CBE ID

0694

Title

Hospital Risk-Standardized Complication Rate Following Implantation of Implantable Cardioverter-Defibrillator (ICD)

Project

Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health

Endorsement Status

Endorsement Removed

E&M Committee Rationale/Justification

Endorsement was removed due to no consensus. The committee raised concern with the lack of updated data to determine whether a gap exists and for scientific acceptability. The measure is also not in use, which makes it challenging to know if the measure is improving over time.

Is Under Review

No

Previous Endorsement Cycle

Fall 2023

Removal Date

Mon, 03/18/2024 - 00:00

Initial Endorsement

Mon, 01/17/2011 - 13:55

1.0 New or Maintenance

Maintenance

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

This measure provides hospital specific risk-standardized rates of procedural complications following the implantation of an Implantable Cardioverter-Defibrillator (ICD) in patients at least 65 years of age. The measure uses clinical data available in the National Cardiovascular Data Registry (NCDR) Electrophysiology Device Implant Registry (EPDI - formerly the ICD Registry) for risk adjustment linked with administrative claims data using indirect patient identifiers to identify procedural complications.

1.7 Composite Measure

Yes

1.7 Measure Type

Outcome

1.8 Level of Analysis

Facility

1.9 Care Setting

Clinician Office/Clinic, Hospital: Inpatient

1.10 Measure Rationale

Not applicable

1.11 Measure Webpage

https://doesnotexist.org

1.13 Data Dictionary

Attached

1.13a Attach Data Dictionary

EPDI_V2.3_DataDictionaryFullSpecifications_0.zip

1.14 Numerator

The outcome for this measure is one or more complications within 30 or 90 days (depending on the complication) following initial ICD implantation. The measure treats complications as a dichotomous (yes/no) variable; we are interested in whether or not a complication has occurred and not how many complications occurred in each hospital.

1.14a Numerator Details

The complications in this measure are defined below.

Complications are identified using International Classification of Diseases, Clinical Modification diagnosis and procedure codes or Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) procedure codes as well as the Medicare Enrollment Database (vital status) as indicated below. This approach was developed by a CMS Technical Expert Panel of clinicians and methodologists who were charged with identifying a comprehensive claims-based approach to identifying serious procedural complications:

Complications identified within 30 days of device implant:

(1) Pneumothorax or hemothorax plus a chest tube

(2) Hematoma plus a blood transfusion or evacuation

(3) Cardiac tamponade or pericardiocentesis

(4) Death (Source: Medicare enrollment database)

Complications identified within 90 days of device implant:

(5) Mechanical complications requiring a system revision

(6) Device related infection

(7) Additional ICD implantation

1.15 Denominator

The target population for this measure includes inpatient and outpatient hospital stays with ICD implants for patients at least 65 years of age who have matching information in the NCDR Electrophysiology Device Implant Registry EPDI (Formerly the ICD registry). The time window can be specified from one to three years.

1.15a Denominator Details

The measure cohort is defined below.

-Implantation of cardiac resynchronization pacemaker without mention of defibrillation, total system (crt-p)

-Implantation of cardiac resynchronization defibrillator, total system (crt-d)

-Implantation or replacement of transvenous lead (electrode) into left ventricular coronary venous system

-Implantation or replacement of cardiac resynchronization pacemaker pulse generator only (crt-p)

-Implantation or replacement of cardiac resynchronization defibrillator pulse generator device only (crt-d)

-Implantation or replacement of automatic cardioverter/defibrillator, total system (aicd)

-Insertion, single chamber transvenous electrode ICD

-Insertion, dual chamber transvenous electrode ICD

-Repair, single chamber transvenous electrode ICD

-Repair, dual chamber transvenous electrode ICD

-Pocket revision ICD

-Initial pulse generator insertion only with existing dual leads

-Initial pulse generator insertion only with existing multiple leads

-Insertion of single or dual chamber ICD pulse generator

-Removal of single or dual chamber ICD pulse generator

-Insertion or repositioning of electrode lead(s) for single or dual chamber pacing ICD and insertion of pulse generator

-Removal pulse generator with replacement pulse generator only single lead system (transvenous)

-Removal pulse generator with replacement pulse generator only dual lead system (transvenous)

-Removal pulse generator with replacement pulse generator only multiple lead system (transvenous)

1.15b Denominator Exclusions

(1) Previous ICD placement. Hospital stays in which the patient had an ICD implanted prior to the index hospital stay are excluded.

Rationale: Ideally, the measure would include patients with a prior ICD, as this is a population known to be at high risk of adverse outcomes. However, for these patients it is difficult to distinguish in the administrative data whether adverse events such as infection were present on admission or complications of the second ICD placement. In order to avoid misclassification, we exclude these patients from the measure.

(2) Previous pacemaker placement, Hospital stays in which the patient had a previous pacemaker placement prior to the index hospital stay are excluded.

Rationale: Some complications (infection or mechanical complication) may be related to a pacemaker that was removed prior to placement of an ICD. Ideally, the measure would include patients with a prior pacemaker, as this is a population known to be at higher risk of adverse outcomes. However, for these patients it is difficult to distinguish in the administrative data whether adverse events such as infection were present on admission or complications of the ICD placement. In order to avoid misclassification, we exclude these patients from the measure.

(3) Not Medicare Fee-for-service (FFS) patient on admission. Patient admissions in which the patient is not enrolled in Medicare FFS at the time of the ICD procedure.

Rationale: Outcome data are being derived only for Medicare FFS patients.

(4) Lack 90-day follow-up in Medicare FFS post-discharge. Patients who cannot be tracked for 90 days following discharge are excluded.

Rationale: There will not be adequate follow-up data to assess complications

(5) Not the first claim in the same claim bundle. There are cases when several claims in the same hospital representing a single episode of care exist in the data together. These claims are bundled together and any claim other than the first is excluded.

Rationale: Inclusion of additional claims could lead to double counting of an index ICD procedure.

