# NATIONAL QUALITY FORUM

National Voluntary Consensus Standards for Patient Outcomes
Measure Summary

**Measure number: OT1-007-09**

**Measure Name:** Hospital Risk-Standardized Complication Rate following Implantation of Implantable Cardioverter-Defibrillator (ICD)

**Description:** This measure provides hospital specific risk-standardized rates of procedural complications following the implantation of an ICD in Medicare Fee-For-Service (FFS) patients at least 65 years of age. The measure uses clinical data available in the National Cardiovascular Data Registry (NCDR) ICD Registry for risk adjustment that has been linked with CMS administrative claims data used to identify procedural complications.

**Numerator statement:** This outcome measure does not have a traditional numerator and denominator like a core process measure (e.g., percentage of adult patients with diabetes aged 18-75 years receiving one or more hemoglobin A1C tests per year); thus, we are using this field to define the outcome (ie adverse events) following ICD implantation. The measured outcome for each index admission is one or more complications or mortality within 30 or 90 days (depending on the complication) following ICD implantation. Complications are counted in the measure only if they occur during a hospital admission.

**Denominator statement:** The target population for this measure includes inpatient or outpatient ICD implants for Medicare fee-for-service (FFS) beneficiaries at least 65 years of age at the time of implantation who have matching information in the National Cardiovascular Disease Registry (NCDR) ICD Registry. The patient cohort is defined by ICD-9 procedures codes from inpatient claims and Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) procedure codes from outpatient claims as outlined in the denominator details.

**Level of Analysis:** Population: national, Facility/Agency

**Type of Measure:** Outcome

**Data source:** Electronic administrative data/claims, registry data

**Measure developer:** CMS / Yale New Haven Health Services Corporation Center for Outcomes Research & Evaluation (YNHHSC/CORE)

**Type of Endorsement (full or time-limited):** Recommended for Endorsement as part of a Composite (Steering Committee – March 24, 2010 [14 recommended, 3 did not recommend, 0 abstain])

**Summary table of TAP ratings of sub criteria and comments:**

| IMPORTANCE TO MEASURE AND REPORT | | |
|---|---|---|
| 1a Impact | Completely | 1a - high impact 1b. opportunity for unrelated visits unclear 1c - |
| 1b gap | Partially | the non-specific nature of the visits may be unrelated to the AMI; |

| | | |
|---|---|---|
| 1c relation to outcomes | Partially/ Minimally | confounded by relationships between the private physicians and hospital staffs on use of the ED versus other venues; NQF has already endorsed the 30-day readmission rate -- will the ED visit add anything? The measure will capture colds and other minor ailments particularly in locations where the ED is used as a primary care source. Would like to see data on reasons for ED visits. Validity is reduced in areas where the ED is used in place of a primary care. |
| SCIENTIFIC ACCEPTABILTY | | |
| 2a specs | Completely | 2a. precise specifications; does not capture non-Fee For Service (FFS) Medicare patients (about 15%) because data is not available 2b. 10% auditing of registry data -- would like more information on results of audits; 2c. separate cohorts validation; codes compared to charts done in a small set -- plan to do more; "cause specific" complications; time frames: 30 days - serious complications, 90 days - mechanical/malfunctions -- make sense; 2d - appropriate exclusions; 2e - risk model c statistic = 0.61 ROC = .65 calibration curve in the supplemental materials; does not include social or economic factors; 2f - distribution curve on p 40 of supplemental report - not much spread; low volumes - may need to bundle several years; 2g. all Medicare patients required to be reported to registry - more than 70% of hospitals report all patients to registry 2h. disparities not addressed in measure -- disparities are known -- women have higher complication rate; stratification likely to have low numbers problem |
| 2b reliability | Partially | |
| 2c validity | Partially | |
| 2d exclusions | Completely | |
| 2e risk adjustment | Completely | |
| 2f meaningful differences | Partially | |
| 2g comparability | Not applicable | |
| 2h disparities | Not applicable | |
| USEABILITY | | |
| 3a distinctive | Completely | 3a. Diverse representation on working group for measure development; consumer testing pending 3b. harmonization not an issue; 3c - new topic area for a high cost procedure |
| 3b harmonization | Not at all | |
| 3c Added value | Completely | |
| FEASIBILITY | | |
| 4a Data a byproduct of care | Completely | data abstraction still the norm 4b registry is electronic 4c exclusions - same data source 4d - would like to see auditing results 4e -data collection through a single registry |
| 4b Electronic | Completely | |
| 4c Exclusions | Completely | |
| 4d Inaccuracies/errors | Partially | |
| 4e Implementation | Completely | |

# NATIONAL QUALITY FORUM

National Voluntary Consensus Standards for Patient Outcomes
Measure Summary

**Measure Developer Response**

| Topic, Measure # and Title | Follow-Up Issues |
|---|---|
| **Topic Area: CHF**<br><br>**Measure#**<br><br>**OT1-007-09**<br><br>**Hospital Risk-Standardized Complication Rate following Implantation of Implantable Cardioverter-Defibrillator (ICD)** | **Questions/Conditions for Measure Developer:**<br><br>1. Results of auditing of the registry data.<br><br>2. Address and clarify why these measures did not address measuring disparities.<br><br>**Response from Measure Developer:**<br>1. Results of audit of registry data.<br>As mentioned during the NQF TAP meeting, the NCDR ICD Registry completed on-site audits of a random sample of hospitals that submitted data in 2006, the first year the registry collected data. The auditors compared chart abstracted data with data submitted to the registry, focusing on the fields needed to determine eligibility for Medicare reimbursement such as ICD indication (primary versus secondary), Left Ventricular Ejection Fraction (LVEF), New York Heart Association Class (NYHA), and history of prior myocardial infarction and percutaneous coronary intervention. Overall, the quality of the submitted data was found to be good, with 14 of 15 hospitals assigned a B grade (overall agreement between data submitted to NCDR and chart abstracted data 80-93%), and the remaining hospital assigned an A grade (overall agreement >93%). As would be expected, agreement was highest among demographic fields such as date of birth and gender, and lower among continuous and multilevel fields such as NYHA and LVEF. Importantly, data abstractor review was limited to hospital records, and reconciliation with hospitals suggested that a substantial proportion of disagreement arose from submission of data that reflected office testing and other information that was not included in the hospital medical record.<br>These audit findings reflect the quality of the data submitted to the ICD Registry in 2006. CMS has the infrastructure in place to audit data submitted for quality measures; for example, CMS currently audits chart abstracted data submitted by hospitals for process of care measures reported on the Hospital Compare website (*www.hospitalcompare.hhs.gov*).<br>2. Address and clarify why these measures did not address measuring disparities. |

| Topic, Measure # and Title | Follow-Up Issues |
|---|---|
| | The TAP was concerned that the measure could exacerbate existing disparities by penalizing hospitals that care for a high proportion of patients with low socioeconomic status (SES). We considered this possibility during measure development. One approach to addressing the effect of SES on the outcome would be to adjust for SES-related covariates at the patient level; however, this approach could obscure important differences in the quality of care delivered by hospitals and would be inconsistent with NQF guidelines. Another approach would be to stratify the cohort by SES; however, given the limited number of implants at individual hospitals, stratifying the measure is not feasible.<br>To examine the potential affect of SES on hospital performance on the measures, we conducted stratified analyses of hospital risk standardized complication rates (RSCR) by (a) hospital safety net status and (b) quartiles of median household income. Both sets of analyses suggested that the range of hospital RSCR was similar irrespective of patient SES status. Specifically, the median RSCR for safety net hospitals was 7.2% with the medians of the lowest and highest deciles being 6.8% and 8.0%, respectively, which is similar to that observed for non-safety net hospitals (median 7.2%, lowest and highest deciles 6.7% and 8.0%, respectively). Likewise, hospital performance was similar across quartiles of hospital median patient household income (median 7.2%, medians of the lowest and highest decile 6.6% and 7.9%, respectively). The results indicate that some hospitals caring for a low proportion of poor patients perform poorly and some hospitals caring for a high proportion of poor patients perform well. Our findings suggest that although SES may be an important predictor for individual patients, it is not a major determinant of hospital RSCR for patients undergoing ICD implantation.<br>Finally, TAP members raised the question of whether the measure should be reported separately for men and women given the known higher rates of complications among women as compared to men. Although we agree that women are more likely to experience ICD complications than men, a stratified measure is not necessary as gender is included as a covariate in the model. Additionally, given the lower volume of cases in women, it is unlikely that a stratified measure would be able to accurately discriminate performance across hospitals. |

# NATIONAL QUALITY FORUM

National Voluntary Consensus Standards for Patient Outcomes
Measure Summary

**Summary table of SC ratings of sub criteria and comments:**

| IMPORTANCE TO MEASURE AND REPORT | |
|---|---|
| The Committee felt the measure should not be limited to Medicare FFS patients only. A complication rate of 18% is high. | SC Vote on Importance<br><br>Yes - 17<br><br>No - 0 |
| SCIENTIFIC ACCEPTABILITY | |
| The Steering Committee was impressed with the risk adjustment methodology, though one Committee members noted that the results cluster around the mean with little variability. He felt that use of hierarchical modeling caused the reduced variability. Others suggested that the high mean complication rate of 18% demonstrated an opportunity for improvement overall.<br>The developers clarified that in the measure submission form, the "prime 0" for measure onset of reporting was discharge was a mistake - it was supposed to say the "time 0" as time of procedure | SC vote on scientific acceptability<br><br>Completely -12<br><br>Partially –4<br><br>Minimally – 0<br><br>Not at all – 1 |
| USABILITY | |
| A Committee member noted that the hierarchal model allows smaller hospitals to be closer to the mean; the small hospitals will never show up as worse than average<br><br>The developer noted that their primary goal had been to produce a composite of care trajectories. The same methodology was used in all three components (readmission; ED visits; and E&M service). The measures speak to each other and there are different ways to dampen the noise aside from shrinkage. | SC vote on usability<br><br>Completely – 8<br><br>Partially – 7<br><br>Minimally – 0<br><br>Not at all – 0 |
| FEASIBILITY | |
| N/A | SC vote on feasibility - N/A<br><br>Completely –<br><br>Partially –<br><br>Minimally - |

| | |
|---|---|
| | Not at all - |

**Summary table of Biostatistical Review:**

| |
|---|
| Type of Risk Model :<br><br>*Hierarchical logistic regression* |
| **RISK FACTORS**<br>Are the risk factors clearly identified in the submission information? *YES* |
| Does the model include risk factors associated with differences/inequalities with care such as race, socioeconomic status or gender? *NO* |
| Are the conceptual and quantitative criteria for inclusion or exclusion or combining of risk factors explained and appropriate? *YES.* |
| Is quantitative assessment of the relative contribution of the model components described in detail?<br><br>*Not discussed in detail, but relevant information is provided.* |
| Does the measure have exclusions that influence outcomes that should be included as risk factors?<br><br>*No.* |
| Comments on risk factors:<br><br>*See below.* |
| **VALIDATION OF THE RISK MODEL**<br>Is there information provided on the cross-validation of the model comparing a development sample and a validation sample provided? *YES*<br><br>Is there information on independent, external validation of the model in another data set? *NO*<br><br>Are the results supportive of a valid model? *YES.* |
| **RISK MODEL PERFORMANCE (2e)** |
| DISCRIMINATION: *C-statistic = 0.611*<br>Does the statistic support good discrimination? *The reported C statistic indicates that the model has limited ability to predict the outcome of individual patients. This does not mean that the measure is invalid. A model can have low discrimination and still succeed at adjusting for case mix bias. A low C statistic should prompt the developers to search for important unmeasured risk factors that could be added to the NCDR data set in future releases.* |

# NATIONAL QUALITY FORUM

National Voluntary Consensus Standards for Patient Outcomes

Measure Summary

CALIBRATION: Is a calibration curve included? Yes.
Is a risk decile plot included? Can be obtained from the calibration curve.
Hosmer-Lemeshow statistic: Not provided. Wald chi-square rejected the hypothesis of perfect fit. The large sample size makes this result hard to interpret.
Does the data support good model calibration? *Graphical comparisons of observed vs. predicted appear to be acceptable. It would be useful to have more information about calibration within important subgroups.*

Comments on Risk Model Performance: *See below.*

**Reliability testing (2b):**
Is the reliability of the key data elements, such as risk factors and the outcome demonstrated?

*NO.*

Is there information about the reliability of the measure score, such as signal to noise ratio?

*NO.*

Has a sensitivity analysis been performed for problem or missing data? *NOT DESCRIBED.*

Does the data demonstrate that the risk model is reliable? *YES*

Comments on reliability testing: *See below.*

**Validity testing (2c):**
Is validity testing of the measure to demonstrate results can be used to make conclusions about quality provided? *YES.*

Are the results supportive of a valid measure? *YES.*

Comments on validity testing:

*See below.*

**Scoring Method Justification (2f):**
Is the choice of method for computing risk-adjusted scores and identifying statistically significant differences justified? *Yes*

Comments on scoring methods:

**Summary comments:** *See below*

**Reviewer: Sean O'Brien, PhD**
**Assistant Professor, Department of Biostatistics and Bioinformatics**

# NATIONAL QUALITY FORUM

National Voluntary Consensus Standards for Patient Outcomes

Measure Summary

**Duke University Medical Center, Duke Clinical Research Institute,**
**Durham, NC**

# NATIONAL QUALITY FORUM

**Measure Evaluation 4.1**
**December 2009**

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

**TAP/Workgroup** (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

**Steering Committee:** Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

| (for NQF staff use) **NQF Review #:** OT1-007-09 **NQF Project:** Patient Outcomes Measures: Phases I and II |
|---|
| **MEASURE DESCRIPTIVE INFORMATION** |
| De.1 **Measure Title:** Hospital Risk-Standardized Complication Rate following Implantation of Implantable Cardioverter-Defibrillator (ICD) |
| De.2 **Brief description of measure***:* This measure provides hospital specific risk-standardized rates of procedural complications following the implantation of an ICD in patients at least 65 years of age. The measure uses clinical data available in the National Cardiovascular Data Registry (NCDR) ICD Registry for risk adjustment that has been linked with administrative claims data used to identify procedural complications. |
| 1.1-2 **Type of Measure:** Outcome<br>De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** |
| De.4 **National Priority Partners Priority Area:** Safety<br>De.5 **IOM Quality Domain**: Efficiency, Safety, Patient-centered<br>De.6 **Consumer Care Need:** Staying healthy |

| **CONDITIONS FOR CONSIDERATION BY NQF** | |
|---|---|
| Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards: | **NQF Staff** |
| **A.** The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.*<br>A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes<br>A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:**<br>A.3 **Measure Steward Agreement:** Government entity and in the public domain - no agreement necessary<br>A.4 **Measure Steward Agreement attached:** | **A**<br>Y☒<br>N☐ |

| | |
|---|---|
| **B.** The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section | **B** Y☒ N☐ |
| **C.** The intended use of the measure includes both public reporting and quality improvement.<br>►**Purpose:** Public reporting, Internal quality improvement | **C** Y☒ N☐ |
| **D.** The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.<br>D.1**Testing:** Yes, fully developed and tested<br>D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes | **D** Y☒ N☐ |
| (for NQF staff use) **Have all conditions for consideration been met?**<br>**Staff Notes to Steward** (*if submission returned*)**:** | **Met** Y☐ N☐ |
| **Staff Notes to Reviewers** (*issues or questions regarding any criteria*)**:** | |
| **Staff Reviewer Name(s):** | |

| | |
|---|---|
| **TAP/Workgroup Reviewer Name:** | |
| **Steering Committee Reviewer Name:** | |
| **1. IMPORTANCE TO MEASURE AND REPORT** | |
| Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. ***Measures must be judged to be important to measure and report*** *in order to be evaluated against the remaining criteria.* (evaluation criteria)<br>**1a. High Impact** | Eval Rating |
| (for NQF staff use) Specific NPP goal: Not specific to a NPP goal | |
| 1a.1 **Demonstrated High Impact Aspect of Healthcare:** Patient/societal consequences of poor quality, Frequently performed procedure, High resource use<br>1a.2<br><br>1a.3 **Summary of Evidence of High Impact:** Over the past two decades, clinical trials have demonstrated that ICDs reduce the risk of sudden cardiac death for select high risk patients. As a result of these trials, there is a large increase in the number of patients undergoing ICD implantation, with an estimated increase in the number of inpatient implantations from 5,600 in 1990 to 108,680 by 2005 (Brown, Croft et al. 2008). Although ICD therapy can improve the survival of appropriately selected patients, device implantation carries a low but unavoidable risk of significant complications, which are associated with increased cost, length of stay, and higher risk of mortality (Al-Khatib, Greiner et al. 2008).<br><br>ICD implantation is an expensive procedure performed on patients with advanced cardiovascular disease and, often, significant comorbidities. Despite improvements in technology and increasing experience with device implantation, the procedure carries a significant risk of complications (Hammill, Curtis, 2008).<br><br>--Roughly 150,000 ICDs are implanted each year and approximately two thirds of implantations are performed on Medicare patients | **1a** C☐ P☐ M☐ N☐ |

--Direct total medical cost per device (2005) (Sanders et al, 2005) is $68,000-$100,000. The total costs to payers ranges from $10-$15 billion, of which $7-$10 billion is fee-for-service Medicare

-- Costly complications are common with 11% of Medicare patients having early complications

--In one study (Reynolds et al, 2006) complications increased length of stay 1-10 days and raised costs $5,000 – 20,000 (mean $7,251), adding roughly $80 million in Medicare costs

1a.4 **Citations for Evidence of High Impact:** Hammill S and Curtis J. Publicly Reporting Implantable Cardioverter Defibrillator Outcomes – Grading the Report Card. Circ Arrhythmia Electrophysiol. 2008;1:235-237).

Sanders GD, Hlatky MA, Owens DK. Cost-Effectiveness of Implantable Cardioverter-Defibrillators. N Engl J M. 2005;353;1471-1480.

Reynolds, M.R., et al., The frequency and incremental cost of major complications among medicare beneficiaries receiving implantable cardioverter-defibrillators. Journal of the American College of Cardiology, 2006. 47(12): p. 2493-7.

Brown, D.W., Croft, J.B., et al. (2008). "Trends in Hospitalizations for the Implantation of Cardioverter-Defibrillators in the United States, 1990-2005." American Journal of Cardiology 101 (12): 1753-1755.

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.

**1b. Opportunity for Improvement**

1b.1 **Benefits (improvements in quality) envisioned by use of this measure:**

1b.2 **Summary of data demonstrating performance gap (variation or overall poor performance) across providers:**

Reported complication rates following ICD implantation vary from 4% to 30%, depending largely on how complications are defined and the period of assessment. In the ACC's NCDR ICD Registry, the incidence of in-hospital complications is approximately 4%. However, complications such as device infection, malfunction, or cardiac tamponade may only become evident following hospital discharge. Recently, Al-Khatib et al. (2008) found overall rates of complication within 90 days of ICD implantation ranged from 18.8% in 2002 to 14.2% in 2005.

Preliminary analyses confirm that ICD implantation is associated with both a significant mortality and complication rate, and that there is substantial variation in these rates across hospitals. We conducted analyses to determine unadjusted ICD-related complication rates in Medicare inpatient claims data for 2007, which included 67,532 ICD admissions for 67,080 patients at 1,792 hospitals. Administrative codes identifying ICD-related complications were identified through review of the literature and subsequently refined in conjunction with input from topic experts to capture the most significant complications. Complications were identified from CMS claims data using ICD-9-CM diagnosis and procedure codes or mortality within specified timeframe (30 days or 90 days following implantation depending on the specific complication). In these preliminary analyses, complications were seen in 5.7% of ICD admissions (3,818 complications).

Complication rates vary substantially across hospitals. In addition to high complication rates following ICD implantation, there is substantial variability in complication rates across hospitals. The median (50th percentile) complication rate following ICD implantation ranges from 0% to 17.8% across deciles of hospitals grouped by their all-cause complication rate.

These findings suggest that the majority of complications are attributable to the ICD, potentially preventable, and thus, actionable.

1b.3 **Citations for data on performance gap:**

**1b**
C☐
P☐
M☐
N☐

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.

**1b.4 Summary of Data on disparities by population group:**
We have not examined health disparities associated with this measure. This measure could be used to assess differences in performance among hospitals that care for different types of populations (e.g. those that serve primarily minority populations versus others).

**1b.5 Citations for data on Disparities:**
N/A

**1c. Outcome or Evidence to Support Measure Focus**

**1c.1 Relationship to Outcomes** (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** This measure will describe hospital-level complication rates following implantation of ICD with the overriding goal to reduce complication rates.

Additionally, the model is designed specifically for national public reporting. Once implemented, the measure can be used by hospitals to benchmark their performance and may motivate hospitals to enhance existing quality improvement efforts with the goal to reduce overall complication rates. A reduction in complication rates translates into improved care for ICD patients.

**1c.2-3. Type of Evidence:** Expert opinion, Systematic synthesis of research

**1c.4 Summary of Evidence** (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
Complications following implantation of Implantable Cardioverter Defibrillators (ICD) are an important patient outcome (Al-Khatib 2005, 2008; Curtis 2009) that may reflect quality of care delivered to patients undergoing invasive cardiac procedures.

ICDs are expensive and are utilized in patients with high cost conditions (coronary artery disease; heart failure). Providing information about the rates of ICD-related complications may provide an opportunity to provide better care for patients and reduce costs for the health care system. The risk of adverse outcomes following ICD implantation has been shown to vary extensively by the experience and training of the implanting physician, the device implanted, and the characteristics of the facility in which the implant has been performed (Curtis, Luebbert et al. 2009). Accordingly, a publicly reported quality measure addressing ICD complications has the potential to increase transparency and stimulate hospitals to critically examine their outcomes, and, when necessary, invest in the infrastructure and/or develop protocols to reduce complication rates.

**1c.5 Rating of strength/quality of evidence (***also provide narrative description of the rating and by whom***):**
N/A

**1c.6 Method for rating evidence:** N/A

**1c.7 Summary of Controversy/Contradictory Evidence:** (1) In defining the complications, we sought clinically sensible definitions which were, to the extent possible, likely attributable to ICD implantation. In consultation with an expert panel, it was agreed that restricting outcomes to complications requiring an intervention would enhance measure acceptance as these complications represent the most clinically significant adverse events.

