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 #:** 1525 **NQF Project:** Cardiovascular Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Chronic Anticoagulation Therapy
De.2 **Brief description of measure**: Prescription of warfarin for all patients with nonvalvular atrial fibrillation or atrial flutter at high risk for thromboembolism.
1.1-2 **Type of Measure:** Process 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:** Population health, Safety De.5 **IOM Quality Domain**: Effectiveness, Safety De.6 **Consumer Care Need:** Staying healthy, Living with illness

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.* 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 A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** A.3 **Measure Steward Agreement:** Agreement will be signed and submitted prior to or at the time of measure submission A.4 **Measure Steward Agreement attached:**	**A** **Y**☐ **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	**B** **Y**☐

every 3 years. Yes, information provided in contact section	N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public reporting, Internal quality improvement Accountability	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. D.1**Testing:** Yes, fully developed and tested 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?** **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) **1a. High Impact**	**Eval Rating**
(for NQF staff use) **Specific NPP goal**:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality 1a.2 1a.3 **Summary of Evidence of High Impact:** Atrial fibrillation (AF) is the most common arrhythmia in the United States. (1-4) It has been estimated that 2.2 million Americans have paroxysmal or persistent AF, but the actual number may be higher.(1-4) The prevalence of AF increases with age, reaching as high as 9% in octogenarians. During the past 20 years, there has been a 66% increase in hospital admissions for AF due to a combination of factors, including the aging of the population, a rising prevalence of chronic heart disease, and more frequent diagnosis through use of ambulatory monitoring devices. (4) AF also poses a major global public health challenge because it is increasing in prevalence and is associated with an increased risk of stroke, dementia, heart failure and death. (4-15) AF results in significant morbidity, mortality, and costs through hemodynamic impairment, disabling symptoms, and thromboembolic events.(4-15) AF is associated with significant morbidity and mortality, including a 4- to 5-fold increased risk for stroke, a doubling of risk for dementia, a tripling of risk for heart failure, and a 40% to 90% increased risk for overall mortality. (5-15) Growth in the size of the AF population and increased recognition of the morbidity, mortality, diminished quality of life, and high healthcare costs associated with AF have spurred numerous investigations to develop more effective treatments for AF and its complications. (4,- 15) 1a.4 **Citations for Evidence of High Impact:** 1) Benjamin EJ, Wolf PA, D'Agostino RB, Silbershatz H, Kannel	**1a** C☐ P☐ M☐ N☐

Comment [KP1]: 1a. The measure focus addresses:
- a specific national health goal/priority identified by NQF's National Priorities Partners; OR
- a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

WB, Levy D. Impact of atrial fibrillation on the risk of death: the Framingham Heart Study. Circulation. 1998;98:946 –952.
http://circ.ahajournals.org/cgi/reprint/98/10/946.pdf
2) Lloyd-Jones DM, Wang TJ, Leip EP, Larson MG, Levy D, Vasan RS, D'Agostino RB, Massaro JM, Beiser A, Wolf PA, Benjamin EJ. Lifetime risk for development of atrial fibrillation: the Framingham Heart Study. Circulation. 2004;110:1042–1046.
http://circ.ahajournals.org/cgi/content/full/110/9/1042
3) Benjamin EJ, Chen PS, Bild DE, Mascette AM, Albert CM, Alonso A, Calkins H, Connolly SJ, Curtis AB, Darbar D, Ellinor PT, Go AS, Goldschlager NF, Heckbert SR, Jalife J, Kerr CR, Levy D, Lloyd-Jones DM, Massie BM, Nattel S, Olgin JE, Packer DL, Po SS, Tsang TS, Van Wagoner DR, Waldo AL, Wyse DG Prevention of atrial fibrillation: Report from a National Heart, Lung, and Blood Institute Workshop. Circulation. 2009;119(4):606-18.
http://circ.ahajournals.org/cgi/content/full/119/4/606
4) Fuster V, Rydén LE, Cannom DS, et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation— executive summary: a report of the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (writing committee to revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation). J Am Coll Cardiol 2006;48:854-906
http://content.onlinejacc.org/cgi/content/full/48/4/854
5) Schnabel RB, Sullivan LM, Levy D, Pencina MJ, Massaro JM, D´Agostino RB, Sr., Newton Cheh C, Yamamoto JF, Magnani JW, Tadros TM, Kannel WB, Wang TJ, Ellinor PT, Wolf PA, Vasan RS, Benjamin EJ. Development of a risk score for atrial fibrillation (Framingham Heart Study): a community based cohort study. Lancet 2009;373:739 45.
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2764235/
6) Wolf PA, Dawber TR, Thomas HE Jr, Kannel WB. Epidemiologic assessment of chronic atrial fibrillation and risk of stroke: the Framingham Study. Neurology. 1978;28:973–977.
http://www.neurology.org/content/28/10/973.abstract?sid=8966cfe2-73d6-41f3-89cd-e8dd0ce75c5f
7) Krahn AD, Manfreda J, Tate RB, Mathewson FA, Cuddy TE. The natural history of atrial fibrillation: incidence, risk factors, and prognosis in the Manitoba Follow-up Study. Am J Med. 1995;98:476–484.
http://www.ncbi.nlm.nih.gov/pubmed/7733127
8) Ott A, Breteler MM, de Bruyne MC, van Harskamp F, Grobbee DE, Hofman A. Atrial fibrillation and dementia in a population-based study: the Rotterdam Study. Stroke. 1997;28:316 –321.
http://stroke.ahajournals.org/cgi/content/short/28/2/316
9) Miyasaka Y, Barnes ME, Petersen RC, Cha SS, Bailey KR, Gersh BJ, Casaclang-Verzosa G, Abhayaratna WP, Seward JB, Iwasaka T, Tsang TS. Risk of dementia in stroke-free patients diagnosed with atrial fibrillation: data from a community-based cohort. Eur Heart J. 2007;28:1962–1967.
http://eurheartj.oxfordjournals.org/content/28/16/1962.long
10) Benjamin EJ, Levy D, Vaziri SM, D'Agostino RB, Belanger AJ, Wolf PA. Independent risk factors for atrial fibrillation in a population-based cohort: the Framingham Heart Study. JAMA. 1994;271:840–844.
http://jama.ama-assn.org/content/271/11/840.full.pdf+html
11) Go AS, Hylek EM, Phillips KA, Chang Y, Henault LE, Selby JV, Singer DE. Prevalence of diagnosed atrial fibrillation in adults: national implications for rhythm management and stroke prevention: the AnTicoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study. JAMA. 2001;285:2370–2375.
http://jama.ama-assn.org/content/285/18/2370.full
12) Psaty BM, Manolio TA, Kuller LH, Kronmal RA, Cushman M, Fried LP, White R, Furberg CD, Rautaharju PM. Incidence of and risk factors for atrial fibrillation in older adults. Circulation. 1997;96:2455–2461.
http://circ.ahajournals.org/cgi/content/full/96/7/245
13) Heeringa J, Van Der Kuip DA, Hofman A, Kors JA, van Herpen G, Stricker BH, Stijnen T, Lip GY, Witteman JC. Prevalence, incidence and lifetime risk of atrial fibrillation: the Rotterdam Study. Eur Heart J. 2006;27:949 –953.
http://eurheartj.oxfordjournals.org/content/27/8/949.long

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Evidence based medicine unequivocally supports a clinically and statistically significant reduction in the risk of stroke by 66% in patients treated with warfarin with the greatest benefit in those with the highest CHADS2 Score. (1-10) Multiple appropriately designed prospective randomized trials with placebo controls have demonstrated

1b
C☐
P☐
M☐
N☐

Comment [KP2]: 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

that warfarin therapy reduces the stoke risk by 66% in patient with nonvalvular AF.(1-8) These randomized controlled trials show that warfarin at a dose adjusted to an international normalized ratio of 2.0 to 3.0 reduces the risk of stroke by approximately 66%.(2-8) Efficacy demonstrated in the trials has been shown to translate into effectiveness in clinical practice. Meta-analysis according to the principle of intention to treat showed that adjusted-dose oral anticoagulation is highly efficacious for prevention of all stroke (both ischemic and hemorrhagic), with a risk reduction of 66% (95% CI 47% to 71%) versus placebo. (1) However, warfarin therapy remains widely underutilized. Multiple studies using a range of methodologies have consistently documented that between 45-55% of patients who are candidates for anticoagulant therapy do not receive appropriate risk stratification or therapy. (1,11-21)

1) Hart RG, Benavente O, McBride R, et al. Antithrombotic therapy to prevent stroke in patients with atrial fibrillation: a meta-analysis. Ann Intern Med 1999;131:492–501.
http://www.ncbi.nlm.nih.gov/pubmed/10507957
2) Stroke Prevention in Atrial Fibrillation Investigators. Stroke Prevention in Atrial Fibrillation Study. Final results. Circulation 1991;84:527–39.
http://circ.ahajournals.org/cgi/reprint/84/2/527
3) Stroke Prevention on Atrial Fibrillation Investigators. Adjusted-dose warfarin versus low-intensity, fixed-dose warfarin plus aspirin for high-risk patients with atrial fibrillation: Stroke Prevention in Atrial Fibrillation III randomised clinical trial. Lancet 1996;348:633– 8.
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2896%2903487-3/abstract
4) EAFT (European Atrial Fibrillation Trial) Study Group Secondary prevention in non-rheumatic atrial fibrillation after transient ischaemic attack or minor stroke. Lancet 1993;342:1255– 62.
http://www.thelancet.com/journals/lancet/article/PII0140-6736%2893%2992358-Z/abstract
5) Petersen P, Boysen G, Godtfredsen J, et al. Placebo-controlled, randomized trial of warfarin and aspirin for prevention of thromboembolic complications in chronic atrial fibrillation. The Copenhagen AFASAK study. Lancet 1989;1:175–9.
http://www.ncbi.nlm.nih.gov/pubmed/2563096?dopt=Abstract
6) Gullov AL, Koefoed BG, Petersen P. Bleeding during warfarin and aspirin therapy in patients with atrial fibrillation: the AFASAK 2 study. Atrial Fibrillation Aspirin and Anticoagulation. Arch Intern Med 1999; 159:1322– 8.
http://archinte.ama-assn.org/cgi/content/full/159/12/1322
7) Warfarin versus aspirin for prevention of thromboembolism in atrial fibrillation: Stroke Prevention in Atrial Fibrillation II Study. Lancet\ 1994;343:687–91.
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2894%2991577-6/abstract
8) Connolly SJ, Laupacis A, Gent M, et al. Canadian Atrial Fibrillation Anticoagulation (CAFA) Study. J Am Coll Cardiol 1991;18:349 –55.
http://content.onlinejacc.org/cgi/content/abstract/18/2/349
9) Fuster V, Rydén LE, Cannom DS, et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation— executive summary: a report of the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (writing committee to revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation). J Am Coll Cardiol 2006;48:854-906
http://content.onlinejacc.org/cgi/content/full/48/4/854
10) Estes NAM III et al. ACC/AHA/Physician Consortium 2008 Clinical Performance Measures for Adults With Nonvalvular Atrial Fibrillation or Atrial Flutter A Report of the American College of Cardiology/American HeartAssociation Task Force on Performance Measures and the Physician Consortium for Performance Improvement (Writing Committee to Develop Clinical Performance Measures for Atrial Fibrillation)Circulation 2008;117;1101-1120.
http://content.onlinejacc.org/cgi/content/full/51/8/865
11) Srivastava A, Hudson M, Hamoud I, Cavalcante J, Pai C, Kaatz S. Examining warfarin underutilization rates in patients with atrial fibrillation: Detailed chart review essential to capture contraindications to warfarin therapy. Thromb J. 2008 Jun 3;6:6.
http://www.ncbi.nlm.nih.gov/pubmed/18522741
12) Darkow T, Vanderplas AM, Lew KH, Kim J, Hauch O: Treatment patterns and real-world effectiveness of warfarin in nonvalvular atrial fibrillation within a managed care system. Curr Med Res Opin 2005, 21(10):1583-1594.
http://www.ncbi.nlm.nih.gov/pubmed/16238898