1.15c Denominator Exclusions Details

Denominator exclusions are identified based on variables contained in the Standard Analytic File (SAF) or Enrollment Database (EDB). Of note, a hospital stay may satisfy multiple exclusion criteria.

(1) Previous ICD placement is a flag in the NCDR EP Device Implant Registry (EPDI - formerly the ICD Registry) that indicates whether or not a patient has an ICD present on admission.

(2) Previous pacemaker is a flag in the NCDR EP Device Implant Registry (EPDI - formerly the ICD Registry)whether or not a patient has a pacemaker present on admission.

(3) Not Medicare FFS patient on admission is determined by patient enrollment in both Part A and Part B in FFS using Center for Medicare and Medicaid Services (CMS) EDB.

(4) Lack 90-day follow-up in Medicare FFS post-discharge is determined by patient enrollment status in both Part A and Part B and in FFS using CMS' EDB; the enrollment indicators must be appropriately marked for any month which falls within 90 days of hospital discharge or enrollment end date (this does not apply for patients who die within 90 days of the index hospital stay).

(5) Not the first claim in the same claim bundle is derived by examining inpatient claims located in the SAF; specifically, the fields for admission and discharge date and provider ID.

1.16 Type of Score

Rate/proportion

1.17 Measure Score Interpretation

Better performance = Lower score

1.18 Calculation of Measure Score

The measure employs a hierarchical logistic regression model to create a hospital-level 30- or 90-day RSCR. In brief, the approach simultaneously models data at the patient and hospital levels to account for the variance in patient outcomes within and between hospitals (Normand & Shahian, 2007). At the patient level, it models the log-odds of hospital complications within 30 or 90 days of discharge using age, selected clinical covariates, and a hospital-specific intercept. At the hospital level, the approach models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of complications at the hospital, after accounting for patient risk. If there were no differences among hospitals, then after adjusting for patient risk, the hospital intercepts should be identical across all hospitals.

The RSCR is calculated as the ratio of the number of "predicted" to the number of "expected" complications, multiplied by the national unadjusted complication rate. For each hospital, the numerator of the ratio ("predicted") is the number of complications within 30 or 90 days predicted on the basis of the hospital's performance with its observed case mix, and the denominator ("expected") is the number of complications expected on the basis of the nation's performance with that hospital's case mix. This approach is analogous to a ratio of "observed" to "expected" used in other types of statistical analyses. It conceptually allows for a comparison of a particular hospital's performance given its case mix to an average hospital's performance with the same case mix. Thus, a lower ratio indicates lower-than-expected complications or better quality and a higher ratio indicates higher-than-expected complications or worse quality.

The "predicted" number of complications (the numerator) is calculated by using the coefficients

estimated by regressing the risk factors and the hospital-specific intercept on the risk of complication. The estimated hospital--specific intercept is added -coefficients.

Normand, Sharon-Lise T.; Shahian, David M. Statistical and Clinical Aspects of Hospital Outcomes Profiling. Statist. Sci. 22 (2007), no. 2, 206--226. doi:10.1214/088342307000000096. https://projecteuclid.org/euclid.ss/1190905519

1.19 Measure Stratification Details

This measure is not stratified.

1.20 Types of Data Sources

Claims Data, Registries

1.25 Data Source Details

This measure relies on claims data. As of Fall 2023 claims data use is currently restricted and unavailable to support performance measures. Legislation to change this has been introduced.

The datasets used to create the measures are described below.

(1) NCDR EP Device Implant Registry (EPDI - formerly ICD Registry) data

The NCDR EP Device Implant Registry (EPDI - formerly ICD Registry) is a cardiovascular data registry which captures detailed information about patients at least 18 years of age undergoing ICD implantation. This includes demographics, comorbid conditions, cardiac status, and laboratory results. As of May 2015, the registry had collected data from 1,786 hospitals in the United States totaling over 1,330,000 implants (NCDR data outcome reports).

The registry, launched on June 30, 2005, was developed through a partnership of the Heart Rhythm Society (HRS) and the (ACC) in response to CMS' expanded ICD coverage decision for primary prevention ICD therapy. Data included in the registry are collected by hospitals and submitted electronically on a quarterly basis to NCDR. The patient records submitted to the registry focus on acute episodes of care, from admission to discharge. The NCDR does not currently link patient records longitudinally across episodes of care.

The data collection form and the complete list of variables collected and submitted by hospitals

can be found at www.ncdr.com. For more information on these data, please see the attached methodology report.

Of note, hospitals are only required to submit data on all primary prevention ICDs implanted in Medicare patients, and, of the 159 data elements collected by the NCDR EP Device Implant Registry (EPDI - formerly ICD Registry), only 54 are forwarded to CMS by American College of Cardiology (ACC) to determine payment eligibility. Nevertheless, the majority of participating hospitals have opted to participate fully in the quality improvement aspect of the registry and submit all data elements on all patients undergoing ICD implantation.

(2) Medicare Data

IMPORTANT NOTE: ACC is not currently able to use this data source as Medicare claims are not currently available for performance measure reporting. This has limited our ability to update and report this measure.

The model was developed in a population of Medicare FFS beneficiaries but can be expanded to all ICD patients at least 65 years of age. We used the administrative claims data to identify complications.

(a) Part A inpatient and outpatient data: Part A data refers to claims paid for Medicare inpatient hospital care, outpatient hospital services, skilled nursing facility care, some home health agency services, and hospice care. For this measure, we used Part A data to identify ICDs implanted for admitted and non-admitted patients (i.e., hospital patients with observation status). For model development, we used 2007 Medicare Part A data to match patient stays associated with an ICD with comparable data from the NCDR EP Device Implant Registry (EPDI - formerly ICD Registry).

(b) Medicare Enrollment Database (EDB): This database contains Medicare beneficiary demographic, benefit/coverage, and vital status information. This dataset was used to obtain information on several inclusion/exclusion indicators, such as Medicare status on admission, and provided the ability to retrieve 90 days follow-up, linking patient Health Insurance Claim (HIC) number to the Part A data. These data have previously been shown to accurately reflect patient vital status (Fleming Fisher et al. 1992).