The original list of complications routinely captured in administrative data included:

1. Pneumothorax
2. Hematoma
3. Tamponade
4. Mechanical complications

**1c**
**C** ☐
**P** ☐
**M** ☐
**N** ☐

5. Pulmonary embolism
6. Infection
7. Other cardiac complication
8. Acute renal failure requiring hemodialysis
9. Death

For several of the complications identified in this measure, we chose to refine the definitions following ICD implantation (as discussed in the literature) to include associated interventions. The resulting modified definitions represent the most clinically significant complications. For example, the claims code used to identify "mechanical complications" in the claims data is broad, including both lead dislodgement requiring open revision as well as minor lead abnormalities that can be addressed simply by reprogramming the device. As such, restricting to mechanical complications with a system revision narrows the focus of the measure on complications of device implantation that require intervention. Similarly, restricting "pneumothorax or hemothorax" and "hematoma" complications to those requiring an intervention was deemed important because those events vary widely in identification, clinical severity, and recommended treatment. "Pulmonary embolism" and "acute renal failure requiring hemodialysis" were dropped from the list of complications as the observed rates were low (less than 0.15%) and they were deemed less clearly attributable to the ICD implantation itself. "Other cardiac complication" was also dropped because it was deemed to be too broad for this measure. Finally, we added two additional complications to the original list: additional ICDs implanted within 90 days of the index procedure and death within 30 days of the index procedure. In both cases, the event would be an unplanned, adverse event.

The final list of complications is as follows:

1. Pneumothorax or hemothorax, with chest tube
2. Hematoma with blood transfusion or evacuation
3. Cardiac tamponade or pericardiocentesis
4. Mechanical complications requiring a system revision
5. Infection that is device related
6. Second ICD within 90 days of the index procedure
7. Death

(2) In consultation with an expert panel, we chose a hybrid complication-specific approach for the outcome time period. Review of preliminary analyses revealed that most complications occur within the initial 15 days following implantation, and qualitatively plateaued between 30 and 45 days following ICD implantation. Accordingly, we initially considered a 30-day time period for follow-up. However, feedback from topic experts suggested that using a single period of assessment for such a wide range of outcomes may not be the optimal approach. For example, device related infections may not become apparent for weeks or months following implantation, suggesting a 90 day time period would be best for this outcome. In contrast, however, hematomas due to the procedure would most likely be recognized and treated within 30 days of implantation, and hematomas identified after that point are more likely due to other procedures (e.g., cardiac catheterization). Given these considerations, we adopted timeframes specific to each complication. The timeframes are as follows:

30-day timeframe
- Pneumothorax or hemothorax, plus chest tube
- Hematoma plus blood transfusion or evacuation
- Cardiac tamponade or pericardiocentesis
- Death

90-day timeframe
- Mechanical complications requiring system revision
- Device related infections
- Additional ICD implantations

(3) This measure was developed for Medicare fee-for-service patients because complication information that covers admissions to all hospitals is currently only available for this population as we are using claims data to determine the outcome (complications). As such, the patient population being measured is patients 65 years of age or older. However, this measure could be implemented in a broader population when

| | |
|---|---|
| additional data become available or when patient health records are standardized nationally, e.g., electronic health records.<br><br>(4) The measure excludes patients with prior ICD implantation, a population known to be at high risk of adverse outcomes. As noted above, this exclusion is necessary to ensure the accurate assessment of complication status. However, this decision will need to be reevaluated once present on admission codes are fully incorporated into Medicare administrative claims. If the present on admission codes prove to be accurate, we would be able to distinguish between comorbid conditions and procedural complications.<br><br>**1c.8 Citations for Evidence (*other than guidelines*):** 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.<br><br>Al-Khatib, S.M., et al., 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 Nov 15;46(10):1964]. Journal of the American College of Cardiology, 2005. 46(8): p 1536-40.<br><br>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.<br><br>**1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number*):**<br>N/A<br><br>**1c.10 Clinical Practice Guideline Citation:** N/A<br>**1c.11 National Guideline Clearinghouse or other URL:** N/A<br><br>**1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom*):**<br>N/A<br><br>**1c.13 Method for rating strength of recommendation** (*If different from* USPSTF system, *also describe rating and how it relates to USPSTF*):<br>N/A<br><br>**1c.14 Rationale for using this guideline over others:**<br>N/A | |
| **TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*** 1a. high cost procedure; 11% complications increase costs 1b. variation in complications has demonstrated 1c. significant complications are an important outcome in terms of both human and financial costs; 4 publications using administrative data report complications rates of 8-16% | **1** |
| **Steering Committee: Was the threshold criterion, *Importance to Measure and Report*, met?**<br>**Rationale:**<br>The Committee felt the measure should not be limited to Medicare FFS patien ts only.<br>A complication rate of 18% is high. | **1**<br>**Y**☒<br>**N**☐ |
| **2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES** | |
| Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria) | Eval Rating |
| **2a. MEASURE SPECIFICATIONS** | |
| **S.1 Do you have a web page where current detailed measure specifications can be obtained?**<br>**S.2 If yes, provide web page URL:** | **2a-specs**<br>**C**☒ |

**2a. Precisely Specified**

P☐ M☐ N☐

**2a.1 Numerator Statement (***Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):**
This outcome measure does not have a traditional numerator and denominator like a core process measure (e.g., percentage of adult patients with diabetes aged 18-75 years receiving one or more hemoglobin A1c tests per year); thus, we are using this field to define the outcome (ie adverse events) following ICD implantation.

The measured outcome for each index admission is one or more complications or mortality within 30 or 90 days (depending on the complication) following ICD implantation. Complications are counted in the measure only if they occur during a hospital admission.

**2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):**
30 or 90 days from ICD implantation, depending on the complication (see numerator details).

**2a.3 Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):**
Complications are identified using International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis and procedure codes as well as the Medicare Enrollment Database (vital status) as indicated below:

Complications measured for 30 days:
(1) Pneumothorax or hemothorax plus a chest tube
Definition: (a) Pneumothorax / hemothorax: 512.1 or 511.8 (diagnosis code)
(b) Chest tube: 34.04, 34.05, 34.06, or 34.09 (procedure code)

(2) Hematoma plus a blood transfusion or evacuation
Definition: (a) Hematoma: 998.1 (diagnosis code)
(b) Blood transfusion: 518.7, 287.4, V59.01, V58.2 (diagnosis code), or 99.00, 99.03, 99.04 (procedure code); Evacuation: 34.04, 34.09 (procedure code)

(3) Cardiac tamponade or pericardiocentesis
Definition: (a) Cardiac tamponade: 420, 423.0, 423.3, 423.9 (diagnosis code), or 37.0, 37.12 (procedure code)

(4) Death
Source: Medicare enrollment database

Complications measured for 90 days
(5) Mechanical complications requiring a system revision
Definition: (a) Mechanical complications with system revision: 996.0 (diagnosis code)
(b) System revision: 37.75, 37.79, 37.97, 37.99, or 00.52(procedure code)

(6) Device related infection
Definition: (a) Infection: 996.61 (diagnosis code)

(7) Additional ICD implantation
Definition: (a) Inpatient or outpatient ICD implantation: 00.50, 00.51, 00.52, 00.53, 00.54, or 37.94 (procedure codes)
(b) Outpatient ICD implantation: 33216, 33217, 33218, 33220,33223, 33240, 33241, or 33249 (CPT codes)

The rationale for using complication specific timeframes is detailed in section 1c.

**2a.4 Denominator Statement (***Brief, text description of the denominator - target population being measured***):**

The target population for this measure includes inpatient or outpatient ICD implants for patients at least 65 years of age at the time of implantation who have matching information in the National Cardiovascular Disease Registry (NCDR) ICD Registry.

The patient cohort is defined by ICD-9 procedures codes from inpatient claims and Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) procedure codes from outpatient claims as outlined in the denominator details.

**2a.5 Target population gender:** Female, Male
**2a.6 Target population age range:** 65 years of age and older

**2a.7 Denominator Time Window (***The time period in which cases are eligible for inclusion in the denominator***):**
This measure is being developed with 12 months of data. The time period for public reporting has not been determined.

**2a.8 Denominator Details (***All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
ICD-9 and CPT codes used to define the target population are listed below:

ICD-9 codes
00.50 Implantation of cardiac resynchronization pacemaker without mention of defibrillation, total system (crt-p)
00.51 Implantation of cardiac resynchronization defibrillator, total system (crt-d)
00.52 Implantation or replacement of transvenous lead (electrode) into left ventricular coronary venous system
00.53 Implantation or replacement of cardiac resynchronization pacemaker pulse generator only (crt-p)
00.54 Implantation or replacement of cardiac resynchronization defibrillator pulse generator device only (crt-d)
37.94 Implantation or replacement of automatic cardioverter/defibrillator, total system (aicd)

CPT codes
33216 Insertion, single chamber transvenous electrode ICD
33217 Insertion, dual chamber transvenous electrode ICD
33218 Repair, single chamber transvenous electrode ICD
33220 Repair, dual chamber transvenous electrode ICD
33223 Pocket revision ICD
33240 Insertion of single or dual chamber ICD pulse generator
33241 Removal of single or dual chamber ICD pulse generator
33249 Insertion or repositioning of electrode lead(s) for single or dual chamber pacing ICD and insertion of pulse generator

**2a.9 Denominator Exclusions (***Brief text description of exclusions from the target population***):** We are using this field to define exclusions to the patient cohort:

(1) Not the first claim in the same claim bundle. When several claims in the same hospital representing the same patient stay exist in the data together (bundled), any claim other than the first in such a bundle is excluded.
Rationale: Inclusion of these patients could result in duplicate counting in the measure.

(2)Patient stays which lack 90-days of follow-up in administrative claims. Patients who cannot be tracked for 90 days following discharge are excluded.
Rationale: There will not be adequate follow-up data to assess complications.

(3)Previous ICD placement. Patient 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 complications of the second ICD placement or were present on admission. The indications for reimplantation include events included in our definition of procedural complications such as device infection, device malfunction, or lead dislodgement. Given current coding practices, we are unable to determine whether a 'complication' code is present on admission or in fact represents a procedural complication. In order to avoid misclassification, we exclude these patients from the measure.

**2a.10 Denominator Exclusion Details (***All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
See above. We are deriving the corresponding codes based on the data for exclusion.

**2a.11 Stratification Details/Variables (***All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
This measure is not stratified.

**2a.12-13 Risk Adjustment Type:**

**2a.14 Risk Adjustment Methodology/Variables (***List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
We developed a risk adjustment model for the measure and calculated hospital 30-day risk-standardized complication rates (RSCRs) using hierarchical regression. Because of the natural clustering of the observations within hospitals, we estimated hierarchical generalized linear models (HGLMs). These models extend generalized linear models (GLMs) to include additional random terms in the linear predictor.

As described in the "Calculation Algorithm," we perform risk adjustment to account for differences in patient severity present before the implantation of the ICD using a hierarchical logistic regression model to calculate RSCRs. The risk adjustment variables are abstracted from the NCDR ICD Registry data.

We used logistic regression with stepwise selection (entry $p<0.15$; retention with $p<0.05$) for variable selection. We also assessed the direction and magnitude of the regression coefficients. This resulted in a final risk-adjusted complications model that included 13 variables. The final risk adjustment variables include:

Demographic
- (1) Age (10 year increments)
- (2) Female

Admission
- (3) Hospital Reason
  - Admitted for this procedure
  - Hospitalized: Cardiac
  - Hospitalized: Non-Cardiac

History and Risk Factors
- (4) New York Heart Association (NYHA) Class: Current Status
  - NYHA I
  - NYHA II
  - NYHA III
  - NYHA IV
- (5) Previous Coronary Artery Bypass Graft (CABG)
- (6) Chronic Lung Disease
- (7) Hypertension
- (8) Renal Failure- Dialysis

Diagnostics
- (9) Atrioventricular Conduction (AVC)
  - AVC: Normal
  - AVC: Abnormal- First Degree Heart Block Only
  - AVC: Abnormal- 2nd/3rd Degree Heart Block
  - AVC: Paced (any)
- (10) BUN > 30 mg/dl
- (11) Sodium

<135 mg/dl
135 to 145 mg/dl
>145 mg/dl
(12) Systolic Blood Pressure < 100mmHG
(13) ICD Type
Single Chamber
Dual Chamber
Biventricular

**2a.15-17 Detailed risk model available Web page URL or attachment:** Attachment ICD_Calculation_Algorithm.pdf

**2a.18-19 Type of Score:** Rate/proportion
**2a.20 Interpretation of Score:**
**2a.21 Calculation Algorithm (***Describe the calculation of the measure as a flowchart or series of steps***):**
We use hierarchical logistic regression modeling to calculate hospital-specific risk-standardized complication rates (RSCRs). These rates are calculated as the ratio of the predicted number of complications to the expected number of complications, multiplied by the national unadjusted complication rate. The expected number of complications for each hospital was estimated using its patient mix and the average hospital-specific intercept. The predicted number of complications in each hospital was estimated given the same patient mix but an estimated hospital-specific intercept. Operationally, the expected number of complications for each hospital is obtained by summing the expected complication rates for all patients in the hospital. The expected complication rate for each patient is calculated via the hierarchical model by applying the subsequent estimated regression coefficients to the observed patient characteristics and adding the average of the hospital-specific intercepts. The predicted number of complications for each hospital is calculated by summing the predicted complications rates for all patients in the hospital. The predicted complication rate for each patient is calculated through the hierarchical model by applying the estimated regression coefficients to the patient characteristics observed and adding the hospital-specific intercept. In order to assess hospital performance in any specific year (e.g. the validation cohort), we re-estimate the model coefficients using that year's data.

Please see attached "ICD_Calculation_Algorithm.pdf" under Detailed Risk Model attachment section above, and attached "ICD_Complications_Technical_Report.pdf" at the end of the application for further information about the algorithm.

**2a.22 Describe the method for discriminating performance** *(e.g., significance testing)***:**
The method for discriminating hospital performance has not been determined. This process relates to implementation and will be addressed during measure implementation planning. However, for 6 publicly-reported CMS measures of hospital outcomes developed with similar methodology (e.g., 30-Day Heart Failure Mortality) CMS currently estimates an interval estimate for each risk-standardized rate to characterize the amount of uncertainty associated with the rate, compares the interval estimate to the national crude rate for the outcome, and categorizes hospitals as "better than the US national rate," "worse than the US national rate," or "no different than the US national rate." CMS has not yet determined if it would use a similar approach to publicly reporting this measure.

**2a.23 Sampling (Survey) Methodology** *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
The measure is not based on a sample or survey.

**2a.24 Data Source (***Check the source(s) for which the measure is specified and tested)*
Electronic administrative data/claims, Survey: Patient

**2a.25 Data source/data collection instrument (***Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
The datasets used to create the measures are described below.

(1)NCDR ICD Registry data
The National 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 June 2009, the registry had collected data from

1,432 hospitals in the United States totaling over 380,000 implants (Hammill, Kremers et al. 2009).

The registry, launched on June 30, 2005, was developed through a partnership of the Heart Rhythm Society (HRS) and the American College of Cardiology Foundation (ACCF) 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 ICD Registry, only 54 are forwarded to CMS by 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
The model was developed in a population of Medicare fee-for-service beneficiaries but can be expanded to all ICD patients at least 65 years of age. We used Medicare 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 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).

2a.26-28 **Data source/data collection instrument reference web page URL or attachment:** URL
http://www.ncdr.com/WebNCDR/NCDRDocuments/ICDCMSDataCollectionImplantForm.pdf

2a.29-31 **Data dictionary/code table web page URL or attachment:** URL
http://www.ncdr.com/WebNCDR/NCDRDocuments/ICDDataDictionaryDefinitionsOnlyv1.0.pdf

2a.32-35 **Level of Measurement/Analysis** (*Check the level(s) for which the measure is specified and tested)*
Population: national, Facility/Agency

2a.36-37 **Care Settings (***Check the setting(s) for which the measure is specified and tested)*
Ambulatory Care: Hospital Outpatient, Hospital

2a.38-41 **Clinical Services** (*Healthcare services being measured, check all that apply*)

## TESTING/ANALYSIS

**2b. Reliability testing**

2b.1 **Data/sample** *(description of data/sample and size)*: N/A

2b.2 **Analytic Method** *(type of reliability & rationale, method for testing)*:
N/A

**2b**
C☐
P☒
M☐
N☐

| | |
|---|---|
| **2b.3 Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:<br>As part of NCDR's Data Quality Program (DQP), the Data Quality Report (DQR) process assesses the completeness and validity of the electronic data submitted by participating hospitals. The 2007 DQR audit was completed but ACC has not yet compiled the results into a report. We will update with results as the information becomes available. | |
| **2c. Validity testing**<br><br>**2c.1 Data/sample** *(description of data/sample and size)*: We are using this section to describe our approach to model validation as well as validation of administrative codes used to identify complications.<br><br>**2c.2 Analytic Method** *(type of validity & rationale, method for testing)*:<br>Overview of development and validation models:<br><br>A risk adjustment model was derived using all matched admissions in 2007 ("development sample") (see section 2e for details on probabilistic matching). The performance of the models was validated using a similar cohort of patients who underwent ICD placement in 2006 ("validation sample"). For both samples, we computed indices that describe their respective performance in terms of predictive ability, discriminant ability, and overall fit, and generated hospital risk-standardized mortality rates and corresponding interval estimates for the development sample.<br><br>Overview of administrative code validation:<br><br>The measure uses administrative claims data to identify ICD-related complications. The accuracy of the specific ICD-9 codes used to identify complications has been evaluated in a single center pilot study (section 2.3.1 of the attached technical report) using chart abstraction. Expansion of this effort to additional sites is currently under way with anticipated completion in the 3rd quarter of 2010.<br><br>**2c.3 Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:<br>Results for both the development and validation sample are presented in 2e. | **2c**<br>C☐<br>P☒<br>M☐<br>N☐ |
| **2d. Exclusions Justified**<br><br>**2d.1 Summary of Evidence supporting exclusion(s):**<br>Rationale for exclusion is described in "Denominator Exclusions."<br><br>**2d.2 Citations for Evidence:**<br>N/A<br><br>**2d.3 Data/sample** *(description of data/sample and size)*: See "data sample" under "Validity Testing."<br><br>**2d.4 Analytic Method** *(type analysis & rationale)*:<br>See "data sample" under "Validity Testing."<br><br>**2d.5 Testing Results** *(e.g., frequency, variability, sensitivity analyses)*:<br>See "data sample" under "Validity Testing." | **2d**<br>C☒<br>P☐<br>M☐<br>N☐<br>NA☐ |
| **2e. Risk Adjustment for Outcomes/ Resource Use Measures**<br><br>**2e.1 Data/sample** *(description of data/sample and size)*: N/A<br><br>**2e.2 Analytic Method** *(type of risk adjustment, analysis, & rationale)*:<br>This measure is fully risk-adjusted using a hierarchical logistic regression model to calculate hospital risk-standardized complication rates (RSCR).<br><br>Approach to probabilistic matching: | **2e**<br>C☒<br>P☐<br>M☐<br>N☐<br>NA☐ |

As the NCDR ICD Registry does not currently track patients over time (episodes of care), this measure required linking registry data to external databases to accurately determine the ICD-related complication rates. The ICD Registry currently captures social security numbers. However, the existing business associate agreements between the NCDR and participating hospitals precluded Yale-CORE from using direct patient identifiers for the purposes of model development. Accordingly, we performed a probabilistic match linking patient stays with ICD implantation in the ICD Registry with corresponding patient stays in the CMS claims data using the following indirect patient identifiers in two distinct steps using different linking fields.

Group 1
-Hospital Medicare Provider Number (MPN)
-Patient age
-Gender
-Date of admission (claim begin date for Medicare Part A outpatient claims)

OR

Group 2
-Hospital Medicare Provider Number (MPN)
-Patient age
-Gender
-Date of ICD procedure

To accomplish this, we performed the following steps

1. We derived hospital MPN for hospitals in the NCDR ICD registry from the hospital's self reported MPN and verified it using hospital information name and address from the NCDR data linked with the American Hospital Association (AHA) database.

2. For hospitals in the NCDR ICD registry with either no self-reported MPN or a duplicate MPN we manually searched and confirmed the MPN.

3. We derived a unique dataset from the ICD Registry (including patients' clinical factors) with patient stays by removing duplicates determined by Group 1 linking fields or by Group 2 linking fields.

4. A comparable dataset is created from CMS claims data by removing direct patient identifiers (i.e., Health Insurance Claim [HIC] number) which contains unique patient admissions with outcomes by removing duplicates determined by Group 1 linking fields or by Group 2 linking fields. In this dataset, we removed all direct patient identifiers, such as Health Insurance Claim (HIC) number. The resulting dataset contained unique patient stays.

The two datasets derived in steps 3 and 4 were merged using Group 1 linking fields first and then repeated using Group 2 linking fields in the remaining unmatched records.

Among ICD patients =65 years old in the 2007 Medicare claims data, 70% were successfully matched to ICD Registry records for 2007. Results of the match were similar when we varied matching criteria (e.g., removing discharge date as a linking field). The overall match rate is similar to that found during development of the two 30-day PCI mortality measures YNHHSC/CORE developed in 2008. When we compared the outcomes of patients in the Medicare claims data who did and did not match, the overall complication rates were comparable

Approach to assessing model performance:

For each the development and validation cohort, we computed 6 summary statistics for assessing model performance (Harrell, 2001):

(1)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)

(2)percentage of variation explained by the risk factors (R2)
(3)predictive ability
(4)area under the receiver operating characteristic (ROC) curve
(5)distribution of residuals
(6) model chi-square (A test of statistical significance usually employed for categorical data to determine whether there is a good fit between the observed
data and expected values; i.e., whether the differences between observed and expected values are attributable to true differences in characteristics or instead the result of chance variation.
For the exact formula for computing the chi-square, see section 3.1.2 of the attached "ICD_Complications_Technical_Report.pdf".

F.E. Harrell and Y.C.T. Shih, Using full probability models to compute probabilities of actual interest to decision makers, Int. J. Technol. Assess. Health Care 17 (2001), pp. 17–26.