13) Hylek EM, D´Antonio J, Evans-Molina C, Shea C, Henault LE, Regan S: Translating the results of randomized trials into clinical practice: the challenge of warfarin candidacy among hospitalized elderly patients with atrial fibrillation. Stroke 2006, 37(4):1075-1080.
http://stroke.ahajournals.org/cgi/content/short/37/4/1075
14) Waldo AL, Becker RC, Tapson VF, Colgan KJ: Hospitalized patients with atrial fibrillation and a high risk of stroke are not being provided with adequate anticoagulation. J Am Coll Cardiol 2005, 46(9):1729-1736.
http://content.onlinejacc.org/cgi/content/full/46/9/1729
15) Go AS, Hylek EM, Phillips KA, Borowsky LH, Henault LE, Chang Y, Selby JV, Singer DE: Implications of stroke risk criteria on the anticoagulation decision in nonvalvular atrial fibrillation: the Anticoagulation and Risk Factors in Atrial Fibrillation (ATRIA) study. Circulation 2000, 102(1):11-13.
http://www.ncbi.nlm.nih.gov/pubmed/10880408

16) Go AS, Hylek EM, Phillips KA, Chang Y, Henault LE, Selby JV, Singer DE: Prevalence of diagnosed atrial fibrillation in adults: national implications for rhythm management and stroke prevention: the AnTicoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study. Jama 2001, 285(18):2370-2375.
http://www.ncbi.nlm.nih.gov/pubmed/11343485

17) McCormick D, Gurwitz JH, Goldberg RJ, Becker R, Tate JP, Elwell A, Radford MJ: Prevalence and quality of warfarin use for patients with atrial fibrillation in the long-term care setting. Arch Intern Med 2001, 161(20):2458-2463.
http://archinte.ama-assn.org/cgi/content/full/161/20/2458
Weisbord SD, Whittle J, Brooks RC: Is warfarin really underused in patients with atrial fibrillation? J Gen Intern Med 2001, 16(11):743-749.

18) http://onlinelibrary.wiley.com/doi/10.1111/j.1525-1497.2001.10432.x/pdf

19) Beyth RJ, Antani MR, Covinsky KE, Miller DG, Chren MM, Quinn LM, Landefeld CS: Why isn´t warfarin prescribed to patients with nonrheumatic atrial fibrillation? J Gen Intern Med 1996,11(12):721-728.
http://www.springerlink.com/content/37514n8173855j1r/
20) Go AS, Hylek EM, Borowsky LH, Phillips KA, Selby JV, Singer DE: Warfarin use among ambulatory patients with nonvalvular atrial fibrillation: the anticoagulation and risk factors in atrial fibrillation (ATRIA) study. Ann Intern Med 1999, 131(12):927-934.
http://www.ncbi.nlm.nih.gov/pubmed/10610643
21) Fihn SD, Callahan CM, Martin DC, McDonell MB, Henikoff JG, White RH: The risk for and severity of bleeding complications in elderly patients treated with warfarin. The National Consortium of Anticoagulation Clinics. Ann Intern Med 1996, 124(11):970-979.
http://www.annals.org/content/124/11/970.full.pdf+html

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

Evidence-based guidelines on the use of warfarin in nonvalvular AF recommend that estimated risk of stroke be part of the decision process regarding long-term anticoagulation. (1) While risk stratification with the CHADS2 Score is an essential initial step in assessing the risk and benefits of anticoagulation therapy with warfarin, available data indicates that the risk factors for stroke are not systematically collected by many healthcare providers in patients presenting with AF. (2-13) Multiple appropriately designed prospective randomized trials with placebo controls have demonstrated that warfarin therapy reduces the stoke risk by 66% in patient with nonvalvular AF. (1) However, warfarin therapy remains widely underutilized. (2-13) Multiple studies using a range of methodologies have consistently documented that between 45-55% of patients who are candidates for anticoagulant therapy do not receive appropriate risk stratification or therapy. (2-13) Disease modeling methodology has estimated that the 1.25 million (55%) patients currently not receiving appropriate stroke prophylaxis in the United States suffer approximately 58,000 strokes annually with an associated total direct cost to Medicare of $ 4.8 billion. (14)

1b.3 Citations for data on performance gap:

1)Fuster V, Rydén LE, Cannom DS, et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation— executive summary: a report of the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for

Comment [k3]: 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

Practice Guidelines (writing committee to revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation). J Am Coll Cardiol 2006;48:854-906.
http://content.onlinejacc.org/cgi/content/full/48/4/854
2) Srivastava A, Hudson M, Hamoud I, Cavalcante J, Pai C, Kaatz S. Examining warfarin underutilization rates in patients with atrial fibrillation: Detailed chart review essential to capture contraindications to warfarin therapy. Thromb J. 2008 Jun 3;6:6.
http://www.ncbi.nlm.nih.gov/pubmed/18522741
3) Darkow T, Vanderplas AM, Lew KH, Kim J, Hauch O: Treatment patterns and real-world effectiveness of warfarin in nonvalvular atrial fibrillation within a managed care system. Curr
Med Res Opin 2005, 21(10):1583-1594.
http://www.ncbi.nlm.nih.gov/pubmed/16238898
4) Hylek EM, D´Antonio J, Evans-Molina C, Shea C, Henault LE, Regan S: Translating the results of randomized trials into clinical practice: the challenge of warfarin candidacy among hospitalized elderly patients with atrial fibrillation. Stroke 2006, 37(4):1075-1080.
http://stroke.ahajournals.org/cgi/content/short/37/4/1075
5) Waldo AL, Becker RC, Tapson VF, Colgan KJ: Hospitalized patients with atrial fibrillation and a high risk of stroke are not being provided with adequate anticoagulation. J Am Coll Cardiol 2005, 46(9):1729-1736.
http://content.onlinejacc.org/cgi/content/full/46/9/1729
6) Go AS, Hylek EM, Phillips KA, Borowsky LH, Henault LE, Chang Y, Selby JV, Singer DE: Implications of stroke risk criteria on the anticoagulation decision in nonvalvular atrial fibrillation: the Anticoagulation and Risk Factors in Atrial Fibrillation (ATRIA) study. Circulation 2000, 102(1):11-13.
http://www.ncbi.nlm.nih.gov/pubmed/10880408
7) Go AS, Hylek EM, Phillips KA, Chang Y, Henault LE, Selby JV, Singer DE: Prevalence of diagnosed atrial fibrillation in adults: national implications for rhythm management and stroke
prevention: the AnTicoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study. Jama 2001, 285(18):2370-2375.
http://www.ncbi.nlm.nih.gov/pubmed/11343485
8) McCormick D, Gurwitz JH, Goldberg RJ, Becker R, Tate JP, Elwell A, Radford MJ: Prevalence and quality of warfarin use for patients with atrial fibrillation in the long-term care setting. Arch Intern Med 2001, 161(20):2458-2463.
http://archinte.ama-assn.org/cgi/content/full/161/20/2458
9) Weisbord SD, Whittle J, Brooks RC: Is warfarin really underused in patients with atrial fibrillation? J Gen Intern Med 2001, 16(11):743-749.
http://onlinelibrary.wiley.com/doi/10.1111/j.1525-1497.2001.10432.x/pdf
10) Beyth RJ, Antani MR, Covinsky KE, Miller DG, Chren MM, Quinn LM, Landefeld CS: Why isn´t warfarin prescribed to patients with nonrheumatic atrial fibrillation? J Gen Intern Med 1996, 11(12):721-728.
http://www.springerlink.com/content/37514n8173855j1r/
11) Go AS, Hylek EM, Borowsky LH, Phillips KA, Selby JV, Singer DE: Warfarin use among ambulatory patients with nonvalvular atrial fibrillation: the anticoagulation and risk factors in atrial
fibrillation (ATRIA) study. Ann Intern Med 1999, 131(12):927-934.
http://www.ncbi.nlm.nih.gov/pubmed/10610643
12) Fihn SD, Callahan CM, Martin DC, McDonell MB, Henikoff JG, White RH: The risk for and severity of bleeding complications in elderly patients treated with warfarin. The National Consortium of Anticoagulation Clinics. Ann Intern Med 1996, 124(11):970-979.
http://www.annals.org/content/124/11/970.full.pdf+html
13) Hart RG, Benavente O, McBride R, Pearce LA: Antithrombotic therapy to prevent stroke in patients with atrial fibrillation: a meta-analysis. Ann Intern Med 1999, 131(7):492-501.
http://www.ncbi.nlm.nih.gov/pubmed/10507957
14) Caro JJ. An economic model of stroke in atrial fibrillation: the cost of suboptimal oral anticoagulation. Am J Manag Care. 2004 Dec;10:451-58
http://www.ajmc.com/media/pdf/AFib451.pdf

1b.4 Summary of Data on disparities by population group:
Among individuals confirmed to have AF by ECG, blacks were approximately one third as likely to be aware that they had AF as whites in this US national biracial large sample of adult men and women. (1) Because AF is such a powerful risk factor for incident stroke, these findings suggest that lower awareness of AF and reduced likelihood of treatment among blacks may place blacks at higher risk of a stroke event, which in

turn could contribute to the higher stroke mortality among blacks. (1) The reasons for disparities in awareness of the diagnosis of atrial fibrillation, risk stratification, and appropriate therapy remain largely unknown. (1-10) Many of the study participants may be undiagnosed, because often AF itself is not symptomatic. (1) Alternatively, these persons may have been diagnosed with the condition but simply did not remember or understand the condition.(1) Among those who were aware that they had AF and who had confirmation of the diagnosis of AF, blacks were approximately one fourth as likely to be treated with warfarin as whites. In striking contrast, risk of stroke as stratified by the CHADS2 score was not a predictor of warfarin use. (1) The fact that risk of future stroke did not significantly alter the likelihood of warfarin use would seem to reflect an evidence-practice gap.(1)
In this large biracial cohort, blacks were less likely to be aware of AF and less likely to be treated with warfarin than whites.(1) These findings are consistent with prior studies demonstrating that blacks are less likely to achieve quality of care goals for stroke risk factors such as glycemic control in diabetes and blood pressure in hypertension.(2-10) Such differences may underlie racial disparities in stroke morbidity and mortality and should lend urgency to focused efforts to improve patient education and medical literacy.(2-10) The additional finding that CHADS2 score was not a predictor of warfarin use highlights an evidence-practice gap that should prompt further efforts focused on practitioner awareness and education. (1)

