Measure #348: HRS-3 Implantable Cardioverter-Defibrillator (ICD) Complications Rate – National Quality Strategy Domain: Patient Safety

2017 OPTIONS FOR INDIVIDUAL MEASURES:
REGISTRY ONLY

MEASURE TYPE:
Outcome

DESCRIPTION:
Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD

INSTRUCTIONS:
This measure is to be reported a minimum of once per **performance period** for patients with a first time implantation of an ICD during the performance period. This measure may be reported by eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

NOTE: Include only patients that have had first time implantation through November 30 for evaluation of complications for 30 days and September 30 for evaluation of complications for 90 days post procedure within the performance period. This will allow the evaluation of ICD implant complications within the reporting year.

This is a risk adjusted measure. Please refer to the "Hierarchical logistic regression" at the end of this specification.

There are 2 performance rates to be calculated for this measure:

1. Complications or mortality at 30 days

OR

2. Complications at 90 days

Measure Reporting:
The listed denominator criteria is used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions allowed by the measure. The quality-data codes listed do not need to be submitted for registry-based submissions; however, these codes may be submitted for those registries that utilize claims data.

THERE ARE TWO REPORTING CRITERIA FOR THIS MEASURE:

1. Patients with first time implants with one or more complications or mortality within 30 days

OR

2. Patients with first time implants with one or more complications within 90 days

The eligible clinician should submit data on both reporting criteria 1 and 2 for a patient that meets the denominator.

REPORTING CRITERIA 1: ALL PATIENTS WITH FIRST TIME IMPLANTS WITH ONE OR MORE OF THE IDENTIFIED COMPLICATIONS OR MORTALITY WITHIN 30 DAYS

DENOMINATOR (REPORTING CRITERIA 1):
Patients with a first time implantation of an ICD

Denominator Instructions: Include patients with procedures that are performed ≥ 31 days prior to the end of the performance period. Denominator patients can be identified using the following ICD-10 codes.

Denominator Criteria (Eligible Cases):
Patient aged ≥ 65 years on date of encounter
AND
Implantation of ICD (ICD-10-PCS): 02H40JZ, 02H43JZ, 02H43KZ, 02H43MZ, 02H44JZ, 02H60JZ, 02H60KZ, 02H63JZ, 02H63KZ, 02H64JZ, 02H64KZ, 02H70KZ, 02H73KZ, 02H74KZ, 02HK0JZ, 02HK0KZ, 02HK3JZ, 02HK3KZ, 02HK4JZ, 02HK4KZ, 02HL0JZ, 02HL0KZ, 02HL3JZ, 02HL3KZ, 02HL4JZ, 02HL4KZ, 0JH607Z, 0JH608Z, 0JH609Z, 0JH637Z, 0JH638Z, 0JH639Z, 0JH807Z, 0JH808Z, 0JH809Z, 0JH837Z, 0JH838Z, 0JH839Z
AND/OR
Patient encounter during **performance period** (CPT): 33216, 33217, 33218, 33220, 33223, 33240, 33249
AND NOT
DENOMINATOR EXCLUSIONS:
Removal of ICD (ICD-10-PCS): 0JPT0PZ, 0JPT3PZ
AND/OR
Removal of ICD (CPT): 33241, 33262, 33263, 33264

NUMERATOR (REPORTING CRITERIA 1):
Number of patients with one or more of the following complications or mortality within 30 days (depending on the complication) following ICD implantation

Numerator Instructions:
INVERSE MEASURE - A lower calculated performance rate for this measure indicates better clinical care or control. The "Performance Not Met" numerator option for this measure is the representation of the better clinical quality or control. Reporting that numerator option will produce a performance rate that trends closer to 0%, as quality increases. For inverse measures a rate of 100% means all of the denominator eligible patients did not receive the appropriate care or were not in proper control.