**2e.3 Testing Results** *(risk model performance metrics)*:
The development cohort consisted of 30,212 patient stays at 1,080 hospitals, with a risk-standardized complication rate of 7.28%. The development model has strong discrimination and fit. The risk-standardized complication or mortality rate ranges from 3.8% in the lowest predicted decile to 13.2% in the highest predicted decile, a range of 9.4%. Results are summarized below:

Residuals lack of fit: <-2 = 0.0%; [-2, 0) = 92.7%; [0, 2) = 0.1%; [2+ = 7.2%
Adjusted R-square: 0.03
Model Chi-square [# of covariates]: 325.61 [20]
Predictive ability (lowest decile %, highest decile %): (3.8, 13.2)
Area under the ROC curve = 0.611 (GLM)

The discrimination and the explained variation of the model are consistent with those of models currently used to publicly report condition specific rates of both mortality and readmission. However, model has limited ability to predict individual patients' risk of experiencing an adverse event following ICD implantation. Complications are more difficult to predict than mortality (Mehta, 2009).It is likely that there are unknown confounders associated with a complication measure. Nevertheless, these confounders may, as in the case of physician training, prove to be a target for efforts to improve the quality of ICD implantation. In addition, we did not consider covariates such as potential complications, certain patient demographics (e.g., race), and patients' admission path (e.g., outpatient, emergency department. These characteristics may be associated with complications and thus could increase the model performance to predict patient complication. However, these variables may be related to quality or supply factors that should not be included in an adjustment that seeks to control for patient clinical characteristics. As a result of these considerations the decision was made to focus on adjustment for clinical differences in the populations among hospitals.

Model Validation Dataset: We identified a comparable cohort of ICDs in which the patient was released from the hospital between January and December 2006. The validation cohort consisted of 27,370 patient stays at 1,023 hospitals, with a risk-standardized complication rate of 6.65%.

The model performance was not substantively different in this validation sample, as compared to the development sample. The 2006 and 2007 models are similarly calibrated. Results are summarized below:

Over-fitting indices: (-0.32, 0.91)
Residuals lack of fit: <-2 = 0.0%; [-2, 0) = 93.4%; [0, 2) = 0.0%; [2+ = 6.6%
Adjusted R-square: 0.02
Model Chi-square [# of covariates]: 257.05 [20]
Predictive ability (lowest decile %, highest decile %): (3.2, 11.4)
Area under the ROC curve = 0.608 (GLM)

We also examined the temporal variation of the standardized estimates and frequencies of the variables in the models. The frequencies and regression coefficients are fairly consistent over the two years of data.

To assess the predictive ability of the model, we grouped patients into deciles of predicted complications.

| | |
|---|---|
| We then compared predicted complications with observed complications for each decile in the derivation cohort. Overall there was excellent correlation between predicted and observed complications.<br><br>2e.4 **If outcome or resource use measure is not risk adjusted, provide rationale:** N/A | |
| **2f. Identification of Meaningful Differences in Performance**<br><br>2f.1 **Data/sample from Testing or Current Use** *(description of data/sample and size)*: N/A<br><br>2f.2 **Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)*:<br>N/A<br><br>2f.3 **Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:<br>N/A | **2f**<br>C☐<br>P☒<br>M☐<br>N☐ |
| **2g. Comparability of Multiple Data Sources/Methods**<br><br>2g.1 **Data/sample** *(description of data/sample and size)*: No comparable data source is available at this time. We performed validity testing of the development model using the same cohort definition but in a different time frame.<br><br>2g.2 **Analytic Method** *(type of analysis & rationale)*:<br>N/A<br><br>2g.3 **Testing Results** *(e.g., correlation statistics, comparison of rankings)*:<br>N/A | **2g**<br>C☐<br>P☐<br>M☐<br>N☐<br>NA☒ |
| **2h. Disparities in Care**<br><br>2h.1 **If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: We have not examined health disparities associated with this measure.<br><br>2h.2 **If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:**<br>There are no plans to detect disparities during measure development. | **2h**<br>C☐<br>P☐<br>M☐<br>N☐<br>NA☒ |
| **TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*** 2a. precise specifications; does not capture non-FFS Medicare patients (about 15% -data not available) 2b. 10% auditing of registry data -- would like more information on results of audits; 2c. separate cohorts validation; codes compared to charts done in a small set -- plan to do more; "cause specific" complications; time frames:30 days - serious complications, 90 days - mechanical/malfunctions -- make sense; 2d - appropriate exlcusions; 2e - risk model c statistic = 0.61 ROC = .65 calibration curve in the supplemental materials; does not include social or economic factors; 2f - distribution curve on p 40 of supplemental report - not much spread; low volumes - may need to bundle several years; 2g. all Medicare patientsrequired tobe reported to registry - more than 70% of hospitals report all patients to registry 2h. disparities not addressed in measure -- disparities are known -- women have higher complication rate; stratification likley to have low numbers problem | **2** |
| **Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, met?**<br>**Rationale:** The Steering Committee was impressed with the risk adjustment methodology, though one Committee members noted that the results cluster around the mean with little variability. He felt that use of hierarchical modeling caused the reduced variability. Others suggested that the high mean complication rate of 18% demonstrated an opportunity for improvemall. ent over The developers clarified that in the measure submission form, the “prime 0” fr measure onset of oreporting was discharge was a mistake - it was supposed to say the “time 0” as time of procedure | ***2***<br>C☒<br>P☐<br>M☐<br>N☐ |
| **3. USABILITY** | |

| Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria) | Eval Rating |
|---|---|
| **3a. Meaningful, Understandable, and Useful Information**<br><br>**3a.1 Current Use:** Testing not yet completed<br><br>**3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*)**:**<br>The measure is designed for use in public reporting but is not currently in use.<br><br>**3a.3 If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years*)**:**<br>The measure is designed for use in public reporting but is not currently in use.<br><br>**Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*)<br>**3a.4 Data/sample** *(description of data/sample and size)***:** Consumer testing will be completed prior to implementation.<br><br>**3a.5 Methods** *(e.g., focus group, survey, QI project)***:**<br>Under current use, we indicate "Testing not yet completed." No consumer or other field testing has been completed at this time. However, during measure development, we consulted with representatives from potential users of this measure including clinicians, professional societies, and consumers. We use this field to describe the role that these representatives played on the working group and Technical Expert Panel (TEP).<br><br>We assembled and held regular conference calls with a working group, including individuals from YNHHSC/CORE, American College of Cardiology (ACC), Heart Rhythm Society (HRS), and National Cardiovascular Disease Registry (NCDR). The specific members of the working group were tailored for the measure and structured to provide regular feedback on measure and development issues and to guide key decisions inherent to measure development. The group included clinicians and other professionals with expertise in interventional cardiology, biostatistics, measure methodology, and quality improvement. The group also included individuals experienced in working with ACC data registries and in model development using ACC registry data. The calls were designed to address key issues, explore options, and reach closure on analytic questions. The working group calls provided an opportunity to discuss issues raised during development and determine the approach that is brought to the TEP.<br><br>In addition to the working group, and in alignment with the CMS Measures Management System (MMS), we released a public call for nominations and convened a TEP. The purpose of convening the TEP is to provide input and feedback during measure development from a group of recognized experts in relevant fields. The TEP represents physician, consumer, hospital, and purchaser perspectives, chosen to represent a diversity of perspectives and backgrounds. Three TEP meetings were conducted during development. In contrast to the working group calls, the TEP calls follow a more structured format consisting of presentation of key issues and our proposed approach, followed by open discussion of these issues by the TEP members.<br><br>Having distinct interest groups present on the calls, the TEP was able to focus broadly on high level issues, including approaches to maximizing consumer interpretability and securing physician acceptance of the measure.<br><br>**3a.6 Results** *(qualitative and/or quantitative results and conclusions)***:**<br>Consumer testing will be completed prior to implementation. | **3a**<br>C☒<br>P☐<br>M☐<br>N☐ |
| **3b/3c. Relation to other NQF-endorsed measures**<br><br>**3b.1 NQF # and Title of similar or related measures:** | |

| | |
|---|---|
| (for NQF staff use) **Notes on similar/related** endorsed **or submitted measures:** | |
| **3b. Harmonization**<br>If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population):<br>3b.2 **Are the measure specifications harmonized? If not, why?** | **3b**<br>C☐<br>P☐<br>M☐<br>N☐<br>NA☒ |
| **3c. Distinctive or Additive Value**<br>3c.1 **Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:**<br><br>5.1 **If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:** | **3c**<br>C☒<br>P☐<br>M☐<br>N☐<br>NA☐ |
| **TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability?*** 3a. Diverse representation on working group for measure development; consumer testing pending 3b. harmonization not an issue; 3c - new topic area for a high cost procedure | **3** |
| **Steering Committee: Overall, to what extent was the criterion, *Usability*, met?**<br>**Rationale:** The measure uses clinical e National Cardiovascular Disease Regiry (NCDR) and data from thstadministrative data. The Committee urged the developers to broaden the population to include all patients undergoing ICD regardless of payer or age. | **3**<br>C☒<br>P☐<br>M☐<br>N☐ |
| **4. FEASIBILITY** | |
| Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria) | Eval Rating |
| **4a. Data Generated as a Byproduct of Care Processes**<br><br>4a.1-2 **How are the data elements that are needed to compute measure scores generated?**<br>Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry) | **4a**<br>C☒<br>P☐<br>M☐<br>N☐ |
| **4b. Electronic Sources**<br><br>4b.1 **Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*)<br>Yes<br><br>4b.2 **If not, specify the near-term path to achieve electronic capture by most providers.** | **4b**<br>C☒<br>P☐<br>M☐<br>N☐ |
| **4c. Exclusions**<br><br>4c.1 **Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?**<br>No<br><br>4c.2 **If yes, provide justification.** | **4c**<br>C☒<br>P☐<br>M☐<br>N☐<br>NA☐ |
| **4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences**<br><br>4d.1 **Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.**<br>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 | **4d**<br>C☐<br>P☒<br>M☐<br>N☐ |

| | |
|---|---|
| monitoring data for variances in case mix, chart audits, and possibly adjudicating cases that are vulnerable to systematic misclassification.<br><br>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. | |
| **4e. Data Collection Strategy/Implementation**<br><br>**4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:**<br>The measure is not currently in use.<br><br>**4e.2 Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:**<br>The NCDR ICD Registry was created in 2006 in response to CMS's coverage with evidence development decision on January 27, 2005. In order to obtain reimbursement, CMS national coverage policy requires that providers implanting ICDs for primary prevention of sudden cardiac death in Medicare patients (i.e., patients without a history of cardiac arrest or spontaneous arrhythmia) submit data on each procedure through the ICD registry. The resulting universal participation in the ICD registry provides a framework for implementing a registry-based measure with minimal incremental burden to sites that do not already submit data on all ICD implantations to the ICD Registry. On balance, an ICD complication measure could conceivably improve hospital efficiency and overall quality of care for ICD patients, ultimately reducing costs associated with ICD implantation complications.<br><br>**4e.3 Evidence for costs:**<br>See above. Cost would vary by hospital's current level of participation in the ICD Registry.<br><br>**4e.4 Business case documentation:** Key points as noted in various sections of this document are as follows:<br><br>(1) Risk adjusted complication rates are high (7.3% at 90 days)<br>(2) There is substantial variation across hospitals (as determined by preliminary analysis of 2005 claims data and review of range of RSCRs across hospitals)<br>(3) Complications increase length of stay 1-10 days and raise costs $5,000 – 20,000 (mean $7,251), adding roughly $80 million in Medicare costs<br>(4) Leverages data CMS already receives under a coverage decision via CMS' Coverage Assessment Group (CAG) | **4e**<br>C☒<br>P☐<br>M☐<br>N☐ |
| **TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility?***<br>4a - data abstraction still the norm 4b registry is electronic 4c exclusions - same data souce 4d - would like to see auditing results 4e -data collection through a single registry | **4** |
| **Steering Committee: Overall, to what extent was the criterion, *Feasibility*, met?**<br>**Rationale:** | **4**<br>C☐<br>P☐<br>M☐ |

| | |
|---|---|
| | N☐ |
| **RECOMMENDATION** | |
| (for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.** | **Time-limited** ☐ |
| **Steering Committee: Do you recommend for endorsement?**<br>**Comments:** | **Y**☒<br>**N**☐<br>**A**☐ |

**CONTACT INFORMATION**

**Co.1 Measure Steward (Intellectual Property Owner)**
**Co.1 Organization**
Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland, 21244

**Co.2 Point of Contact**
Lein, Han, Ph.D., lein.han@cms.hhs.gov, 410-786-0205-

**Measure Developer If different from Measure Steward**
**Co.3 Organization**
CMS / Yale New Haven Health Services Corporation Center for Outcomes Research & Evaluation (YNHHSC/CORE), 1 Church Street, Suite 200, New Haven, Connecticut, 06510

**Co.4 Point of Contact**
Harlan, Krumholz, MD, SM, harlan.krumholz@yale.edu, 203-764-5885-

**Co.5 Submitter If different from Measure Steward POC**
Lori, Geary, MPH, lori.geary@yale.edu, 203-764-5699-, Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE)

**Co.6 Additional organizations that sponsored/participated in measure development**

**ADDITIONAL INFORMATION**

**Workgroup/Expert Panel involved in measure development**
**Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**
For a description of the respective roles of the working group and the Technical Expert Panel (TEP), please see the "Testing of Interpretability" section.

Working Group:
Jim Beachy, RCIS
Barbara Christensen, R.N., M.H.A.
Susan Fitzgerald, R.N., M.B.A.
Stephen Hammill, M.D.
Paul Heidenreich, M.D.
Kathleen Hewitt, R.N., M.S.N., C.P.H.Q.
Alan Kadish, M.D.
Christie Lang
Isabelle LeBlanc
Frederick Masoudi, M.D.
Kristi Mitchell, M.P.H.
Kathy Pontzer
John Rumsfeld, M.D., Ph.D
Lara Slattery, M.H.S.
John Spertus, M.D., M.P.H.
Al Woodward, Ph.D., M.B.A.

Technical Expert Panel:

| |
|---|
| Francis Ferdinand, M.D.<br>Ziad Issa, M.D.<br>Neil Jensen, MHA, MBA<br>Alan Kadish, M.D.<br>Bradley Knight, M.D.<br>Bruce Koplan, M.D., M.P.H.<br>Frederick Masoudi, M.D.<br>John Onufer, M.D.<br>Russell Robbins, M.D., MBA<br>John Rumsfeld, M.D., Ph.D<br>Andrea Russo, M.D.<br>Stuart Winston, D.O. |
| **Ad.2 If adapted, provide name of original measure:** N/A<br>**Ad.3-5 If adapted, provide original specifications URL or attachment** |
| **Measure Developer/Steward Updates and Ongoing Maintenance**<br>**Ad.6 Year the measure was first released:**<br>**Ad.7 Month and Year of most recent revision:**<br>**Ad.8 What is your frequency for review/update of this measure?** Annual<br>**Ad.9 When is the next scheduled review/update for this measure?** 03, 2010 |
| **Ad.10 Copyright statement/disclaimers:** |
| **Ad.11 -13 Additional Information web page URL or attachment:** Attachment ICD_Complications_Technical Report_11-5-09_Final_to_NQF.pdf |
| **Date of Submission** (*MM/DD/YY*)**:** 07/02/2010 |

# Hospital Risk-Standardized Complication Rate following Implantation of Implantable Cardioverter-Defibrillator (ICD) Measure

## Measure Methodology Report

**Submitted By Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation (YNHHSC/CORE):**

Jeptha P. Curtis, MD
Elizabeth E. Drye, MD, SM
Conor O. Duffy, BA
Lori L. Geary, MPH
Harlan M. Krumholz, MD, SM
Chohreh Partovian, MD, PhD
Yongfei Wang, MS

Contract # HHSM-500-2008-00025I Task Order HHSM-500-T0001

**Prepared For:**

Centers for Medicare & Medicaid Services (CMS)

**Submitted September 29, 2009**

## ACKNOWLEDGEMENTS

We would like to acknowledge the ongoing support from our colleagues affiliated with the American College of Cardiology, the National Cardiovascular Data Registry, and the Heart Rhythm Society. Without their continued support, this project would not have been possible.

Special thanks are due to the working group members. These individuals participated on fortnightly calls, provided insight and guidance, and otherwise contributed to this work on a regular basis. These individuals include:

Jim Beachy, RCIS
Barbara Christensen, R.N., M.H.A.
Susan Fitzgerald, R.N., M.B.A.
Stephen Hammill, M.D.
Paul Heidenreich, M.D.
Kathleen Hewitt, R.N., M.S.N., C.P.H.Q.
Allen Kadish, M.D.
Christie Lang
Isabelle LeBlanc
Fred Masoudi, M.D.
Kristi Mitchell, M.P.H.
Kathy Pontzer
John Rumsfeld, Ph.D., M.D.
Lara Slattery, M.H.S.
John Spertus, M.D., M.P.H.
Al Woodward, Ph.D., M.B.A.

We would also like to thank all of the Technical Expert Panel members, who provided great support and insight on key measure decisions. These members include:

Francis Ferdinand, M.D.
Ziad Issa, M.D.
Neil Jensen, M.H.A., M.B.A
Alan Kadish, M.D., M.H.A.
Bradley Knight M.D.
Bruce Koplan, M.D., M.P.H.
Frederick Masoudi, M.D.
John Onufer, M.D.
Russell Robbins, M.D.,M.B.A.
John Rumsfeld, M.D., Ph.D.
Andrea Russo, M.D.
Stuart Winston, D.O.

## TABLE OF CONTENTS

## LIST OF TABLES

## LIST OF FIGURES

# 1. INTRODUCTION

## 1.1 Overview of Measure

Over the past two decades, clinical trials have demonstrated that, for select high-risk patients, implantable cardioverter-defibrillators (ICD) reduce the risk of sudden cardiac death (Bardy, Lee, et al. 2005; Moss, Zareba, et al. 2002). These trials greatly increased the number of patients eligible for ICD therapy, and the number of inpatient implantations rose accordingly, from 5,600 in 1990 to 108,680 by 2005 (Brown, Croft et al. 2008). Although ICD therapy can improve the survival of appropriately selected patients, device implantation carries a significant risk of complications, which are associated with increased cost, length of stay, and higher risk of mortality (Al-Khatib, Greiner et al. 2008)

Accordingly, the Centers for Medicare & Medicaid Services (CMS) contracted with Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) to develop a measure of ICD complications that is suitable for public reporting. To accomplish this, we have partnered with the American College of Cardiology Foundation (ACCF), the Heart Rhythm Society (HRS), and the National Cardiovascular Data Registry (NCDR). This partnership has allowed us to build a risk-standardized outcomes measure that uses robust clinical registry data for risk adjustment while incorporating the extensive clinical and measurement expertise of these organizations into the process of measure development.

The goal of the ICD measure is to improve the quality of care delivered to patients undergoing ICD implantation. To accomplish this, we developed a model that estimates hospital-specific, risk-standardized, ICD-related complication rates. For model development, we used clinical registry data from the NCDR ICD Registry for risk adjustment linked to CMS claims and enrollment data to obtain ICD-related complication information. We linked clinical and claims data using a probabilistic match. To account for the clustering of observations within hospitals and differences in the number of patient stays across hospitals, we used hierarchical logistic regression to estimate risk-standardized complication rates (RSCRs).

The model is designed for use in national public reporting. It is aligned with the American Heart Association (AHA) published standards for publicly reported outcomes measures (Krumholz, Brindis et al. 2006). The development of the model proceeded with several assumptions about how it would be implemented for public reporting. First, the parameters will need to be re-estimated using the entire cohort of Medicare Fee-For-Service patients undergoing ICD implantation. Second, direct identifiers would be required to link clinical data and claims data. Finally, adequate mechanisms would need to be established in order to ensure data quality.

This ICD complications measure adds to a set of outcomes measures CMS has developed to improve hospital quality and meet its mandate under the Deficit Reduction Act (DRA) of 2005 to publicly report outcomes and efficiency measures on the consumer Web site, Hospital Compare (http://www.hospitalcompare.hhs.gov ). CMS began publicly reporting acute myocardial infarction (AMI) and heart failure (HF) 30-day mortality measures as outcomes measures in June 2007, and added a pneumonia (PN) 30-day mortality measure in August 2008. In addition, CMS began publicly reporting 30-day readmission measures for AMI, HF, and PN in July 2009. Building on this foundation, YNHHSC/CORE, in partnership with ACC and NCDR, previously developed two CMS 30-day all-cause PCI mortality measures suitable for public reporting that were recently endorsed by the National Quality Forum (NQF).

## 1.2 Purpose of the Measure

ICDs are expensive and are utilized in patients with high cost conditions (coronary artery disease; heart failure). Although advances in technology have improved procedural success and safety of ICD implantation, the procedure carries small but significant risks of short term adverse outcomes. Providing information about the rates of ICD-related complications may provide an opportunity to provide better care for patients and reduce costs for the health care system. The risk of adverse outcomes following ICD implantation has been shown to vary extensively by the experience and training of the implanting physician, the device implanted, and the characteristics of the facility in which the implant has been performed (Curtis, Luebbert et al. 2009). Accordingly, a publicly reported quality measure addressing ICD complications has the potential to increase transparency and stimulate hospitals to critically examine their outcomes, and, when necessary, invest in the infrastructure and/or develop protocols to reduce complication rates.

A measure of ICD complications also provides an excellent opportunity to demonstrate the feasibility of a registry-based measure for purposes of public reporting. Prior research has demonstrated that administrative claims data can be used to develop risk-adjusted outcomes measures for mortality following admission for myocardial infarction, heart failure, and death. However, using the clinical data available in clinical registries can improve both the performance and face validity of the resulting risk adjustment models.

A national registry already exists for ICD implantations. The NCDR ICD Registry was created in 2005 in response to a January 27, 2005 CMS Coverage with Evidence Development (CED) decision requiring that providers implanting ICDs for primary prevention of sudden cardiac death in Medicare patients (i.e., patients without a history of cardiac arrest or spontaneous ventricular arrhythmia) submit data on each procedure as a condition of Medicare reimbursement. All hospitals that implant ICDs currently submit data to CMS through the NCDR ICD registry. The resulting universal participation in the NCDR ICD registry provides an

opportunity for implementing a registry-based measure with minimal incremental burden to sites.

## 1.3 Why ICD Complications

ICD implantation is an expensive procedure performed on patients with advanced cardiovascular disease and, often, significant comorbidities. Despite improvements in technology and increasing experience with device implantation, the procedure carries a significant risk of complications (Hammill, Curtis, 2008).

- Roughly 150,000 ICDs are implanted each year and approximately two thirds of implantations are performed on Medicare patients
- Direct total medical cost per device (2005) (Sanders, Hlatky et al. 2005) is $68,000-$100,000. The total national costs range from $10-$15 billion, of which $7-$10 billion represents fee-for-service Medicare
- Complications are expensive and in one study (Reynolds et al, 2006) associated with increased length of stay (1-10 days) and raised costs $5,000 – 20,000 (mean $7,251), adding roughly $80 million in Medicare costs

Reported complication rates following ICD implantation vary from 4% to 30%, depending largely on how complications are defined and the period of assessment. In the NCDR ICD Registry, the incidence of in-hospital complications is approximately 4%. However, complications such as device infection, malfunction, or cardiac tamponade are not fully captured by the registry since they may only become evident following hospital discharge. Recently, Al-Khatib et al (2008) analyzed administrative claims data and found overall rates of complication within 90 days of ICD implantation ranged from 18.8% in 2002 to 14.2% in 2005 (Al-Khatib et al, 2005).

