Appendix I: Detailed Description of the Databases and Data Linkage [posted as supplied by author]

ACC-NCDR and CMS-ICD Registry

We combined data from two national ICD registries for this study, namely, the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) ICD registry and the CMS-ICD registry.

The CMS ICD registry is a subset of the American College of Cardiology (ACC)-National Cardiovascular Data Registry (NCDR) ICD Registry, which is the sole repository for ICD implantation data for Medicare beneficiaries.¹⁻⁴ The registry was developed through a partnership of the Heart Rhythm Society and the American College of Cardiology utilizing the expertise of the National Cardiovascular Data Registry. The data are entered by hospital personnel and are only included in the analytic file if hospitals achieve certain completeness on specific data elements. In a 2010 audits, the participant average raw accuracy of data abstraction for the ICD Registry is 91.2% (range, 83.7% minimum, 95.7% maximum).⁵ Currently, over 400,000 patients are included in the CMS-ICD registry, which contains 37 out of 170 data elements that the ACC-NCDR collects. These 37 elements include identifying information of patients, history and clinical characteristics, medications, facility information, provider information, ICD indications, device information, and in-hospital complications. The ACCF provided 7 additional variables (admission reason, prior heart failure hospitalization, ICD type, creatinine, sodium level, BNP level, and systolic blood pressure) to the research team for patients in the CMS-ICD registry.

Heart Failure Registry

The national clinical registries data for patients with heart failure were aggregated from several quality improvement and accreditation programs managed on the same platform (AHA GWTG) from Outcome Sciences, Inc, using common data elements, data clarification procedures, and quality assurance practices meeting requirements for submission of data to the Joint Commission and/or Centers for Medicare and Medicaid Services for core measures in heart failure. The aggregate database includes data from over 800 US hospitals in all 50 states with close to 300,000 patients with primary diagnoses of heart failure. Portions of the dataset have been successfully used to assess quality-of-care outcomes in patients with heart failure.^{6,7} All data collected receives appropriate privacy and institutional board review as determined by each participating center. Information included in the registry includes: demographics, characteristics of heart failure, cardiac and non-cardiac medical history, laboratory data, vital signs, relevant physical examination findings and medications on admission and at discharge, as well as, other relevant treatment/procedures before and during admission. The data collection system provides real-time data quality checks based on a pre-determined set of out-of-range values and logical checks. A second set of guality checks is performed prior to guarterly compilation of the data for use for accreditation purposes, and these errors are relayed to and corrected by the site

personnel. A portion of the data (approximately 5%) undergoes a standardized data quality audit.

Medicare Institutional and Non-institutional Files

The Medicare institutional files contain final action claims data submitted by inpatient hospital providers, skilled nursing facility providers, institutional outpatient providers, home health agency providers, and hospice providers for reimbursement of services provided to Medicare fee-for-service beneficiaries. Examples of institutional outpatient providers include

hospital outpatient departments, rural health clinics, renal dialysis facilities, outpatient rehabilitation facilities, comprehensive outpatient rehabilitation facilities, and community mental health centers. The main information contained in those files includes diagnosis and procedure, dates of service, reimbursement amount, provider number, and beneficiary demographic information.

The Medicare non-institutional files include the carrier claim files and durable medical equipment (DME) files. The files contain final action claims data submitted by the non-institutional providers and DME suppliers for reimbursement of services provided to Medicare fee-for-service beneficiaries. Examples of non-institutional providers include physicians, physician assistants, clinical social workers, nurse practitioners, independent clinical laboratories, ambulance providers, and free-standing ambulatory surgical centers. The main information contained in those files includes diagnosis and procedure, dates of service, reimbursement amount, provider numbers, and beneficiary demographic information.

Data Linkage

We linked the combined ICD Registry and the heart failure registry to Medicare claims data using 4 nonunique identifiers: date of birth, sex, admission date for the ICD implantation, and provider ID, similar to previously described methods. We did not expect that 100% of records for patients 66 years or older in the ICD registry would be linked to Medicare data, even if all linkage variables were complete and accurately recorded. The expected best linkage rate was between 55% and 65%, because the Medicare data used for linkage did not include claims for ICD procedures for patients enrolled in Medicare managed care plans or in the Veterans Health Administration (VA), patients receiving ICDs at VA hospitals, patients with supplemental insurance covering inpatient care, or patients with ICD placements not resulting in an overnight hospitalization. We verified this estimate by analyzing data for 5% of Medicare beneficiaries from 2005 to 2008, of whom approximately 20% were outpatients and 80% were inpatients. Furthermore, approximately 20% to 30% of all inpatient ICD implantations were in patients enrolled in Medicare managed care, a VA plan, or supplemental insurance. Therefore, only the remaining 55% to 65% of all implantations in the ICD registry were linkable. We validated the linkage method using non-unique identifiers among the subset of 196,923 patients who had a unique identifier in the ICD Registry. Our linkage using nonunique identifiers

yielded 98% specificity, 95% sensitivity, and 98% positive predictive value compared to the gold standard linkage method using unique identifiers.⁸

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