From the experience of the PINNACLE Registry and sample of 27 practices comprised of 14,464 patients encompassing 18,021 clinical visits analysis shows sex differences in rates of compliance for this measure. Men (n=7,671) were compliant 80.7% while women (n=6,743) were compliant 75.7; adjusted RR: 0.94 [95% ci: 0.89-0.99); P =0.03(11)

1b.5 Citations for data on Disparities:

1) Meschia JF, Merrill P, Soliman EZ, Howard VJ, Barrett KM, Zakai NA, Kleindorfer D, Safford M, Howard G Racial disparities in awareness and treatment of atrial fibrillation: the REasons for Geographic and Racial Differences in Stroke (REGARDS) study. Stroke. 2010 Apr;41(4):581-7.
http://www.ncbi.nlm.nih.gov/pubmed/20190000
2) Howard G, Prineas R, Moy C, Cushman M, Kellum M, Temple E, Graham A, Howard V. Racial and geographic differences in awareness, treatment, and control of hypertension: the REasons for Geographic And Racial Differences in Stroke study. Stroke. 2006 May;37(5):1171-8.
http://www.ncbi.nlm.nih.gov/pubmed/16556884
3) Howard VJ, Cushman M, Pulley L, Gomez CR, Go RC, Prineas RJ, Graham A, Moy CS, Howard G. The REasons for Geographic And Racial Differences in Stroke study: objectives and design. Neuroepidemiology. 2005; 25: 135–143.
http://stroke.ahajournals.org/cgi/content/full/37/5/1147
4) Sacco RL, Boden-Albala B, Gan R, et al. Stroke incidence among white, black, and Hispanic residents of an urban community: the Northern Manhattan Stroke Study. Am J Epidemiol 1998;147:259–68.
http://aje.oxfordjournals.org/content/147/3/259.abstract
5) Pandey DK, Gorelick PB. Epidemiology of stroke in African Americans and Hispanic Americans. Med Clin North Am 2005;89:739 –52.
http://www.ophsource.org/periodicals/ophtha/medline/record/MDLN.15925647
6) Thrift AG, Dewey HM, Macdonell RA, McNeil JJ, Donnan GA. Incidence of the major stroke subtypes: initial findings from the North East Melbourne stroke incidence study (NEMESIS). Stroke 2001;32: 1732–8.
http://stroke.ahajournals.org/cgi/content/short/32/8/1732
7) Hu HH, Sheng WY, Chu FL, Lan CF, Chiang BN. Incidence of stroke in Taiwan. Stroke 1992;23:1237– 41.
http://stroke.ahajournals.org/cgi/content/short/23/9/1237
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http://content.onlinejacc.org/cgi/content/full/35/1/183
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http://archinte.ama-assn.org/cgi/reprint/165/10/1185.pdf
11) Chan PS,Oetgen WJ, Buchanan D,Mitchell K,Fiocchi FF,Tang F,Jones PG, Breeding T, Thrutchley D,

Rumsfeld JS, Spertus JA. Cardiac Performance Measure Compliance in Outpatients: The American College of Cardiology and National Cardiovascular Data Registry´s PINNACLE (Practice Innovation And Clinical Excellence) Program J Am Coll Cardiol 2010 56: 8-14
http://content.onlinejacc.org/cgi/content/abstract/56/1/8

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*)**:** Randomized controlled trials show that warfarin at a dose adjusted to an international normalized ratio of 2.0 to 3.0 reduces the risk of stroke by approximately 66%.(1-7) Efficacy demonstrated in the trials has been shown to translate into effectiveness in clinical practice. Multiple randomized trials involving patients with nonvalvular AF have performed with a total of over 20, 000 participants with an average follow-up of 1.6 y, a total exposure of about 32 800 patient-years with anticoagulation with vitamin K antagonist agents.(1-7) Multiple large randomized trials published evaluated oral anticoagulation mainly for primary prevention of thromboembolism in patients with nonvalvular AF. (1-7). Meta-analysis according to the principle of intention to treat showed that adjusted-dose oral anticoagulation is highly efficacious for prevention of all stroke (both ischemic and hemorrhagic), with a risk reduction of 66% (95% CI 47% to 71%) versus placebo. (2) The duration of follow-up was generally between 1 and 2 years; the longest was 2.2 years, whereas in clinical practice, the need for antithrombotic therapy in patients with AF typically extends over much longer periods. (1-7)

1) Stroke Prevention in Atrial Fibrillation Investigators. Stroke Prevention in Atrial Fibrillation Study. Final results. Circulation 1991;84:527–39.
http://circ.ahajournals.org/cgi/reprint/84/2/527
2) Hart RG, Benavente O, McBride R, et al. Antithrombotic therapy to prevent stroke in patients with atrial fibrillation: a meta-analysis. Ann Intern Med 1999;131:492–501.
http://www.annals.org/content/131/7/492.1.abstract
3) Stroke Prevention on Atrial Fibrillation Investigators. Adjusted-dose warfarin versus low-intensity, fixed-dose warfarin plus aspirin for high-risk patients with atrial fibrillation: Stroke Prevention in Atrial Fibrillation III randomised clinical trial. Lancet 1996;348:633– 8.
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2896%2903487-3/abstract
3)EAFT (European Atrial Fibrillation Trial) Study Group Secondary prevention in non-rheumatic atrial fibrillation after transient ischaemic attack or minor stroke. Lancet 1993;342:1255– 62.
http://www.thelancet.com/journals/lancet/article/PII0140-6736%2893%2992358-Z/abstract
4) Petersen P, Boysen G, Godtfredsen J, et al. Placebo-controlled, randomized trial of warfarin and aspirin for prevention of thromboembolic complications in chronic atrial fibrillation. The Copenhagen AFASAK study. Lancet 1989;1:175–9.
http://www.ncbi.nlm.nih.gov/pubmed/2563096?dopt=Abstract
5) Gullov AL, Koefoed BG, Petersen P. Bleeding during warfarin and aspirin therapy in patients with atrial fibrillation: the AFASAK 2 study. Atrial Fibrillation Aspirin and Anticoagulation. Arch Intern Med 1999; 159:1322– 8.
http://archinte.ama-assn.org/cgi/content/full/159/12/1322
6)Warfarin versus aspirin for prevention of thromboembolism in atrial fibrillation: Stroke Prevention in Atrial Fibrillation II Study. Lancet 1994;343:687–91.
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2894%2991577-6/abstract
7) Connolly SJ, Laupacis A, Gent M, et al. Canadian Atrial Fibrillation Anticoagulation (CAFA) Study. J Am Coll Cardiol 1991;18:349 –55.
http://content.onlinejacc.org/cgi/content/abstract/18/2/349

1c.2-3. Type of Evidence: Cohort study, Evidence-based guideline, Randomized controlled trial, Systematic synthesis of research, Meta-analysis

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
As noted in 1c1 above, multiple randomized controlled trials show that risk stratification followed by warfarin at a dose adjusted to an international normalized ratio of 2.0 to 3.0 reduces the risk of stroke by approximately 66%.(1-7) Efficacy demonstrated in the trials has been shown to translate into effectiveness in clinical practice. In an observational study of outpatients with atrial fibrillation assessment was made of

1c
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N☐

Comment [k4]: 1c. The measure focus is:
•an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;
OR
•if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
oIntermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
oProcess – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
oStructure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
oPatient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
oAccess – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
oEfficiency – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

the outcomes of guideline adherence in a large group of outpatients being followed in clinical practice. The effect of antithrombotic guideline adherence or deviance was analyzed exclusively in 3634 high-risk patients with AF because these composed the majority (89%) and because few cardiovascular events occurred in low-risk patients. Among high-risk patients, antithrombotic treatment was in agreement with the guidelines in 61% of patients, whereas 28% were undertreated and 11% overtreated. Compared to guideline adherence, undertreatment was associated with a higher chance of thromboembolism (odds ratio [OR], 1.97; 95% CI, 1.29-3.01; P = .004) and the combined end point of cardiovascular death, thromboembolism, or major bleeding (OR, 1.54, P = .024). This increased risk was nonsignificant for the end point of stroke alone (OR, 1.42; 95% CI, 0.82-2.46; P = .170). Overtreatment was nonsignificantly associated with a higher risk for major bleeding (OR, 1.52, P = .405). These important observations demonstrate that antithrombotic undertreatment of high-risk patients with AF was associated with a worse cardiovascular prognosis during 1 year, whereas overtreatment was not associated with a higher chance for major bleeding.

1) Stroke Prevention in Atrial Fibrillation Investigators. Stroke Prevention in Atrial Fibrillation Study. Final results. Circulation 1991;84:527–39.
http://circ.ahajournals.org/cgi/reprint/84/2/527
2) Hart RG, Benavente O, McBride R, et al. Antithrombotic therapy to prevent stroke in patients with atrial fibrillation: a meta-analysis. Ann Intern Med 1999;131:492–501.
http://www.annals.org/content/131/7/492.1.abstract
3) Stroke Prevention on Atrial Fibrillation Investigators. Adjusted-dose warfarin versus low-intensity, fixed-dose warfarin plus aspirin for high-risk patients with atrial fibrillation: Stroke Prevention in Atrial Fibrillation III randomised clinical trial. Lancet 1996;348:633– 8.
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2896%2903487-3/abstract
3)EAFT (European Atrial Fibrillation Trial) Study Group Secondary prevention in non-rheumatic atrial fibrillation after transient ischaemic attack or minor stroke. Lancet 1993;342:1255– 62.
http://www.thelancet.com/journals/lancet/article/PII0140-6736%2893%2992358-Z/abstract
4) Petersen P, Boysen G, Godtfredsen J, et al. Placebo-controlled, randomized trial of warfarin and aspirin for prevention of thromboembolic complications in chronic atrial fibrillation. The Copenhagen AFASAK study. Lancet 1989;1:175–9.
http://www.ncbi.nlm.nih.gov/pubmed/2563096?dopt=Abstract
5) Gullov AL, Koefoed BG, Petersen P. Bleeding during warfarin and aspirin therapy in patients with atrial fibrillation: the AFASAK 2 study. Atrial Fibrillation Aspirin and Anticoagulation. Arch Intern Med 1999; 159:1322– 8.
http://archinte.ama-assn.org/cgi/content/full/159/12/1322
6)Warfarin versus aspirin for prevention of thromboembolism in atrial fibrillation: Stroke Prevention in Atrial Fibrillation II Study. Lancet 1994;343:687–91.
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2894%2991577-6/abstract
7) Connolly SJ, Laupacis A, Gent M, et al. Canadian Atrial Fibrillation Anticoagulation (CAFA) Study. J Am Coll Cardiol 1991;18:349 –55.
http://content.onlinejacc.org/cgi/content/abstract/18/2/349
8) Nieuwlaat et al for the Euro Heart Survey Guideline-adherent antithrombotic treatment is associated with improved outcomes compared with undertreatment in high-risk patients with atrial fibrillation. The Euro Heart Survey on Atrial Fibrillation Am Heart J 2007;153:1006212.)
http://www.ahjonline.com/article/S0002-8703%2807%2900214-1/abstract