We analyzed data from 2007 Medicare FFS administrative claims to assess complication rates following ICD implantation. We confirmed that there is a significant risk of complications (8.07%) among patients who undergo ICD implantation, and that the unadjusted complication rate varies substantially across hospitals with an inter-quartile range ($25^{th}$ to $75^{th}$ percentiles) of 0.00% to 9.8%, suggesting that hospitals may be able to improve care. The majority of complications occur within 90 days of implantation, but certain complications are most prevalent within 30 days.

We developed a model that estimates risk-standardized complication rates at the institutional level for first-time placement of ICDs. The model adjusts for 13 clinical variables and measures seven complications associated with ICD implantation.

## 1.4 Core Principles for Hospital Outcomes Models Suitable for Public Reporting

The proposed measure is consistent with the approach to outcomes measurement articulated in the AHA scientific statement, "Standards for Statistical Models Used for Public Reporting of Health Outcomes" (Krumholz, Brindis et al. 2006), outlined below in Table 1.

**Table 1** – Preferred Attributes of Models Used for Publicly Reported Outcomes

| No. | Attribute |
|---|---|
| 1 | Clear and explicit definition of an appropriate patient sample |
| 2 | Clinical coherence of model variables |
| 3 | Sufficiently high-quality and timely data |
| 4 | Designation of an appropriate reference time before which covariates are derived and after which outcomes are measured |
| 5 | Use of an appropriate outcome and a standardized period of outcome assessment |
| 6 | Application of an analytical approach that takes into account the multilevel organization of data |
| 7 | Disclosure of the methods used to compare outcomes, including disclosure of performance of risk-adjustment methodology in derivation and validation samples |

We designed the ICD Complications model to reflect all of these attributes. We derived the models using a risk adjustment methodology that excludes certain variables so that the estimated risks were based on characteristics prior to, rather than during or after, the procedure. To calculate risk-standardized complication rates (RSCRs), we used a hierarchical logistic regression model, a statistical approach that takes into account the clustering of patients within hospitals and differences in sample size across hospitals. We computed indices that describe model performance in terms of calibration (over-fitting indices), discriminant ability (R-Square, ROC, and predicted vs. observed readmission), and overall fit (residuals, lack of fit, and model chi-square).

# 2. METHODS

## 2.1 Overview

We developed a measure of hospital-specific complication rates following ICD implantation using data from the NCDR ICD Registry for risk adjustment combined with CMS claims data for outcome information. We developed this model for all patient stays with an ICD procedure that met the cohort criteria and that had available outcome data. We fit a hierarchical generalized linear model (HGLM) that estimates hospital-level risk-standardized complication rate.

To develop the model, we used 2007 Medicare Part A inpatient and outpatient claims to identify all ICD implantations, and subsequent complications associated with these claims. We linked these cases with data submitted to the ICD Registry that met the NCDR's threshold for inclusion in the analytic file. However, the existing business associate agreements between the NCDR and participating hospitals precluded YNHHSC/CORE from using direct patient identifiers for the purposes of model development. We therefore performed a probabilistic match linking patient stays with ICD implantation in the ICD Registry with corresponding patient stays in the CMS claims data using the following indirect patient identifiers in two combinations. Specifically, we matched the patient stays using indirect patient identifiers including hospital Medicare Provider Number (MPN), patient age, gender, admission date (for Medicare Part-A outpatient claims, this is the claim begin date) or hospital Medicare Provider Number (MPN), patient age, gender, and procedure date. In the future, the NCDR agreements will allow the use of direct identifiers to allow a direct match.

We assessed model performance using indices that describe their respective performance in terms of predictive ability, discriminant ability, and overall fit. We validated model performance using a similar cohort of patients who underwent ICD in 2006 ("validation sample").

## 2.2 Technical Expert Consultation

Throughout measure development, we obtained expert and stakeholder input on the measure through three mechanisms: first, through regular discussions with a working group; second, through a series of three conference calls with a national Technical Expert Panel (TEP); and third, through a public comment period.

The working group was assembled and regular conference calls were held throughout development. The working group included individuals from YNHHSC/CORE, ACC, NCDR, and HRS. The membership of the working group was tailored for the measure, and included clinicians and other professionals with expertise in interventional cardiology, biostatistics, measure methodology, and

quality improvement. The group also included individuals from the NCDR with extensive experience with not only the NCDR registries but also the use of this data to develop risk adjustment models. The working group meetings were generally held on a bimonthly basis and provided an opportunity to address key issues surrounding measure development, explore in detail the strengths and limitations of specific options, and ensure the methodological rigor of the measure.

In alignment with the CMS Measures Management System (MMS), we convened a TEP to provide input and feedback during measure development from a national group of recognized experts in relevant fields. To assemble the TEP, we released a public call for nominations and selected individuals so that it provided representation from a range of perspectives including those of physicians, consumers, hospitals, and purchasers. For the ICD complications measure, we held three TEP meetings via conference call. In contrast to the working group calls, the TEP meetings followed a more structured format consisting of presentation of key issues, relevant data, and our proposed approach. This presentation was followed by open discussion of these issues by the TEP members.

Finally, we solicited public comment on the proposed measure through the MMS website (https://www.cms.hhs.gov/apps/QMIS/publicComment.asp). Public comments were summarized and publicly posted. The resulting content was taken into consideration during the final stages of measure development.

## 2.3 Outcome Definition

As outlined above, this measure uses CMS administrative claims data used to identify procedural complications and vital status following ICD implantation.

To identify relevant outcomes, YNHHSC/CORE and the working group initially considered a list of potential ICD complications identified through extensive review of the literature. Based on review of the literature, the original list of complications included:

- Pneumothorax
- Hematoma
- Tamponade
- Mechanical complications
- Pulmonary embolism
- Infection
- Other cardiac complication
- Acute renal failure requiring hemodialysis

We then worked with the working group and TEP to create comprehensive but inclusive definitions of complications that are both in alignment with the purpose of

the measure and acceptable to clinicians that perform ICD implantation. Specifically, we looked to create definitions that were:

- Clinically significant complications attributable to the ICD implantation
- Captured in administrative claims data
- Equitable to hospitals and physicians

In defining the complications, we sought clinically sensible definitions which were, to the extent possible, very likely attributable to ICD implantation. Working group and TEP members agreed that restricting outcomes to complications requiring an intervention would enhance measure acceptance as these complications represent the most clinically significant adverse events. For example, the claims code used to identify "mechanical complications" in the claims data is broad, including both lead dislodgement requiring open revision as well as minor lead abnormalities that can be addressed simply by reprogramming the device. As such, restricting to mechanical complications with a system revision narrows the focus of the measure on complications of device implantation that require intervention. Similarly, restricting "pneumothorax or hemothorax" and "hematoma" complications to those requiring an intervention was deemed important because those events vary widely in identification, clinical severity, and recommended treatment. Finally, we added two additional complications to the original list: additional ICDs implanted within 90 days of the index procedure and death within 30 days of the index procedure. In both cases, the event would be an unplanned, adverse event.

"Pulmonary embolism" and "acute renal failure requiring hemodialysis" were dropped from the list of complications as the observed rates were low (less than 0.15%) and they were deemed less clearly attributable to the ICD implantation itself. "Other cardiac complication" was also dropped because it was deemed to be too broad for this measure.

### 2.3.1 Pilot Chart Validation

To determine the accuracy of the administrative claims codes, we conducted a single center pilot study with the goal of determining whether the International Classification of Diseases, 9$^{th}$ Revision, Clinical Modification (ICD-9-CM) and Healthcare Common Procedure Coding System/Current Procedural Terminology (CPT) codes reported on Medicare claims reliably identify ICD complications.

We abstracted charts of 202 Medicare FFS patients who underwent ICD implantation at Yale-New Haven Hospital (YNHH) between January 2006 and December 2007. We developed a chart abstraction tool that systematically collected information regarding the existence and severity of ICD-related complications.

A team of trained clinicians and researchers performed the chart abstraction and identified 15 patients with at least one complication (7.4%). The corresponding administrative codes identified 13 admissions with at least one potential

complication. Overall, 10 (66.7%) of the complications identified by chart review were also identified by administrative codes, and 76.9% of complications identified by administrative codes were confirmed by chart review. In 8 cases, there was disagreement between administrative codes and chart review. These cases were reviewed.

In five cases, complications in the clinical charts were not identified by the administrative codes used in our model. The misclassification in four of these cases occurred because we had not included ICD-9-CM and CPT codes in our model that coders at YNHH used to define these events. Based on these results, we modified the codes defining complications to include the following:

- 37.12 (pericardiotomy)
- 37.75 (revision of lead/electrode)
- 37.79 (revision or relocation of pacemaker pocket)
- 37.97 (replacement of automatic cardioverter/defibrillator leads only).

In the fifth case, there was discrepancy in the admission and discharge dates that precluded accurate determination of existence of the code in the administrative data.

In three cases, complications in the administrative data were not confirmed by chart review. In one case, the complication likely occurred at another hospital and we did not obtain the corresponding chart. In the other two cases, the administrative codes reflected conditions (infection and pocket erosion) that were present on admission and reflected the reason that the prior ICD needed to be replaced. That is, given the way the cohort was being defined in the model, conditions present on admission (and the reason for the ICD) were being picked up as complications of the procedure, rather than the reason for the procedure. Based on these results, we decided to exclude patients with prior ICD from the model until present on admission codes are available.

The revisions we made based on this single-center study resulted in a model that would have correctly characterized 14 out of the 15 complications (93%) identified by chart review. In addition, exclusion of patients with prior ICD would have correctly avoided misclassification of the two cases where the condition was not a result of the ICD implantation. We incorporated these changes into the proposed measure and, to further inform cohort and complication specifications, we will expand the chart validation study this year to additional sites representative of institutions performing ICD implantation.

The TEP and working group were supportive of the resulting list of adapted definitions.

We define ICD-related complications as either:

- an inpatient hospital stay with at least one complication or death following an index procedure (Table 2), or
- an outpatient hospital stay within 90 days during which an ICD is implanted

**Table 2** – Complication Specific Definitions and Timeframes

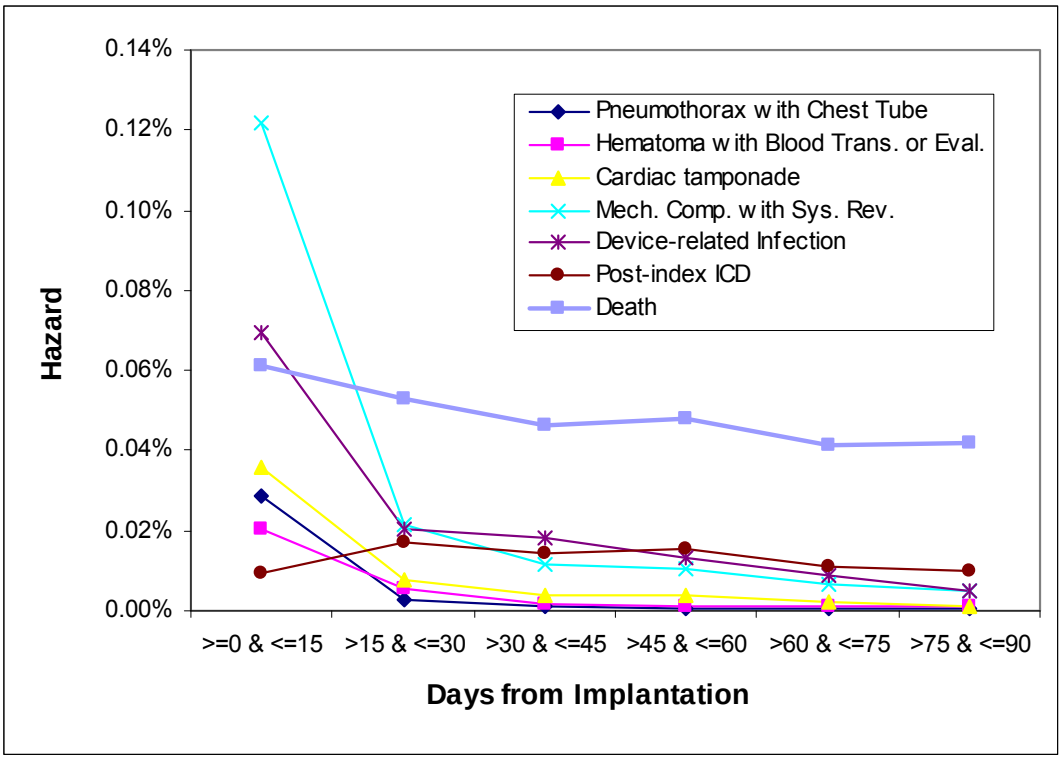
| Complication Description | Definition | Timeframe |
|---|---|---|
| Pneumothorax or hemothorax with chest tube | Pneumothorax or hemothorax: 512.1 or 511.8 (diagnosis code) Chest tube: 34.04, 34.05, 34.06, or 34.09 (procedure code) | 30 days |
| Hematoma, with blood transfusion or evacuation | Hematoma: 998.1 (diagnosis code) Blood transfusion: 518.7, 287.4, V59.01, V58.2 (diagnosis code), or 99.00, 99.03, 99.04 (procedure code) Evacuation: 34.04, 34.09 (procedure code) | 30 days |
| Cardiac tamponade or pericardiocentesis | Cardiac tamponade: 420, 423.0, 423.3, 423.9 (diagnosis code), or 37.0, 37.12 (procedure code) | 30 days |
| Mechanical complications requiring a system revision | Mechanical complications with system revision: 996.0 (diagnosis code) System revision: 37.75, 37.79, 37.97, 37.99 or 00.52 (procedure code) | 90 days |
| Infection that is device related | Infection: 996.61 (diagnosis code) | 90 days |
| Subsequent ICDs within 90 days of the index procedure | Inpatient ICD implantation: 00.50, 00.51, 00.52, 00.53, 00.54, or 37.94 (procedure codes) Outpatient ICD implantation: 33216, 33217, 33218, 33220, 33223, 33240, 33241, or 33249 (CPT codes) | 90 days |
| Death | | 30 days |

Specific code definitions for the respective ICD-9 and CPT codes used to define these complications are available in Appendix A and Appendix B.

### 2.3.2 Measure Timeframe

Review of preliminary analyses revealed that most complications occur within the initial 15 days following implantation, and qualitatively leveled off between 30 and 45 days following ICD implantation (Figure 1). Accordingly, the TEP recommended a 90-day time period for follow-up. However, defining a single optimal period of assessment appropriate for such a wide range of outcomes was challenging. For example, device related infections may not become apparent for weeks or months following implantation, suggesting a 90 day time period would be best. In contrast, a hematoma due to the procedure would most likely be recognized and treated within 30 days of implantation, while a hematoma identified after that point might more likely be due to subsequent procedures (eg cardiac catheterization). Both the working group and TEP strongly suggested that different timeframes specific to each complication would be more appropriate for the proposed measure than a fixed time frame for all complications. Accordingly, we reviewed each complication with the working group and TEP, selecting either a 30 or 90 day timeframe by consensus.

**Figure 1** – Hazard of ICD Related Complications Following ICD Implantation (Medicare Part A, Inpatient and Outpatient, 2007)



The complication-specific timeframes are outlined in Table 3.

**Table 3** – Complication-Specific Timeframes

| 30 Days | 90 Days |
|---|---|
| Pneumothorax or hemothorax, plus chest tube | Mechanical complications requiring system revision |
| Hematoma, plus blood transfusion or evacuation | Device related infections |
| Cardiac tamponade or pericardiocentesis | Additional ICD implantations |
| Death | |

The working group and TEP recognized that a model using both 30-day and 90-day complications in the outcome may make measure interpretation more complex, but there was agreement that this potential disadvantage was offset by its improving the clinical face validity and acceptability of the measure.

## 2.4 Data Sources

The datasets used to create the measures are described below.

### 2.4.1 NCDR ICD Registry Data

The National 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 June 2009, the registry had collected data from 1,432 hospitals in the United States totaling over 380,000 implants.

The registry, launched on June 30, 2005, was developed through a partnership of the Heart Rhythm Society (HRS) and the American College of Cardiology Foundation (ACCF) 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 CMS and the NCDR (the data collection form and the complete list of variables collected and submitted by hospitals can be found at http://www.ncdr.com/). 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. We developed the measure using only data that had passed the NCDR's data quality standards and was thus included in their analytic file.

Of note, hospitals are only required to submit data on all primary prevention ICDs implanted on Medicare patients, and, of the 159 data elements collected by the ICD Registry, the NCDR forwards to CMS only the 54 elements required by CMS to determine eligibility for payment. Nevertheless, hospitals are required to complete all data elements on primary prevention implants for Medicare patients. In addition, 78% of hospitals have opted to submit data on all implants (i.e. both primary and secondary prevention implantations, regardless of insurance coverage).

Institutions that participate fully in the ICD Registry reflect the full spectrum of hospitals that perform ICD implantation. Using data from the 2007 Medicare claims data linked with information from the 2007 American Hospital Association (AHA) Survey, we compared characteristics of hospitals whose data passed the NCDR's threshold for inclusion in the analytic file with hospitals whose data was not included in the analytic file. Compared with other hospitals, those hospitals whose data was included in the analytic file are larger and more likely to be located in the Northeast. Furthermore, a higher proportion of these hospitals are not-for-profit, teaching, and perform open heart surgeries including coronary artery bypass grafting (Table 4).

**Table 4** – Comparison of the characteristics of hospitals whose data was included in the analytic file (and thus included in the process of measure development) with hospitals whose data was not included in the analytic file. (Hospitals in both CMS Part A 2007 [inpatient & outpatient] data and AHA 2007 data)

| Description | Total # | Total % | Hospitals Performing ICD Implantation not included in ICD Registry's Analytic File # | Hospitals Performing ICD Implantation not included in ICD Registry's Analytic File % | Hospitals included in ICD Registry Analytic File # | Hospitals included in ICD Registry Analytic File % | P |
|---|---|---|---|---|---|---|---|
| All | 1,804 | 100.0 | 685 | 100.0 | 1,119 | 100.0 | |
| Number of beds | | | | | | | 0.0000 |
| < 300 | 1,092 | 60.5 | 521 | 76.1 | 571 | 51.0 | |
| 300 to 600 | 562 | 31.2 | 131 | 19.1 | 431 | 38.5 | |
| > 600 | 150 | 8.3 | 33 | 4.8 | 117 | 10.5 | |
| Mean (SD) | 300.5 | 217.2 | 231.6 | 194.4 | 342.7 | 219.7 | 0.0000 |
| Ownership | | | | | | | 0.0078 |
| Government | 223 | 12.4 | 100 | 14.6 | 123 | 11.0 | |
| Not-for-profit | 1,238 | 68.6 | 441 | 64.4 | 797 | 71.2 | |
| For profit | 343 | 19.0 | 144 | 21.0 | 199 | 17.8 | |
| Region | | | | | | | 0.0011 |
| Associated area | 8 | 0.4 | 6 | 0.9 | 2 | 0.2 | |
| New England | 83 | 4.6 | 36 | 5.3 | 47 | 4.2 | |
| Middle Atlantic | 199 | 11.0 | 86 | 12.6 | 113 | 10.1 | |
| South Atlantic | 341 | 18.9 | 123 | 18.0 | 218 | 19.5 | |
| East North Central | 314 | 17.4 | 101 | 14.7 | 213 | 19.0 | |
| East South Central | 125 | 6.9 | 44 | 6.4 | 81 | 7.2 | |
| West North Central | 139 | 7.7 | 37 | 5.4 | 102 | 9.1 | |
| West South Central | 235 | 13.0 | 106 | 15.5 | 129 | 11.5 | |
| Mountain | 116 | 6.4 | 44 | 6.4 | 72 | 6.4 | |
| Pacific | 244 | 13.5 | 102 | 14.9 | 142 | 12.7 | |
| Teaching status | | | | | | | 0.0000 |
| COTH[1] | 255 | 14.1 | 58 | 8.5 | 197 | 17.6 | |
| Teaching | 390 | 21.6 | 98 | 14.3 | 292 | 26.1 | |
| Non-Teaching | 1,159 | 64.2 | 529 | 77.2 | 630 | 56.3 | |
| Cardiac facility | | | | | | | 0.0000 |
| CABG surgery | 1,137 | 63.0 | 299 | 43.65 | 838 | 74.9 | |

The NCDR possesses a Data Quality Program (DQP) to ensure validity of the data collected. 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

[1] COTH = Council of Teaching Hospitals and Health Systems

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 many of the variables used in our measure. The entire quarter of patient discharge information is not accepted until the DQR completeness thresholds are met for all patient data. 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 ICD Registry audit focuses on variables used to determine eligibility for reimbursement for primary prevention implants. 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.

