Group:

I, the first author, confirm that all the coauthors have given their approval for this manuscript proposal. __GS__ [please confirm with your initials electronically or in writing]

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3. Timeline: Scientific abstract to be submitted to the Scientific sessions of the American Heart Association in 2016. Manuscript to be completed coincident with the annual sessions of the AHA in November 2016
4. **Rationale:** Contemporary data from the Medicare 5% sample indicate that there has been a steady temporal decrease in claims for acute myocardial infarction (AMI) using code 410 in the primary position but an increase in the use of diagnostic claims for AMI in the secondary position (1) among hospitalized patients. The decreasing trend of code 410 in the primary position is an optimistic observation indicating benefit of preventive therapies resulting in a reduction in the incidence of spontaneous AMI. However, the trend of an increasing use of diagnostic codes for AMI in the secondary position is likely driven by greater use of the diagnostic code 410 for type 2 AMI or “secondary” AMI due to supply-demand mismatch; reflecting changes in the definition of AMI due to the increasing use of more sensitive biomarkers. (2, 3) Recently, it has been reported that there is considerable discrepancy between claims (Medicare) based diagnosis of AMI and self-reported AMI, (4) likely also emanating from the increasing tendency towards coding for type 2 AMI nationwide. The differentiation of type 1 (or spontaneous) and type 2 (or secondary) AMI is not only important from the standpoint of the individual patient, but also critical to differentiate from an epidemiological perspective and for insurance companies. (3)

Rosamond et al (5) previously demonstrated that the sensitivity of claims based codes for diagnosis of AMI was modest with significant variations among individuals of different races. It is likely that the validity of diagnostic claims is further reduced in recent years because of changing definitions of AMI (with the evolution of Universal definitions of AMI) and reliance on more sensitive cardiac biomarkers. (2) Also, we hypothesize that the increasing use of the diagnostic code 410 in the secondary position at hospital discharge can significantly confound an assessment of the “true” epidemiological incidence of AMI. The highest discrepancy may occur among NSTEMI patients because STEMI patients are defined by very characteristic ECG findings of ST elevation or new LBBB. We further hypothesize that there is likely an increasing trend of coronary revascularization procedures for AMI in the secondary position, with significant attendant economic ramifications. We propose to assess the contemporary trends in the accuracy of diagnostic codes for AMI compared to study adjudicated AMI diagnosis, and assess the relationship to coronary revascularization procedures and mortality. This assessment has significant implications from clinical, patient perception and economic perspectives.

5. **Main Hypothesis/Study Questions:**

The objectives of this study are to use data from the Atherosclerosis Risk in Communities (ARIC) community based cohorts to:

- Assess validity of AMI claims based diagnosis of AMI (ICD9-CM code 410) compared to previously published ARIC study criteria in the contemporary era (1996-2013) relative to prior decades.
- To assess the validity of the use of AMI (ICD-9CM code 410) in the primary vs. secondary positions using claims based data compared to ARIC study criteria for AMI definition. AMI will be further categorized into NSTEMI and STEMI.
• Evaluate the effects of evolving definitions of AMI during the 15-year study period in a younger population (compared to Medicare data) by studying temporal trends in coding for AMI in the primary vs. secondary positions at hospital discharge.
• Evaluate trends in mortality (in hospital mortality and case fatality rates), coronary angiography and coronary revascularization rates (percutaneous coronary intervention (PCI)/coronary artery bypass graft (CABG)) occurring during the hospitalization for an AMI code in the primary vs secondary position in this community based sample.

References:


6. Design and analysis (study design, inclusion/exclusion, outcome and other variables of interest with specific reference to the time of their collection, summary of data analysis, and any anticipated methodologic limitations or challenges if present).

Study population: From the ARIC Study, a continuous surveillance of hospital discharges for CHD (coronary heart disease) among residents aged 35-74 years in 4 varied US communities will be made available. Based on annual hospital discharge lists, a selection of all patients with CHD events (ICD9 codes 402, 410-414, 427, 428, 518.4) will be identified. Since data on cardiac troponin measurements is available only after 1996, the 1996 data will be considered the baseline data for the purposes of this study.

Identification of cases with AMI: All cases hospitalized with acute AMI will be identified by the following 2 methods:

1) ICD-9-CM code 410: further subcategorized into whether AMI was coded in the primary or secondary position.
2) ARIC study criteria: by trained abstractors on the basis of patient’s presenting symptoms, medical history, ECGs and biomarkers.

All eligible AMI events among the CHD events will be further subcategorized into one of four categories: a) Definite AMI b) Probable AMI c) Possible AMI d) No AMI based on methodology previously described by Rosamond et al (Am J Epi 2004).

For all cases of AMI, the following baseline information will be collected:
1) Demographics (age, gender, ethnicity, community)
2) Medical comorbidities (hypertension, diabetes, prior AMI/ chronic ischemic heart disease or prior coronary revascularization [angioplasty or bypass surgery], stroke, valvular disease or cardiomyopathy, serum creatinine on presentation or history of dialysis, overall comorbidity index if available)
3) Categorization into STEMI vs. NSTEMI.
4) Coronary revascularization occurring during index hospitalization (percutaneous coronary intervention, coronary bypass graft surgery)
5) Clinical events during hospitalization (in-hospital mortality, recurrent AMI, heart failure, stroke, need for dialysis) based on ARIC abstraction or ICD-9 codes.
6) Measures of AMI severity based on ARIC criteria. Examples include items under #28 in HRA (shock or cardiogenic shock, congestive heart failure/pulmonary edema/S3/rales, ventricular fibrillation/cardiac arrest/asystole, pulmonary embolism, stroke, pneumonia.
7) Post procedural AMI occurring after coronary revascularization will be excluded by excluding 29c1A; 29c3A, 29f1A.