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

The strength and quality of the evidence supporting risk stratification and anticoagulation for patients with AF is very rigorous and robust. The evidence has been rated by the American College of Cardiology, American Heart Association, the European Society of Cardiology and the Heart Rhythm Society as Level A based on data dervied from multiple randomized clinical trials or meta-analyses as noted by the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines. Relevant recommendations and level of evidence are as follows: Class I Antithrombotic therapy to prevent thromboembolism is recommended for all patients with AF, except those with lone AF or contraindications. (Level of Evidence: A) The selection of the antithrombotic agent should be based upon the absolute risks of stroke and bleeding and the relative risk and benefit for a given patient. (Level of Evidence: A) Anticoagulation with a vitamin K antagonist is recommended for patients with more than 1 moderate risk factor. Such factors include age 75 y or greater, hypertension, HF, impaired LV systolic function (ejection

Comment [k6]: 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

fraction 35% or less or fractional shortening less than 25%), and diabetes mellitus. (Level of Evidence: A)

1c.6 **Method for rating evidence:** The weight of evidence in support of the recommendation is listed as follows:
-Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses
-Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies
-Level of Evidence C: Only consensus opinion of experts, case studies, or standard-of-care

1c.7 **Summary of Controversy/Contradictory Evidence:** In the trials that validated the utility of warfarin for prevention of stroke and systemic embolism in patients with AF the target intensity of anticoagulation varied, broadly overlapping the target INR range of 2.0 to 3.0 currently recommended. Pooled data from these trials, which involved a total of 2,854 participants, show that adjusted-dose warfarin decreased the risk of nonfatal stroke by two-thirds. Anticoagulation also increases the risk of nonfatal major extracranial bleeding, although the 95% confidence interval for the estimate of incremental bleeding risk is wide. For fatal outcomes related to thromboembolism and bleeding, point estimates favor warfarin therapy but 95% confidence bounds encompass no effect.
Adjusted-dose warfarin is superior to aspirin for prevention of stroke in patients with AF, but may be associated with a greater risk of bleeding, based upon studies involving 6,526 patients enrolled in 11 randomized trials, in which anticoagulant therapy was typically targeted to an INR range of 2.0 to 3.0 (higher in the earlier trials). Pooled data from these trials show that adjusted-dose warfarin reduce the risk of nonfatal stroke by half compared to antiplatelet monotherapy, most commonly aspirin 75 to 325 mg/day. When data from these trials are pooled, the relative risk for nonfatal major extracranial bleeding on anticoagulant is 1.35, but the 95% confidence interval (0.91 to 2.01) encompasses no effect. Evidence from other populations suggests that vitamin K antagonist (VKA) therapy is likely associated with an increased risk of major bleeding.
The ACTIVE-W trial comparing dual antiplatelet therapy with aspirin plus clopidogrel to VKA therapy (INR 2.0 to 3.0) (1) was terminated because of superiority of VKA therapy for prevention of the primary outcome of stroke, systemic embolism, myocardial infarction, or vascular death, while there was no difference in the risk of major bleeding. Most patients (77%) were receiving VKA therapy prior to randomization, raising concerns about generalizability of the results to newly anticoagulated patients. In a prespecified secondary analysis, there was no significant difference in rates of the primary outcomes among patients who were and were not receiving VKA therapy at entry, but there was a statistically significant interaction of the risk of major bleeding based on prior VKA use.
Several studies assessed oral anticoagulation at lower INR intensities or fixed low doses and found that adjusted dose warfarin at INR of 2.0 to 3.0 was more effective in reducing the risk of stroke. (2)
Observational studies have shown that the risk of ischemic stroke is much greater when INR levels are below 2.0, and efficacy is not appreciably greater with levels greater than 2.0, but the risk of intracranial hemorrhage increases at INR levels above 3.0 in patients with AF. (3,4,5,6) These data support a target INR range of 2.0 to 3.0. Increasing time out of range is associated with higher rates of mortality, ischemic stroke, thromboembolism and major bleeding. (7,8,9,10) A minimum time in therapeutic range of at least 50% to 60%) appears necessary to realize the benefits of warfarin therapy for stroke prevention.
Antithrombotic therapy for AF is evolving as new oral anticoagulants that directly target the coagulation pathway, have a more predictable anticoagulant effect, and do not require regular INR monitoring are introduced into clinical practice. Among these are the direct thrombin inhibitor dabigatran and the factor Xa inhibitors apixaban, rivaroxaban and edoxaban, among others. Results of large phase 3 clinical trials of these agents have been recently published (11) or are expected in 2011 (12,13,14) and dabigatran was approved for clinical use in the U.S. in October 2010. Experience with these anticoagulants is rapidly evolving, but since they have not yet been widely adopted in clinical practice, uncertainties persist about their effectiveness and safety in clinical practice outside the context of highly controlled clinical trials.
1) Connolly S, Pogue J, Hart R, et al. Clopidogrel plus aspirin versus oral anticoagulation for atrial fibrillation in the Atrial
fibrillation Clopidogrel Trial with Irbesartan for prevention of Vascular Events (ACTIVE W): A randomised controlled trial. Lancet
2006;367:1903-1912.
2) Hart RG, Benavente O, McBride R, et al. Antithrombotic therapy to prevent stroke in patients with atrial fibrillation: a
meta-analysis. Ann Intern Med 1999;131:492-501.
http://www.annals.org/content/131/7/492.1.abstract

3) Fang MC, Chang Y, Hylek EM, et al. Advanced age, anticoagulation intensity, and risk for intracranial hemorrhage among
patients taking warfarin for atrial fibrillation. Ann Intern Med 2004;141:745-752.
4) Hylek EM, Go AS, Chang Y, et al. Effect of intensity of oral anticoagulation on stroke severity and mortality in atrial
fibrillation. N Engl J Med 2003;349:1019-1026.
5) Hylek EM, Skates SJ, Sheehan MA, Singer DE. An analysis of the lowest effective intensity of prophylactic anticoagulation for
patients with nonrheumatic atrial fibrillation. N Engl J Med 1996;335:540-546.
6) Walker AM, Bennett D. Epidemiology and outcomes in patients with atrial fibrillation in the United States. Heart Rhythm
2008;5:1365-1372.
7) Jones M, McEwan P, Morgan CL, Peters JR, Goodfellow J, Currie CJ. Evaluation of the pattern of treatment, level of
anticoagulation control, and outcome of treatment with warfarin in patients with non-valvar atrial fibrillation: a record linkage
study in a large British population. Heart 2005;91:472-477.
8) White HD, Gruber M, Feyzi J, et al. Comparison of outcomes among patients randomized to warfarin therapy according to
anticoagulant control: results from SPORTIF III and V. Arch Intern Med 2007;167:239-245.
9) Connolly SJ, Pogue J, Eikelboom J, et al. Benefit of oral anticoagulant over antiplatelet therapy in atrial fibrillation depends
on the quality of international normalized ratio control achieved by centers and countries as measured by time in therapeutic
range. Circulation 2008;118:2029-2037.
10) Wan Y, Heneghan C, Perera R, et al. Anticoagulation control and prediction of adverse events in patients with atrial
fibrillation: a systematic review. Circ Cardiovasc Qual Outcomes 2008;1:84-91.
11) Connolly SJ, Ezekowitz MD, Yusuf S, et al. Dabigatran versus warfarin in patients with atrial fibrillation. N Engl J Med 2009;
361: 1139–51.
12)The Executive Steering Committee, on behalf of the ROCKET AF Study Investigators. Rivaroxaban—Once daily, oral, direct
factor Xa inhibition compared with vitamin K antagonism for prevention of stroke and embolism trial in atrial fibrillation:
Rationale and design of the ROCKET-AF study Am Heart J 010;159:340-347.
13) Lopes RD, Alexander JH, Al-Khatib SM, et al. Apixaban for reduction in stroke and other thromboembolic events in atrial
fibrillation (ARISTOTLE) trial: Design and rationale. Am Heart J 2010;159:331-9.
14) Ruff CT, Giugliano RP, Antman EM, et al. Evaluation of the novel factor Xa inhibitor edoxaban compared with warfarin in
patients with atrial fibrillation: Design and rationale for the effective anticoagulation with factor Xa next generation in atrial
fibrillation - Thrombolysis in Myocardial Infarction study 48 (ENGAGE AF-TIMI 48). Am Heart J 2010;160:635-41.

1c.8 Citations for Evidence (*other than guidelines*): 1A4 and 1B1 citations

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number*):
e179
2006 ACC/AHA/ESC Guidelines for the Management of Atrial Fibrillation Patients with AF
Chronic Anticoagulation Therapy
(Recommendations other those listed below pertain to antithrombotic therapy for patients with AF undergoing cardioversion) (4)
Class I
1. Antithrombotic therapy to prevent thromboembolism is recommended for all patients with AF, except those with lone AF or contraindications. (Level of Evidence: A)
2. The selection of the antithrombotic agent should be based upon the absolute risks of stroke and bleeding

and the relative risk and benefit for a given patient. (Level of Evidence: A)
3. Anticoagulation with a vitamin K antagonist is recommended for patients with more than one moderate risk factor. Such factors include age 75 y or greater, hypertension, HF, impaired LV systolic function (ejection fraction 35% or less or fractional shortening less than 25%), and diabetes mellitus. (Level of Evidence: A)
4. For patients without mechanical heart valves at high risk of stroke, chronic oral anticoagulant therapy with a vitamin K antagonist is recommended in a dose adjusted to achieve the target intensity INR of 2.0 to 3.0, unless contraindicated. Factors associated with highest risk for stroke in patients with AF are prior thromboembolism (stroke, TIA, or systemic embolism) and rheumatic mitral stenosis. (Level of Evidence: A)
5. The INR should be measured at least weekly during initiation of therapy and monthly when anticoagulation is stable. (Level of Evidence: A)
6. Aspirin, 81–325 mg daily, is recommended as an alternative to vitamin K antagonists in low-risk patients or in those with contraindications to anticoagulation. (Level of Evidence: A)
7. Antithrombotic therapy is recommended for patients with atrial flutter as for those with AF. (Level of Evidence: C)

1c.10 **Clinical Practice Guideline Citation:** Fuster V, Rydén LE, et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation—executive summary: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Guidelines and the European Society of Cardiology Committee for Practice Guidelines and Policy Conferences (Writing Committee to Revise the 2001 Guidelines for the Management of Patients with Atrial Fibrillation). Developed in Collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. J Am Coll Cardiol 2006;48:854-906.

In Press Citation--Wann LS, Curtis AB, Ellenbogen KA, et al. 2010 ACCF/AHA/HRS Focused Update on the Management of Patients With Atrial Fibrillation (Updating the 2006 Guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines.