Definition:
Complications measured for 30 days:

1. Death
2. Pneumothorax or hemothorax plus a chest tube
3. Hematoma plus a blood transfusion or evacuation
4. Cardiac tamponade or pericardiocentesis

Numerator Options:

Performance Met:	Documentation of patient with one or more complications or mortality within 30 days (G9267)

OR

Performance Not Met:	Documentation of patient without one or more complications and without mortality within 30 days (G9269)

OR

REPORTING CRITERIA 2: ALL PATIENTS WITH FIRST TIME IMPLANTS WITH ONE OR MORE OF THE IDENTIFIED COMPLICATIONS WITHIN 90 DAYS

DENOMINATOR (REPORTING CRITERIA 2):
Patients with a first time implantation of an ICD

Denominator Instructions: Include patients with procedures that are performed ≥ 91 days prior to the end of the performance period. Denominator patients can be identified using the following ICD-10 codes.

Denominator Criteria (Eligible Cases):
Patient aged ≥ 65 years on date of encounter
AND
Implantation of ICD (ICD-10-PCS): 02H40JZ, 02H43JZ, 02H43KZ, 02H43MZ, 02H44JZ, 02H60JZ, 02H60KZ, 02H63JZ, 02H63KZ, 02H64JZ, 02H64KZ, 02H70KZ, 02H73KZ, 02H74KZ, 02HK0JZ, 02HK0KZ, 02HK3JZ, 02HK3KZ, 02HK4JZ, 02HK4KZ, 02HL0JZ, 02HL0KZ, 02HL3JZ, 02HL3KZ, 02HL4JZ, 02HL4KZ, 0JH607Z, 0JH608Z, 0JH609Z, 0JH637Z, 0JH638Z, 0JH639Z, 0JH807Z, 0JH808Z, 0JH809Z, 0JH837Z, 0JH838Z, 0JH839Z
AND/OR
Patient encounter during **performance period** (CPT): 33216, 33217, 33218, 33220, 33223, 33240, 33241, 33249, 33262, 33263, 33264
AND NOT
DENOMINATOR EXCLUSIONS:
Removal of ICD (ICD-10-PCS): 0JPT0PZ, 0JPT3PZ
AND/OR
Removal of ICD (CPT): 33241, 33262, 33263, 33264

NUMERATOR (REPORTING CRITERIA 2):
Number of patients with one or more of the following complications within 90 days (depending on the complication) following ICD implantation

Numerator Instructions:
INVERSE MEASURE - A lower calculated performance rate for this measure indicates better clinical care or control. The "Performance Not Met" numerator option for this measure is the representation of the better clinical quality or control. Reporting that numerator option will produce a performance rate that trends closer to 0%, as quality increases. For inverse measures a rate of 100% means all of the denominator eligible patients did not receive the appropriate care or were not in proper control.

Definition:
Complications measured for 90 days:

1. Mechanical complications requiring a system revision
2. Device related infection
3. Additional ICD implantation

Numerator Options:

Performance Met:	Documentation of patient with one or more complications within 90 days (G9268)
OR	
Performance Not Met:	Documentation of patient without one or more complications within 90 days (G9270)

RATIONALE:
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 physician 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.

In summary, we present an ICD complications measure that is suitable for public reporting. The proposed measure capitalizes on the National Cardiovascular Data Registry (NCDR) ICD Registry data already collected as part of an ongoing collaboration between CMS and NCDR. Accordingly, the incremental burden of data collection on physicians would be minimal and the proposed measure could be implemented by using the direct patient identifiers already being collected by CMS.

CLINICAL RECOMMENDATION STATEMENTS:
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 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.
- 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 Medicare FFS administrative claims to assess complications rates following ICD implantation. From 2006 through 2009, a total of 105,575 implants performed by 3,488 physicians met inclusion/exclusion criteria and were included in the analysis. The number of eligible implants increased over time from 22,931 in 2006 to 28,383. The overall complication rate decreased modestly over this time period, from 8.60% to 7.55%. The rate of mechanical complications requiring system revision had the largest decrease over time (0.78%), but similar relative declines were seen across all complications. As expected, the characteristics of patients with and without adverse events differed significantly. Most notably, patients receiving a CRT-D device had a significantly higher complication rate than patients receiving a single and dual chamber device (8.09%, 6.30%, and 5.33% respectively). These results demonstrate an opportunity to improve physician-level performance.