### 2.4.2 Medicare Data

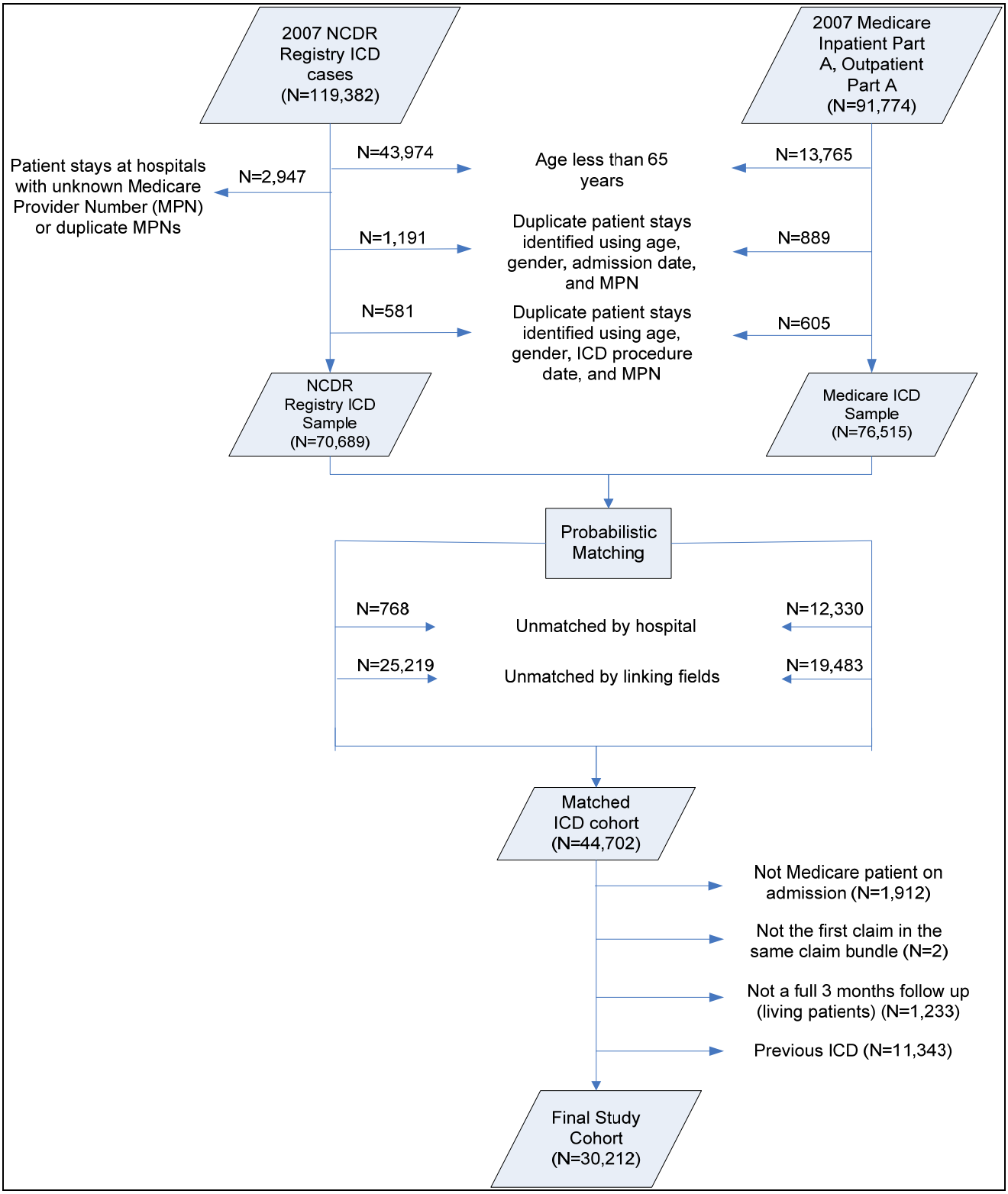
The measure uses Medicare Part A inpatient and outpatient data and the Medicare Enrollment Database (EDB). "Part A" data refers to claims paid for Medicare inpatient hospital care, outpatient services, skilled nursing facility care, some home health agency services, and hospice care. For purposes of this project, Part A is used to refer to inpatient and outpatient services. For model development, we used 2007 Medicare Part A data to match patient stays from the ICD Registry for the corresponding time periods. For validation, we used 2006 Medicare Part A data to match index patient stays from the ICD Registry for the corresponding time periods.

The EDB contains Medicare beneficiary demographic, benefit/coverage, and vital status information. Patient death information was linked by patient HIC number to the Part A data. This data has previously been shown to accurately reflect patient vital status (Fleming Fisher et al. 1992).

## 2.5 Cohort Derivation

We initially considered data from the ICD Registry and CMS claims data separately. In each dataset, a potential index patient stay was one in which an ICD was implanted. The flow chart depicting the derivation of the set of patient stays is presented in Figure 2.

**Figure 2** – Cohort for Model Development



If a patient had more than one patient stay with an ICD implantation during the follow-up period (90 days from discharge), any additional ICD implantation on an individual patient was considered as complications to the first implantation, and accordingly excluded from consideration as an index procedure.

In the ICD Registry, all patient stays with ICD implantation are collected. In the CMS claims data, patient stays with ICD are identified by ICD-9 procedure codes from inpatient and outpatient claims and CPT procedure codes from outpatient claims shown in Table 5.

**Table 5** – ICD-9-CM and HCPCS/CPT Procedure Codes that Define ICD Implantation During Hospitalization or Outpatient Services in the Medicare Dataset

| Code Type | Code | Definition |
|---|---|---|
| ICD-9-CM | 00.50 | Implantation of cardiac resynchronization pacemaker without mention of defibrillation, total system (crt-p) |
| ICD-9-CM | 00.51 | Implantation of cardiac resynchronization defibrillator, total system (crt-d) |
| ICD-9-CM | 00.52 | Implantation or replacement of transvenous lead [electrode] into left ventricular coronary venous system |
| ICD-9-CM | 00.53 | Implantation or replacement of cardiac resynchronization pacemaker pulse generator only (crt-p) |
| ICD-9-CM | 00.54 | Implantation or replacement of cardiac resynchronization defibrillator pulse generator device only (crt-d) |
| ICD-9-CM | 37.94 | Implantation or replacement of automatic cardioverter/defibrillator, total system (aicd) |
| HCPCS/CPT | 33216 | Insertion, single chamber transvenous electrode ICD |
| HCPCS/CPT | 33217 | Insertion, dual chamber transvenous electrode ICD |
| HCPCS/CPT | 33218 | Repair, single chamber transvenous electrode ICD |
| HCPCS/CPT | 33220 | Repair, dual chamber transvenous electrode ICD |
| HCPCS/CPT | 33223 | Pocket revision ICD |
| HCPCS/CPT | 33240 | Insertion of single or dual chamber ICD pulse generator |
| HCPCS/CPT | 33241 | Removal of single or dual chamber ICD pulse generator |
| HCPCS/CPT | 33249 | Insertion or repositioning of electrode lead(s) for single or dual chamber pacing ICD and insertion of pulse generator |

### 2.5.1 Probabilistic Matching Methodology for Merging ICD Data and CMS Claims Data for Measure Development

As the NCDR ICD Registry does not currently track patients over time (episodes of care), this measure required linking registry data to external databases to accurately determine the ICD-related complication rates. The ICD Registry currently captures social security numbers. However, the existing business associate agreements between the NCDR and participating hospitals precluded Yale-CORE from using direct patient identifiers for the purposes of model development. Accordingly, we performed a probabilistic match linking patient stays with ICD implantation in the ICD Registry with corresponding patient stays in the CMS claims data using the following indirect patient identifiers in two distinct steps using different linking fields.

Group 1

- Hospital Medicare Provider Number (MPN)
- Patient age
- Gender
- Date of admission (claim begin date for Medicare Part A outpatient claims)

OR

Group 2

- Hospital Medicare Provider Number (MPN)
- Patient age
- Gender
- Date of ICD procedure

To accomplish this, we performed the following steps:

1. We derived hospital MPN for hospitals in the NCDR ICD registry from the hospital's self reported MPN and verified it using hospital information name and address from the NCDR data linked with the American Hospital Association (AHA) database.

2. For hospitals in the NCDR ICD registry with either no self-reported MPN or a duplicate MPN we manually searched and confirmed the MPN.

3. We derived a unique dataset from the ICD Registry (including patients' clinical factors) with patient stays by removing duplicates determined by Group 1 linking fields or by Group 2 linking fields.

4. A comparable dataset is created from CMS claims data by removing direct patient identifiers (i.e., Health Insurance Claim [HIC] number) which contains unique patient admissions with outcomes by removing duplicates determined by Group 1 linking fields or by Group 2 linking

fields. In this dataset, we removed all direct patient identifiers, such as Health Insurance Claim (HIC) number. The resulting dataset contained unique patient stays.

5. The two datasets derived in steps 3 and 4 were merged using Group 1 linking fields first and then repeated using Group 2 linking fields in the remaining unmatched records.

Matching Results

Among ICD patients ≥65 years old in the 2007 Medicare claims data, 70% were successfully matched to ICD Registry records for 2007. Results of the match were similar when we varied matching criteria (e.g., removing discharge date as a linking field). The overall match rate is similar to that found during development of the two 30-day PCI mortality measures YNHHSC/CORE developed in 2008.

There are several potential explanations for patients ≥65 not matching. Approximately 14% of Medicare patients ≥65 are enrolled in Medicare managed care plans. Accordingly, administrative claims data is not available for this subset of patients. Other contributing factors include patients ineligible for Medicare (e.g., non-U.S. citizens), patients with non-governmental insurance, and inaccuracies in linking fields (e.g., substituting age for date of birth).

The characteristics and outcomes of matched and unmatched patients were similar, suggesting that the match was adequate for measure development, but not for measure implementation. Although 30% of patients did not match, the observed differences in characteristics of patients who did match and those who did not match were clinically modest (Table 6). Age, for example, was roughly one year higher in the matched group as compared to the unmatched group, which is statistically significant but clinically not very different. Many of the characteristics matched identically across the two groups, such as diabetes, hypertension, serum sodium, and systolic blood pressure.

**Table 6** – Selected Patient Characteristics in NCDR ICD Data for Matched and Unmatched Patients (2007)

| Description | | Not Matched # | Not Matched % | Matched # | Matched % |
|---|---|---|---|---|---|
| **Demographics** | Age: Mean (SD) | 74.5 | 6.2 | 75.3 | 6.3 |
| | Gender | 6337 | 25.1 | 11299 | 25.3 |
| | Race: non-white | 12,103 | 16.6 | 16,931 | 11.6 |
| **Admission** | Reason for Admission | | | | |
| | Admitted for this procedure | 18,969 | 75.2 | 28,784 | 64.4 |
| | Hospitalized: cardiac | 2,084 | 8.3 | 5,565 | 12.4 |
| | Hospitalized: non-cardiac | 3,499 | 13.9 | 8,900 | 19.9 |
| | Missing or unknown | 667 | 2.6 | 1,453 | 3.3 |
| **History and Risk Factors** | Congestive Heart Failure | 20,082 | 79.6 | 35,985 | 80.5 |
| | Previous Valvular Surgery | 1,982 | 7.9 | 3,956 | 8.8 |
| | Cerebrovascular Disease | 3,958 | 15.7 | 7,942 | 17.8 |
| | Peripheral Vascular Disease | | | | |
| | Chronic Lung Disease | 5,674 | 22.5 | 11,041 | 24.7 |
| | Diabetes | 9,394 | 37.2 | 16,764 | 37.5 |
| | Hypertension | 19,658 | 77.9 | 34,805 | 77.9 |
| | Previous ICD | | | | |
| | No | 19,063 | 75.6 | 32,577 | 72.9 |
| | single chamber | 1,626 | 6.5 | 2,722 | 6.1 |
| | dual chamber | 2,723 | 10.8 | 5,447 | 12.2 |
| | biventricular | 1,795 | 7.1 | 3,937 | 8.8 |
| | Previous PCI | 8,222 | 32.6 | 15,043 | 33.7 |
| | Previous CABG | 10,405 | 41.3 | 19,418 | 43.4 |
| **Diagnostics** | Atrioventricular Conduction | | | | |
| | normal | 15,200 | 60.3 | 25,090 | 56.1 |
| | abnormal: 1st degree heart block only | 4,424 | 17.5 | 8,099 | 18.1 |
| | Abnormal: 2nd/3rd degree heart | 971 | 3.9 | 2,017 | 4.5 |
| | paced (any) | 4,624 | 18.3 | 9,496 | 21.2 |
| | Intraventricular Conduction | | | | |
| | normal | 8,984 | 35.6 | 14,327 | 32.1 |
| | abnormal: LBBB | 6,699 | 26.6 | 12,088 | 27.0 |
| | abnormal: RBBB, bifascicular | 2,232 | 8.9 | 4,396 | 9.8 |
| | paced | 4,238 | 16.8 | 8,588 | 19.2 |
| | other | 3,066 | 12.2 | 5,303 | 11.9 |
| | Ejection Fraction Percentage | | | | |
| | N/A or missing | 1,101 | 4.4 | 1,875 | 4.2 |
| | <20 | 3,068 | 12.2 | 5,575 | 12.5 |
| | 20 to <30 | 10,334 | 41.0 | 18,107 | 40.5 |
| | 30 to <40 | 8048 | 31.9 | 13,858 | 31.0 |
| | >=40 | 2,668 | 10.6 | 5,287 | 11.8 |
| | Creatinine level: mean (SD) | | | | |
| | BUN level: mean (SD) | 25.9 | 13.9 | 27.1 | 14.8 |
| | Sodium level: mean (SD) | 138.8 | 3.5 | 138.6 | 3.6 |
| | Systolic BP: mean (SD) | 132.5 | 22.5 | 131.8 | 22.6 |

We also compared the rates of adverse events in the claims data of patients that did and did not match (Table 7). The overall rate of

complications or mortality in those who did not match versus those that did was higher (8.9 and 7.5, respectively). This may reflect the increased risk profile of patients receiving an ICD for secondary prevention, differences in case mix of hospitals whose data was not included in the analytic file, or other patient and hospital factors.

**Table 7** – Outcomes in Medicare Claims Data for Matched and Unmatched Patients (2007)

| **Outcome** | Not Matched # | Not Matched % | Matched # | Matched % |
|---|---|---|---|---|
| Complication | 1,395 | 7.2 | 2,673 | 6.0 |
| Mortality | 381 | 2.0 | 730 | 1.6 |
| Complication or Mortality | 1,739 | 8.9 | 3,338 | 7.5 |

### 2.5.2 Exclusion Criteria

We excluded the following patient stays from the cohort prior to the merge:

1) Age <65 (Medicare and NCDR datasets). Stays for patients less than 65 years old at the time of the patient stay were excluded.
   *Rationale:* Patients younger than 65 in the Medicare dataset represent a distinct population that qualifies for Medicare due to disability. The characteristics and outcomes of these patients may not be representative of the larger population of ICD patients.

2) Patient stays at hospitals with missing or duplicate MPN (NCDR dataset). Any patient stays with a missing or duplicate MPN number are excluded.
   *Rationale:* If the MPN number is unreliable, we are unable to match NCDR patients to CMS claims data, assign complication rates to hospitals with certainty, or accurately measure the performance of the hospital.

3) Patient stays with duplicate fields (Medicare and NCDR datasets). Patient stays that have identical information in either dataset indicated for (a) age, gender, admission date, and MPN, and (b) age, gender, ICD procedure date, and MPN are excluded.
   *Rationale:* Patient stays with identical demographics are excluded to avoid making matching errors upon merging of the two datasets.

4) Unmatched patient stays. Patient stays that are not matched based on hospitals or the linking fields are excluded.
*Rationale:* We lack necessary information (e.g., risk adjustment variables, outcome information) in unmatched patient stays.

The following exclusions are applied to the merged dataset:

(1) Non Medicare patients on the first day of the patient stay. Patient stays in which the patient is not a Medicare patient on admission.
*Rationale:* Outcome data are being derived only for Medicare fee-for-service patients.

(2) Not the first claim in the same claim bundle. When several claims in the same hospital representing the same patient stay exist in the data together (bundled), any claim other than the first in such a bundle is excluded.
*Rationale:* Inclusion of these patients could result in duplicate counting in the measure.

(3) Patient stays which lack 90-days of Medicare fee-for-service enrollment 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.

(4) Previous ICD placement. Patient 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 complications of the second ICD placement or were present on admission. The indications for reimplantation include events included in our definition of procedural complications such as device infection, device malfunction, or lead dislodgement. Given current coding practices, we are unable to determine whether a 'complication' code is present on admission or in fact represents a procedural complication. In order to avoid misclassification, we exclude these patients from the measure.

## 2.6 Observation Period

For model development and validation, we used observations for one calendar year.

## 2.7 Registry Model Development

### 2.7.1 Model Overview

We use NCDR ICD Registry data that contains patient stays with ICD implantation. We derive the model using patient stays with ICD implantation for patients discharged in 2007 ("development sample"). The performance of the model is then validated using patient stays with ICD implantation for patients discharged in 2006 ("validation sample"). We compute indices that describe model performance in terms of predictive ability, discriminant ability, and overall fit.

Specific information about each step in the process of ICD complications model development and validation, as summarized in the Overview section of this report, is described below.

## 2.8 Developmental Dataset

We use patient stays with ICD implantation in the merged data from 2007. Figure 2 presents the total number of patient stays with ICD implantation, the proportion excluded as a result of each exclusion criterion, and the number included in the final sample as index patient stays. The development sample consisted of 41,430 patient stays at 1,080 hospitals. The overall unadjusted complication rate is 5.3%.

## 2.9 Candidate and Final Variables

We sought to develop a model that included key variables that were clinically relevant and based on strong association with complications.

To select candidate variables, a team of clinicians began with a review of the variables from the NCDR ICD Registry database and modified the final variable list as appropriate for a complication measure (a copy of the data collection form and the complete list of variables collected and submitted by hospitals can be found at http://www.ncdr.com/). We did not consider as candidate variables those that we would not want to adjust for in a quality measure, such as potential complications, certain patient demographics (e.g., race, socioeconomic status), and patients' admission path (e.g., admitted from), or discharged status. Variables were also considered ineligible if they were particularly vulnerable to gaming or were deemed to lack clinical relevance. Based on careful review by the working group and TEP, and further informed by a review of the literature, a total of 30 variables were determined to be appropriate for consideration as candidate variables. Our set of candidate variables (see Table 8) included two "demographic" variables (age and gender), one "admission" variable (admission reason), 18 "history and risk factor"

variables, seven “diagnostics” variables, and two “procedure” variables (ICD indication and type).

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%). There were three continuous variables with missing values: body mass index (BMI, 0.1%), glomerular filtration rate (GFR, 3.7%), and left ventricular ejection fraction (LVEF, 28.5%); we considered the missing of GFR and LVEF as an independent category of “unmeasured” and imputed the missing of BMI into the median value of males for male and the median value of female for female. For continuous variables, the missing values were imputed into the median value.

We used logistic regression with stepwise selection (entry $p<0.10$; retention with $p<0.05$) 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 13 variables, presented in Table 9.

**Table 8** – ICD Complications Model Candidate Variables

| Description | NCDR Item Number | Name |
|---|---|---|
| **Demographics** | | |
| Age: Mean (SD) | 2050 | Age |
| Gender | 2060 | FEMALE |
| **Admission** | | |
| Reason for Admission | 3030 | AdmissionReason |
| Admitted for this procedure | | Reference |
| Hospitalized: cardiac | | ADMS2=( AdmissionReason=2) |
| Hospitalized: non-cardiac | | ADMS3=( AdmissionReason=3) |
| Missing or unknown | | Imputed into the above categories |
| **History and Risk Factors** | | |
| Syncope | 3060 | SYNCOPE |
| Family History Sudden Death | 3070 | FHSUDDEATH |
| Heart Failure | 3080 | CHF |
| NYHA Class - Current Status | 3100 | NYHACLASS |
| Class I | | Reference |
| Class II | | NYHAC2=(NYHACLASS=2) |
| Class III | | NYHAC3=(NYHACLASS=3) |
| Class IV | | NYHAC4=(NYHACLASS=4) |
| Cardiac Arrest | 3110 | ARREST=(ARREST>0) |
| Atrial Fibrillation/Atrial Flutter | 3120 | FLUTTER |
| Ventricular Tachycardia | 3130 | VT |
| No | | Reference |
| Yes-Non-Sustained | | VT1=(VT=1) |
| Yes-Sustained | | VT2=(VT>1) |
| Non-Ischemic Dilated Cardiomyopathy | 3160 | NIDCM=(NIDILILATEDCARDMYO>0) |

**Table 8** – ICD Complications Model Candidate Variables *(cont.)*

| Description | NCDR Item Number | Name |
|---|---|---|
| Ischemic Heart Disease | 3180 | IHD=(ISCHEMICHD>0) |
| Previous MI | 3190 | PMI=(PREVMITIME>0) |
| Previous CABG | 3200 | PREVCABG |
| Previous PCI | 3220 | PREVPCI=(PREVPCI>0) |
| Previous Valvular Surgery | 3230 | PREVVALVESURG |
| Cerebrovascular Disease | 3310 | CVDISEASE |
| Chronic Lung Disease | 3320 | LUNGDISEASE |
| Diabetes | 3330 | DIABETES |
| Hypertension | 3340 | HYPERTENSION |
| Renal Failure-Dialysis | 3350 | DIALYSIS |
| **Diagnostics** | | |
| Atrioventricular Conduction | 3440 | AVCONDUCT |
| Normal | | Reference |
| Abnormal: 1st degree heart block only | | AVC2=(AVCONDUCT=2) |
| Abnormal: 2nd/3rd degree heart block | | AVC3=(AVCONDUCT=3) |
| Paced (any) | | AVC4=(AVCONDUCT=4) |
| Intraventricular Conduction | 3450 | IVCONDUCT |
| Normal | | Reference |
| Abnormal: LBBB | | IVC2=(IVCONDUCT=2) |
| Abnormal: RBBB, bifascicular block (RBBB plus LAF, RBBB plus LPF) | | IVC3=(IVCONDUCT=3) |
| Paced | | IVC4=(IVCONDUCT=4) |
| Other | | IVC5=(IVCONDUCT=5) |
| Ejection Fraction Percentage | 3370 | EFPERCENT |
| Not measured | | EFPC0=(EFPERCENT=.) |
| <20 | | EFPC1=(,<EFPERCENT<20) |
| 20 to <30 | | EFPC2=(20<=EFPERCENT<30) |
| 30 to <40 | | EFPC3=(30<=EFPERCENT<40) |
| >=40 | | Reference |
| Creatinine level > 2.0 mg/dl | 3460 | CRTGT2=(CREATININE>2) |
| BUN level > 30 mg/dl | 3470 | BUNGT30=(BUNLEVEL>30) |
| Sodium level | 3480 | NALEVEL |
| <135 md/dl | | NA1=( NALEVEL<135) |
| 135 to 145 mg/dl | | Reference |
| >145 mg/dl | | NA3=( NALEVEL>145) |
| Systolic BP < 100 mmHg | 3500 | SBPLT100=(SYSTOLICBP<100) |
| **ICD Procedures** | | |
| ICD indication: primary prevention | 3505 | ICDIND=(ICDINDICATION=1) |
| ICD type | 3540 | ICDTYPE |
| Single chamber | | ICDTYPE1=(ICDTYPE=1) |
| Dual chamber | | ICDTYPE2=(ICDTYPE=2) |
| Biventricular | | Reference |

**Table 9 – Final ICD Complication Model Variables**

| Description | NCDR Item Number | Name |
|---|---|---|
| **Demographics** | | |
| Age: Mean (SD) | 2050 | Age |
| Gender | 2060 | FEMALE |
| **Admission** | | |
| Reason for Admission | 3030 | AdmissionReason |
| Admitted for this procedure | | Reference |
| Hospitalized: cardiac | | ADMS2=( AdmissionReason=2) |
| Hospitalized: non-cardiac | | ADMS3=( AdmissionReason=3) |
| **History and Risk Factors** | | |
| NYHA Class - Current Status | 3100 | NYHACLASS |
| Class I | | Reference |
| Class II | | NYHAC2=(NYHACLASS=2) |
| Class III | | NYHAC3=(NYHACLASS=3) |
| Class IV | | NYHAC4=(NYHACLASS=4) |
| Cardiac Arrest | 3110 | ARREST=(ARREST>0) |
| Previous CABG | 3200 | PREVCABG |
| Chronic Lung Disease | 3320 | LUNGDISEASE |
| Renal Failure-Dialysis | 3350 | DIALYSIS |
| **Diagnostics** | | |
| Atrioventricular Conduction | 3440 | AVCONDUCT |
| Normal | | Reference |
| Abnormal: 1st degree heart block only | | AVC2=(AVCONDUCT=2) |
| Abnormal: 2nd/3rd degree heart block | | AVC3=(AVCONDUCT=3) |
| Paced (any) | | AVC4=(AVCONDUCT=4) |
| BUN level > 30 mg/dl | 3470 | BUNGT30=(BUNLEVEL>30) |
| Sodium level | 3480 | NALEVEL |
| <135 md/dl | | NA1=( NALEVEL<135) |
| 135 to 145 mg/dl | | Reference |
| >145 mg/dl | | NA3=( NALEVEL>145) |
| Systolic BP < 100 mmHg | 3500 | SBPLT100=(SYSTOLICBP<100) |
| ICD Type | 3540 | ICDTYPE |
| Single Chamber | | ICDTYPE1=(ICDTYPE=1) |
| Dual Chamber | | ICDTYPE2=(ICDTYPE=2) |
| Biventricular | | Reference |

## 2.10 Statistical Approach to Model Development

We developed the risk adjustment model for the measure using the following methodology:

Because of the natural clustering of the observations within hospitals, we estimated hierarchical generalized linear models (HGLMs). We modeled the log-odds of ICD-related complication as a function of patient demographic and clinical characteristics and a random hospital-specific intercept. This strategy accounts for within-hospital correlation of the observed outcomes and models the assumption that underlying differences in quality among the health care facilities being evaluated lead to systematic differences in outcomes.

