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# THE CANADIAN CARDIOVASCULAR SOCIETY QUALITY INDICATORS E- CATALOGUE

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## QUALITY INDICATORS FOR ATRIAL FIBRILLATION/FLUTTER

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*A CCS CONSENSUS DOCUMENT*

**FINAL v1.1**

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## BACKGROUND

The quality indicators outlined in this document have been selected through a national consensus process as the key quality indicators specific to **Atrial Fibrillation (AF)/Atrial Flutter (AFL)**.

In addition, there is a complementary Atrial Fibrillation/Flutter Data Dictionary Chapter comprising of AF/AFL related data elements and definitions. Visit [www.ccs.ca/](http://www.ccs.ca/) for the latest data dictionary. Several of the quality indicators provide the following types of analysis options:

**Cross-sectional Analysis** – definition of indicator estimation using existing registries or databases.

**Follow-up Analysis** – definition of indicator calculation for more precise and detailed analysis using prospective databases including those designed specifically for this purpose.

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**DIAGNOSIS OF NONVALVULAR AF/AFL AND AT HIGH RISK OF STROKE RECEIVING AN ORAL ANTICOAGULANT**

<b>Description</b>	The percentage of patients with a diagnosis of nonvalvular atrial fibrillation/flutter ≥75 years of age OR <75 years of age with a CHADS <sub>2</sub> score ≥ 2*, and without a contraindication for anticoagulation, who are receiving an oral anticoagulant (warfarin [or other vitamin K antagonist], dabigatran, rivaroxaban, apixaban).  *CHADS <sub>2</sub> ≥ 2 in this instance means prior stroke/TIA/Systemic embolus, or at least two of hypertension, heart failure, or diabetes.
<b>Numerator</b>	Is a subset of the denominator: the number of patients in the denominator who are receiving an oral anticoagulant (warfarin [or other vitamin K antagonist], dabigatran, rivaroxaban, apixaban).
<b>Denominator</b>	The number of patients with a diagnosis of nonvalvular atrial fibrillation/flutter who also meet the following inclusion criteria: <ol style="list-style-type: none"> <li>≥75 years of age OR &lt;75 years of age with a CHADS<sub>2</sub> score ≥ 2, (in this instance either prior stroke/TIA/systemic embolus or at least two of hypertension, heart failure, or diabetes)</li> <li>Without a contraindication for anticoagulation.</li> <li>Patients alive at the end of first encounter from their qualifying episode of nonvalvular AF/AFL</li> <li>Case selection time window to be determined at the time of analysis</li> </ol> <p><u>Cross-sectional Analysis:</u> Patients meeting the above inclusion criteria at the end of first encounter from qualifying episode of nonvalvular AF/AFL.</p> <p><u>Follow-up Analysis:</u> Patients meeting the above inclusion criteria at the end of first encounter from a qualifying episode of nonvalvular AF/AFL and at each follow-up encounter over a two year period following the end date of their first encounter for their qualifying nonvalvular AF/AFL episode; excluding patients who died, or were lost to follow-up or developed a contraindication for anticoagulation.</p>
<b>Method of Calculation</b>	<p><u>Cross-sectional Analysis:</u> Snapshot in time at the end of first encounter and at one year after the end of first encounter from a qualifying nonvalvular AF/AFL episode. Calculated as the percentage of qualifying nonvalvular AF/AFL patients who are receiving an oral anticoagulant at the time of their index first encounter and at the follow-up encounter closest to one year from the end of their index encounter. The cross-sectional analyses will use data routinely collected for administrative or other purposes.</p> <p><u>Follow-up Analysis:</u> Oral anticoagulant usage at the end of first encounter from qualifying nonvalvular AF/AFL episode and usage attrition at each follow-up encounter over the two years after the end of their index encounter from a qualifying nonvalvular AF/AFL episode. Calculated as the percentage of qualifying nonvalvular AF/AFL patients who are receiving an oral anticoagulant at the end of the index first encounter and at each follow-up encounter over a two-year period from end of the index encounter; excluding those who died, were lost to follow-up or developed a contraindication for anticoagulation. The follow-up analysis will use data specifically collected for this QI analysis</p>
<b>Sources of Data</b>	EMR or Administrative databases, Hospitalization and Physician Billing databases for diagnoses (e.g. Discharge Abstract Database, Ambulatory Care Database, Physicians Claims Database), Provincial formularies for drug information (e.g. Blue Cross) or specific AF/AFL QI database.