1.26 Minimum Sample Size

This measure requires a minimum sample of 25 patients per facility.

2.1 Attach Logic Model

0694 Attachment 20231101_0.pdf

2.2 Evidence of Measure Importance

Complications following insertion of Implantable Cardioverter Defibrillators (ICD) are an important patient outcome (Al-Khatib 2005, 2008; Curtis 2009, Peterson, 2013) that reflects the quality of care delivered to patients. Complications following ICD insertion represent an increased risk of all-cause mortality. A 2017 retrospective NCDR ICD registry study done by Kipp et al showed complications during the index hospitalization occurred in 5.18% of patients. Within 90 days of implantation complications occurred in 7.34% of patients. The occurrence of complications within 90 days of ICD implantation was associated with increased risk of all-cause mortality and all-cause mortality or hospitalization at 1 and 3 years. Patient, procedure, and hospital characteristics associated with mortality at 3 years after implantation were similar regardless of whether acute procedural complication occurred. (Kipp et al, 2017).

The risk of adverse outcomes following ICD implantation varies markedly by the experience and training of the implanting physician, the device implanted, and the characteristics of the facility in which the procedure is performed (Curtis, 2009). Additionally, patient characteristics are associated with early mortality following ICD implantation. Early mortality is associated with older age, advanced NYHA class and atrial fibrillation. These factors may change as patient populations selected for ICD implantation continue to evolve over time and with advances in heart failure medical therapy. Even when studying a large cohort, there was no single powerful clinical feature predicting early mortality after ICD implantation as only 12.7% having all the 3 risk factors described above as dying within the first year. (Garcia, 2020).

Infection is one of the most serious complications of ICD implantation and closely associated with mortality and morbidity. End stage renal disease was consistently associated with the highest risk of infection with respect to patient-related factors. The presence of hematoma was associated with a 9-fold increase risk of infection with respect to procedure related factors. Pre-procedural measures for prevention include patient selection, lead management (decreasing number of leads), delaying procedure to produce more favorable patient factors (improving glycemic control), anticoagulation and antiplatelet drugs and sterile procedure. (EHRA International consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections). These structures and processes of care that prevent these costly and undesirable complications are difficult to measure in a way that is reliable, valid and meaningful to providers and patients. It is important that ICDs are provided to those patients for whom it is deemed appropriate based on guideline-based assessments and evaluations and hospitals ensure provision of the highest quality of care. Reporting the rate of procedure-related complications provides relevant information on whether these characteristics were achieved.

Measuring complications have improved treatment. For example, the safety and efficacy of venous access techniques for cardiac implantable electronic device implantation has been a recent area of study. The risk of pneumothorax and lead failure was found to be lowered when using cephalic vein cutdown versus subclavian vein puncture. Additionally, it was reported that axillary vein puncture and cephalic vein cutdown were both effective approached for IED lead implantation and offer the potential to avoid complications usually observed with traditional SVP. (Atti et al, 2020)

ICDs are expensive and are utilized in patients with high cost conditions such as coronary artery disease or heart failure. Reynolds, et al (2006) found that just over 10% of all patients with an ICD placed had a complication deemed attributable the procedure. The cost to treat these unexpected complications was more than $7,000 for each patient and frequently extended a patient's hospital stay.

Al-Khatib SM, Greiner MA, Peterson ED, Hernandez AF, Schulman KA, Curtis LH. Patient and Implanting Physician Factors Associated With Mortality and Complications After Implantable Cardioverter-Defibrillator Implantation, 2002-2005. Circ Arrhythmia Electrophysiol. 2008;1:240-249. doi: 10.1161/CIRCEP.108.777888

Al-Khatib, SM, Lucas LF, Jollis JG, Malenka DJ, Wennberg DE. The relation between patients' outcomes and the volume of cardioverter-defibrillator implantation procedures performed by physicians treating Medicare beneficiaries.[see comment][erratum appears in J Am Coll Cardiol. 2005;46:1964]. Journal of the American College of Cardiology, 2005;46: p 1536-40.

Atti, V., Turagam, M., Garg, J., Koerber, S., Angirekula, A., Gopinathannair, R., Natale, A. and Lakkireddy, D., 2020. Subclavian and Axillary Vein Access Versus Cephalic Vein Cutdown for Cardiac Implantable Electronic Device Implantation. JACC: Clinical Electrophysiology, 6(6), pp.661-671.

Curtis JP, Luebbert JJ, Wang Y; et al. Association of physician certification and outcomes among patients receiving an implantable cardioverter-defibrillator. JAMA. 2009;301(16):1661-1670.

Blomström-Lundqvist, C., Traykov, V., Erba, P., Burri, H., Nielsen, J., Bongiorni, M., Poole, J., Boriani, G., Costa, R., Deharo, J., Epstein, L., Saghy, L., Snygg-Martin, U., Starck, C., Tascini, C., Strathmore, N., Kalarus, Z., Boveda, S., Dagres, N., Rinaldi, C., Biffi, M., Gellér, L., Sokal, A., Birgersdotter-Green, U., Lever, N., Tajstra, M., Kutarski, A., Rodríguez, D., Hasse, B., Zinkernagel,

A. and Mangoni, E., 2019. European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections—endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), the Latin American Heart Rhythm Society (LAHRS), International Society for Cardiovascular Infectious Diseases (ISCVID) and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS). European Journal of Cardio-Thoracic Surgery, 57(1), pp.e1-e31.

Garcia, R., Boveda, S., Defaye, P., Sadoul, N., Narayanan, K., Perier, M., Klug, D., Fauchier, L., Leclercq, C., Babuty, D., Bordachar, P., Gras, D., Deharo, J., Piot, O., Providencia, R., Marijon, E. and Algalarrondo, V., 2020. Early mortality after implantable cardioverter defibrillator: Incidence and associated factors. International Journal of Cardiology, 301, pp.114-118.