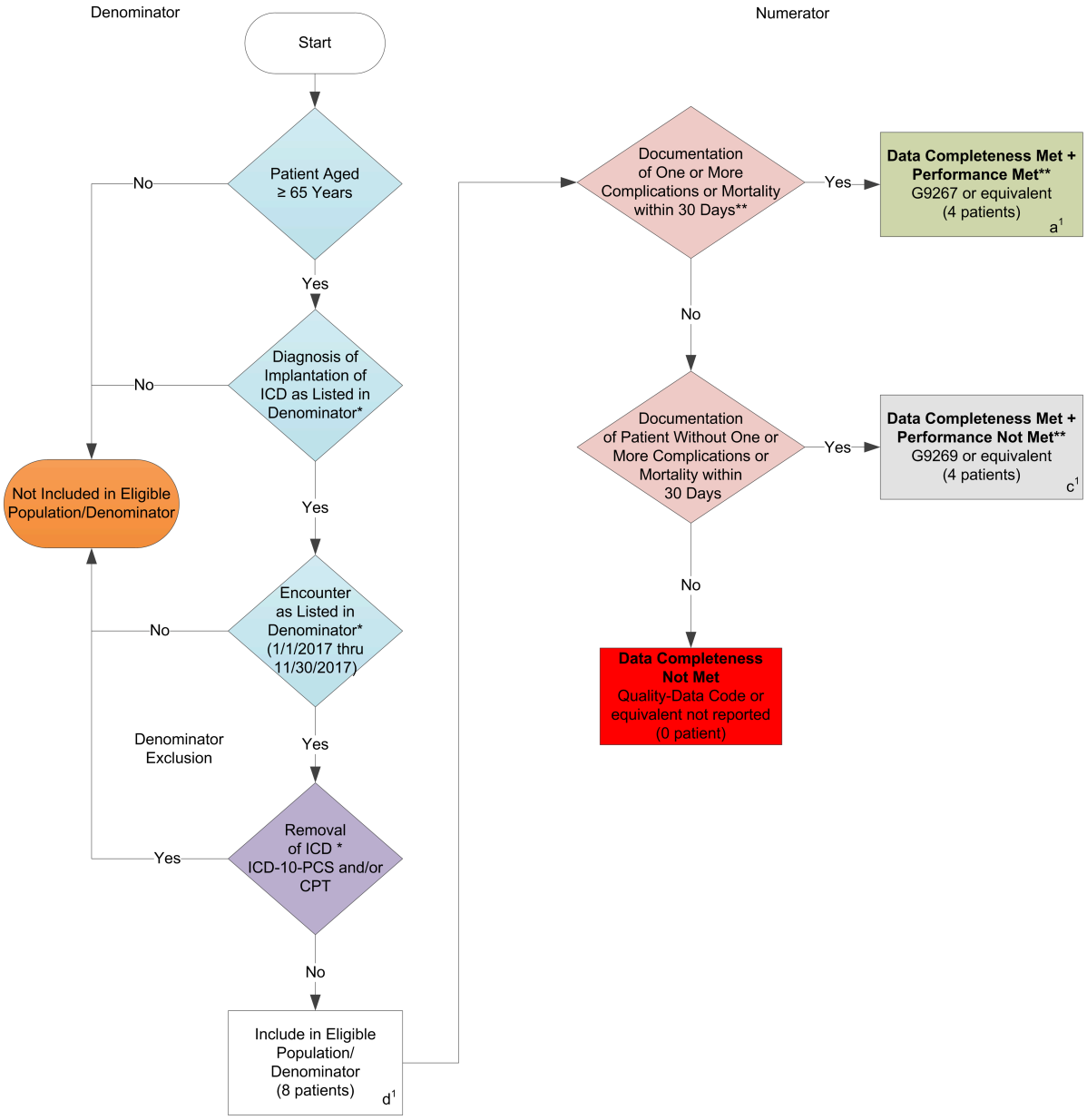
Hierarchical logistic regression

The specification is designed to align with the NQF-endorsed *Hospital Risk-Standardized Complication Rate following Implantation of Implantable Cardioverter-Defibrillator* performance measure (NQF #0694).

The variables apply to both the 30 and 90 day outcomes, but how the variables are to be utilized within the performance calculation is part of a risk model developed by Yale.