1c.11 **National Guideline Clearinghouse or other URL:**
http://content.onlinejacc.org/cgi/content/full/51/8/865 and
http://content.onlinejacc.org/cgi/content/full/51/8/865

1c.12 **Rating of strength of recommendation (***also provide narrative description of the rating and by whom***):**
Class I: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective

1c.13 **Method for rating strength of recommendation** (*If different from USPSTF system, also describe rating and how it relates to USPSTF)***:**
ACCF/AHA Task Force on Practice Guidelines Method:
Indications are categorized as class I,II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowlege and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows:
Class I: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective
Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment
Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy
Class IIb: Usefulness/efficacy is less well established by evidence/opinion
Class III: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

1c.14 **Rationale for using this guideline over others:**
The CHADS2 score forms the basis for risk-based treatment recommendations because it has been extensively validated, uses readily available clinical risk factors, and is easily applied by clinicians. No alternative risk stratification scheme yet developed predicts stroke better than the CHADS2 score. The performance measures derive from estimates of annual stroke risk specific to patients in CHADS2 score categories greater than or equal to 2 as observed in aspirin-treated arms of six clinical trials of antithrombotic therapy in patients with AF. While fewer than 10% of screened patients were enrolled in these historical trials and evidence suggests that stroke rates may now be lower than then when these trials

Comment [k7]: USPSTF grading system **http://www.ahrq.gov/clinic/uspstf/grades.htm**: **A -** The USPSTF recommends the service. There is high certainty that the net benefit is substantial. **B -** The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. **C -** The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. **D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. **I -** The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

were conducted, data regarding stroke events in these trials were systematically and prospectively collected and remain the best available source of stroke rates stratified by CHADS2 score. Balancing this limitation, absolute rates of nonfatal major extracranial bleeding in cohorts of prevalent VKA users are also appreciably lower (average rate 1.3% per year) than during initiation of VKA therapy (inception cohorts), in reported rates have been as high as 4.7% per year. Data from prevalent users are the most relevant because they more accurately reflect the long-term risk of bleeding over the period of antithrombotic therapy for typical patient with AF. When expressed in proportion to estimate rates of bleeding off VKA therapy reported in observational studies the relative risk is 2.58. For relevant fatal outcomes (fatal thromboembolism and hemorrhage), point estimates favor VKA therapy, but the total small number of events is relatively small such that confidence intervals typically include no effect. Compared to antiplatelet monotherapy, pooled data from clinical trials show that adjusted-dose VKA therapy reduces the risk of nonfatal stroke by one-half. The ACTIVE trials found dual antiplatelet therapy with aspirin plus clopidogrel effective in reducing the risk of nonfatal stroke in patients with AF compared to aspirin alone, but the combination was associated with a increased risk of nonfatal major extracranial bleeding. Dual antiplatelet therapy with aspirin plus clopidogrel in AF is not an approved use of the combination in the United States.	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report*, **met?** **Rationale:**	**1** **Y☐** **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? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	
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***):** All patients with nonvalvular atrial fibrillation or atrial flutter at high risk of thromboembolism (i.e., those with any high-risk factor or more than 1 moderate-risk factor) for whom warfarin was prescibed. Low risk: No risk factors; Asprin 81 to 325 mg daily Intermediate risk: One moderate-risk factor; Aspirin 81 mg to 325 mg daily or warfarin (INR 2.0 to 3.0, target 2.5) High risk: Any high risk-factor or more than 1 moderate-risk factor; Warfarin (INR 2.0 to 3.0, target 2.5) **2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** Reporting year **2a.3 Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):**	
2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):** Patients with nonvalvular AF or atrial flutter for whom assessment of the specified thromboembolic risk factors documented one or more high-risk factor or more than one moderate-risk factor. **2a.5 Target population gender:** Female, Male **2a.6 Target population age range:** 18 years or older	**2a-specs** **C☐** **P☐** **M☐** **N☐**

Comment [KP8]: 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP) .

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***):**
Reporting year

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
Claims/Administrative: Denominator (Eligible Population): All patients aged 18 years and older with a diagnosis of nonvalvular AF or
atrial flutter at high risk for thromboembolism
ICD-9 diagnosis codes: 427.31, 427.32
AND
Not ICD-9 diagnosis codes: 394.0, 394.2 (mitral stenosis); 996.02, 996.71, V42.2, V43.3 (prosthetic heart valve)
AND
CPT E/M Service Code: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99245
AND (Report a CPT Category II code for risk of thromboembolism)
• CPT Category II code: 3552F- High risk for thromboembolism
• CPT Category II code: 3551F- Intermediate risk for thromboembolism
• CPT Category II code: 3550F- Low risk for thromboembolism
NOTE: ONLY PATIENTS AT HIGH RISK FOR THROMBOEMBOLISM ARE INCLUDED IN THE MEASURE'S DENOMINATOR WHEN CALCULATING PERFORMANCE
Numerator: Patients who were prescribed warfarin during the 12 month reporting period
• CPT Category II code: 4012F-Warfarin therapy prescribed
Denominator Exclusion: Documentation of medical reason(s) for not prescribing warfarin during the 12 month
reporting period
• Append modifier to CPT Category II code: 4012F-1P
Documentation of patient reason(s) for not prescribing warfarin during the 12 month reporting period
• Append modifier to CPT Category II code: 4012F-2P
Electronic Specifications:
The assessment of patients with nonvalvular AF for thromboembolic risk factors should include the following criteria:

Risk factors:
prior stroke or transient ischemic attack--> High risk
Age = 75 years--> Moderate risk
Hypertension--> Moderate risk
Diabetes mellitus--> Moderate risk
Heart failure or impaired LV systolic function--> Moderate risk

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** -Patients with valvular AF, specifically those with prosthetic heart valves or mitral stenosis.
-Patients at low risk for thromboembolism (i.e., those with none of the risk factors listed above).
-Patients with only one moderate risk factor.
-Postoperative patients.
-Patients with transient or reversible causes of AF (e.g., pneumonia or hyperthyroidism).
-Patients who are pregnant.
-Medical reason(s) documented by a physician, nurse practitioner, or physician assistant for not prescribing warfarin. Examples of medical reasons for not prescribing warfarin include, but are not limited to:
-Allergy
-Risk of bleeding
-Documentation of patient reason(s) for not prescribing warfarin (e.g., economic, social, and/or religious impediments, noncompliance or other reason for refusal to take warfarin)

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
None

Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
None

2a.12-13 Risk Adjustment Type: No risk adjustment necessary

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
N/A

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

2a.18-19 Type of Score: Rate/proportion
2a.20 Interpretation of Score: Better quality = Higher score
2a.21 Calculation Algorithm (*Describe the calculation of the measure as a flowchart or series of steps***):**
The ACCF Pinnacle Registry flowchart:
1.) Check if patient is documented to be 18 years of age or older; Exclude those patients younger than 18 or NULL
2.) Check encounter date in reporting period; exclude No or NULL
3.) System checks current and all previous encounters for this patient for documentation of atrial fibrillation/atrial flutter; Exclude NULL or no
4.) Check for diagnosis of atrial fibrillation/atrial flutter; Exclude NULL or No
5.) Check for Non-valvular atrial fibrillation/atrial flutter (Include if no documentation); Exclude Valvular atrial fibrillation
6.) Exclude transient/reversible cause (e.g. pneumonia, hyperthyroidism)
7.) Exclude cardiac surgery within past 3 months
8.) Exclude patients who are pregnant
9.) Check for documentation of 1 or more thromembolic high risk factors
10.) Check for documentation of 2 or more thromembolic moderate risk factors
11.) Check for the prescription of warfarin
12.) Exclude patients who have medical reasons (e.g. allergy to warfarin or risk of bleeding)
13.)Exclude patients who have patient reasons for not prescribing warfarin (e.g. economic, social, and/religious impediments, noncompliance)
14.) Exclude patients with system reasons

Assumes that if multiple date of births are found for a patient the most recent date of birth will be used.

2a.22 Describe the method for discriminating performance *(e.g., significance testing)***:**
Physician performance for this measure is benchmarked each quarter and annually. Benchmarks help to identify poorer performers. Standard deviations are presented on all benchmarks at the practice level to assess variation. Physicians could calculate their scores and assess variation among other practices based on the sample mean assuming normal distribution.

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)*:
N/A

2a.24 Data Source (*Check the source(s) for which the measure is specified and tested)*
Paper medical record/flow-sheet, Electronic clinical data, Electronic Health/Medical Record, Registry data

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.***):**
ACCF PINNACLE Registry

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL Journal-see Appendix E http://content.onlinejacc.org/cgi/content/full/51/8/865
https://www.pinnacleregistry.org/Documents/PINNACLE_DataCollectionForm_1.2.pdf

2a.29-31 Data dictionary/code table web page URL or attachment: URL
https://www.pinnacleregistry.org/Documents/PINNACLE_DataCollectionForm_1.2.pdf

2a.32-35 Level of Measurement/Analysis (*Check the level(s) for which the measure is specified and tested)*
Clinicians: Individual

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

2a.38-41 Clinical Services (*Healthcare services being measured, check all that apply*)
Clinicians: PA/NP/Advanced Practice Nurse, Clinicians: Physicians (MD/DO)

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample *(description of data/sample and size)***:** The first cohort is October 2009 and the second patient cohort is June 2010, each made up of 24 practices representing approximately 150 sites and 350 physicians. There are 5,949 patient records over the age of 18 in the first cohort and 6,462 patients in the second cohort, 79.1% of which are unique.

2b.2 Analytic Method *(type of reliability & rationale, method for testing)***:**
Overview
Assessing the reliability of measures in large scale electronic databases being sourced by disparate EHR systems requires the application of novel techniques. While we expect coding for commonly used data elements to become more standardized in the medium to long term, the proliferation of EHR vendors and the predisposition toward practice-level customization precipitated by stimulus funding has only exacerbated the variation in electronic documentation in the short term. As a result, registries like PINNACLE must rely on a layered normalization and data quality approach to ensure reliability. PINNACLE presently applies four layers of quality control: 1) custom data mapping with multi-iteration, multi-stakeholder validation, 2) a formal Data Quality Report utility and tight XSD schema, 3) inter-database benchmarking, and 4) continuous aggregate data quality review. In addition, for the purposes of this application, PINNACLE analysts have applied statistical sampling techniques (described below) to replicate at scale (tens of thousands of records) more traditional, small scale chart audits.

Custom Data Mapping with Multi-Iteration, Multi-Stakeholder Validation
The System Integration technology employed by the PINNACLE Registry is partially automatic and partially manual. The automatic portions of the process rely on standard data maps that correspond with the data structure of individual EHR products and versions. Relatively straightforward data elements, such as date of birth and atrial fibrillation diagnosis, are generally structured consistently across practices with similar EHRs and can thus be identified and mapped automatically with software. More complex or less common elements, AF transience for example, must be identified and mapped manually. This process relies on clinical and technical experts from the practice working with PINNACLE project managers and engineers to locate, and potentially normalize, the relevant data element. While potentially time consuming, this process ensures that multiple, highly-trained stakeholders (providers, practice technologists, PINNACLE project managers, engineers, and clinical staff) are reviewing and concurring on the accuracy of the data maps.

Furthermore, at multiple stages during the integration process practices and providers are reviewing both raw data pulls and calculated performance measures on test data extracts, full data extracts, and production extracts. Only after mapping is completed and the practice and PINNACLE staff have signed off on the accuracy of the data maps is the system placed into production.