Kipp R, Hsu JC, Freeman J, Curtis J, Bao H, Hoffmayer KS. Long-term morbidity and mortality after implantable cardioverter-defibrillator implantation with procedural complication: A report from the National Cardiovascular Data Registry. *Heart Rhythm*. 2018;15(6):847-854. doi:10.1016/j.hrthm.2017.09.043

Reynolds MR, et al. Complications among Medicare beneficiaries, receiving implantable cardioverter-defibrillators. J Am Coll Cardiol. 2006; 47:2493-2497.

Peterson PE, et al. Association of single- vs dual-chamber ICDs with mortality, readmissions and complications among patients receiving an ICD for primary prevention. JAMA. 2013;309:2025-2034.

Additional relevant articles:

Pokorney SD, et al. Primary prevention implantable cardioverter-defibrillators in older racial and ethnic minority patients. Circ Arrhythm Electrophysiol. 2015 Feb;8(1):145-51

Dodson, JA, et al. 2014. Developing a Risk Model for in-Hospital Adverse Events following ICD Implantation: A Report from the NCDR® Registry. Journal of the American College of Cardiology, 63(8), 788–796. doi:10.1016/j.jacc.2013.09.079

2.4 Performance Gap

See Table 1 below.

Table 1. Performance Scores by Decile

		Performance Gap									
	Overall	**Minimum**	**Decile_1**	**Decile_2**	**Decile_3**	**Decile_4**	**Decile_5**	**Decile_6**	**Decile_7**	**Decile_8**	**Decile_9**	**Decile_10**	**Maximum**
Mean Performance Score	5.7					0-17.8						
N of Entities	1792					1792						
N of Persons / Encounters / Episodes	67080					67080						

2.6 Meaningfulness to Target Population

This measure was developed with input from a technical expert panel that includes patient and caregiver representation. Generally, patients indicate that outcomes such as complications following a procedure are useful for decision-making purposes and we believe that this measure would be found meaningful by them.

3.1 Contributions Towards Closing Care Gaps

optional question

4.1 Feasibility Assessment

Not applicable during the Fall 2023 cycle.

4.3 Feasibility Informed Final Measure

The data elements required to generate this measure are coded by an individual other than the person obtaining the original information (e.g., DRG, ICD-10 codes on claims). All data elements are available in defined fields in electronic clinical data (e.g., clinical registry). This measure uses clinical data from the NCDR Electrophysiology Device Implant Registry EPDI (Formerly the ICD registry) for risk adjustment and that data are linked to CMS administrative claims data to identify the ICD-related complications.

During initial measure testing when considering that the administrative database may be subject to coding errors and variation in coding practices within and across care settings, the ICD measure development team at YNHHSC/CORE chose to conduct a chart validation study. The goal was to determine whether ICD-9-CM diagnosis and procedure codes reported on Medicare claims and used in the measure specifications accurately identify patients experiencing ICD complications within 30 or 90 days of ICD implantation as reported in the medical charts. This approach required obtaining medical records of patients who had an ICD implanted from participating hospitals, abstracting data related to ICD complications (including number of

complications, timing, severity and treatment), conducting a head-to-head comparison of data between Medicare claims and medical records to assess the degree of agreement, and finally, where appropriate, adjusting the list of codes and/or the cohort definition in the ICD measure specifications to improve the agreement.

We calculated the sample size requirement based on the desired degree of agreement between medical records and claims data, which can be categorized as fair, moderate, substantial, or almost perfect depending on the magnitude of the kappa coefficient2. Our initial calculation was based on achieving a "substantial" degree of agreement, and accounting for a within-hospital correlation coefficient of 0.03. This would have required approximately 860 medical records. To compensate for missing charts, we added 10-20 percent to the required sample size. This increased the required number to nearly 1000 charts, which would have resulted in doubling our budgetary allotment. We therefore decided to keep the sample size at 500 medical records from 9 candidate hospitals. This sample size would allow a qualitative assessment of the ICD-9-CM codes used in the claims model while meeting NQF review committee standards, considering budgetary and time constraints.

Thus, our approach was to recruit 9 hospitals and request copies of medical charts for approximately 60 Medicare FFS patients who had an ICD implanted between 2005 and 2007, 30 with and 30 without complications at each hospital. This number also accounted for 10 to 20 percent of medical records that may be missing. Given the low ICD complication rate, we selected sites that had a minimum of 25 cases with complications over the three-year period.

Although we planned to review approximately 540 charts from 9 hospitals, the final sample size was 411. One of the 9 hospitals withdrew from the project and did not provide the charts, though it previously signed both, a data use agreement (DUA) and a business associate agreement (BAA). Because they withdrew 9 months into the study, there was insufficient time remaining in the contract to recruit a replacement hospital. The remaining 8 hospitals provided 411 charts out of the 480 requested, with 69 (14.4%) missing charts.

Summary of Study and Findings:

- 9 Hospitals agreed to participate in the study; 8 completed the study and one withdrew
- Of the 480 charts requested, 411 were obtained from 8 hospitals (14.4% of missing charts)
- Charts were abstracted by professional chart abstractors at an independent company, Information Collection Enterprises, LLC (ICE)
- We excluded 95 cases because they had a previous ICD (consistent with current measure specifications). Thus, the study was based on 316 patients
- We identified 149 patients with complications (1 or more complication) in the chart, while administrative codes identified 166 patients with complications; 144 patients with complications were identified by both charts and codes; 22 by codes only; and 5 by charts only.

- These findings resulted in an overall agreement between chart and claims (based on all paired ratings) of 91.5% [Yes/Yes(144) + No/No(145) / total (316)=0.915] with a kappa coefficient of 0.83 (0.7865 – 0.8907) which is in the “almost perfect” range. A depiction of the overall agreement can be found in section 2b2.2 of the testing form (figure 1. and table 2).