2017 Registry Individual Measure Flow
#348 HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate
Reporting Criteria One

Multiple Performance Rate

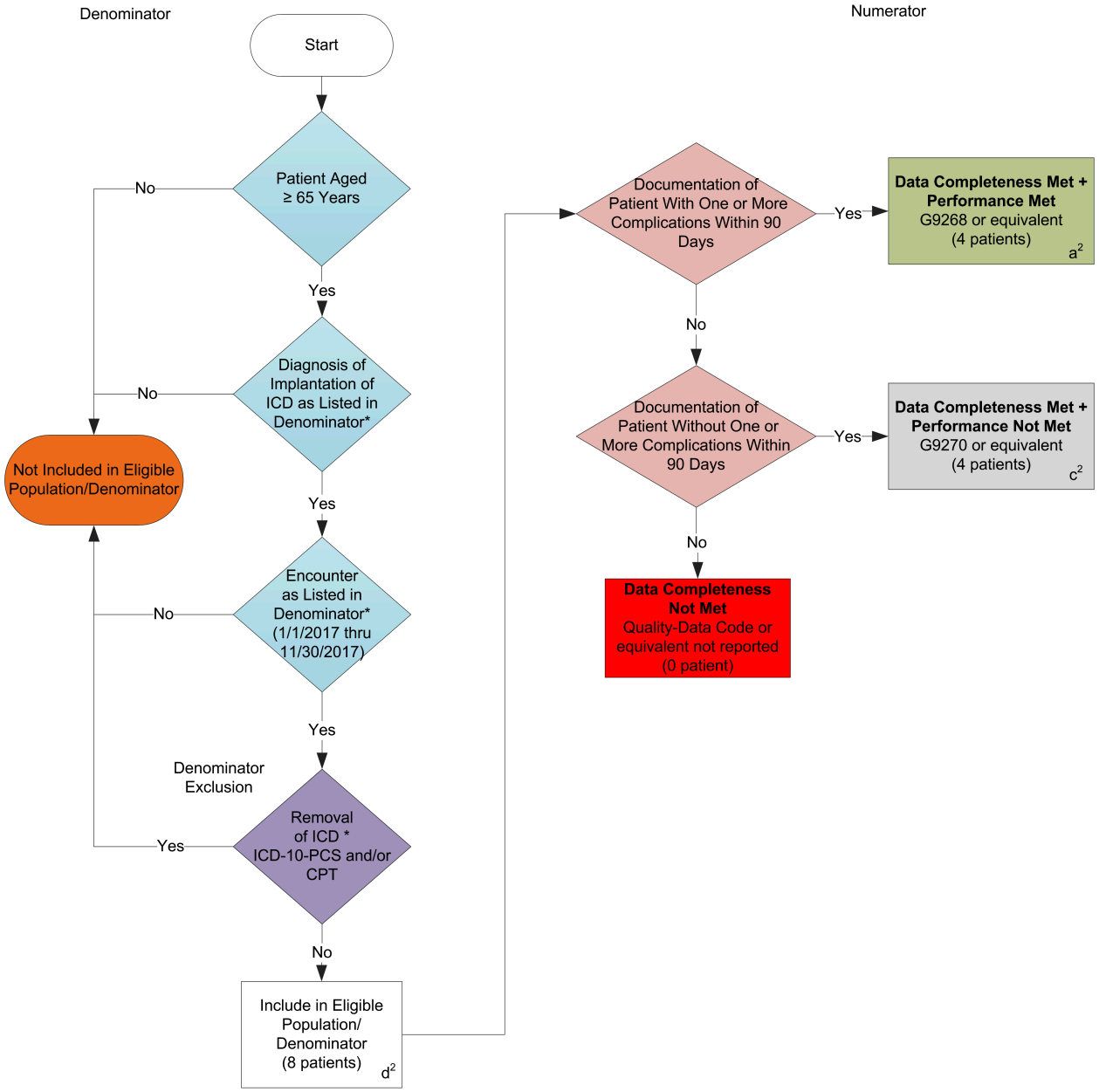


*See the posted Measure Specification for specific coding and instructions to report this measure. This measure flow illustrates denominator eligible encounters as requiring a diagnosis AND an encounter. Another option, as specified within the measure to determine denominator eligibility, could be a diagnosis OR an encounter.
**A lower calculated performance rate for this measure indicates better clinical care or control.
NOTE: Reporting Frequency: Patient-process

v1

2017 Registry Individual Measure Flow
#348 HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate
Reporting Criteria Two