Data Quality Report utility and XSD Schema
Production-level data extraction occurs on a massive scale. Initial production data extracts to generate baseline performance in the registry for even a single large practice can number in the hundreds of thousands of patient encounters. More routine monthly and quarterly extracts can generate thousands, or even tens of thousands, of encounters per practice. At that volume, human validation of inbound data quality is impossible.

Instead PINNACLE deploys a two layered automated data quality validation process. The first layer is a data

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Comment [KP10]: 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

Comment [k11]: 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

quality utility, called the DQR, which applies 65 unique tests to inbound data. These tests include valid range checks, parent child relationships, data completeness, and coding accuracy. The utility then generates a report alerting PINNACLE engineers, EHR vendors, or sometimes the practices themselves, to data errors. Depending on the scale of error, files may either be rejected in their entirety for revision and re-submittal or individual records may be segregated from the data load. After the file clears the DQR it must then pass a final XSD validation before being loaded into the data warehouse for production reporting.

Inter-Database Benchmarking
One of the most effective tools for assessing population level accuracy of performance measures is to compare descriptive statistics of disease populations (such as AF) and calculated aggregate performance across similarly scaled databases. PINNACLE currently collaborates with another large ambulatory database—currently containing in excess of ten million ambulatory encounters—to calibrate data collection accuracy and performance. The PINNACLE Registry and our partner database currently extract data from largely independent sources yet are finding AF population descriptors and average AF performance rates that are statistically equivalent across hundreds of thousands of AF patients. With north of 300,000 AF patients across the two databases, such combined and comparative analyses can actively evaluate over 10% of all diagnosed AF patients in the country.

Continuous Aggregate Data Quality Review
Once data has been calculated and aggregated at the practice and national level it then becomes possible and appropriate to reapply human scrutiny to data quality and measure reliability management. PINNACLE employs highly skilled professional assets, including the former chief data quality analyst for the 2010 United States Census, to be continuously reviewing and evaluating the accuracy of PINNACLE's reporting. In addition to evaluating data completeness, PINNACLE data quality resources also monitor inter- and intra-practice and provider, as well as inter-temporal, performance variability. PINNACLE is now of sufficient maturity that patterns in provider and practice level performance can be quickly interpreted to indentify 1) failures in data mapping, 2) failures in physician documentation (especially exclusion documentation), and 3) accurate assessments of performance.

Statistical Sampling Techniques for Assessment of Measure Reliability
Due to the scale of the PINNACLE Registry, as well as a series of outstanding methodological questions as to the value of EHR chart audits for validating information that was extracted from the same electronic source data, PINNACLE has not conducted such analyses. Instead, PINNACLE analysts use the scale of the registry itself to create smaller sample cohorts to assess the reliability and stability of measures. This approach requires certain assumptions, which we believe have prima facie validity and are confirmed from large scale analysis of the registry. The assumptions are as follows:

1. Physician performance is non-stochastic over time
2. Physician performance is statistically stable over modest time intervals absent exogenous shocks (i.e. major new scientific findings or direct performance improvement interventions)
3. At large patient population sizes, independent AF populations present consistently and normally
2b.3. Testing Results (Reliability statistics, assessment of adequacy in the context of norms for the test conducted)
Using these assumptions, then, PINNACLE analysts established two patient cohorts separated by nine months. The first cohort
is from October 2009 and the second patient cohort is from June 2010. Analysis of the two cohorts shows that 79.1% of the patients in the sample are primary cases and thus the cohorts contain sufficient uniqueness to assess the reliability of measures with a test-retest methodology. Furthermore, the AF population in each cohort presents consistently with near identical clinical descriptors, including first episode detected (15.30%, 15.99%) chronic paroxysmal (14.70%, 13.88%), chronic persistent/permanent (8.53%, 8.61%), valvular (2.18%, 0.97%), and non-valvular or undocumented (97.82%, 99.03%).

Once the cohorts were defined, performance was calculated at the individual physician level and the practice level. These rates were then aggregated to calculate the mean and standard deviation by cohort. Means were compared using the independent sample t-test to demonstrate that it is not possible to reject the null hypothesis at the .05 level. Specifically, the October 2009 mean performance rate (M=0.6976,

s=0.2673) was not statistically distinguishable from the June 2010 mean performance rate (M=0.5832, s=0.3403), where t(39)=1.2, p=0.237, a=0.05.

We interpret this finding to indicate that the performance measure is reliable for the following reasons:

1. We have demonstrated that the two cohorts are largely unique, with 79.1% of the sample populations composed of non-overlapping patients.
2. We have also demonstrated that despite this uniqueness, the AF population attributes are highly consistent, as expected with large sample sizes and expected mean regression.
3. We have asserted based on experience and detailed registry analysis that absent major scientific change or aggressive PI or QI interventions, physician performance is both non-stochastic and consistent over time.
4. Thus, the fact that physician performance was statistically non-differentiable between the two cohorts indicates measure repeatability and hence reliability.

2b.3 **Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)***:**
Using these assumptions, then, PINNACLE analysts established two patient cohorts separated by nine months. The first cohort
is from October 2009 and the second patient cohort is from June 2010. Analysis of the two cohorts shows that 79.1% of the patients in the sample are primary cases and thus the cohorts contain sufficient uniqueness to assess the reliability of measures with a test-retest methodology. Furthermore, the AF population in each cohort presents consistently with near identical clinical descriptors, including first episode detected (15.30%, 15.99%) chronic paroxysmal (14.70%, 13.88%), chronic persistent/permanent (8.53%, 8.61%), valvular (2.18%, 0.97%), and non-valvular or undocumented (97.82%, 99.03%).

Once the cohorts were defined, performance was calculated at the individual physician level and the practice level. These rates were then aggregated to calculate the mean and standard deviation by cohort. Means were compared using the independent sample t-test to demonstrate that it is not possible to reject the null hypothesis at the .05 level. Specifically, the October 2009 mean performance rate (M=0.3765, s=0.4052) was not statistically distinguishable from the June 2010 mean performance rate (M=0.3983, s=0.4450), where t(44)=0.174, p=0.863, a=0.05.

We interpret this finding to indicate that the performance measure is reliable for the following reasons:

1. We have demonstrated that the two cohorts are largely unique, with 79.1% of the sample populations composed of non-overlapping patients.
2. We have also demonstrated that despite this uniqueness, the AF population attributes are highly consistent, as expected with large sample sizes and expected mean regression.
3. We have asserted based on experience and detailed registry analysis that absent major scientific change or aggressive PI or QI interventions, physician performance is both non-stochastic and consistent over time.
4. Thus, the fact that physician performance was statistically non-differentiable between the two cohorts indicates measure repeatability and hence reliability.

2c. Validity testing

2c.1 **Data/sample** *(description of data/sample and size)***:** CONTENT/CONTEXT VALIDITY: To determine the content/context validity of the measures, a Delphi like peer review process was utilized. An explicit part of all ACCF/AHA/PCPI performance measures development is conducting a formal 30 day public comment period.
Content/context validity of the measures were established by virtue of the specialized expertise of the Performance Measures Work Group members who were involved in identifying and drafting the performance measures are all leaders and experts in the field of atrial fibrillation. Members chosen by the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), the American College of Cardiology (ACC), and the American Heart Association (AHA) included senior clinicians, specialists in cardiac arrhythmias and electrophysiology, a representative from the ACC/AHA/ESC Atrial Fibrillation Guideline Update Writing Committee, members of the American Medical Association (AMA), and members of the American College of Physicians (ACP). Lastly, this validity was achieved by the structured discussions that the work group conducted, and rigorous peer review and public comment.

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Comment [KP12]: 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

Additional validity can be seen in ACCF´s PI-CME program under section 3a3 (feasibility)

2c.2 Analytic Method *(type of validity & rationale, method for testing)*:
CONTENT/CONTEXT VALIDITY: Determined by structured work group discussions, in addition to rigorous peer review and public comment. The steps in the analytic method were: 1. Formation of the Development Committee: This measure was developed by the ACC/AHA/PCPI Performance Measures for Adults with Nonvalvular Atrial Fibrillation or Atrial Flutter Writing Committee, which was initially convened in September 2006. The Writing Committee was composed of appointed representatives from the American College of Cardiology (ACC) and the American Heart Association (AHA), including senior clinicians, current representatives of the ACCF/AHA Task Force on Performance Measures, specialists in cardiac arrhythmias and electrophysiology, a representative from the ACC/AHA/ESC Atrial Fibrillation Guideline Update Writing Committee, members of the American Medical Association, and members of the American College of Physicians. 2. Identification of Potential Factors for Inclusion: The Writing Committee initially identified 8 potential measures. To select measures for inclusion in the performance measurement set, the Writing Committee prioritized the Class I and Class III recommendations from the 2001 ACC/AHA/ESC AF Guideline and the Grade 1 recommendations from the 2003 ACP/AAFP Management of Newly Detected Arial Fibrillation Guidelines (Fuster V, Rydén LE, et al. ACC/AHA/ESC guidelines for the management of patients with atrial fibrillation—executive summary: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines and Policy Conferences (Committee to Develop Guidelines for the Management of Patients with Atrial Fibrillation). J Am Coll Cardiol 2001;38:1266i) (Snow V, Weiss KB, LeFevre M, McNamara R, Bass E, Green L, Michl K, Owens DK, Susman J, Allen D, Mottur-Pilson C for the Joint AAFP/ACP Panel on Atrial Fibrillation Management of Newly Detected Atrial Fibrillation. A clinical practice guideline from the American Academy of Family Physicians and the American College of Physicians. Annals of Internal Medicine 2003:139;1009-18.) Following publication of the ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation (Fuster V, Rydén LE, et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation—executive summary: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Guidelines and the European Society of Cardiology Committee for Practice Guidelines and Policy Conferences (Writing Committee to Revise the 2001 Guidelines for the Management of Patients with Atrial Fibrillation). Developed in Collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. J Am Coll Cardiol 2006;48:854-906.) the Writing Committee re-evaluated the performance measures to ensure consistency with the 2006 recommendations for risk stratification and anticoagulation.