We examined all cases of disagreement between the charts and the claims for each complication. Complications reported in the charts but not identified in the claims were due to either missing codes from our measure specifications or a failure to report the complication in the claims (e.g. evacuation of a hematoma). Examination of cases where the complication was reported in the claims but not in the charts, revealed that the complication was not related to the ICD but to another procedure, device, or medical condition. Based on these results, we made the following changes to the cohort and definitions of complications:

- Added the following administrative claim codes to the measure specifications to capture more mechanical complications with revision: 996.72; 39.94; 37.77
- Excluded patients with a previous pacemaker from the cohort, considering the lack of availability of present-on-admission codes at this time

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4.4 Proprietary Information

Not a proprietary measure and no proprietary components

4.4a Fees, Licensing, or Other Requirements

The ACCF’s program the National Cardiovascular Data Registry (NCDR) provides evidence based solutions for cardiologists and other medical professionals committed to excellence in cardiovascular care. NCDR hospital participants receive confidential benchmark reports that include access to measure macro specifications and micro specifications, the eligible patient population, exclusions, and model variables (when applicable). In addition to hospital sites, NCDR Analytic and Reporting Services provides consenting hospitals’ aggregated data reports to interested federal and state regulatory agencies, multi-system provider groups, third-party payers, and other organizations that have an identified quality improvement initiative that supports NCDR-participating facilities. Lastly, the ACCF also allows for licensing of the measure specifications outside of the Registry.

It should be noted that the centers already have to participate in this specific registry for reimbursement purposes so that currently almost all hospitals that implant ICDs in Medicare populations already participate. Hence there is no additional cost.

Measures that are aggregated by ACCF and submitted to the CBE are intended for public

reporting and therefore there is no charge for a standard export package. However, on a case by case basis, requests for modifications to the standard export package will be available for a separate charge.

5.1.1 Data Used for Testing

The specifications for this measure have not changed since the prior review.

Several sections of this application for this measure could not be updated, including information on reliability and validity. This uniquely valuable measure was developed when access to CMS claims data was feasible. Current data access restrictions to the same CMS claims data prevents ACC from conducting the patient matching to assess long term follow up. Imposing requirements upon hospitals to acquire follow up data themselves during the past two plus years of the pandemic-induced hospital crisis was not possible. Thus, ACC-NCDR was prevented from linking claims data to our registry data.

The existing data set used was a clinical registry, the National Cardiovascular Data Registry (NCDR) ICD Registry, which has since been renamed to the EP Device Implant (EPDI) Registry. Some states and healthcare systems mandate participation. Rigorous quality standards are applied to the data and both quarterly and ad hoc performance reports are generated for participating centers to track and improve their performance.

The measure links clinical data from NCDR to Medicare claims data to ascertain complications.

The measure reliability dataset linked the ICD registry and Medicare Part A claims data from 2010Q2-2011Q4. The combined two-year sample included 43, 711 to 1,279 hospitals with 21,856 admissions to 1,254 hospitals in one randomly selected sample and 21,855 admissions to 1,246 hospitals in the remaining sample for patients aged 65 years and older. After excluding hospitals with fewer than 25 cases in each sample, the first sample contained 297 hospitals and the second sample contained 298 hospitals. In addition to being used for reliability testing, the linked dataset was used for measure exclusions testing.

These analyses used a cohort of patients undergoing ICD placement for whom NCDR ICD Registry data were linked with corresponding administrative claims data. However, we also conducted additional analyses to meet newer testing requirements, and these analyses were performed using comparable linked data from 2010-2011. Details are provided below.

Reliability testing and exclusions testing

The measure reliability dataset linked the ICD and Medicare Part A claims data for claims between 2010Q2 and 2011Q4. The sample included ICD placement in a cohort of 43,711 Medicare FFS patients aged 65 years and older performed in 1279 hospitals. We then randomly split the sample, leaving 21,856 admissions to 1,254 hospitals in one randomly selected sample and 21,855 admissions to 1,246 hospitals in the remaining sample for patients aged 65 years and older. After excluding hospitals with fewer than 25 cases in each sample, the first sample contained 297 hospitals and the second sample contained 298 hospitals.

Validity testing

A summary of validity testing undertaken was provided in the Feasibilty section of this form. A chart validation study has been completed to determine whether ICD-9-CM diagnosis and procedure codes reported on Medicare claims and used in the measure specifications accurately identified patients experiencing ICD complications within 30 and 90 days of ICD implantation as reported in the medical charts. The findings of the study reported an overall agreement between chart and claims (based on paired ratings) of 91.5%.

Measure development and risk-adjustment dataset

In measure development, we identified ICD procedures in the NCDR ICD Registry in which the patient was released from the hospital between April 2010 and December 2011. We merged ICD admissions in the NCDR ICD Registry data and ICD admissions in Medicare claims data to derive cohorts for development using probabilistic matching methodology. There were 21,855 cases discharged from the 1226 hospitals in the validation sample. This validation sample had a crude complication rate of 6.71%.

5.1.2 Differences in Data

Information on the differences with the data used is described above.

5.1.3 Characteristics of Measured Entities

For this measure, hospitals are the measured entities. All non-federal, acute inpatient US hospitals (including territories) that participate in the American College of Cardiology (ACC) NCDR’s ICD Registry and care for Medicare Fee-for-Service (FFS) beneficiaries who are 65 years of age or older are included. The number of measured entities (hospitals) varies by testing type as described in the question above.

5.1.4 Characteristics of Units of the Eligible Population

Please refer to table 1 in the attachment.