**Rationale**

Patients with a diagnosis of nonvalvular atrial fibrillation/flutter who are at high risk for stroke and without a contraindication should be on an oral anticoagulant for stroke prevention.

**Clinical Recommendation(s)**

CCS AF Guidelines 2012 Focused Update recommends that patients at high risk of stroke should receive oral anticoagulation therapy (warfarin (or other vitamin K antagonist), dabigatran, rivaroxaban, or apixaban). (Strong recommendation, High Quality Evidence).

**Method of Reporting**

The reported statistic will be the percentage of patients with a clear indication for oral anticoagulant and without a contraindication that are actually on oral anticoagulation therapy at or following the end of the encounter for a qualifying nonvalvular AF/AFL episode.

**Challenges to Implementation/Interpretation**

- Contraindication to anticoagulation will need to be recorded.
- Reasons for not receiving anticoagulation, such as patient refusal, will not be recorded.

<b>RATE OF STROKE IN PATIENTS WITH NONVALVULAR AF/AFL</b>	
<b>Description</b>	The annualized rate of stroke (excluding TIA) in patients with diagnosis of nonvalvular atrial fibrillation/flutter.
<b>Numerator</b>	Is a subset of the denominator: the number of patients in the denominator who suffer any stroke (excluding TIA). Patients in the numerator will have their antithrombotic therapy at the end of their index encounter compared to that at the time of stroke (see below in the denominator description).
<b>Denominator</b>	The total number of patients with a qualifying episode of nonvalvular atrial fibrillation/flutter. Case selection window to be determined at the time of analysis.  Patients will be further sub-categorized according to CHA <sub>2</sub> DS <sub>2</sub> -VASc* and antithrombotic therapy at end of the encounter for the qualifying episode of nonvalvular AF/AFL (see below). *Heart failure, Stroke/TIA/systemic embolus, hypertension, age >75, diabetes, atherosclerotic disease, age 65-74, female sex.  CHA <sub>2</sub> DS <sub>2</sub> -VASc Score at the end of encounter for qualifying episode of nonvalvular AF/AFL <ol style="list-style-type: none"> <li>1. Score = 0</li> <li>2. Score = 1</li> <li>3. Score = 2</li> <li>4. Score = 3</li> <li>5. Score = 4 or greater</li> <li>6. Score Unknown/Uncertain</li> </ol> Antithrombotic Therapy: <ol style="list-style-type: none"> <li>1. No antithrombotic therapy</li> <li>2. Anticoagulation only <ol style="list-style-type: none"> <li>a. Warfarin or other vitamin K antagonist</li> <li>b. Dabigatran</li> <li>c. Rivaroxaban</li> <li>d. Apixaban</li> </ol> </li> <li>3. Antiplatelet only</li> <li>4. Anticoagulation and antiplatelet <ol style="list-style-type: none"> <li>a. Warfarin or other vitamin K antagonist</li> <li>b. Dabigatran</li> <li>c. Rivaroxaban</li> <li>d. Apixaban</li> </ol> </li> <li>5. Unknown/Uncertain</li> </ol>
<b>Method of Calculation</b>	<b>Cross-sectional Analysis:</b> A snapshot at one year after a qualifying episode of nonvalvular AF/AFL. Calculated as the percentage of patients with a qualifying episode of nonvalvular atrial fibrillation/flutter who suffer stroke (excluding TIA) within a year after the end of their index encounter. The rates will be calculated as total and also stratified by CHA <sub>2</sub> DS <sub>2</sub> -VASc* Score and type of antithrombotic therapy at the end of their encounter for qualifying AF/AFL episode. A sub-analysis will compare antithrombotic therapy received at the end of their index encounter to that at the time of their stroke in the numerator. The cross-sectional analyses will use data routinely collected for administrative or other purposes.  <b>Follow-up Analysis:</b> Annualized risk of stroke (excluding TIA) from a Kaplan-Meier-type analysis of the first two years after a qualifying nonvalvular AF/AFL subcategorized by CHA <sub>2</sub> DS <sub>2</sub> -VASc Score, and antithrombotic therapy. Calculated as annual rate of [first] stroke (excluding TIA) over a two year period post qualifying episode of nonvalvular AF/AFL and rates by sub-categories according to CHA <sub>2</sub> DS <sub>2</sub> -VASc* Score and type of antithrombotic therapy at end of the encounter for their qualifying episode of nonvalvular AF/AFL, censoring for death or lost to follow-up. A sub-analysis will compare antithrombotic therapy received at the end of their index encounter to that at the time of their stroke in the numerator. The follow-up analysis will use data specifically collected for this analysis.
<b>Sources of Data</b>	EMR or Administrative databases, Hospitalization and Physician Billing databases for diagnoses (e.g. Discharge Abstract Database, Ambulatory Care Database, Physicians Claims Database), Provincial formularies for drug information (e.g. Blue Cross) or specific AF/AFL QI database.