From analysis of these recommendations, the Writing Committee identified potential measures relevant to the management of patients with AF, and then independently evaluated their potential for use as performance measures using exclusion criteria adapted from the ACC/AHA Attributes for Good Performance Measures (Table 4: http://content.onlinejacc.org/cgi/content/full/51/8/865) and the Quality Indicator Survey Form and Definitions (Appendix B: http://content.onlinejacc.org/cgi/content/full/51/8/865). Member ratings of all the potential measures were collated and discussed by the full committee to reach consensus about which measures should advance for inclusion in the final measure set. The 8 potential measures then advanced for full specification to assess their suitability as performance measures. The Writing Committee met again to review and clarify these specifications and to select measures for inclusion in the final set. At this stage, the Committee also decided to include as an additional measure the assessment of thromboembolic risk factors. 3. Scoring of the Factors/Expert Opinion: Utilizing the ACCF/AHA system for classification of recommendations and level of evidence for guidelines and clinical recommendations system those measures that were deemed to be most evidence-based, interpretable, actionable, clinically meaningful, valid, reliable, and feasible were included in the final performance measurement sets. 4. Refinement of the PM by the Development Committee: After the measures were identified, the Writing Committee discussed and refined these measures, developing the definition, content, and other details. 5. Public Comment Period/Peer Review: The measurement set underwent a public comment period between January 15, 2007 and February 15, 2007. 6. Further Refinement: After the public comment period the measures were identified, the Writing Committee discussed and refined these measures, developing the definition, content, and other details. The final measure set was approved by the American College of Cardiology Foundation Board of Trustees in September 2007, by the American Heart Association Science Advisory and Coordinating Committee in September 2007, and by the Physician Consortium for Performance Improvement in December 2007. The performance measure set was also reviewed via AHA and ACC processes as well as through PCPI membership vote and executive committee. 7. Peer Review Publication/Endorsement: The final document was

Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

submitted to the Journal of the American College of Cardiology (the official journal of the American College of Cardiology), and Circulation (the official journal of the American Heart Association) for peer review and publication and on the PCPI website at http://www.physicianconsortium.org

2c.3 Testing Results *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:
CONTENT/CONTEXT VALIDITY: In March 2008 the final peer reviewed publication of the performance measures document was approved by the American College of Cardiology Foundation Board of Trustees, by the American Heart Association Science Advisory and Coordinating Committee, and the Physician Consortium for Performance Improvement Executive Committee. Additionally, the publication was done in collaboration with the Heart Rhythm Society. The final document was published the Journal of the American College of Cardiology (the official journal of the American College of Cardiology), Circulation (the official journal of the American Heart Association), and the PCPI website at http://www.physicianconsortium.org. The document can also be be found at http://content.onlinejacc.org/cgi/content/full/51/8/865

2d. Exclusions Justified

2d.1 Summary of Evidence supporting exclusion(s):
The following exclusions were made based on multiple considerations: 1) patients with mitral stenosis or prosthetic heart valves 2) patients with transient or reversible causes of AF (e.g., pneumonia or hyperthyroidism) 3) postoperative patients 4) patients who are pregnant 5) medical reason(s) documented by a physician, nurse practitioner, or physician assistant for not assessing risk factors.-examples of me dical reasons for not assessing risk factors include but are not limited to allergy to warfarin or risk of bleeding. The primary consideration in excluding these measures in the risk stratification process was that the evidence base supporting the clinical utility of risk stratification in these excluded populations using the CHADS2 Score was insufficient. In addition, these exclusions were included to allow for appropriate clinical decision making in individuals with an allergic reaction to warfarin or at risk for adverse effects due to bleeding complications. (1-3)

2d.2 Citations for Evidence:
1) Estes NAM III et al. ACC/AHA/Physician Consortium 2008 Clinical Performance Measures for Adults With Nonvalvular Atrial Fibrillation or Atrial Flutter A Report of the American College of Cardiology/American HeartAssociation Task Force on Performance Measures and the Physician Consortium for Performance Improvement (Writing Committee to Develop Clinical Performance Measures for Atrial Fibrillation)Circulation 2008;117;1101-1120.
http://content.onlinejacc.org/cgi/content/full/51/8/865
2) Bonow RO, Masoudi FA, Rumsfeld JS, Delong E, Estes NA 3rd, Goff DC Jr, Grady K, Green LA, Loth AR, Peterson ED, Piña IL, Radford MJ, Shahian DM; American College of Cardiology; American Heart Association Task Force on Performance Measures. ACC/AHA classification of care metrics: performance measures and quality metrics: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol. 2008 Dec 9;52(24):2113-7.
http://content.onlinejacc.org/cgi/content/full/j.jacc.2008.10.014
3) Fuster V, Rydén LE, Cannom DS, et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation— executive summary: a report of the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (writing committee to revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation). J Am Coll Cardiol 2006;48:854-906.
http://content.onlinejacc.org/cgi/content/full/48/4/854

2d.3 Data/sample *(description of data/sample and size)*: The sample population, which ranges from October 1st, 2009 through September 30th, 2010, is made up of 30 practices representing approximately 180 sites and 475 physicians. There are 435,530 patient records over the age of 18 of which 26,997 patients were eligible for this measure after exclusions.

2d.4 Analytic Method *(type analysis & rationale)*:
Frequency of exclusion coding

2d.5 Testing Results *(e.g., frequency, variability, sensitivity analyses)*:
Pinnacle registry rates of exclusion coding:

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P ☐
M ☐
N ☐
NA ☐

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND
•a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
AND
•precisely defined and specified:
–if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

Comment [k15]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

-Patients with valvular AF, specifically those with prosthetic heart valves or mitral stenosis: 4.95%
-Cardiac Surgery past 3 months: 0.22%
-Patients with transient or reversible causes of Atrial Fibrillation (e.g., pneumonia or hyperthyroidism).
-Patients who are pregnant: 0.03%
-Medical reason(s) documented by a physician, nurse practitioner, or physician assistant for not prescribing warfarin: 0.32%
-Documentation of patient reason(s) for not prescribing warfarin (e.g., economic, social, and/or religious impediments, noncompliance or other reason for refusal to take warfarin): 1.54%
-Documentation of system reason(s) for not prescribing warfarin (e.g. lack of drug availability or other reasons attributable to the health care system): 2.34%
The low numbers are discussed in section 4e1.
The incidence of "noncardiac surgery" causing atrial fibrillation in the PINNACLE Registry is relatively low-reflecting the low clinical frequency. As we cannot exclude the "noncardiac surgery" from the PINNACLE registry, it should be noted that since the PINNACLE exclusions are narrower than the measure was originally specified, the calculation algorithm used may include a relatively small (and unquantifiable) number patients that were not intended to be included. The PINNACLE Registry is actively looking at ways to reconcile the differences in the flowsheet and plans to update the flowsheet in the 1st quarter of 2011.

2e. Risk Adjustment for Outcomes/ Resource Use Measures

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

2e.2 **Analytic Method** *(type of risk adjustment, analysis, & rationale)*:
N/A

2e.3 **Testing Results** *(risk model performance metrics)*:
N/A

2e.4 **If outcome or resource use measure is not risk adjusted, provide rationale:** N/A

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N☐
NA☐

2f. Identification of Meaningful Differences in Performance

2f.1 **Data/sample from Testing or Current Use** *(description of data/sample and size)*: The ACCF PINNACLE Registry sample population is made up of 30 practices representing approximately 180 sites and 475 physicians. The sample ranges from October 1st, 2009 through September 30, 2010 with 435,530 patient records over the age of 18 of which 26,997 patients were eligible for this measure after exclusions.

2f.2 **Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)*:
Distribution of rates for prescriptions given for warfarin for all patients with nonvalvular atrial fibrillation or atrial flutter at high risk for thromboembolism.

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)*:
Performance ranges from 40.1% at the 10 percentile, 53.3% at the 25 percentile, 63.2% at the median; 68.9% at the 75 percentile; and 82.8% at the 90th percentile. The mean is 59.4% +_ Standard deviation 23.1%. Gaps are largely driven by poor physician documentation. Physicians actually performed all the elements required for CHAD score. However, it appears like they are underperforming because they are not documenting this.

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2g. Comparability of Multiple Data Sources/Methods

2g.1 **Data/sample** *(description of data/sample and size)*: We specify in section 4d1 what strategies we are currently doing and plan to perform in the future.

2g.2 **Analytic Method** *(type of analysis & rationale)*:

2g.3 **Testing Results** *(e.g., correlation statistics, comparison of rankings)*:

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P☐
M☐
N☐
NA☐

Comment [KP16]: 2e. For outcome measures and other measures (e.g., resource use) when indicated:
•an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care;[Error! Bookmark not defined.] OR rationale/data support no risk adjustment.

Comment [k17]: 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

Comment [KP18]: 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

Comment [KP20]: 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

2h. Disparities in Care **2h.1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)***:** **2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:**	**2h** **C☐** **P☐** **M☐** **N☐** **NA☐**
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties***, met?** **Rationale:**	*2* **C☐** **P☐** **M☐** **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 **3a.1 Current Use:** In use **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)***:** This measure is not yet used in any public reporting initiative. The measure will, however, be eligible for inclusion in the CMS PQRS and other government programs in 2012 and would thus provide information about clinician participation to the public. The ACCF, AHA, and PCPI believes that the reporting of such participation information is a beneficial first step on a trajectory toward the public reporting of performance results, which is most appropriate after the measures are thoroughly tested and the reliability of the performance data has been validated."The goal of all performance measures is to link processes of care to meaningful outcomes. As its an evolving process, we are evaluating public reporting options. As seen in our registries, ACCF and AHA are both committed to investing significant resources into these initiatives. **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***):** The American Heart Association's Get With The Guidelines®-Outpatient (GWTG-O) is a virtual performance improvement program that will improve adherence to evidence-based care in the outpatient setting, including specialist practices, general healthcare practices and health clinics. GWTG-Outpatient historically has had a long history of quality improvement for cardiovascular care. They have published 65 publications over the past 10 years. This program is designed to assist healthcare professionals in the outpatient setting to provide the best possible care to patients. This program collects a number of clinical measures for primary and secondary prevention. Clinical measure sets include those developed by American Heart Association, including those co-developed with other organizations, such as the American College of Cardiology Foundation and the American Medical Association, as well as other National Quality Forum endorsed measures. Through this program, we collect data on clinical measures affecting a number of cardiovascular-related conditions including, atrial fibrillation, coronary artery disease, heart failure, hypertension, diabetes, and preventative care. The primary analytical system used is Duke Clinical Research Institute. Get With The Guidelines®-Outpatient is a quality improvement program that can be utilized for Maintenance of Certification (MOC) with groups like American Board of Internal Medicine (ABIM) and American Board of Family Medicine (ABFM). ABIM has confirmed that the reports received from Get With The Guidelines-Outpatient can be utilized in completion of their Self-Directed Practice Improvement Module (PIM). The Self-Directed PIM provides one pathway for earning practice performance credit in ABIM's MOC program. This program includes several integral components: A preliminary Continuing Education (CE) course for the	**3a** **C☐** **P☐** **M☐** **N☐**

Comment [KP21]: 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);OR rationale/data justifies why stratification is not necessary or not feasible.

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

care team, data submission and reporting that is integrated with existing Electronic Health Records (EHRs)/health technology platforms, corresponding professional and provider education including webinars, online tools and resources, digital access to reference materials and videos through the Get With The Guidelines®-Outpatient website (http://outpatient.heart.org). The free continuing education activity titled, Outpatient Quality Improvement Focus, addresses the quality chasm and treatment gap, presents the benefits of quality improvement and identifies the steps necessary for implementation in the practice setting. This continuing education activity is certified for physicians, nurses and pharmacists.