5.2.1 Level(s) of Reliability Testing Conducted

Person or encounter level (i.e., data element) (e.g., inter–abstractor reliability), Accountable entity level (i.e., measure score) (e.g., signal-to-noise analysis)

5.2.2 Method(s) of Reliability Testing

Patient or Encounter-Level Reliability

In constructing the measure we aim to utilize only those data elements from the claims that have both face validity and reliability. We avoid the use of fields that are thought to be coded inconsistently across hospitals or providers. Specifically, we use fields that are consequential for payment and which are audited. We identify such variables through empiric analyses and our understanding of CMS auditing and billing policies and seek to avoid variables which do not meet this standard. For example, “discharge disposition” is a variable in Medicare claims data that is not thought to be a reliable variable for identifying a transfer between two acute care facilities. Thus, we derive a variable using admission and discharge dates as a surrogate for “discharge disposition” to identify hospital admissions involving transfers. This allows us to identify these admissions using variables in the claims data which have greater reliability than the “discharge disposition” variable. In addition, CMS has in place several hospital auditing programs used to assess overall claims code accuracy, to ensure appropriate billing, and for overpayment recoupment. CMS routinely conducts data analysis to identify potential problem areas and detect fraud, and audits important data fields used in our measures, including diagnosis and procedure codes and other elements that are consequential to payment.

In addition, as an example of some of the methods that could be used to ensure data quality, we describe the NCDR’s existing Data Quality Program (DQP). The two main component of the DQP are complementary and consist of the Data Quality Report (DQR) and the Data Audit Program (DAP). The DQR process assesses the completeness and validity of the electronic data submitted by participating hospitals. Hospitals must achieve >95% completeness of specific data elements identified as ‘core fields’ to be included in the registry’s data warehouse for analysis. The ‘core fields’ include the variables included in 25 our risk adjustment models. The process is iterative, providing hospitals with the opportunity to correct errors and resubmit data for review and acceptance into the data warehouse. The DAP consists of annual on-site chart review and data abstraction. Among participating hospitals that pass the DQ random charts of 10% of submitted

cases.

Finally, we assess the reliability of the data elements by comparing model variable frequencies and odds ratios in two years of data.

Accountable Entity-Level Reliability

The reliability of a measurement is the degree to which repeated measurements of the same entity agree with each other. For measures of hospital performance, the measured entity is naturally the hospital, and reliability is the extent to which repeated measurements of the same hospital give similar results. In line with this thinking, our approach to assess reliability is to consider the extent to which assessments of a hospital using different, but randomly selected subsets of patients, produce similar measures of hospital performance. That is, we take a "test-retest" approach in which hospital performance is measured once using a random subset of patients, then measured again using a second random subset exclusive of the first, and finally comparing the agreement between the two resulting performance measures across hospitals (Rousson et al., 2002).

For test-retest reliability of the measure score, from the study cohort, we randomly sampled half of patients within each hospital, calculated the measure for each hospital in the first half, and then repeated the calculation using the second half. Thus, each hospital is measured twice, but each measurement is made using an entirely distinct set of patients. To the extent that the calculated measures of these two subsets agree, we have evidence that the measure is assessing an attribute of the hospital, not of the patients. As a metric of agreement we calculated the intra-class correlation coefficient (ICC) (Shrout and Fleiss, 1979), and assessed the values according to conventional standards (Landis and Koch, 1977). Specifically, we used the two data samples and calculated the risk-standardized complication rate (RSCR) for each hospital for each sample. The agreement of the two RSCRs was quantified for hospitals in each sample using the intra-class correlation (ICC) as defined by Shrout and Fleiss (1979).

Using two independent samples provides an honest estimate of the measure’s reliability, compared with using two random, but potentially overlapping samples, which would exaggerate the agreement. Moreover, because our final measure is derived using hierarchical logistic regression, and a known property of hierarchical logistic regression models is that small volume hospitals contribute less ´signal´. As such a split sample using a single measurement period likely introduces extra noise; potentially underestimating the actual test-retest reliability that would be achieved if the measures were reported using additional years of data. Furthermore, the measure is specified for the entire ICD population, but we tested it only in the subset of Medicare FFS

patients for whom information about vital status was available.

References:

1) Rousson V, Gasser T, Seifert B. Assessing intrarater, interrater and test–retest reliability of continuous measurements. Statistics in Medicine 2002;21:3431-3446.

2) Shrout P, Fleiss J. Intraclass correlations: uses in assessing rater reliability. Psychological Bulletin 1979;86:420-428.

3) Landis J, Koch G, The measurement of observer agreement for categorical data. Biometrics 1977;33:159-174.

5.2.3 Reliability Testing Results

Patient or encounter-level reliability results

Overall, risk factor frequencies changed little across years, and there were no notable differences in the odds ratios across years of data (please refer to table 2 in the attachment).

The 2 split samples were calculated during the same timeframe to avoid the potential for changes in hospital performance over time. After splitting the cohort into two random samples, we compared measure scores calculated at hospitals with at least 25 cases in both random samples. The distribution of hospital performance was similar in the two samples (figure below), and there was a fair correlation between hospital performances assessed in the two samples (r 0.1494).

Accountable entity-level reliability results

In the most recent years of data (2010Q1-2011Q4), there were 43,711 admissions in the combined two-year sample, with 21,856 admissions to 1,254 hospitals in the first randomly selected sample (mean RSCR 7.01%), and 21,855 admissions to 1,246 hospitals in the second randomly-selected sample (mean RSCR 6.58%). The agreement between the two RSCRs for each hospital was 0.1494, which according to the conventional interpretation is “slight” (Landis & Koch, 1977). The intra-class correlation coefficient is based on a split sample of 2 years of data, resulting in a volume of patients in each sample equivalent to only 1 year of data, whereas the measure is likely to be reported with a full two years of data.

Reference.

Landis J, Koch G. The measurement of observer agreement for categorical data, Biometrics 1977;33:159-174..

5.2.4 Interpretation of Reliability Results

The stability over time of the risk factor frequencies and odds ratios indicate that the underlying data elements are reliable. Additionally, the ICC score demonstrates fair agreement across samples using a “strict” approach to assessment that would likely improve with greater sample size.

5.3.1 Level(s) of Validity Testing Conducted

Person or encounter level (i.e., data element) (e.g., sensitivity and specificity), Accountable entity level (i.e., measure score) (e.g., criterion validity)

5.3.3 Method(s) of Validity Testing

Measure validity is demonstrated through prior validity testing done on our other measures, through use of established measure development guidelines, by systematic assessment of measure face validity by a technical expert panel (TEP) of national experts and stakeholder organizations, and through registry data validation.