#### Rationale

This quality indicator does not correspond directly to one of our chapter's recommendations, but reflects the epidemiology and impact of therapy on the principal outcome we wish to prevent.

#### Clinical Recommendation(s)

None

#### Method of Reporting

The reported statistic will be an annualized percentage of patients with nonvalvular atrial fibrillation/flutter who suffer a stroke according to the risk of stroke and antithrombotic therapy.

#### Challenges to Implementation/Interpretation

- Not all strokes might be related to atrial fibrillation.
- The rarer but equivalent outcome of systemic embolus may not be included.
- The distinction between types of stroke (thrombotic/hemorrhagic/unknown) may not be available.

**RATE OF MAJOR HEMORRHAGE IN PATIENTS WITH NONVALVULAR AF/AFL**

<b>Description</b>	The annualized rate of major hemorrhage in patients with diagnosis of nonvalvular atrial fibrillation/flutter.
<b>Numerator</b>	Is a subset of the denominator: the number of patients in the denominator who have a major hemorrhage. Patients in the numerator will have their antithrombotic therapy at index encounter compared to that at the time of major hemorrhage (see below in the denominator description).
<b>Denominator</b>	<p>The total number of patients with a qualifying episode of nonvalvular atrial fibrillation/flutter. Case selection window to be determined at the time of analysis.</p> <p>Patients will be further sub-categorized according to CHA<sub>2</sub>DS<sub>2</sub>-VASC* Score and Antithrombotic Therapy at the time of their qualifying episode of nonvalvular AF/AFL (see below).</p> <p>*Heart failure, Stroke/TIA/systemic embolus, hypertension, age &gt;75, diabetes, atherosclerotic disease, age 65-74, female sex.</p> <p>CHA<sub>2</sub>DS<sub>2</sub>-VASC Score at end of encounter for qualifying episode of nonvalvular AF/AFL</p> <ol style="list-style-type: none"> <li>1. Score = 0</li> <li>2. Score = 1</li> <li>3. Score = 2</li> <li>4. Score = 3</li> <li>5. Score = 4 or greater</li> <li>6. Score Unknown/Uncertain</li> </ol> <p>Antithrombotic Therapy:</p> <ol style="list-style-type: none"> <li>1. No antithrombotic therapy</li> <li>2. Anticoagulation only             <ol style="list-style-type: none"> <li>a. Warfarin or other vitamin K antagonist</li> <li>b. Dabigatran</li> <li>c. Rivaroxaban</li> <li>d. Apixaban</li> </ol> </li> <li>3. Antiplatelet only</li> <li>4. Anticoagulation and antiplatelet             <ol style="list-style-type: none"> <li>a. Warfarin or other vitamin K antagonist</li> <li>b. Dabigatran</li> <li>c. Rivaroxaban</li> <li>d. Apixaban</li> </ol> </li> <li>5. Unknown/Uncertain</li> </ol>
<b>Method of Calculation</b>	<p><b>Cross-sectional Analysis:</b> A snapshot at one year after a qualifying episode of nonvalvular AF/AFL. Calculated as the percentage of patients with a qualifying episode of nonvalvular atrial fibrillation/flutter who are hospitalized with major hemorrhage within a year after index encounter. The rates will be calculated as total and also stratified by CHA<sub>2</sub>DS<sub>2</sub>-VASC* Score and type of antithrombotic therapy at end of encounter for qualifying AF/AFL episode. A sub-analysis will compare antithrombotic therapy received at index encounter to that at the time of their major hemorrhage in the numerator. The cross-sectional analyses will use data routinely collected for administrative or other purposes.</p> <p><b>Follow-up Analysis:</b> Annualized risk of major hemorrhage from a Kaplan-Meier-type analysis of the first two years after a qualifying nonvalvular AF/AFL subcategorized by CHA<sub>2</sub>DS<sub>2</sub>-VASC Score, and antithrombotic therapy. Calculated as annual rate of [first] major hemorrhage, whether or not hospitalized, over a two year period post qualifying episode of nonvalvular AF/AFL and rates by sub-categories according to CHA<sub>2</sub>DS<sub>2</sub>-VASC* Score and type of antithrombotic therapy at the end of the encounter for their qualifying episode of nonvalvular AF/AFL, censoring for death or lost to follow-up. A sub-analysis will compare antithrombotic therapy received at the end of their index encounter to that at the time of their major hemorrhage in the numerator. The follow-up analysis will use data specifically collected for this analysis.</p>
<b>Sources of Data</b>	EMR or Administrative databases, Hospitalization and Physician Billing databases for diagnoses (e.g. Discharge Abstract Database, Ambulatory Care Database, Physicians Claims Database), Provincial formularies for drug information (e.g. Blue Cross) or specific AF/AFL QI database.