The American College of Cardiology Foundation's Cardiology Practice Improvement Pathway (CPIP) uses clinical measure sets that are developed and specified by the American College of Cardiology Foundation with the American Heart Association and the American Medical Association's Physician Consortium for Performance Improvement for Hypertension, Stable Coronary Artery Disease, Heart Failure, and Atrial Fibrillation/Atrial Flutter. This program is intended as an approved quality improvement product that can be applied toward ABIM's Part IV practice performance requirement for Maintenance of Certification (ABIM AQI application submitted). They are in the process of creating a homepage on the Cardiosource.org homepage. The URL will be cardiosource.org/cpip. The web-based tool will be available after spring 2011. Through an online webinar hosted in November 2010, CPIP anticipates enrolling 50 - 100 practices during 2011 which will provide data from about 500-1,000 cardiologists. This ACCF initiative has contracted with the NY QIO: IPRO to analyze and scores based on thresholds. Of the 100 points needed to achieve recognition in the program, 70 come directly from clinical points such as the 2 AFIB measures that are being submitted to NQF for consideration. IPRO will audit 5% of practices who submit their data for recognition evaluation.

The American College of Cardiology Foundation's has an Performance Improvement program entitled "A New Era" which is an educational format approved for credit by the American Medical Association (AMA) and the American Nursing Credentialing Center. This continuing medical education program blends both quality improvement and educational methodologies to provide a high quality learning experience that impacts changes to practice. These activities are structured, long-term processes in which a healthcare professional learns about the two atrial fibrillation specific performance metrics, uses metrics to retrospectively assess his practice, applies these metrics prospectively over a useful interval, and reevaluates his performance. As part of this process, clinicians set goals for change and engage in structured learning activities to improve their performance. As of Decemer 6th, 2010:

- 425 clinicians have enrolled in "A New ERA"

- The data is generated from all but four states (Montana, New Hampshire, South Dakota, and Wyoming)

- 82% are physicians

- 90% agreed or strongly agreed that performance metric data were valuable

- 80% agreed or strongly agreed that performance metric data review would help them improve their practice

- No one has finished the program, as it takes several months to do so

- Performance measure data for enrollees are:

Afib Performance Measure	Range	Median	National Average
Assessment of thromboembolitic factors	3.5-100%;	18.6%;	15.1%
Chronic anticoagulation therapy	0-100%;	50.5%;	49.7%

http://www.cardiosource.org/Certified-Education/Performance-Improvement.aspx

In 2008, the American College of Cardiology Foundation launched the PINNACLE program (formerly known as the Improving Continuous Cardiac Care or IC3). This was the first, national, prospective, outpatient based cardiac QI registry in the US. While participation is voluntary, this registry collects a variety of

longituditional patient data at the point of service, including patients' symptoms, vital signs, medication, and recent hospitalizations. Jointly developed ACCF/AHA/PCPI measures for Coronary Artery Disease, Heart Failure, and Atrial Fibrillation. Data collection is achieved in 2 ways for the practices: paper forms or practice's electronic medical record data collection systems. The primary analytical system used is St. Luke's Mid America Heart Institute. The ACCF registry, PINNACLE, pulls data from outpatient facilities via paper flowsheets or 14 EHR vendors. As of December 10, 2010, there are 47 practices collecting data at 200 sites with 276,000 unique patients representing 1 million documented encounters. **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) **3a.4 Data/sample** *(description of data/sample and size)*: See 4e1 **3a.5 Methods** *(e.g., focus group, survey, QI project)*: **3a.6 Results** *(qualitative and/or quantitative results and conclusions)*:	
3b/3c. Relation to other NQF-endorsed measures **3b.1 NQF # and Title of similar or related measures:** NQF #0241: Anticoagulant therapy prescribed for atrial fibrillation at discharge; NQF #0624:Atrial Fibrillation-warfarin therapy; NQF #0084: Heart Failure:Warfarin therapy patients with atrial fibrillation; NQF #0600 New Atrial Fibrillation: Thryroid Function Test; NQF #0436: Patients with Atrial Fibrillation Receiving Anticoagulation Therapy	
(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**	
3b. Harmonization 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): **3b.2 Are the measure specifications harmonized? If not, why?** 0241- Measure is being retired; care setting is inpatient 0624- Measure has different source; clinically enriched level 2 data which is better than Level 1, but essentially is still claims data 0084- The patient population focus is stroke 0600- The condition focus is thyroid function and measure has different source; clinically enriched level 2 data which is better than Level 1, but essentially is still claims data 0436- Care Setting focus is inpatient; proposed measure for submission is outpatient settings	**3b** C☐ P☐ M☐ N☐ NA☐
3c. Distinctive or Additive Value **3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:** While one could use the ICD-9 codes for Atrial Fibrillation or Atrial Flutter, the measure is designed for use with electronic clinical data, EHR/EMR, flowsheet, or registry data. **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** C☐ P☐ M☐ N☐ NA☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability*?	**3**
Steering Committee: Overall, to what extent was the criterion, *Usability*, **met?** **Rationale:**	**3** C☐ P☐ M☐ N☐
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be	**Eval**

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

Comment [k24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., *influenza immunization* of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for *patients with diabetes*), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).

implemented for performance measurement. (evaluation criteria)	Rating
4a. Data Generated as a Byproduct of Care Processes 4a.1-2 **How are the data elements that are needed to compute measure scores generated?** Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), 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 C☐ P☐ M☐ N☐
4b. Electronic Sources 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*) Yes 4b.2 **If not, specify the near-term path to achieve electronic capture by most providers.**	4b C☐ P☐ M☐ N☐
4c. Exclusions 4c.1 **Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No 4c.2 **If yes, provide justification.**	4c C☐ P☐ M☐ N☐ NA☐
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences 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.** The PINNACLE Registry takes a number of steps to minimize any potential for inaccuracies or errors in data used to report on performance back to outpatient • Meetings, resource guides on the website, and clinical quality consultants available via email, toll free number • Changing the quarterly feedback to a monthly cycle • Feedback loop allows practices to go back and add fields to better capture the clinical data The certification process provides checks of data elements within the data collection. The Data Quality Report process checks (discussed under section 2b3) ensures accurate quality data submissions. If an EHR is uncustomized for PINNACLE, while its no cost to the outpatient practice, there is a chance the data is less complete. However, modifying a practice's EHR, allows for more robust data. The ACC Practice Improvement Pathway has a number of steps to minimize unintended consequences including having a contractor (IPRO-NY QIO) audit 5% of practices who submit their data for recognition evaluation.	4d C☐ P☐ M☐ N☐
4e. Data Collection Strategy/Implementation 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:** -Ambiguity regarding medical or patient reasons for not prescribing warfarin -Difficulty locating reasons in the medical record for not prescribing warfarin --Lack of documentation regarding medical or patient reasons for not prescribing warfarin; clinicians are collecting data elements needed for the measure but they are either choosing not to document some parts of the measure or the EHR has not been customized to document. For example, the reason why medical exclusions for warfarin is low is because clinicians do not document why they didn't prescribe warfarin. An unintended consequence of this measure, is that clinicians not documenting the information on the flowsheet lowers the score in the performance measure. Clinicians leave some areas blank on the flowsheet	4e C☐ P☐ M☐ N☐

Comment [KP26]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

Comment [KP27]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

Comment [KP28]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

Comment [KP30]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

which gives a false impression of poor clinician performance. 4e.2 **Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** Pinnacle electronic flowsheet Economic: No cost Time: Doctor should be documenting this information anyhow -Additional 15-30 seconds per patient to complete all measures (PINNACLE flowsheet captures AFIB, CAD, HTN, and HF) -Faxing paper form takes 2.5-5 minutes per encounter 4e.3 **Evidence for costs:** 4e.4 **Business case documentation:**	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, **met?** **Rationale:**	**4** **C☐** **P☐** **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? **Comments:**	**Y☐** **N☐** **A☐**
CONTACT INFORMATION	
Co.1 **Measure Steward (Intellectual Property Owner)** Co.1 **Organization** American College of Cardiology Foundation/ American Heart Association/American Medical Association´s Physician Consortium for Performance Improvement, 2400 N. Street NW, Washington DC, District Of Columbia, 20037 Co.2 **Point of Contact** Jensen, Chiu, MHA, jensen.chiu@acc.org, 202-375-6285-	
Measure Developer If different from Measure Steward Co.3 **Organization** American College of Cardiology Foundation/ American Heart Association/American Medical Association´s Physician Consortium for Performance Improvement, 2400 N. Street NW, Washington DC, District Of Columbia, 20037 Co.4 **Point of Contact** Jensen, Chiu, MHA, jensen.chiu@acc.org, 202-375-6285-	
Co.5 **Submitter If different from Measure Steward POC** Jensen, Chiu, MHA, jensen.chiu@acc.org, 202-375-6285-, American College of Cardiology Foundation/ American Heart Association/American Medical Association´s Physician Consortium for Performance Improvement	
Co.6 **Additional organizations that sponsored/participated in measure development** Heart Rhythm Society collaborated during the measure development process. The HRS representatives during measure development were Drs. Mark Estes, III, Albert Waldo, and George Wyse	
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. The workgroup selected all measures, developed the measure specifications and the text for the published journal article. The workgroup selected all measures, developed the measure specifications and the text for the published journal article. N.A Mark Estes, III MD, FACC, FAHA, FHRS, Jonathan L. Halperin, MD, FACC, FAHA, Hugh Calkins, MD, FACC,FAHA, Michael D. Ezekowitz, MB, ChB, DPhil, FACC, Paul Gitman, MD, MACP, Alan S. Go, MD, Robert L. McNamara, MD, MHS, FACC, Joseph V. Messer, MD, MACC, FAHA, James L. Ritchie, MD, FACC, FAHA, Sam J. W. Romeo, MD, MBA, Albert L. Waldo, MD, FACC, FAHA, FHRS, D. George Wyse, MD, PhD, FACC, FAHA, FHRS
Ad.2 If adapted, provide name of original measure: **Ad.3-5 If adapted, provide original specifications URL or attachment** URL http://content.onlinejacc.org/cgi/content/full/51/8/865
Measure Developer/Steward Updates and Ongoing Maintenance **Ad.6 Year the measure was first released:** 2008 **Ad.7 Month and Year of most recent revision:** 2008 **Ad.8 What is your frequency for review/update of this measure?** This measure is consistent with current Guidelines; will revise these annually based on new evidence **Ad.9 When is the next scheduled review/update for this measure?** 2011
Ad.10 Copyright statement/disclaimers: 1.) Check if patient is documented to be 18 years of age or older; Exclude those patients younger than 18 or NULL 2.) Check encounter date in reporting period; exclude No or NULL 3.) System checks current and all previous encounters for this patient for documentation of atrial fibrillation/atrial flutter; Exclude NULL 4.) Check for diagnosis of atrial fibrillation/atrial flutter; Exclude NULL or No 5.) Check for Non-valvular atrial fibrillation/atrial flutter (Include if no documentation); Exclude Valvular atrial fibrillation 6.) Exclude transient/reversible cause (e.g. pneumonia, hyperthyroidism) 7.) Exclude cardiac surgery within past 3 months 8.) Exclude patients who are pregnant 9.) Exclude patients who have medical reasons (e.g. allergy to warfarin or risk of bleeding) 10.)Exclude patients who have patient reasons Assumes that if multiple date of births are found for a patient the most recent date of birth will be used.
Ad.11 -13 Additional Information web page URL or attachment:
Date of Submission (*MM/DD/YY*)**:** 12/14/2010