Validity of Registry Data

Data element validity testing was done on the specified measure by comparing with variables in the ACC audit program. The NCDR ICD Registry has an established DQP that serves to assess and improve the quality of the data submitted to the registry. There are two complementary components to the Data Quality Program- the Data Quality Report (DQR) and the Data Audit Program (DAP). The DQR process assesses the completeness of the electronic data submitted by participating hospitals. Hospitals must achieve >95% completeness of specific data elements identified as “core fields” to be included in the registry’s data warehouse for analysis. The “core fields” encompass the variables included in our risk adjustment models. The process is iterative, providing hospitals with the opportunity to correct errors and resubmit data for review and acceptance into the data warehouse. All data for this analysis passed the DQR completeness thresholds.

The DAP consists of annual on-site chart review and data abstraction. Among participating hospitals that pass the DQR for a minimum of two quarters, at least 5% are randomly selected to participate in the DAP. At individual sites, auditors review charts of 10% of submitted cases. The audits focus on variables that are used in the NCDR risk-adjusted in-hospital mortality model including demographics, comorbidities, cardiac status, coronary anatomy, and ICD status. However, the scope of the audit could be expanded to include additional fields. The DAP includes an appeals process for hospitals to dispute the audit findings.

We also examined the temporal variation of the standardized estimates and frequencies of the variables in the development and validation models.

To assess the predictive ability of the model, we grouped patients into deciles of predicted 30 or 90 day complication and compared predicted complication with observed complication for each decile in the derivation cohort (figure 3 in the attachment).

As noted in more detail in feasibility section of the form, a chart validation study has been completed to determine whether ICD-9-CM diagnosis and procedure codes reported on Medicare claims and used in the measure specifications accurately identified patients experiencing ICD complications within 30 and 90 days of ICD implantation as reported in the medical charts. The findings of the study reported an overall agreement between chart and claims (based on paired ratings) of 91.5%. Table 3 and figure 2 provide a depiction of the agreement and disagreement for patients with complication identified by charts and claims.

Validity as Assessed by External Groups

During original measure development and in alignment with the CMS Measures Management System (MMS), we released a public call for nominations and convened a TEP when originally developing the measure. The purpose of convening the TEP was to provide input and feedback during measure development from a group of recognized experts in relevant fields. The TEP represented physician, consumer, hospital, and purchaser perspectives, chosen to represent a diverse of perspectives and backgrounds.

5.3.4 Validity Testing Results

See table 4 in the attachment. The performance of the derivation and validation samples is similar. The areas under the receiver operating characteristic (ROC) curve are 0.640 and 0.642, respectively, for the two samples. In addition, they are similar with respect to predictive ability. For the derivation sample, the predicted complication rate ranges from 3% in the lowest predicted decile to 14% in the highest predicted decile, a range of 11%. For the validation sample, the corresponding range is 3% to 14%, also a range of 11%.

5.3.5 Interpretation of Validity Results

The audits conducted by the ACC support the overall validity of the data elements included in this measure. The data elements used for risk adjustment were consistently found for all patients and

were accurately extracted from the medical record.

Additionally, the frequencies and regression coefficients are fairly consistent over the two years of data. Also, there was excellent correlation between predicted and observed complications.

5.3.2 Type of Accountable Entity Level Validity Testing Conducted (derived)

Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis)

5.4.1 Methods Used to Address Risk Factors

Statistical risk adjustment model with risk factors

5.4.2 Conceptual Model Rationale

See table 5 in the attachment. We developed a parsimonious model that included key variables previously shown to be associated with complications following ICD implantation. Importantly, the variables included in the risk model were fully harmonized with the NCDR's existing risk model used to provide hospitals with risk adjusted in-hospital adverse events. In the development of that model, a team of clinicians had reviewed all variables in the NCDR ICD Registry database (a copy of the data collection form and the complete list of variables collected and submitted by hospitals can be found at www.ncdr.com and also in this application).

Based on clinical review informed by the literature, a total of 15 variables were determined to be appropriate for consideration as candidate variables. We used logistic regression with stepwise selection (entry $p<0.05$; retention with $p<0.01$) for variable selection. We also assessed the direction and magnitude of the regression coefficients. This resulted in a final risk-adjusted complication model that included 9 variables (table 5). To harmonize the models, we elected to apply this approach to risk adjustment to the 30/90 day complications risk model. Several variables were not clinically significantly associated with risk of complications at 30/90 days, but we elected to retain them in the model for consistency. We compared hospitals' RSCR calculated using this model with the output from a risk model that been developed specifically for 30/90 day complications and found them to be almost identical (correlation coefficient 0.996).

For categorical variables with missing values, the value from the reference group was added. The percentage of missing values for all categorical variables was very small (<1%) and they were imputed to a specific categories based on our previous experience. There were three continuous variables with missing values: **Hemoglobin** (HGB, 1.9%), **BUN** (1.3%), and **Sodium** (1.1%); and these missing values were imputed as the median of the non-missing values of the corresponding variable.

5.4.3 Variable Distribution Across Measured Entities

Information on the descriptive statistics on the distribution across the measured entities of the risk variables identified was not previously required and as a result, we do not have these data to share.

5.4.4 Risk/Case-Mix Adjustment Modeling and/or Stratification Results

See table 6 and 7 in the attachment.

5.4.5 Calibration and Discrimination

Approach to assessing model performance

During measure development, we computed three summary statistics for assessing model performance (Harrell and Shih, 2001) for the development and validation cohort:

Discrimination Statistics:

(1) Area under the receiver operating characteristic (ROC) curve (the c statistic (also called ROC) is the probability that predicting the outcome is better than chance, which is a measure of how accurately a statistical model is able to distinguish between a patient with and without an outcome.)