**Rationale**

This quality indicator does not correspond directly to one of our chapter's recommendations, but provides data on the rate of major hemorrhage, the major risk of antithrombotic therapy, in patients with nonvalvular atrial fibrillation/flutter according to risk of stroke and antithrombotic use.

**Rationale**

This quality indicator does not correspond directly to one of our chapter's recommendations, but provides data on the rate of major hemorrhage, the major risk of antithrombotic therapy, in patients with nonvalvular atrial fibrillation/flutter according to risk of stroke and antithrombotic use.

**Method of Reporting**

The reported statistic will be an annualized percentage of patients with nonvalvular atrial fibrillation/flutter hospitalized with major hemorrhage according to the risk of stroke and antithrombotic therapy.

**Challenges to Implementation/Interpretation**

- Hospitalization for major bleeding (Retrospective Analysis) is an arbitrary definition for bleeding complications.
- Some major bleeding will be missed in the Retrospective Analysis (treated but not hospitalized).
- Some bleeding might be indirectly related to medications (e.g. from a trauma).

**RISK STRATIFICATION OF PATIENTS WITH NONVALVULAR AF/AFL FOR STROKE**

<b>Description</b>	The percentage of patients with a newly diagnosed nonvalvular atrial fibrillation/flutter that have a stroke risk prediction score (CHADS <sub>2</sub> or CHA <sub>2</sub> DS <sub>2</sub> VASc) documented in their medical record, or have the relevant elements of such scores recorded in the medical record such that a stroke risk prediction score may be readily calculated.
<b>Numerator</b>	A subset of the denominator who have a CHADS <sub>2</sub> or CHA <sub>2</sub> DS <sub>2</sub> VASc Score documented on their medical record or have all of the risk criteria of these scores documented in their medical record.  CHADS <sub>2</sub> or CHA <sub>2</sub> DS <sub>2</sub> VASc Score risk criteria are: stroke/TIA/Systemic embolus, hypertension, heart failure, age >75, diabetes, atherosclerotic disease, age 65-74, female sex.
<b>Denominator</b>	The total number of patients with a newly diagnosis of nonvalvular atrial fibrillation/flutter. Case selection window to be defined at the time of analysis.
<b>Method of Calculation</b>	Snapshot in time at time of entry in database with newly diagnosed AF/AFL. Calculated as the proportion of patients with each of the stroke risk factors defined by CHADS <sub>2</sub> or CHA <sub>2</sub> DS <sub>2</sub> VASc Score or a statement of the actual score recorded in their medical record among newly diagnosed nonvalvular AF/AFL patients.
<b>Sources of Data</b>	The medical record.

**Rationale**

All AF/AFL patients should have a documented assessment of their stroke risk using an objective tool (CHADS<sub>2</sub> or CHA<sub>2</sub>DS<sub>2</sub>VASc).

**Clinical Recommendation(s)**

We recommend that all patients with AF or AFL (paroxysmal, persistent or permanent), should be stratified using a predictive index for the risk for stroke (e.g. CHADS<sub>2</sub>) and for the risk of bleeding (e.g. HAS-BLED), and that most patients should receive antithrombotic therapy. (Strong Recommendation, High Quality Evidence.)