Multiple Performance Rate



*See the posted Measure Specification for specific coding and instructions to report this measure. This measure flow illustrates denominator eligible encounters as requiring a diagnosis AND an encounter. Another option as specified within the measure to determine denominator eligibility, could be a diagnosis OR an encounter.
A lower calculated performance rate for this measure indicates better clinical care or control.
NOTE: Reporting Frequency: Patient Process

v1

2017 Registry Individual Measure Flow
#348 HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate

Multiple Performance Rate

SAMPLE CALCULATIONS: Complications or Mortality at 30 Days

Data Completeness=

Performance Met (a^1= 4 patients) + Performance Not Met (c^1=4 patients) = 8 patients = **100.00%**
Eligible Population / Denominator (d^1=8 patients) = 8 patients

Performance Rate=

Performance Met (a^1=4 patients) = 4 patients = **57.14%**
Data Completeness Numerator (7 patients) = 7 patients

SAMPLE CALCULATIONS: Complications at 90 Days

Data Completeness=

Performance Met (a^2=4 patients) + Performance Not Met (c^2=4 patients) = 8 patients = **100.00%**
Eligible Population / Denominator (d^2=8 patients) = 8 patients

Performance Rate=

Performance Met (a^2=4 patients) = 4 patients = **57.14%**
Data Completeness Numerator (7 patients) = 7 patients

*See the posted Measure Specification for specific coding and instructions to report this measure.
A lower calculated performance rate for this measure indicates better clinical care or control.
**It is anticipated for registry reporting that for every performance rate, a data completeness will be submitted. CMS will determine or use the overall data completeness and performance rate.
NOTE: Reporting Frequency: Patient-process

v1

2017 Registry Individual Measure Flow
#348: HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate

Please refer to the specific section of the Measure Specification to identify the denominator and numerator information for use in reporting this Individual Measure. NOTE: A lower calculated performance rate for this measure indicates better clinical care or control.

Reporting Criteria One:

1. Start with Denominator
2. Check Patient Age:
    a. If Patient Age is greater than or equal to 65 Years of age at Date of Service and equals No during the measurement period, do not include in Eligible Patient Population. Stop Processing.
    b. If Patient Age is greater than or equal to 65 Years of age at Date of Service and equals Yes during the measurement period, proceed to check Diagnosis.
3. Check Patient Diagnosis:
    a. If Diagnosis of Implantation of ICD as Listed in Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If Diagnosis of Implantation of ICD as Listed in Denominator equals Yes, proceed to check Encounter.
4. Check Encounter Performed:
    a. If Encounter as Listed in the Denominator equals No, do not include in Eligible Population or Denominator. Stop Processing.
    b. If Encounter as Listed in the Denominator equals Yes, proceed to check Removal of ICD at an ICD-10-PCS and/or CPT Encounter.
5. Check Removal of ICD at an ICD-10-PCS and/or CPT Encounter:
    a. If Removal of ICD at an ICD-10-PCS and/or CPT Encounter equals No, include in the Eligible Population.
    b. If Removal of ICD at an ICD-10-PCS and/or CPT Encounter equals Yes, do not include in Eligible Population or Denominator. Stop Processing.
6. Denominator Population:
    a. Denominator population is all Eligible Patients in the denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d^1 equals 8 patients in the sample calculation.
7. Start Numerator
8. Check Documentation of One or More Complications or Mortality within 30 Days:
    a. If Documentation of One or More Complications or Mortality within 30 Days equals Yes, include in Data Completeness Met and Performance Met.

b. Data Completeness Met and Performance Met is represented as Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a^1 equals 4 patients in Sample Calculation.

c. If Documentation of One or More Complications or Mortality within 30 Days equals No, proceed to check Documentation of Patient Without One or More Complications or Mortality within 30 Days.