(2) Predictive ability (discrimination in predictive ability measures the ability to distinguish high-risk subjects from low-risk subjects. Therefore, we would hope to see a wide range between the lowest decile and highest decile)

Calibration Statistics:

(3) Over-fitting indices (over-fitting refers to the phenomenon in which a model accurately describes the relationship between predictive variables and outcome in the development dataset but fails to provide valid predictions in new patients)

We compared the model performance in the development sample with its performance in another sample of half of the patients randomly selected from the whole 2010Q2-2011Q4 study cohort. There were 21, 856 cases discharged from the 1222 hospitals in the 2010-2011 validation dataset. This validation sample had a crude complication rate of 6.86%. We also computed statistics (1) and (2) for the current measure cohort, which includes discharges from 2010Q2-2011Q4.

For the derivation cohort the results are summarized below:

C-statistic=0.640

Predictive ability (lowest decile %, highest decile %): 4.05%, 25.08%

For the validation cohort the results are summarized below:

C-statistic=0.642

Predictive ability (lowest decile %, highest decile %): 3.80%, 23.80%

For the validation cohort the results are summarized below:

Calibration: (0.03, 1.02)

The risk decile plot is a graphical depiction of the deciles calculated to measure predictive ability. Below, we present the risk decile plot showing the distributions for the current measure cohort. See figure 3 in the attachment.

Discrimination Statistics

The C-statistics of 0.640 and 0.642 indicate fair model discrimination in the derivation and validation cohorts. Complications, as opposed to other outcomes such as mortality consistently have a lower c-statistic, even in medical record models. This is likely because complications are less determined by patient comorbidities and more by health system factors. The model indicated a wide range between the lowest decile and highest decile, indicating the ability to distinguish high-risk patients with low-risk patients.

Calibration Statistics

Over-fitting (calibration y0, y1)

If the Y0 in the validation samples are substantially far from zero and the y1 is substantially far from 1, there is potential evidence of over-fitting. The calibration value close to 0 at one end and close to 1 on the other end indicates good calibration of the model.

Risk Decile Plots

Higher deciles of the predicted outcomes are associated with higher observed outcomes, which

show a good calibration of the model. This plot indicates excellent discrimination of the model and good predictive ability.

Overall Interpretation

Interpreted together, our diagnostic results demonstrate the risk-adjustment model adequately controls for differences in patient characteristics (case mix).

5.4.6 Interpretation of Risk/Case-mix Factor Findings

See fields above.

5.4.7 Final Approach to Address Risk Factors

Statistical risk adjustment model with risk factors

6.1.3b Rationale for Not In Use

Efforts have been unsuccessful to gain access to CMS claims data. Should these become available to the ACC we will provide a detailed plan of implementation.

6.1.3 Current Use(s)

Not in use

6.1.3 Program Details

Name of the program and sponsor
NA
URL of the program
https://doesnotexist.org
Purpose of the program
NA
Geographic area and percentage of accountable entities and patients included
NA
Applicable level of analysis and care setting

NA

6.2.1 Actions of Measured Entities to Improve Performance

In general, registry participants receive feedback though quarterly benchmark reports. These reports contain detailed analyses of the institution’s performance. In these reports, institutional performance is compared to national aggregates. A thorough understanding of performance can

be gleaned from the executive summary dashboard which contains visual displays of metric performance as well as patient level drill downs. Sites have the capability to export their information into their own excel spreadsheets to conduct their own analysis. Supporting documentation in the form of the coder's dictionary and outcome reports guide includes additional support for the sites. Monthly Registry Site Manager (RSM) Calls, sessions at the NCDR annual conference and access to Clinical Quality Associates are other ways that sites can get updates on data interpretation.

6.2.2 Feedback on Measure Performance

Because ACC is unable to currently report on the measure, we have not received any new feedback on measure performance and implementation.

Once implemented, feedback will be collected during monthly RSM calls, ad hoc phone calls tracked with Salesforce software, and during registry –specific break-out sessions at the NCDR's annual meeting. Registry Steering Committee members may also provide feedback during regularly scheduled calls.

6.2.3 Consideration of Measure Feedback

Because ACC is unable to currently report on the measure, we have not received any new feedback on measure performance and implementation.

6.2.4 Progress on Improvement

Because ACC is unable to currently report on the measure, we are not able to track improvement on the measure at this time.

6.2.5 Unexpected Findings

As noted earlier, publicly reporting hospital risk-standardized ICD complication rates requires that the data submitted by hospitals be complete, consistent, and accurate. A protocol that assures accurate data for public reporting should be established prior to implementation. Steps to ensure data quality could include monitoring data for variances in case mix, chart audits, and possibly adjudicating cases that are vulnerable to systematic misclassification.

As an example of some of the methods that could be used to ensure data quality, we describe the NCDR's existing Data Quality Program (DQP). The two main components of the DQP are complementary and consist of the Data Quality Report (DQR) and the Data Audit Program (DAP).

The DQR process assesses the completeness and validity of the electronic data submitted by participating hospitals. Hospitals must achieve >95% completeness of specific data elements identified as ‘core fields’ to be included in the registry’s data warehouse for analysis. The ‘core fields’ capture many of the variables included in our risk adjustment models. The process is iterative, providing hospitals with the opportunity to correct errors and resubmit data for review and acceptance into the data warehouse. The DAP consists of annual on-site chart review and data abstraction. Among participating hospitals that pass the DQR for a minimum of two quarters, at least 5% are randomly selected to participate in the DAP. At individual sites, on-site auditors review charts of 10% of submitted cases. The NCDR audit focuses on variables used to determine whether patients meet accepted criteria for ICD implantation. However, the scope of the audit could be expanded to include additional fields. The DAP includes an appeals process that allows hospitals to reconcile audit findings.

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Measure Developer POC

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Measured/accountable entity (reliability and/or validity) methodology and results (if available)

Measured entity (reliability and validity) methodology and results (if available)

Responder for Survey

Patient

Specify number of risk factors

9

The measure developer is different from the measure steward

No

Steward Address

United States