**Method of Reporting**

The reported statistic will be a percentage of patients with nonvalvular atrial fibrillation/flutter that have stroke risk factors documented using a recommended objective tool (CHADS<sub>2</sub> or CHA<sub>2</sub>DS<sub>2</sub>VASc).

**Challenges to Implementation/Interpretation**

- Finding all of this data in the medical record is a potential problem.
- Stroke risk is dynamic over time, and this metric may not assay re-evaluation of stroke risk when subjects accrue new risk factors for stroke and their status, per CHADS<sub>2</sub> or CHA<sub>2</sub>DS<sub>2</sub>VASc, changes.

**DIAGNOSIS OF AF/AFL AND ECHOCARDIOGRAPHIC ASSESSMENT**

<b>Description</b>	The percentage of patients with newly diagnosed atrial fibrillation/flutter who have had an echocardiography assessment within 12 months ( $\pm$ 6 months from the date of the episode of newly diagnosed AF/AFL).
<b>Numerator</b>	A subset of the denominator who have had an echocardiogram performed $\pm$ 6 months from date of their episode of newly diagnosed AF/AFL.
<b>Denominator</b>	The total number of patients with a newly diagnosed episode of AF/AFL. Case selection window to be defined at the time of analysis.
<b>Method of Calculation</b>	A snapshot in time of a one year period, consisting of the six months before and the six months after the date of a newly diagnosed episode of AF/AFL. Calculated as a proportion of patients with a new diagnosed episode of AF/AFL who have had an echocardiogram performed $\pm$ 6 months from date of diagnosis.
<b>Sources of Data</b>	EMR or Administrative databases, Hospitalization and Physician Billing databases for diagnoses (e.g. Discharge Abstract Database, Ambulatory Care Database, Physicians Claims Database), Provincial formularies for drug information (e.g. Blue Cross) or specific AF/AFL QI database.

**Rationale**

Assessment of cardiac function, left atrial size, and ruling out valve disease are important components for management of newly diagnosed AF/AFL.

**Clinical Recommendation(s)**

We recommend that all patients newly diagnosed with AF/AFL undergo an echocardiogram for assessment of cardiac structure and function.

**Method of Reporting**

The reported statistic will be a percentage of patients with newly diagnosed atrial fibrillation/flutter who have an echocardiogram within a year of their diagnosis.

**Challenges to Implementation/Interpretation**

- Echocardiogram availability may vary depending on the geographic location of the patient.
- The statistic does not strictly distinguish between Access (test ordered and completed) vs. Physician performance (test not ordered).



## DEFINITIONS

The following are the definitions of terminology and key outcome indicators used throughout the CCS Atrial Fibrillation/Flutter Data Dictionary and are duplicated herein for use with the Quality Indicators Atrial Fibrillation/Flutter E-Catalogue(s).