9. Check Documentation of Patient Without One or More Complications or Mortality within 30 Days:

a. If Documentation of Patient Without One or More Complications or Mortality within 30 Days equals Yes, include in Data Completeness Met and Performance Not Met.

b. Data Completeness Met and Performance Not Met is represented as Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter c^1 equals 3 patients in the Sample Calculation.

c. If Documentation of Patient Without One or More Complications or Mortality within 30 Days equals No, proceed to check Data Completeness Not Met.

10. Check Data Completeness Not Met

a. If Data Completeness Not Met, the Quality Data Code or equivalent was not reported. 1 patient has been subtracted from the data completeness numerator in sample calculation.

SAMPLE CALCULATIONS: Complications or Mortality at 30 Days

Data Completeness=

Performance Met (a^1= 4 patients) + Performance Not Met (c^1=4 patients) = 8 patients = **100.00%**

Eligible Population / Denominator (d^1=8 patients) = 8 patients

Performance Rate=

Performance Met (a^1=4 patients) = 4 patients = **57.14%**

Data Completeness Numerator (7 patients) = 7 patients

2017 Registry Individual Measure Flow
#348: HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate

Please refer to the specific section of the Measure Specification to identify the denominator and numerator information for use in reporting this Individual Measure. NOTE: A lower calculated performance for this measure indicates better clinical care or control.

Reporting Criteria Two:

1. Start with Denominator
2. Check Patient Age:
    a. If Patient Age is greater than or equal to 65 Years of age at Date of Service and equals No during the measurement period, do not include in Eligible Patient Population. Stop Processing.
    b. If Patient Age is greater than or equal to 65 Years of age at Date of Service and equals Yes during the measurement period, proceed to check Diagnosis.
3. Check Patient Diagnosis:
    a. If Diagnosis of Implantation of ICD as Listed in Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If Diagnosis of Implantation of ICD as Listed in Denominator equals Yes, proceed to check Encounter.
4. Check Encounter Performed:
    a. If Encounter as Listed in the Denominator equals No, do not include in Eligible Population or Denominator. Stop Processing.
    b. If Encounter as Listed in the Denominator equals Yes, proceed to check Removal of ICD at an ICD-10-PCS and/or CPT Encounter.
5. Check Removal of ICD at an ICD-10-PCS and/or CPT Encounter:
    a. If Removal of ICD at an ICD-10-PCS and/or CPT Encounter equals No, include in the Eligible Population.
    b. If Removal of ICD at an ICD-10-PCS and/or CPT Encounter equals Yes, do not include in Eligible Population or Denominator. Stop Processing.
6. Denominator Population:
    a. Denominator population is all Eligible Patients in the denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d^2 equals 8 patients in the sample calculation.
7. Start Numerator
8. Check Documentation of Patient With One or More Complications within 90 Days:
    a. If Documentation of Patient With One or More Complications Within 90 Days equals Yes, include in Data Completeness Met and Performance Met.

b. Data Completeness Met and Performance Met is represented as Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a^2 equals 4 patients in Sample Calculation.

c. If Documentation of Patient With One or More Complications Within 90 Days equals No, proceed to check Documentation of Patient Without One or More Complications within 90 Days.

9. Check Documentation of Patient Without One or More Complications within 90 Days:

a. If Documentation of Patient Without One or More Complications Within 90 Days equals Yes, include in Data Completeness Met and Performance Not Met.

b. Data Completeness Met and Performance Not Met is represented as Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter c^2 equals 3 patients in the Sample Calculation.

c. If Documentation of Patient Without One or More Complications Within 90 Days equals No, proceed to check Data Completeness Not Met.

10. Check Data Completeness Not Met

a. If Data Completeness Not Met, the Quality Data Code or equivalent was not reported. 1 patient has been subtracted from the data completeness numerator in sample calculation.

SAMPLE CALCULATIONS: Complications at 90 Days

Data Completeness=

Performance Met (a^2=4 patients) + Performance Not Met (c^2=4 patients) = 8 patients = **100.00%**

Eligible Population / Denominator (d^2=8 patients) = 8 patients

Performance Rate=

Performance Met (a^2=4 patients) = 4 patients = **57.14%**

Data Completeness Numerator (7 patients) = 7 patients