We then calculated hospital risk-standardized complication rates (RSCRs) using a hierarchical logistic regression model. These rates are calculated as the ratio of the predicted number of complications to the expected number of complications, multiplied by the national unadjusted complication rate. The expected number of complications for each hospital was estimated using its patient mix and the average hospital-specific intercept. The predicted number of complications in each hospital was estimated given the same patient mix but an estimated hospital-specific intercept. Operationally, the expected number of complications for each hospital is obtained by summing the expected complication rates for all patients in the hospital. The expected complication rate for each patient is calculated via the hierarchical model by applying the subsequent estimated regression coefficients to the observed patient characteristics and adding the average of the hospital-specific intercepts. The predicted number of complications for each hospital is calculated by summing the predicted complication rates for all patients in the hospital. The predicted complication rate for each patient is calculated through the hierarchical model by applying the estimated regression coefficients to the patient characteristics observed and adding the hospital-specific intercept. In order to assess hospital performance in any specific year (e.g. the validation cohort), we re-estimate the model coefficients using that year's data.

More specifically, we estimate two types of regression models (Table 10). First, we fit a generalized linear model (GLM) linking the outcome to the risk factors (McCullagh P 1989). Let $Y_{ij}$ denote the outcome (equal to 1 if patient presents with ICD related complications, zero otherwise) for the $j^{th}$ patient who underwent ICD implantation at the $i^{th}$ hospital; $\mathbf{Z}_{ij}$ denotes a set of risk factors based on the data. Let $I$ denote the total number of hospitals and $n_i$ the number of index patient stays in hospital $i$. We assume the outcome is related linearly to the covariates via a known linked function, $h$, where

$$\text{GLM} \qquad h(Y_{ij}) = \alpha + \beta \mathbf{Z}_{ij} \qquad (1)$$

and $\mathbf{Z}_{ij} = (Z_{1ij}, Z_{2ij}, \ldots, Z_{pij})$ is a set of $p$ patient-specific covariates. In our case, $h$ = the logit link.

To account for the natural clustering of observations within hospitals, we estimate an HGLM that links the risk factors to the same outcome and a hospital-specific random effect,

$$\text{HGLM} \qquad h(Y_{ij}) = \alpha_i + \beta \mathbf{Z}_{ij} \qquad (2)$$

$$\alpha_i = \mu + \omega_i; \qquad \omega_i \sim N(0, \tau^2) \qquad (3)$$

where $\alpha_i$ represents the hospital-specific intercept, $\mathbf{Z}_{ij}$ is defined as above, $\mu$ the adjusted average outcome over all hospitals in the sample, and $\tau^2$ the between-hospital variance component (Gatsonia CA 1999). This model separates within-hospital variation from between-hospital variation. Both HGLMs and GLMs are

estimated using the SAS software system (GLIMMIX and LOGISTIC procedures, respectfully).

We first fit the GLM described in Equation (1) using the logit link.
Having identified the covariates that remained, we next fit the HGLM described in Equations (2) and (3), again using the logit link function; e.g.,

$$\text{Logit } (P(Y_{ij} = 1)) = \alpha_i + \beta \mathbf{Z}_{ij}$$
$$\alpha_i = \mu + \omega_i, \quad \omega_i \sim N(0, \tau^2)$$

where $\mathbf{Z}_{ij}$ consisted of the covariates retained in the GLM model. As before, $Y_{ij} = 1$ if patient *j* treated at hospital *i* had the event; 0 otherwise.

## 2.11 Hospital Performance Reporting

Using the set of risk factors in the GLM, we fit the HGLM defined by Equations (2) - (3) and estimate the parameters, $\hat{\mu}$, $\{\hat{\alpha}_i, \hat{\alpha}_2, ..., \hat{\alpha}_I\}$, $\hat{\beta}$, and $\hat{\tau}^2$. We calculate a standardized outcome, $s_i$, for each hospital by computing the ratio of the number of predicted complications to the number of expected complications, multiplied by the unadjusted overall complication rate, $\bar{y}$. Specifically, we calculate

Predicted $$\hat{y}_{ij}(Z) = h^{-1}(\hat{\alpha}_i + \hat{\beta}\mathbf{Z}_{ij}) \quad (4)$$

Expected $$\hat{e}_{ij}(Z) = h^{-1}(\hat{\mu} + \hat{\beta}\mathbf{Z}_{ij}) \quad (5)$$

$$\hat{s}_i(Z) = \frac{\sum_{j=1}^{n_i} \hat{y}_{ij}(Z)}{\sum_{j=1}^{n_i} \hat{e}_{ij}(Z)} \times \bar{y} \quad (6)$$

If more (fewer) "predicted" cases than "expected" cases have the outcome in a hospital, then $\hat{s}_i$ will be higher (lower) than the unadjusted average. For each hospital, we compute an interval estimate of $s_i$ to characterize the level of uncertainty around the point estimate using bootstrapping simulations. The point estimate and interval estimate can be used to characterize and compare hospital performance (e.g., higher than expected, as expected, or lower than expected).

### 2.11.1 Creating Interval Estimates

Because the statistic described in Equation (6) is a complex function of parameter estimates, we use re-sampling and simulation techniques to derive an interval estimate. The bootstrapping simulation has the advantage of avoiding unnecessary distributional assumptions.

### 2.11.2 Algorithm

Let *I* denote the total number of hospitals in the sample. We repeat steps 1 – 4 below for b = 1,2,…B times:

1. Sample *I* hospitals with replacement.

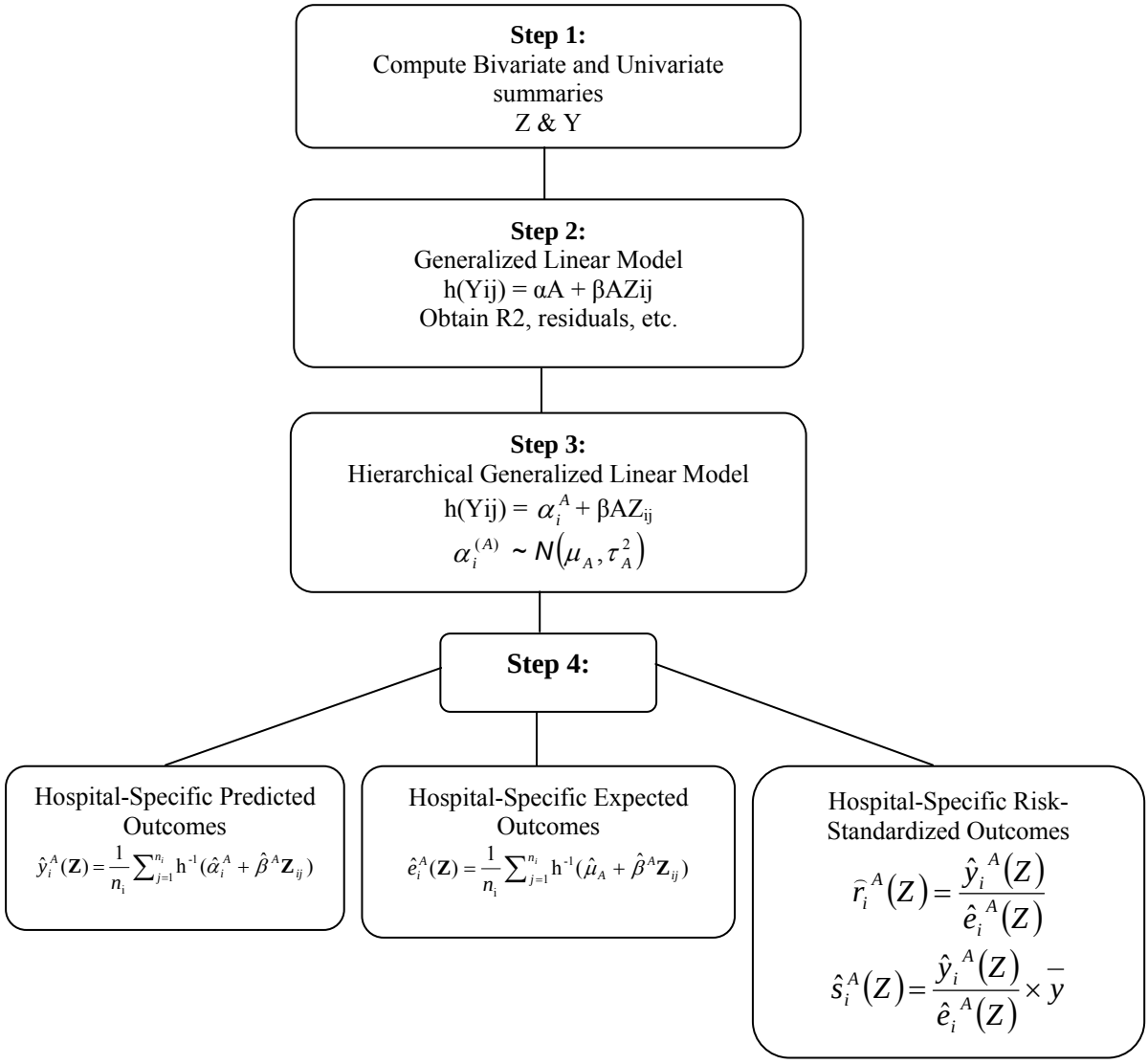
2. Fit the HGLM using all patients within each sampled hospital. We use as starting values the parameter estimates obtained by fitting the model to all hospitals. If some hospitals are selected more than once in a bootstrapped sample, we treat them as distinct so that we have *I* random effects to estimate the variance components. At the conclusion of Step 2, we have:
   a. $\hat{\beta}^{(b)}$ (the estimated regression coefficients of the risk factors).
   b. The parameters governing the random effects, hospital adjusted outcomes, distribution, $\hat{\mu}^{(b)}$ and $\hat{\tau}^{2(b)}$.
   c. The set of hospital-specific intercepts and corresponding variances, $\{\hat{\alpha}_i^{(b)}, \hat{\text{var}}(\alpha_i^{(b)})$; *i* = 1,2,…,*I*$\}$.

3. We generate a hospital random effect by sampling from the distribution of the hospital-specific distribution obtained in Step 2c. We approximate the distribution for each random effect by a normal distribution. Thus, we draw $\alpha_i^{(b*)} \sim N(\hat{\alpha}_i^{(b)}, \hat{\text{var}}(\hat{\alpha}_i^{(b)}))$ for the unique set of hospitals sampled in Step 1.

4. Within each unique hospital *i* sampled in Step 1, and for each case *j* in that hospital, we calculate $\hat{y}_{ij}^{(b)}$, $\hat{e}_{ij}^{(b)}$, and $\hat{s}_i(Z)^{(b)}$ where $\hat{\beta}^{(b)}$ and $\hat{\mu}^{(b)}$ are obtained from Step 2 and $\hat{\alpha}_i^{(b*)}$ is obtained from Step 3.

Ninety-five percent interval estimates (or alternative interval estimates) for the hospital-standardized outcome can be computed by identifying the 2.5$^{th}$ and 97.5$^{th}$ percentiles of randomly half of the B estimates (or the percentiles corresponding to the alternative desired intervals) (Normand, Wang et al. 2007).

**Figure 3** – Analysis Steps - Risk Factors Based on: NCDR ICD Registry Data



# 3. RESULTS

## 3.1 Model Results

### 3.1.1 Development

The variable descriptions, standardized estimates, and standard errors are shown in Table 10 (GLM) and Table 15 (HGLM). The standardized estimates are regression coefficients expressed in units of standard deviations and can range between -1 and 1, with ±1 indicating a perfect linear relationship and 0 indicating no linear relationship.[1]

### 3.1.2 Model Performance

We computed 6 summary statistics for assessing model performance (Harrell, 2001): over-fitting indices[2], percentage of variation explained by the risk factors, predictive ability, area under the receiver operating characteristic (ROC) curve, distribution of residuals, and model chi-square[3] (see Table 12).

The development model has strong discrimination and fit. The complication rate ranges from 4% in the lowest predicted decile to 13% in the highest predicted decile, a range of 9%. The area under the ROC curve is 0.611 (GLM).

The discrimination and the explained variation of the model are consistent with those of models currently used to publicly report condition specific rates of both mortality and readmission. However, model has limited ability to predict individual patients' risk of experiencing an adverse event

[1] Standardized estimates are like correlation coefficients. We compute them in order to compare the size of the coefficients by standardizing the coefficients to be unitless.

[2] Over-fitting refers to the phenomenon in which a model well describes the relationship between predictive variables and outcome in the development dataset, but fails to provide valid predictions in new patients.

[3] Chi-Square – A test of statistical significance usually employed for categorical data to determine whether there is a good fit between the observed data and expected values; i.e., whether the differences between observed and expected values are attributable to true differences in characteristics or instead the result of chance variation. The formula for computing the chi-square is as follows:

$$\sum \frac{(O-E)^2}{E}$$

where O = observed value
E = expected value, and
degrees of freedom (df) = (rows-1)(columns-1)

following ICD implantation. Complications are more difficult to predict than mortality (Mehta, Frutkin et al. 2009). It is likely that there are unmeasured confounders associated with a complication measure. In addition, we did not consider covariates such certain patient demographics (e.g., race), patients' admission path (e.g., outpatient, emergency department), and implanting physician characteristics (e.g. training and certification). These characteristics may be associated with complications and thus could increase the model performance to predict patient complication. However, these variables may be related to quality or supply factors that should not be included in an adjustment that seeks to control for patient clinical characteristics. As a result of these considerations the decision was made to focus on adjustment for clinical differences in the populations among hospitals. That is, we focused on patient characteristics at the time of admission even though the time zero for the measure was discharge.

**Table 10** – ICD Related Complication Model (2007 Development Sample-GLM Results [ROC=0.611])*

| Variable Description | Estimate | Standard Error | Wald Chi-Square | Pr > ChiSq | Standardized Estimates | OR (LOR, UOR) |
|---|---|---|---|---|---|---|
| Age | 0.01 | 0.00 | 3.04 | 0.08 | 0.02 | 1.01 (1.00, 1.01) |
| Gender | 0.18 | 0.05 | 13.09 | 0.00 | 0.04 | 1.19 (1.08, 1.32) |
| Hospital Reason: Hospitalized-Cardiac | 0.18 | 0.06 | 8.48 | 0.00 | 0.04 | 1.20 (1.06, 1.35) |
| Hospital Reason: Hospitalized-Non-Cardiac | 0.20 | 0.05 | 13.45 | 0.00 | 0.05 | 1.22 (1.10, 1.36) |
| NYHAC: II | 0.02 | 0.09 | 0.05 | 0.82 | 0.01 | 1.02 (0.85, 1.22) |
| NYHAC: III | 0.19 | 0.09 | 4.12 | 0.04 | 0.05 | 1.20 (1.01, 1.44) |
| NYHAC: IV | 0.45 | 0.12 | 13.83 | 0.00 | 0.05 | 1.57 (1.24, 1.99) |
| Previous CABG | -0.27 | 0.05 | 33.09 | 0.00 | -0.07 | 0.76 (0.69, 0.84) |
| Chronic Lung Disease | 0.18 | 0.05 | 13.00 | 0.00 | 0.04 | 1.20 (1.09, 1.32) |
| Hypertension | -0.12 | 0.05 | 4.50 | 0.03 | -0.03 | 0.89 (0.80, 0.99) |
| Renal Failure-Dialysis | 0.29 | 0.09 | 9.80 | 0.00 | 0.03 | 1.33 (1.11, 1.60) |
| AVC: Abnormal-1st Degree Heart Block Only | 0.05 | 0.06 | 0.66 | 0.42 | 0.01 | 1.05 (0.93, 1.18) |
| AVC: Abnormal-Heart Block 2nd or 3rd Degree | 0.31 | 0.09 | 11.48 | 0.00 | 0.04 | 1.37 (1.14, 1.64) |
| AVC: Paced (any) | 0.21 | 0.07 | 8.99 | 0.00 | 0.04 | 1.23 (1.07, 1.41) |
| BUN > 30 mg/dl | 0.31 | 0.05 | 40.88 | 0.00 | 0.08 | 1.37 (1.24, 1.51) |
| Sodium < 135 | 0.24 | 0.06 | 13.19 | 0.00 | 0.04 | 1.26 (1.11, 1.44) |
| Sodium > 145 | 0.38 | 0.17 | 4.78 | 0.03 | 0.02 | 1.46 (1.04, 2.06) |
| SBP < 100 mmHG | 0.30 | 0.09 | 11.04 | 0.00 | 0.04 | 1.35 (1.13, 1.61) |
| ICD Type: Single Chamber | -0.27 | 0.07 | 13.27 | 0.00 | -0.06 | 0.77 (0.67, 0.88) |
| ICD Type: Dual Chamber | -0.03 | 0.06 | 0.33 | 0.56 | -0.01 | 0.97 (0.87, 1.08) |

* N=30,212 in 1,080 hospitals; 7.28% mortality or complication rate

### 3.1.3 Model Validation

We compared the model performance in the development sample with its performance in a similarly derived sample from patients discharged in 2006 who had undergone ICD implantation. There were 27,370 patient stays in 1,023 hospitals in the 2006 validation dataset. This validation sample had a crude complication rate of 6.65%.

The standardized estimates and standard errors for the 2006 validation dataset are shown in Table 11, and the performance metrics are shown in Table 12. The performance was not substantively different in this validation sample (ROC=0.608), as compared to the development sample (ROC=0.611). As the results in Table 12 show, the 2006 and 2007 models are similarly calibrated.

We also examined the temporal variation of the standardized estimates and frequencies of the variables in the models (Tables 13 and 14). The frequencies and regression coefficients are fairly consistent over the two years of data.

To assess the predictive ability of the model, we grouped patients into deciles of predicted complication rate. We then compared predicted complication rate with observed complication rate for each decile in the derivation cohort (Figure 4). Overall there was excellent correlation between predicted and observed complication rate.

**Table 11** – ICD Related Complication Model (2006 Validation Sample-GLM Results [ROC:0.608])*

| Variable Description | Estimate | Standard Error | Wald Chi-Square | Pr > ChiSq | Standardized Estimates | OR (LOR, UOR) |
|---|---|---|---|---|---|---|
| Age | 0.00 | 0.00 | 0.70 | 0.40 | 0.01 | 1.00 (1.00, 1.01) |
| Female | 0.27 | 0.05 | 25.23 | 0.00 | 0.07 | 1.31 (1.18, 1.45) |
| Hospital Reason: Hospitalized-Cardiac | 0.28 | 0.07 | 17.21 | 0.00 | 0.05 | 1.32 (1.16, 1.50) |
| Hospital Reason: Hospitalized-Non-Cardiac | 0.21 | 0.06 | 12.77 | 0.00 | 0.05 | 1.24 (1.10, 1.39) |
| NYHAC: II | -0.04 | 0.10 | 0.20 | 0.65 | -0.01 | 0.96 (0.79, 1.16) |
| NYHAC: III | 0.17 | 0.10 | 3.32 | 0.07 | 0.05 | 1.19 (0.99, 1.43) |
| NYHAC: IV | 0.33 | 0.13 | 6.95 | 0.01 | 0.04 | 1.40 (1.09, 1.79) |
| Previous CABG | -0.13 | 0.05 | 6.79 | 0.01 | -0.04 | 0.87 (0.79, 0.97) |
| Chronic Lung Disease | 0.18 | 0.06 | 10.00 | 0.00 | 0.04 | 1.19 (1.07, 1.33) |
| Hypertension | 0.01 | 0.06 | 0.01 | 0.92 | 0.00 | 1.01 (0.90, 1.13) |
| Renal Failure-Dialysis | 0.29 | 0.11 | 7.36 | 0.01 | 0.03 | 1.33 (1.08, 1.64) |
| AVC: Abnormal-1st Degree Heart Block Only | 0.01 | 0.06 | 0.02 | 0.88 | 0.00 | 1.01 (0.89, 1.15) |
| AVC: Abnormal-Heart Block 2nd or 3rd Degree | 0.30 | 0.09 | 10.46 | 0.00 | 0.04 | 1.34 (1.12, 1.61) |
| AVC: Paced (any) | 0.23 | 0.08 | 8.51 | 0.00 | 0.04 | 1.25 (1.08, 1.46) |
| BUN > 30 mg/dl | 0.25 | 0.05 | 20.52 | 0.00 | 0.06 | 1.28 (1.15, 1.42) |
| Sodium < 135 | 0.21 | 0.07 | 8.93 | 0.00 | 0.04 | 1.24 (1.08, 1.42) |
| Sodium > 145 | -0.08 | 0.24 | 0.12 | 0.73 | 0.00 | 0.92 (0.58, 1.47) |
| SBP < 100 mmHG | 0.18 | 0.10 | 2.96 | 0.09 | 0.02 | 1.19 (0.98, 1.46) |
| ICD Type: Single Chamber | -0.27 | 0.08 | 11.71 | 0.00 | -0.06 | 0.77 (0.66, 0.89) |
| ICD Type: Dual Chamber | -0.13 | 0.06 | 4.25 | 0.04 | -0.03 | 0.88 (0.78, 0.99) |

* N=27,370 in 1,023 hospitals; 6.65% mortality or complication rate

**Table 12** – ICD Related Complication Model Performance: Results Based on the GLM

| Indices | Development Sample | Validation Sample |
|---|---|---|
| Year | 2007 | 2006 |
| N | 30212 | 27,370 |
| CR | 7.28% | 6.65% |
| Calibration (γ0, γ1)[1] | (0.00, 1.00) | (-0.32, 0.91) |
| Discrimination- Adjusted R-Square[2] | 0.03 | 0.02 |
| Discrimination -Predictive Ability[3] (lowest decile %, highest decile %) | (3.8%, 13.2%) | (3.2%, 11.4%) |
| Discrimination – ROC | 0.611 | 0.608 |
| Residuals Lack of Fit (Pearson Residual Fall %) | | |
| <-2 | 0.00 | 0.00 |
| [-2, 0) | 92.73 | 93.35 |
| [0, 2) | 0.06 | 0.02 |
| [2+ | 7.22 | 6.62 |
| Model $\chi^2$ [Number of Covariates][4] | 325.613 [20] | 257.045 [20] |

[1] Over-Fitting Indices ($\gamma_0$, $\gamma_1$) provide evidence of over-fitting and require several steps to calculate. Let *b* denote the *estimated vector* of regression coefficients. *Predicted Probabilities* ( $\hat{p}$ ) = 1/(1+exp{-Xb}), and *Z* = *Xb* (e.g., the linear predictor that is a scalar value for everyone). A new logistic regression model that includes only an intercept and a slope by regressing the logits on Z is fitted in the validation sample; e.g., Logit(P(Y=1|Z)) = $\gamma_0 + \gamma_1 Z$. Estimated values of $\gamma_0$ far from 0 and estimated values of $\gamma_1$ far from 1 provide evidence of over-fitting.