TERMINOLOGY	
TERM	DEFINITION
Atrial Fibrillation (AF)	Atrial fibrillation is a supraventricular tachyarrhythmia characterized by uncoordinated atrial activation with consequent deterioration of atrial mechanical function. On the electrocardiogram (ECG), AF is described by the replacement of consistent P waves by rapid oscillations or fibrillatory waves that vary in size, shape, and timing, associated with an irregular, frequently rapid ventricular response when atrioventricular (AV) conduction is intact. [Modified from Source: J Am Coll Cardiol 2006;45:e155]
Typical Atrial Flutter (AFL)	Atrial flutter in the typical form is characterized by a saw-tooth pattern of regular atrial activation called flutter ( <i>f</i> ) waves on the ECG, particularly visible in leads II, III, aVF, and V1. In the untreated state, the atrial rate in atrial flutter typically ranges from 240 to 320 beats per minute, often around 300 per minute, with <i>f</i> waves inverted in ECG leads II, III, and aVF and upright in lead V1. The direction of activation in the right atrium (RA) may be reversed, resulting in <i>f</i> waves that are upright in leads II, III, and aVF and inverted in lead V1. Atrial flutter commonly occurs with 2:1 AV block, resulting in a regular or irregular ventricular rate of 120 to 160 beats per minute (most characteristically about 150 beats per minute). [Modified from Source: J Am Coll Cardiol 2006;45:e155]
Atypical Atrial Flutter (AFL)	In the atypical form there is regular, organized atrial activity in the ECG in 3 or more leads but not the typical saw tooth pattern in the inferior leads and the rhythm often originates in the left atrium.  It is defined as the absence of a typical sawtooth pattern when there was clear evidence of regular, organized atrial activity in other leads (particularly lead V <sub>2</sub> ) within this range of rates and often but not always with a fixed AV conduction (2:1, 3:1, etc.) and a regular ventricular rate. [Modified from Source: Europace 2012;12:804]
Electrocardiographic documentation (ECG)	12-lead ECG, rhythm strip, Holter monitor, intracardiac electrograms or event recorder
Nonvalvular AF/AFL	By convention, the term “nonvalvular AF/AFL” is restricted to cases in which the rhythm disturbance occurs in the absence of rheumatic mitral valve disease, a prosthetic heart valve, or mitral valve repair. [Modified from Source: J Am Coll Cardiol 2006;45:e157]
Valvular AF/AFL	Conversely, “valvular AF/AFL” is used to describe cases in which the rhythm disturbance occurs in the presence of rheumatic mitral valve disease, a prosthetic heart valve, or mitral valve repair.
Rheumatic mitral valve disease	As rheumatic mitral regurgitation cannot be reliably diagnosed without a pathological specimen, “rheumatic mitral valve disease” is defined as mitral stenosis (usually an echocardiographic diagnosis) that is moderate or greater in severity (valve area $\leq 1.5 \text{ cm}^2$ [Source: BSE Echocardiography: Guidelines for Valve Quantification]).
Newly Diagnosed AF/AFL	First electrocardiographic documentation occurred within the last 6 months, whether or not there were previous symptoms compatible with AF/AFL AND whether or not there has been more than one electrocardiographic documented episode within the period of time since the first electrocardiographic documentation.  Date of Newly Diagnosed AF/AFL (YYYYMMDD)
Qualifying AF/AFL	Episode of AF/AFL that resulted in first entry into the database, regardless of whether or not it is newly diagnosed.  Date of Qualifying AF/AFL (YYYYMMDD)

**KEY OUTCOME INDICATORS**

<b>TERM</b>	<b>DEFINITION</b>
Stroke	<p>Stroke is an acute onset of a focal neurologic deficit of presumed vascular origin lasting for <math>\geq 24</math> hours or resulting in death. Stroke [is] [can be] categorized as ischemic or hemorrhagic or cause unknown (based on computed tomographic or magnetic resonance scanning or autopsy) [but in this instance all strokes are included]. Fatal stroke is defined as death from any cause within 30 days of stroke. [Modified from Source: Am Heart J 2009;157:810.e1]</p> <p>Stroke must be confirmed by imaging of the brain (computed tomographic or magnetic resonance scanning) or by autopsy.</p> <p>Date of Stroke (YYYYMMDD): date of onset of symptoms of stroke</p> <p>CHA<sub>2</sub>DS<sub>2</sub>-VASc score at time of stroke = CHA<sub>2</sub>DS<sub>2</sub>-VASc Score</p> <ol style="list-style-type: none"> <li>1. Score = 0</li> <li>2. Score = 1</li> <li>3. Score = 2</li> <li>4. Score = 3</li> <li>5. Score = 4 or greater</li> <li>6. Score Unknown/Uncertain</li> </ol> <p>Antithrombotic therapy at time of stroke = Antithrombotic Therapy</p> <ol style="list-style-type: none"> <li>1. No antithrombotic therapy</li> <li>2. Anticoagulation only               <ol style="list-style-type: none"> <li>a. Warfarin or other vitamin K antagonist</li> <li>b. Dabigatran</li> <li>c. Rivaroxaban</li> <li>d. Apixaban</li> </ol> </li> <li>3. Antiplatelet only</li> <li>4. Anticoagulation and antiplatelet               <ol style="list-style-type: none"> <li>a. Warfarin or other vitamin K antagonist</li> <li>b. Dabigatran</li> <li>c. Rivaroxaban</li> <li>d. Apixaban</li> </ol> </li> <li>5. Unknown/Uncertain</li> </ol>
Contraindication to Anticoagulation	<p>List of examples from the ROCKET AF Study:</p> <ul style="list-style-type: none"> <li>• Active internal bleeding</li> <li>• History of, or condition associated with, increased bleeding risk, including:           <ul style="list-style-type: none"> <li>○ Major surgical procedure or trauma within 30 days before randomization</li> <li>○ Clinically significant gastrointestinal bleeding within 6 months before randomization</li> <li>○ History of intracranial, intraocular, spinal, or atraumatic intra-articular bleeding</li> <li>○ Chronic hemorrhagic disorder</li> <li>○ Known intracranial neoplasm, arteriovenous malformation, or aneurysm</li> <li>○ Planned invasive procedure with potential for uncontrolled bleeding, including major surgery</li> </ul> </li> </ul> <p>[Source: Am Heart J 2010;159:340-7.e1]</p> <p>Date when Contraindication was First Noted (YYYYMMDD)</p>