Statistical methodology

1) The accuracy (sensitivity, false positive rate, and positive predictive value) of ICD-9-CM codes for AMI will each be compared to the gold standard i.e. ARIC study criteria for diagnosis of AMI.
2) ICD-9-CM code 410 based categorization of discharge diagnosis of AMI in the primary and secondary position will be separately compared to the ARIC diagnostic criteria for AMI and temporal trends obtained, and subcategorized into STEMI vs NSTEMI.
3) A frequency count of all ICD 410 codes in the secondary position will be further explored to determine any relation of the specific coding position with outcomes.
4) The temporal trends in hospital revascularization (with either PCI or CABG) and will be obtained during the study period for AMI in the primary and secondary positions for NSTEMI and STEMI patients. An adjusted analysis of revascularization will be performed to account for any confounding due to race/gender.
5) The temporal trends in 28 day case fatality rates for AMI in primary and secondary positions will be obtained during the study period, subcategorized into NSTEMI and STEMI.
6) A special analysis will be performed for the subgroup of individuals (ages 75-84) with AMI; a burgeoning subcategory of patients that has not been well studied in randomized controlled trials, and poorly represented in most observational studies also.

Methodological challenges

Using observational and abstracted data to differentiate between spontaneous/type 1 AMI vs secondary/type 2 AMI by relying on the use of ICD-9-CM code 410 in the primary vs secondary position may be somewhat simplistic and challenging due to the fact that ECG abnormalities and biomarker elevation may be present in both of them, and symptoms may be unreliable or absent due to patient-related factors (such as critically ill, mechanically ventilated etc.) These challenges may be reflected in the accuracy of ICD-9 coding at hospital discharge, but may also be reflected in the adjudication by the ARIC study adjudicators. However, because of the absence of a separate ICD-9 code for “secondary” or type 2 AMI (3), there is no other meaningful way to make that important distinction. This would be the strength of this study because it would highlight discrepancies between ICD-9 codes for AMI hospital discharges and abstracted clinical information by trained ARIC adjudicators and potentially highlight a problematic area for future epidemiological work in this area (in the absence of distinct ICD codes).

Previous studies have identified concerns regarding positive predictive value of ICD-9 410 subcategories to accurately identify NSTEMI and STEMI patients (Reference 4 below). These previously raised concerns will be appropriately reconciled in the analysis of this manuscript.

7.a. Will the data be used for non-CVD analysis in this manuscript?  ____ Yes  ____ No

b. If Yes, is the author aware that the file ICTDER03 must be used to exclude persons with a value RES_OTH = “CVD Research” for non-DNA analysis, and for DNA analysis RES_DNA = “CVD Research” would be used?  ____ Yes  ____ No

(This file ICTDER has been distributed to ARIC PIs, and contains the responses to consent updates related to stored sample use for research.)

8.a. Will the DNA data be used in this manuscript?  ____ Yes  ____ No

8.b. If yes, is the author aware that either DNA data distributed by the Coordinating Center must be used, or the file ICTDER03 must be used to exclude those with value RES_DNA = “No use/storage DNA”?  ____ Yes  ____ No
9. The lead author of this manuscript proposal has reviewed the list of existing ARIC Study manuscript proposals and has found no overlap between this proposal and previously approved manuscript proposals either published or still in active status. ARIC Investigators have access to the publications lists under the Study Members Area of the web site at: http://www.cscc.unc.edu/ARIC/search.php

___x___ Yes  _______ No

10. What are the most related manuscript proposals in ARIC (authors are encouraged to contact lead authors of these proposals for comments on the new proposal or collaboration)?


11.a. Is this manuscript proposal associated with any ARIC ancillary studies or use any ancillary study data? _____ Yes    ___x___ No

11.b. If yes, is the proposal

___ A. primarily the result of an ancillary study (list number* __________)

___ B. primarily based on ARIC data with ancillary data playing a minor role (usually control variables; list number(s)* __________ __________ __________)

*ancillary studies are listed by number at http://www.cscc.unc.edu/aric/forms/

12a. Manuscript preparation is expected to be completed in one to three years. If a manuscript is not submitted for ARIC review at the end of the 3-years from the date of the approval, the manuscript proposal will expire.
12b. The NIH instituted a Public Access Policy in April, 2008 which ensures that the public has access to the published results of NIH funded research. It is your responsibility to upload manuscripts to PUBMED Central whenever the journal does not and be in compliance with this policy. Four files about the public access policy from http://publicaccess.nih.gov/ are posted in http://www.cscu.unc.edu/aric/index.php, under Publications, Policies & Forms. http://publicaccess.nih.gov/submit_process_journals.htm shows you which journals automatically upload articles to PubMed central.

13. Per Data Use Agreement Addendum for the Use of Linked ARIC CMS Data, approved manuscripts using linked ARIC CMS data shall be submitted by the Coordinating Center to CMS for informational purposes prior to publication. Approved manuscripts should be sent to Pingping Wu at CC, at pingping_wu@unc.edu. I will be using CMS data in my manuscript _____ Yes __x__ No.