[2] Max-rescaled R-Square

[3] Observed rates

[4] Wald Chi-square

**Figure 4** – Observed Complications by Predicted Complications per Decile ($R^2$=0.9798)

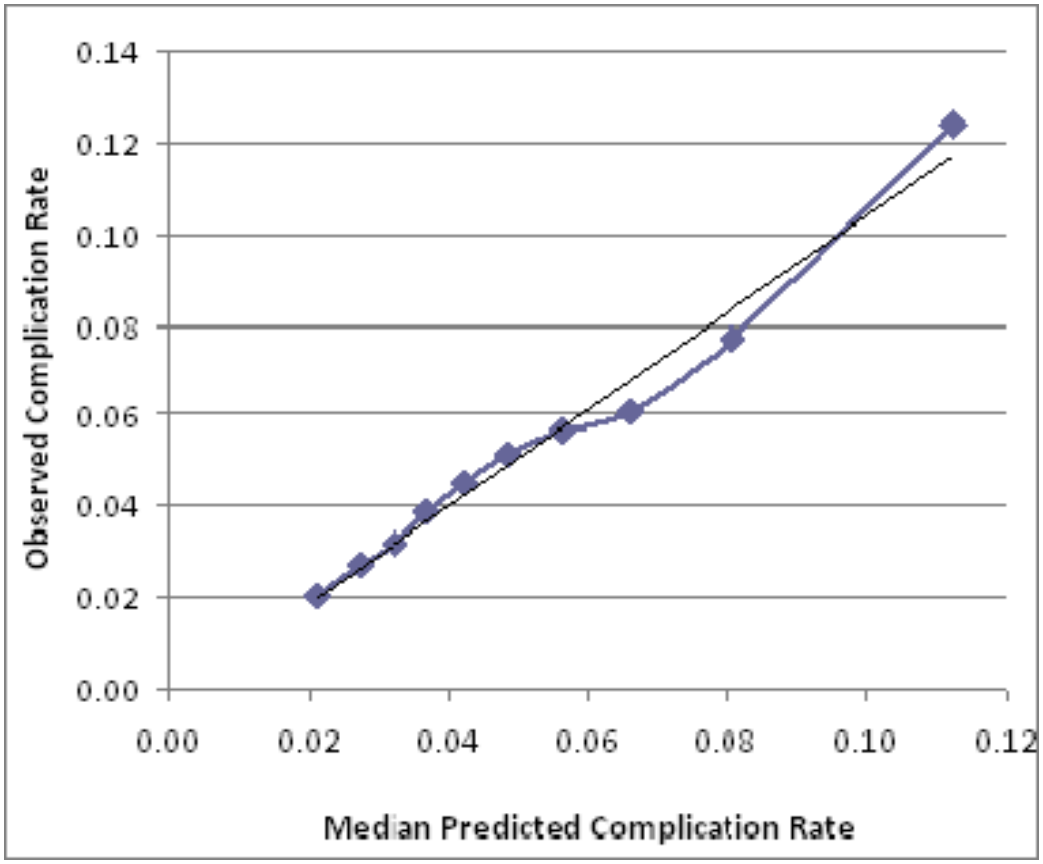


**Table 13** – ICD Related Complication Model (GLM) Standardized Estimates by Year of Discharge (2006-2007)

| **Variable Description** | **2006 (Validation)** (N=27,370 in 1,023 hospitals; 6.65% C/MR*) | **2007 (Development)** (N=30,212 in 1,080 hospitals; 7.28% C/MR) |
|---|---|---|
| Age | 0.01 | 0.02 |
| Female | 0.07 | 0.04 |
| Hospital Reason: Hospitalized-Cardiac | 0.05 | 0.04 |
| Hospital Reason: Hospitalized-Non-Cardiac | 0.05 | 0.05 |
| NYHAC: II | -0.01 | 0.01 |
| NYHAC: III | 0.05 | 0.05 |
| NYHAC: IV | 0.04 | 0.05 |
| Previous CABG | -0.04 | -0.07 |
| Chronic Lung Disease | 0.04 | 0.04 |
| Hypertension | 0.00 | -0.03 |
| Renal Failure-Dialysis | 0.03 | 0.03 |
| AVC: Abnormal-1st Degree Heart Block Only | 0.00 | 0.01 |
| AVC: Abnormal-Heart Block 2nd or 3rd Degree | 0.04 | 0.04 |
| AVC: Paced (any) | 0.04 | 0.04 |
| BUN > 30 mg/dl | 0.06 | 0.08 |
| Sodium < 135 | 0.04 | 0.04 |
| Sodium > 145 | 0.00 | 0.02 |
| SBP < 100 mmHG | 0.02 | 0.04 |
| ICD Type: Single Chamber | -0.06 | -0.06 |
| ICD Type: Dual Chamber | -0.03 | -0.01 |

* C/MR=Complication or mortality rate

**Table 14** – ICD Related Complication Model (GLM) Risk Factor Frequency by Year of Discharge (2006-2007)

| **Variable Description** | **2006 (Validation)** (N=27,370 in 1,023 hospitals; 6.65% C/MR[†]) | **2007 (Development)** (N=30,212 in 1,080 hospitals; 7.28% C/MR) |
|---|---|---|
| Age | 6.2 | 6.2 |
| Female | 27.0 | 27.2 |
| Hospital Reason: Hospitalized-Cardiac | 14.3 | 15.0 |
| Hospital Reason: Hospitalized-Non-Cardiac | 23.9 | 25.2 |
| NYHAC: II | 32.2 | 33.4 |
| NYHAC: III | 51.4 | 52.3 |
| NYHAC: IV | 5.6 | 4.9 |
| Previous CABG | 41.5 | 41.6 |
| Chronic Lung Disease | 23.4 | 25.2 |
| Hypertension | 76.1 | 79.3 |
| Renal Failure-Dialysis | 4.2 | 4.6 |
| AVC: Abnormal-1st Degree Heart Block Only | 20.2 | 20.0 |
| AVC: Abnormal-Heart Block 2nd or 3rd Degree | 6.4 | 5.0 |
| AVC: Paced (any) | 10.5 | 11.8 |
| BUN > 30 mg/dl | 26.9 | 27.6 |
| Sodium < 135 | 11.0 | 11.0 |
| Sodium > 145 | 1.1 | 1.2 |
| SBP < 100 mmHG | 4.8 | 4.8 |
| ICD Type: Single Chamber | 19.7 | 18.5 |
| ICD Type: Dual Chamber | 38.0 | 38.4 |

[†] C/MR = Complication or mortality rate

**Table 15** – ICD Related Complication Model (2007 Development Sample – HGLM Results [ROC=0.650])[*] [+]

| Description | Estimate | Standard Error | T-Value | Pr > T-Value | Odds Ratio (95% CI) |
|---|---|---|---|---|---|
| Intercept | -3.30 | 0.29 | -11.52 | 0.00 | |
| Age | 0.01 | 0.00 | 1.76 | 0.08 | 1.01 (1.00, 1.01) |
| Female | 0.18 | 0.05 | 3.71 | 0.00 | 1.20 (1.09, 1.31) |
| Hospital Reason: Hospitalized-Cardiac | 0.18 | 0.06 | 2.92 | 0.00 | 1.20 (1.06, 1.35) |
| Hospital Reason: Hospitalized-Non-Cardiac | 0.19 | 0.05 | 3.59 | 0.00 | 1.21 (1.09, 1.34) |
| NYHAC: II | 0.01 | 0.09 | 0.13 | 0.89 | 1.01 (0.85, 1.21) |
| NYHAC: III | 0.18 | 0.09 | 1.98 | 0.05 | 1.20 (1.00, 1.43) |
| NYHAC: IV | 0.44 | 0.12 | 3.70 | 0.00 | 1.56 (1.23, 1.97) |
| Previous CABG | -0.27 | 0.05 | -5.89 | 0.00 | 0.76 (0.69, 0.83) |
| Chronic Lung Disease | 0.18 | 0.05 | 3.60 | 0.00 | 1.19 (1.08, 1.31) |
| Hypertension | -0.12 | 0.05 | -2.21 | 0.03 | 0.89 (0.80, 0.99) |
| Renal Failure-Dialysis | 0.28 | 0.09 | 3.13 | 0.00 | 1.33 (1.11, 1.59) |
| AVC: Abnormal-1st Degree Heart Block Only | 0.05 | 0.06 | 0.93 | 0.35 | 1.05 (0.94, 1.18) |
| AVC: Abnormal-Heart Block 2nd or 3rd Degree | 0.31 | 0.09 | 3.45 | 0.00 | 1.37 (1.14, 1.63) |
| AVC: Paced (any) | 0.20 | 0.07 | 2.92 | 0.00 | 1.22 (1.07, 1.39) |
| BUN > 30 mg/dl | 0.32 | 0.05 | 6.58 | 0.00 | 1.37 (1.25, 1.51) |
| Sodium < 135 | 0.23 | 0.06 | 3.68 | 0.00 | 1.26 (1.12, 1.43) |
| Sodium > 145 | 0.37 | 0.17 | 2.16 | 0.03 | 1.45 (1.04, 2.02) |
| SBP < 100 mmHG | 0.30 | 0.09 | 3.36 | 0.00 | 1.35 (1.13, 1.60) |
| ICD Type: Single Chamber | -0.26 | 0.07 | -3.64 | 0.00 | 0.77 (0.67, 0.89) |
| ICD Type: Dual Chamber | -0.03 | 0.06 | -0.58 | 0.56 | 0.97 (0.87, 1.08) |

[*] Between hospital variance = 0.06789, standard error = 0.02109

[+] N=30,212 in 1,080 hospitals; 7.28% complication or mortality rate

### 3.1.4 ICD Related Complication Rate Distribution - With and Without Risk-Adjustment

Figures 5 and 6 display the frequency distributions of the hospital-specific complication rates, with and without risk-adjustment in the 2007 derivation cohort. Subsequent figures Figures 7, 8, and 9 display these results by hospital volume for the unadjusted rates (figures 7, 8, and 9) and risk-adjusted rates (figures 10, 11, and 12).

The observed complication rate ranged from 0% to 100% across the 1,080 hospitals (Figure 5), with low-volume hospitals demonstrating the greatest variation in crude rates (Figure 7). After adjusting for patient and clinical characteristics, the risk-standardized rates were found to be more normally distributed, both overall (Figure 6) and by hospital volume (figures 10, 11, and 12).

**Figure 5** – Distribution of Hospital Unadjusted Complication Rates (2007 Development Sample; N=1,080 Hospitals)

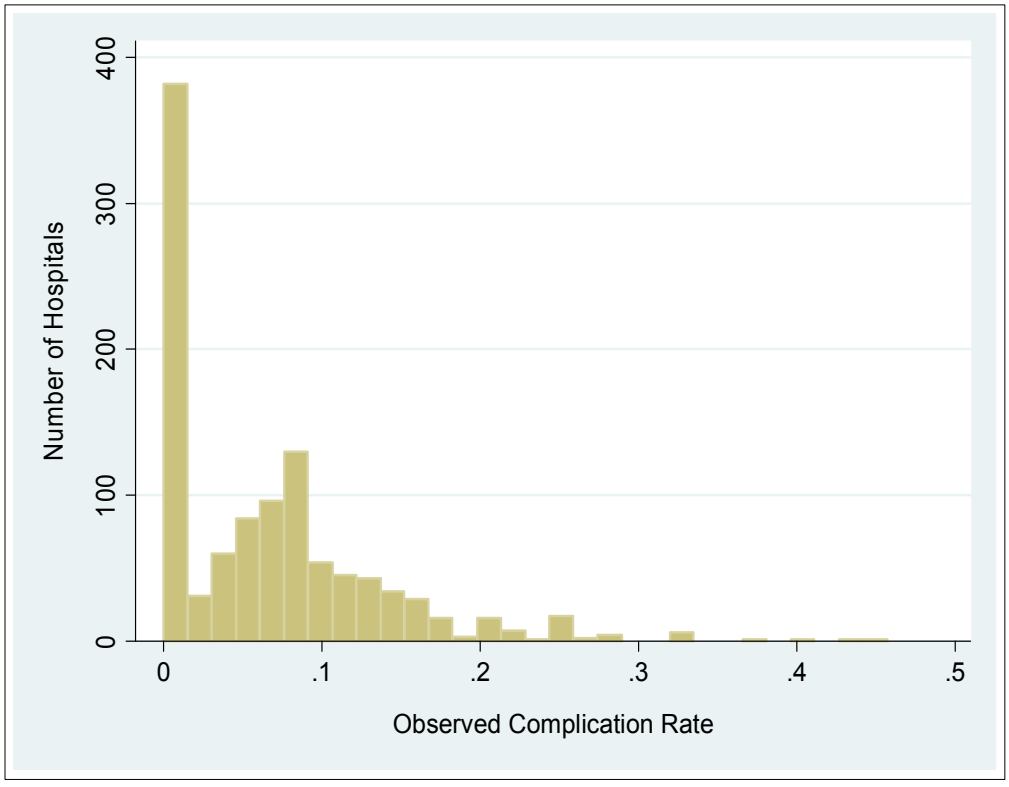


**Figure 6** – Distribution of Hospital Risk-Standardized Complication Rates (2007 Development Sample; N=1,080 Hospitals) – HGLM

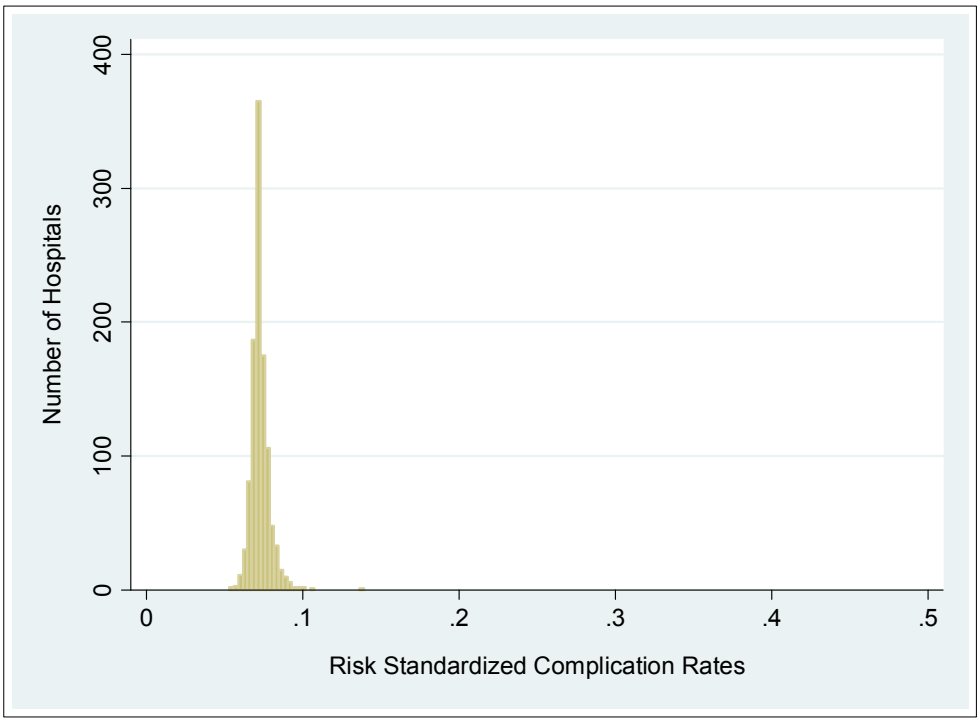



**Figure 7** – Distribution of Hospital Unadjusted Complication Rates for Hospitals with Fewer than 25 Cases in 2007 (Development Sample; N=646 Hospitals)

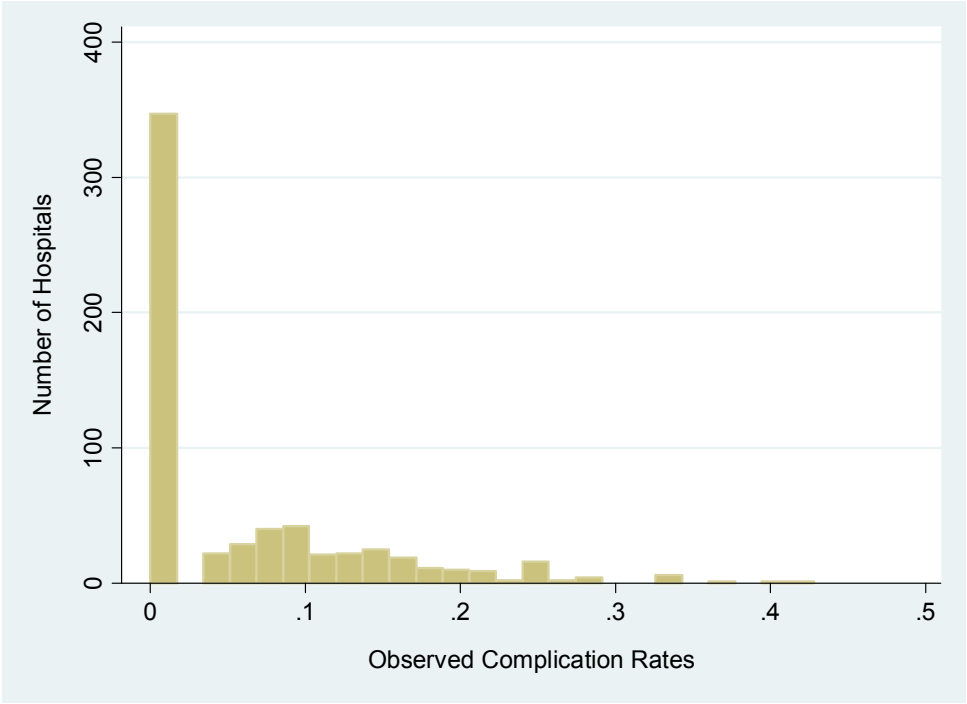


**Figure 8** – Distribution of Hospital Unadjusted Complication Rates for Hospitals with Between 25 and 50 Cases in 2007 (Development Sample; N=252 Hospitals)

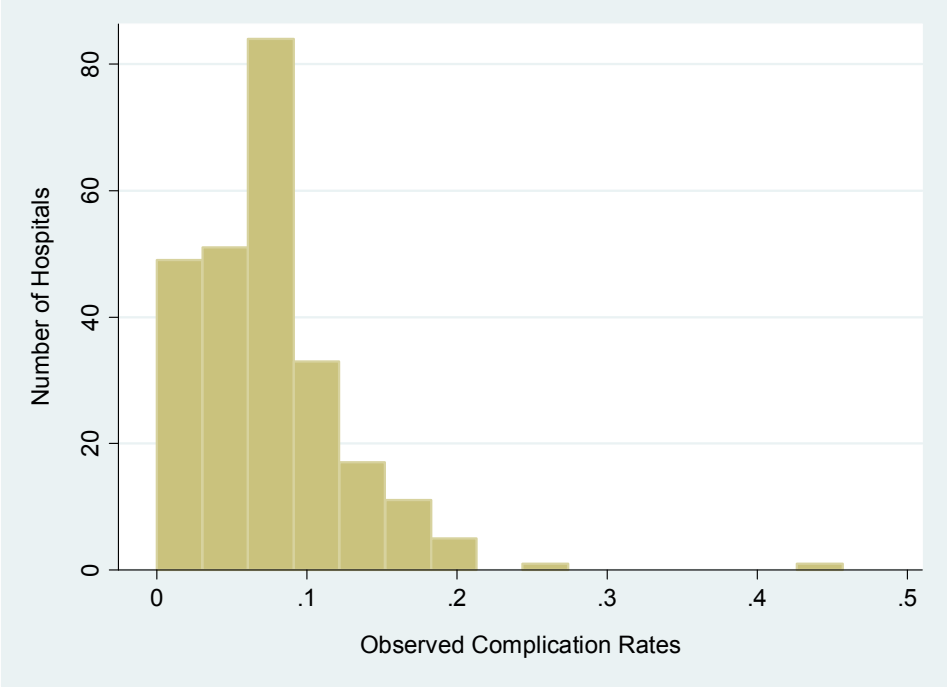



**Figure 9** – Distribution of Hospital Unadjusted Complication Rates for Hospitals with Greater than 50 Cases in 2007 (Development Sample; N=182 Hospitals)