Systemic Embolus	<p>Systemic embolism is an acute vascular occlusion of the extremities or any organ (kidneys, mesenteric arteries, spleen, retina or grafts) and must be documented by angiography, surgery, scintigraphy, or autopsy. [Modified from Source: Am Heart J 2009;157:810.e1]</p> <p>Date of Systemic Embolus (YYYYMMDD): date of the onset of symptoms of systemic embolus</p> <p>CHA<sub>2</sub>DS<sub>2</sub>VASc Score at time of Systemic Embolus = CHA<sub>2</sub>DS<sub>2</sub>-VASc Score</p> <ol style="list-style-type: none"> <li>1. Score = 0</li> <li>2. Score = 1</li> <li>3. Score = 2</li> <li>4. Score = 3</li> <li>5. Score = 4 or greater</li> <li>6. Score Unknown/Uncertain</li> </ol> <p>Antithrombotic Therapy at Time of Systemic Embolus = Antithrombotic Therapy</p> <ol style="list-style-type: none"> <li>1. No antithrombotic therapy</li> <li>2. Anticoagulation only <ol style="list-style-type: none"> <li>a. Warfarin or other vitamin K antagonist</li> <li>b. Dabigatran</li> <li>c. Rivaroxaban</li> <li>d. Apixaban</li> </ol> </li> <li>3. Antiplatelet only</li> <li>4. Anticoagulation and antiplatelet <ol style="list-style-type: none"> <li>a. Warfarin or other vitamin K antagonist</li> <li>b. Dabigatran</li> <li>c. Rivaroxaban</li> <li>d. Apixaban</li> </ol> </li> <li>5. Unknown/Uncertain</li> </ol>
TIA	<p>Same as stroke but symptoms resolve within &lt;24h and no imaging evidence of cerebral infarct or hemorrhage.</p> <p>Date of TIA (YYYYMMDD): date of onset of symptoms of TIA</p> <p>CHA<sub>2</sub>DS<sub>2</sub>VASc at Time of TIA = CHA<sub>2</sub>DS<sub>2</sub>-VASc Score</p> <ol style="list-style-type: none"> <li>1. Score = 0</li> <li>2. Score = 1</li> <li>3. Score = 2</li> <li>4. Score = 3</li> <li>5. Score = 4 or greater</li> <li>6. Score Unknown/Uncertain</li> </ol> <p>Antithrombotic Therapy at Time of TIA = Antithrombotic Therapy</p> <ol style="list-style-type: none"> <li>1. No antithrombotic therapy</li> <li>2. Anticoagulation only <ol style="list-style-type: none"> <li>a. Warfarin or other vitamin K antagonist</li> <li>b. Dabigatran</li> <li>c. Rivaroxaban</li> <li>d. Apixaban</li> </ol> </li> <li>3. Antiplatelet only</li> <li>4. Anticoagulation and antiplatelet <ol style="list-style-type: none"> <li>a. Warfarin or other vitamin K antagonist</li> <li>b. Dabigatran</li> <li>c. Rivaroxaban</li> <li>d. Apixaban</li> </ol> </li> <li>5. Unknown/Uncertain</li> </ol>

Major Hemorrhage	<p>Major hemorrhage is defined by <math>\geq 1</math> of the following criteria:</p> <ul style="list-style-type: none"> <li>• Overt bleeding associated with reduction in haemoglobin level of at least 2.0 g/L;</li> <li>• Overt bleeding leading to transfusion of at least 2 U of blood or packed cells; or</li> <li>• Symptomatic bleeding in a critical area or organ such as intraocular, intracranial, intraspinal or intramuscular with compartment syndrome, retroperitoneal bleeding, intra-articular bleeding, or pericardial bleeding.</li> </ul> <p>[Modified from Source: Am Heart J 2009;157:810.e2]</p> <p>In the AF Quality Indicators e-Catalogue the Cross-sectional Analysis is based on hospitalization for major hemorrhage as defined above.</p> <p>Date of Major Bleeding (YYYYMMDD) = date of onset of symptoms of bleeding or detection of overt bleeding when asymptomatic</p> <p>CHA<sub>2</sub>DS<sub>2</sub>-VASc at Time of TIA = CHA<sub>2</sub>DS<sub>2</sub>-VASc Score</p> <ol style="list-style-type: none"> <li>1. Score = 0</li> <li>2. Score = 1</li> <li>3. Score = 2</li> <li>4. Score = 3</li> <li>5. Score = 4 or greater</li> <li>6. Score Unknown/Uncertain</li> </ol> <p>Antithrombotic Therapy at Time of Major Hemorrhage = Antithrombotic Therapy</p> <ol style="list-style-type: none"> <li>1. No antithrombotic therapy</li> <li>2. Anticoagulation only <ol style="list-style-type: none"> <li>a. Warfarin or other vitamin K antagonist</li> <li>b. Dabigatran</li> <li>c. Rivaroxaban</li> <li>d. Apixaban</li> </ol> </li> <li>3. Antiplatelet only</li> <li>4. Anticoagulation and antiplatelet <ol style="list-style-type: none"> <li>a. Warfarin or other vitamin K antagonist</li> <li>b. Dabigatran</li> <li>c. Rivaroxaban</li> <li>d. Apixaban</li> </ol> </li> <li>5. Unknown/Uncertain</li> </ol>
CV Hospitalization	<p>Primary reason for hospitalization was cardiovascular categorized by reason(s) for hospitalization (Check all that apply):</p> <ol style="list-style-type: none"> <li>1. Rhythm management of AF/AFL</li> <li>2. Bleeding</li> <li>3. Acute HF</li> <li>4. MI</li> <li>5. Other Acute Coronary Syndrome</li> <li>6. Rhythm management for other SVT</li> <li>7. Bradycardia Management</li> <li>8. Rhythm management for VT/VF/SCD</li> <li>9. Other, specify</li> </ol> <p>Date of CV Hospitalization (YYYYMMDD)</p>
Non-CV Hospitalization Only	<p>Primary reason for hospitalization was non-cardiovascular and no secondary CV problem during hospitalization</p> <p>Date of Non-CV Hospitalization (YYYYMMDD)</p>

<p>Non-CV Hospitalization with Secondary CV Problem</p>	<p>Primary reason for hospitalization was non-cardiovascular but a secondary cardiovascular problem developed during hospitalization categorized by CV problem(s) (Check all that apply):</p> <ol style="list-style-type: none"> <li>1. Rhythm management for AF/AFL</li> <li>2. Bleeding</li> <li>3. Acute HF</li> <li>4. MI</li> <li>5. Other Acute Coronary Syndrome</li> <li>6. Rhythm management for other SVT</li> <li>7. Bradycardia Management</li> <li>8. Rhythm management for VT/VF/SCD</li> <li>9. Other, specify</li> </ol> <p>Date of Non-CV Hospitalization with Secondary CV Problem (YYYYMMDD)</p>
<p>CV Emergency Department Visit (whether or not followed by hospital admission)</p>	<p>Primary reason for Emergency Department Visit was cardiovascular categorized by reason(s) for ER Visit (Check all that apply):</p> <ol style="list-style-type: none"> <li>1. Rhythm management of AF/AFL</li> <li>2. Bleeding</li> <li>3. Acute HF</li> <li>4. MI</li> <li>5. Other Acute Coronary Syndrome</li> <li>6. Rhythm management for other SVT</li> <li>7. Bradycardia Management</li> <li>8. Rhythm management for VT/VF/SCD</li> <li>9. Other, specify</li> </ol> <p>Date of CV Emergency Department Visit (YYYYMMDD)</p>
<p>Lost to Follow-up</p>	<p>Patient is permanently lost to any further follow-up due to moving or any other administrative or other reason they are no longer included in the database.</p> <p>Date of Last Contact (YYYYMMDD)</p>
<p>Death</p>	<p>Patient died and no longer available for follow-up.</p> <p>Date of Death (YYYYMMDD)</p>

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