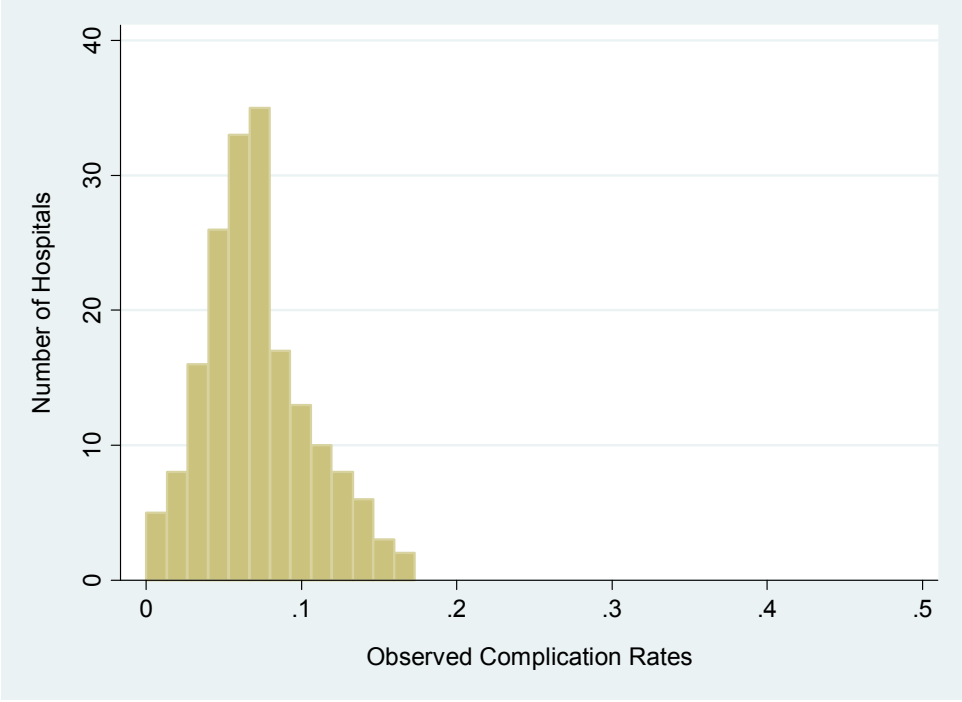


**Figure 10** – Distribution of Hospital Risk-Standardized Complication Rates for Hospitals with Fewer than 25 Cases in 2007 (Development Sample; N=646 Hospitals)

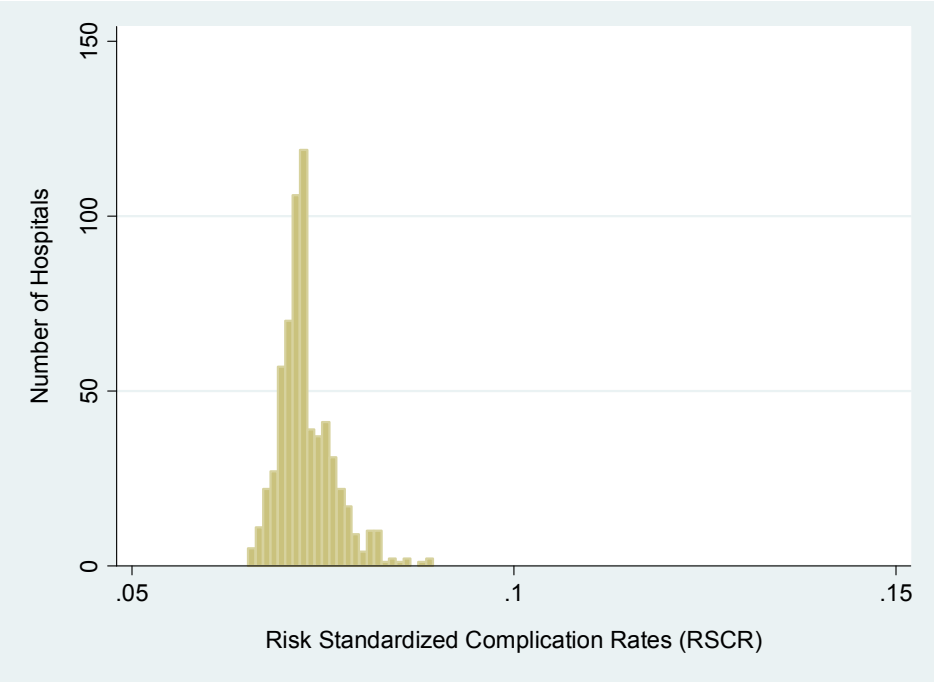



**Figure 11** – Distribution of Hospital Risk-Standardized Complication Rates for Hospitals with Between 25 and 50 Cases in 2007 (Development Sample; N=252 Hospitals)

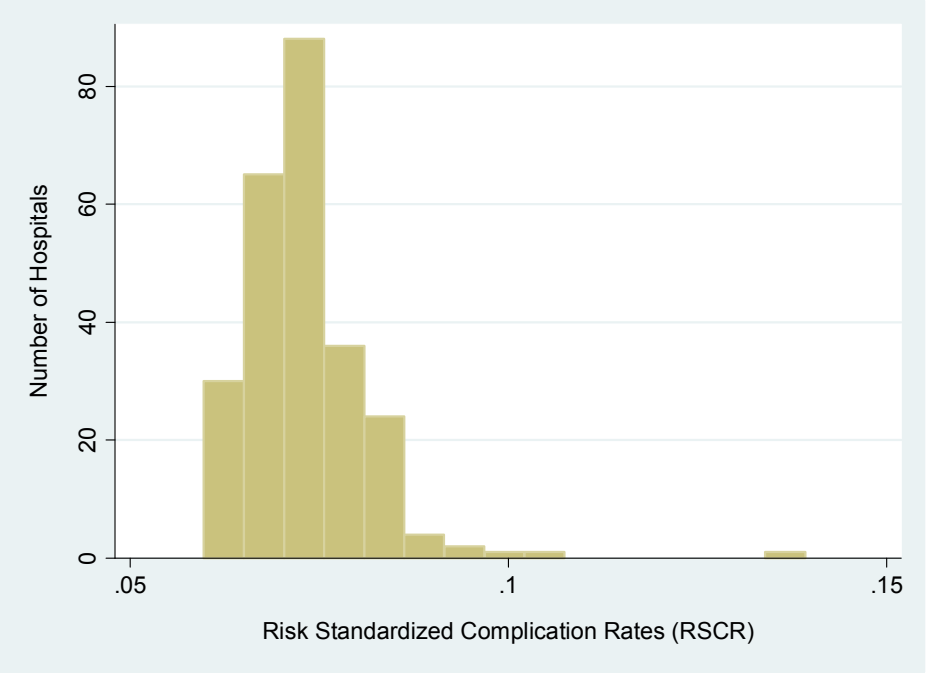
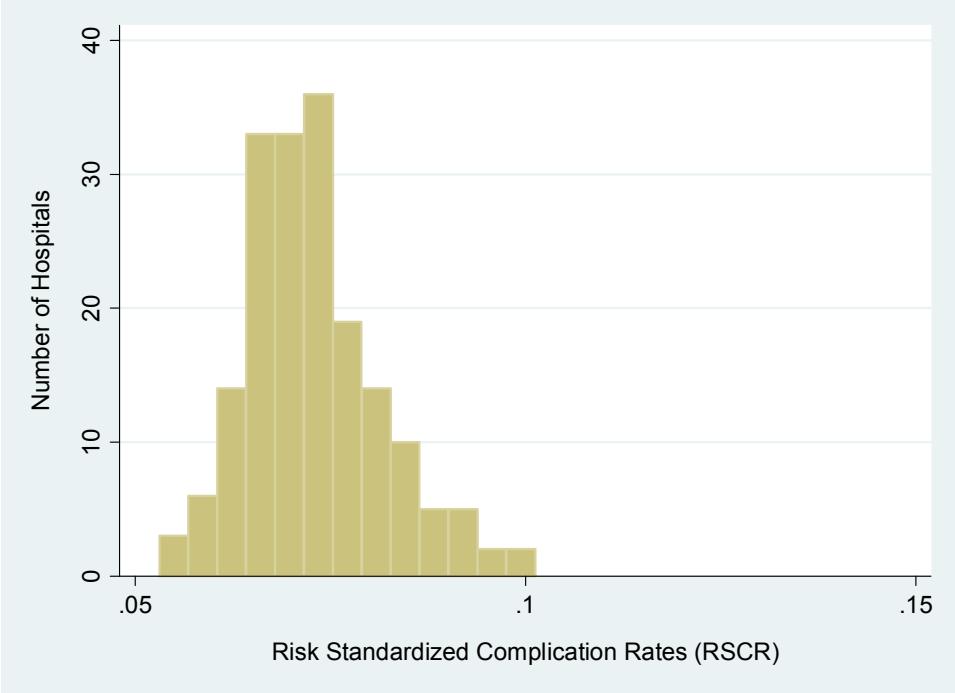


**Figure 12** – Distribution of Hospital Risk-Standardized Complication Rates for Hospitals with Greater than 50 Cases in 2007 (Development Sample; N=182 Hospitals)



# 4. POTENTIAL APPROACHES TO IMPLEMENTATION

While the model we developed has attributes that make it suitable for public reporting, it could be further strengthened in several ways. The claims used to identify complications will be further validated against chart abstraction at additional sites representative of hospitals that implant ICDs to ensure that the sensitivity and specificity of these codes are adequate to fairly characterize hospital performance (to be completed within 12 months). In addition, the proposed measure excludes patients with prior ICDs. In the future, this population could be included in the measure when present on admission codes are available. Furthermore, the use of claims data to identify complications means that the measure will only report the outcomes of ICD implantations performed on Medicare FFS patients. However, if suitable data become available (for example, by combining FFS data with either Medicare Advantage or other payors), the measure methodology could be applied to the broader population of patients undergoing ICD implantation.

Although the model we developed has attributes that make it suitable for public reporting, additional steps will ideally be necessary prior to implementation. First, implementing the measure will require linking clinical data regarding ICD implantation with administrative data sources based on a unique patient identifier common to both the ICD Registry and administrative data sets. Although a unique identifier is routinely collected by the ICD Registry on all Medicare patients undergoing ICD, this information could not be used during the process of measure development due to the nature of existing agreements between hospitals and the NCDR. Barriers to the collection and use of direct identifiers will need to be addressed prior to implementation. Second, although all hospitals that perform ICD implantation in the United States currently participate in the ICD Registry, not all hospitals submit data on their secondary prevention patients. Implementation of the proposed measure will require collecting data used for risk adjustment on all patients undergoing ICD implantation irrespective of the indication (ie both primary and secondary prevention).

Finally, 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.

## 5. MAIN FINDINGS / SUMMARY

The proposed measure of ICD complications has the potential to significantly improve the quality of care delivered to patients with advanced heart disease. The model used for risk adjustment meets recognized standards for outcomes measurement and was developed with extensive input from stakeholders with a broad range of expertise and perspectives. The study sample is appropriately defined, consisting of an ICD population that has distinct outcomes that will allow for valid comparisons of hospital quality. The definition of the complications, the complication-specific period of assessment, and the risk-adjustment variables all have strong face validity, which may facilitate physician acceptance. We excluded covariates that we would not want to adjust for in a quality measure. The statistical approach takes into account the clustering of patients within hospitals and differences in sample size across hospitals.

In summary, we present a registry-based model of ICD complications that is suitable for public reporting. The proposed measure capitalizes on the registry data already collected as part of an ongoing collaboration between CMS and professional societies. Accordingly, the incremental burden of data collection on hospitals would be small, and the proposed measure could be implemented by using the direct patient identifiers already being collected by the registry.

## 6. REFERENCES


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.

Al-Khatib, S.M., et al., The relation between patients' outcomes and the volume of cardioverter-defibrillator implantation procedures performed by physicians treating Medicare beneficiaries. Journal of the American College of Cardiology, 2005. 46(8): p. 1536-40.

Bardy GH, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med (2005) 352:225–37.

Brown, D.W., Croft, J.B., et al. (2008). “Trends in Hospitalizations for the Implantation of Cardioverter-Defibrillators in the United States, 1990-2005.” American Journal of Cardiology 101 (12): 1753-1755.

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.

Fleming C, Fisher ES, Chang CH, Bubolz TA, Malenka DJ. Study outcomes and hospital utilization in the elderly: the advantages of a merged database for Medicare and Veterans Affairs hospitals. Med Care. 1992;30:377-391

Gatsonia CA, D. M. (1999). "Hierarchical Generalized Linear Models in the Analysis of Variations in Health Care Utilization." Journal of the American Statistical Assocation 94(445): 29.

Hammill S and Curtis J. Publicly Reporting Implantable Cardioverter Defibrillator Outcomes – Grading the Report Card. Circ Arrhythmia Electrophysiol. 2008;1:235-237).

Krumholz, H. M., R. G. Brindis, et al. (2006). "Standards for statistical models used for public reporting of health outcomes: an American Heart Association Scientific Statement from the Quality of Care and Outcomes Research Interdisciplinary Writing Group: cosponsored by the Council on Epidemiology and Prevention and the Stroke Council. Endorsed by the American College of Cardiology Foundation." Circulation 113(3): 456-62.

McCullagh P, N. J. (1989). Generalized Linear Models, Chapman and Hall.

Medicare Payment Advisory Committee (MedPAC) Report to the Congress: Promoting Greater Efficiency in Medicare. Available at http://www.medpac.gov/documents/Jun07_EntireReport.pdf, accessed August 3, 2009.

Mehta, S.K, Frutkin, A. D., et al. on Behalf of the National Cardiovascular Data Registry. Bleeding in Patients Undergoing Percutaneous Coronary Intervention: The Development of a Clinical Risk Algorithm From the National Cardiovascular Data Registry. Circ Cardiovasc Intervent 2: 222-229; published online before print as doi:10.1161/CIRCINTERVENTIONS.108.846741

Moss AJ, Zareba W, Hall WJ; et al, Multicenter Automatic Defibrillator Implantation Trial II Investigators. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. New England Journal of Medicine. 2002;346(12):877-883.

Normand, S. L. (2008). Percutaneous Coronary Intervention in the Commonwealth of Massachusetts Fiscal Year 2006 Report: October 1, 2005 - September 30, 2006. Boston, MA, Massachusetts Data Analysis Center, Department of Health Care Policy-Harvard Medical School: 1-52.

Normand, S. L., Y Wang, et al. (2007). "Assessing surrogacy of data sources for institutional comparisons." Health Services and Outcomes Research Methodology 7:79-96.

Reynolds, M.R., et al., The frequency and incremental cost of major complications among medicare beneficiaries receiving implantable cardioverter-defibrillators. Journal of the American College of Cardiology, 2006. 47(12): p. 2493-7.

Rosamond W, Flegal K, et al. Heart Disease and Stroke Statistics_2008 Update: A Report From the American Heart Association Statistics Committee and Stroke Statistics Subcommittee and for the American Heart Association Statistics Committee and Stroke Statistics Subcommittee *Circulation* 2008;117;e25-e146; originally published online Dec 17, 2007; DOI: 10.1161/CIRCULATIONAHA.107.187998

Sanders GD, Hlatky MA, Owens DK. Cost-Effectiveness of Implantable Cardioverter-Defibrillators. *N Engl J M*. 2005;353;1471-1480.

YNHH-CORE (2008). Medicare Quality Measurement Support Project: Mortality Implementation and Measure Development and Monitoring: Measure Specific Literature Review-Cardiac Registry Task. New Haven, CT, Yale New Haven Hospital-Center for Outcomes Research & Evaluation: 1-21.

# 7. APPENDIX

## 7.1 Appendix A: ICD-9 Code Definitions

| Complication | ICD-9 Code ( Type) | Definition |
|---|---|---|
| Pneumothorax or hemothorax, plus a chest tube | 511.8 (Diagnosis Code) | Other specified forms of pleural effusion except tuberculosis |
| | 512.1 (Diagnosis Code) | Iatrogenic pneumothorax |
| | 34.04 (Procedure Code) | Insertion of intercostal catheter for drainage |
| | 34.05 (Procedure Code) | Creation of intercostal catheter for drainage |
| | 34.06 (Procedure Code) | Thoracoscopic drainage of pleural cavity |
| | 34.09 (Procedure Code) | Other incision of pleura |
| Hematoma, with a blood transfusion or evacuation | 998.1 (Diagnosis Code) | Hemorrhage or hematoma complicating a procedure not elsewhere classified |
| | 518.7 (Diagnosis Code) | Transfusion related acute lung injury (trali) |
| | 287.4 (Diagnosis Code) | Secondary thrombocytopenia |
| | V58.2 (Diagnosis Code) | Blood transfusion without reported diagnosis |
| | V59.01 (Diagnosis Code) | Blood donors whole blood |
| | 99.00 (Procedure Code) | Perioperative autologous transfusion of whole blood or blood components |
| | 99.03 (Procedure Code) | Other transfusion of whole blood |
| | 99.04 (Procedure Code) | Transfusion of packed cells |
| | 34.04 (Procedure Code) | Insertion of intercostal catheter for drainage |
| | 34.09 (Procedure Code) | Other incision of pleura |
| Cardiac Tamponade or pericardiocentesis | 420 (Diagnosis Code) | Acute pericarditis |
| | 423.0 (Diagnosis Code) | Hemopericardium |
| | 423.3 (Diagnosis Code) | Cardiac tamponade |
| | 423.9 (Diagnosis Code) | Unspecified disease of pericardium |
| | 37.0 (Procedure Code) | Pericardiocentesis |
| | 37.12 (Procedure Code) | Pericardiotomy |

7.1 Appendix A: ICD-9 Code Definitions *(cont.)*

| Complication | ICD-9 Code ( Type) | Definition |
|---|---|---|
| Mechanical Complications requiring a system revision | 996.0 (Diagnosis Code) | Mechanical complication of cardiac device implant and graft |
| | 37.75 (Procedure Code) | Revision of lead [electrode] |
| | 37.79 (Procedure Code) | Revision or relocation of pacemaker pocket |
| | 37.97 (Procedure Code) | Replacement of automatic cardioverter/defibrillator lead(s) only |
| | 37.99 (Procedure Code) | Revision or relocation of pacemaker, defibrillator or other implanted cardiac device |
| | 00.52 (Procedure Code) | Implantation or replacement of transvenous lead [electrode] into left ventricular coronary venous system |
| Infection that is device related | 996.61 (Diagnosis Code) | Infection and inflammatory reaction due to cardiac device implant and graft |
| Second ICD within 90 days of the index procedure | 00.50 (Procedure Code) | Implantation of cardiac resynchronization pacemaker without mention of defibrillation, total system (crt-p) |
| | 00.51 (Procedure Code) | Implantation of cardiac resynchronization defibrillator, total system (crt-d) |
| | 00.52 (Procedure Code) | Implantation or replacement of transvenous lead [electrode] into left ventricular coronary venous system |
| | 00.53 (Procedure Code) | Implantation or replacement of cardiac resynchronization pacemaker pulse generator only (crt-p) |
| | 00.54 (Procedure Code) | Implantation or replacement of cardiac resynchronization defibrillator pulse generator device only (crt-d) |
| | 37.94 (Procedure Code) | Implantation or replacement of automatic cardioverter/defibrillator, total system (aicd) |

## 7.2 Appendix B: CPT Code Definitions

| Complication | CPT Code | Definition |
|---|---|---|
| Second ICD within 90 days of index procedure | 33216 | Insert Transvenous Electrode Single Chamber Pacemaker or ICD |
| | 33217 | Insert Transvenous Electrode Dual Chamber Pacemaker or ICD |
| | 33218 | Revision of Transvenous Electrode for Single Chamber, Permanent Pacemaker or ICD |
| | 33220 | Revision of Two Transvenous Electrodes for Dual Chamber, Permanent Pacemaker or ICD |
| | 33223 | Revision of Skin Pocket for Single or Dual Chamber ICD |
| | 33240 | Insertion of Single or Dual Chamber Pacing Cardioverter-Defibrillator Pulse Generator |
| | 33241 | Removal of Single or Dual Chamber Pacing Cardioverter-Defibrillator Pulse Generator |
| | 33249 | Insertion or repositioning of electrode leads for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator |

ICD Calculation Algorithm

Let *I* denote the total number of hospitals in the sample. We repeat steps 1 – 4 below for b = 1,2,…B times:

1. Sample *I* hospitals with replacement.

2. Fit the HGLM using all patients within each sampled hospital. We use as starting values the parameter estimates obtained by fitting the model to all hospitals. If some hospitals are selected more than once in a bootstrapped sample, we treat them as distinct so that we have *I* random effects to estimate the variance components. At the conclusion of Step 2, we have:
   a. $\hat{\beta}^{(b)}$ (the estimated regression coefficients of the risk factors).
   b. The parameters governing the random effects, hospital adjusted outcomes, distribution, $\hat{\mu}^{(b)}$ and $\hat{\tau}^{2(b)}$.
   c. The set of hospital-specific intercepts and corresponding variances, $\{\hat{\alpha}_i^{(b)}, \hat{\text{var}}\left(\alpha_i^{(b)}\right); i = 1,2,\ldots,I\}$.

3. We generate a hospital random effect by sampling from the distribution of the hospital-specific distribution obtained in Step 2c. We approximate the distribution for each random effect by a normal distribution. Thus, we draw $\alpha_i^{(b^*)} \sim N\left(\hat{\alpha}_i^{(b)}, \hat{\text{var}}\left(\hat{\alpha}_i^{(b)}\right)\right)$ for the unique set of hospitals sampled in Step 1.

4. Within each unique hospital *i* sampled in Step 1, and for each case *j* in that hospital, we calculate $\hat{y}_{ij}^{(b)}$, $\hat{e}_{ij}^{(b)}$, and $\hat{s}_i\left(Z\right)^{(b)}$ where $\hat{\beta}^{(b)}$ and $\hat{\mu}^{(b)}$ are obtained from Step 2 and $\hat{\alpha}_i^{(b^*)}$ is obtained from Step 3.

Ninety-five percent interval estimates (or alternative interval estimates) for the hospital-standardized outcome can be computed by identifying the 2.5$^{th}$ and 97.5$^{th}$ percentiles of randomly half of the B estimates (or the percentiles corresponding to the alternative desired intervals) (Normand, Wang et al. 2007).

**Figure 1** – Analysis Steps - Risk Factors Based on: NCDR ICD Registry Data