TV-120-100720-90

SYLLABUS AND COURSE GUIDE

Keeping the Beat: Screening and Management of High-Risk Patients with Non-Valvular Atrial Fibrillation

A Free, 90-Minute Live and OnDemand Activity
Premiere Date: Wednesday, October 7, 2020
6:30 PM - 8:00 PM ET (live)
Credit Expiration Date: Thursday, October 7, 2021

www.cmeoutfitters.com/NVAFbeat

#NVAFbeat

LIVE FACULTY:
Deepak L. Bhatt, MD, MPH, FACC, FAHA, FSCAI, FESC
Christopher P. Cannon, MD
Margot Savoy, MD, MPH, FAAFP, FABC, CPE, CMQ, FAAPL

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INFORMATION FOR PARTICIPANTS

Statement of Need

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, projected to affect 12 million Americans by 2030. However, a significant number of AF cases, particularly non-valvular atrial fibrillation (NVAF) remain undiagnosed, putting patients at risk for severe cardiovascular (CV) complications, including increased risk of stroke. It is imperative that clinicians identify the symptomatology of AF and effectively diagnose NVAF, as these complications can potentially be avoided by increased screening and guideline-directed anticoagulation treatment. Unfortunately, despite the fact that both opportunistic and systematic screening have been shown to be effective in detecting NVAF, clinicians often lack knowledge of the available tools and strategies for implementing it, particularly in primary care settings.

This CME Outfitters Live and OnDemand webcast will feature expert faculty addressing the impact of undiagnosed NVAF, the benefit and use of screening tools for early detection, best practices for optimizing screening, implementing oral anticoagulant therapy for stroke prevention, and the use of digital health technologies, with a goal of fostering collaborative care and optimizing patient outcomes.

Learning Objectives

At the end of this CME/CE activity, participants should be able to:

- Implement opportunistic and systematic screening in primary care settings to identify patients with NVAF who might benefit from anticoagulant therapy.
- Integrate current guidelines into the management of patients with NVAF.
- Incorporate the latest resources and strategies to facilitate collaborative care and optimize patient outcomes.

The following learning objectives pertain only to those requesting CNE or CPE credit:

- Explain how to identify patients with NVAF in the primary care setting who might benefit from anticoagulant therapy.
- Summarize current guidelines on the management of patients with NVAF.
- Discuss the latest resources and strategies for collaborative care and optimized patient outcomes.

Target Audience

Primary care physicians, cardiologists, nurse practitioners, PAs, nurses, and pharmacists

Financial Support

Supported by an educational grant from the Bristol-Myers Squibb and Pfizer Alliance.

CREDIT INFORMATION

CME Credit (Physicians)

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Universal Activity Number: Live: 0376-0000-20-121-L01-P; Enduring: 0376-0000-20-121-H01-P
Type: Knowledge-based

ABIM/MOC Credit

Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 1.5 MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Learning Formats: Live activity; Enduring material

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This activity counts towards MIPS Improvement Activity requirements under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Clinicians should submit their improvement activities by attestation via the CMS Quality Payment Program website.

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FACULTY BIOS & DISCLOSURES

Deepak L. Bhatt, MD, MPH, FACC, FAHA, FSCAI, FESC (Co-Moderator)

After graduating as valedictorian from Boston Latin School, Dr. Bhatt obtained his undergraduate science degree as a National Merit Scholar at MIT while also serving as a research associate at Harvard Medical School. He received his medical doctorate from Cornell University and a Master of Public Health with a concentration in clinical effectiveness from Harvard University. His internship and residency in internal medicine were at the Hospital of the University of Pennsylvania, and his cardiovascular training was at Cleveland Clinic. Dr. Bhatt completed fellowships in interventional cardiology and cerebral and peripheral vascular intervention and served as Chief Interventional Fellow at Cleveland Clinic, where he spent several years as an interventional cardiologist and an Associate Professor of Medicine. Most recently he received the AHA's Distinguished Scientist Award in 2019 in addition to numerous other honors. Dr. Bhatt has been listed in Best Doctors in America from 2005 to 2020.

Dr. Bhatt's research interests include acute coronary syndromes, preventive cardiology, and advanced techniques in cardiac, cerebral, and peripheral intervention. He has authored or co-authored over 1500 publications and has been listed by the Web of Science Group as a Highly Cited Researcher from 2014 to 2019. He was the international principle for the CHARISMA and CRESCENDO trials and co-principle of the three CHAMPION trials. He served as chair of COGENT and co-principle of STAMPEDE. Additionally, Dr. Bhatt serves as chair for REDUCE-IT and SCORED. In 2018, REDUCE-IT was listed and named the top cardiology trial by NEJM. In 2014, he was listed in the AHA/ASA top ten advances in heart disease and stroke research (for STAMPEDE and SYMPLICITY HTN-3).He serves as Senior Associate Editor for News and Clinical Trials for ACC.org, Editor of the peer-reviewed *Journal of Invasive Cardiology*, as well as Editor of *Cardiovascular Intervention: A Companion to Braunwald's Heart Disease and Atherothrombosis in Clinical Practice* published by Oxford University Press. He also serves as Editor-in-Chief of the *Harvard Heart Letter* for patients.

Christopher P. Cannon, MD (Co-Moderator)

Dr. Cannon is a Professor of Medicine at Harvard Medical School, and senior physician in the Preventive Cardiology section of the Cardiovascular Division at Brigham and Women's Hospital. He currently serves as Education Director in the Cardiovascular Innovation group. For 25 years, Dr. Cannon served as an investigator in the TIMI Study Group. He has been principal investigator of more than 20 multicenter clinical trials, including TACTICS-TIMI 18, PROVE IT, IMPROVE IT, and RE-DUAL PCI trials, and is a lead investigator for VERTIS CV. In his role at Cardiovascular Innovation he is helping to implement the quality improvement program 'Remote Health' for lipids and hypertension.

Margot Savoy, MD, MPH, FAAFP, FABC, CPE, CMQ, FAAPL

Dr. Savoy is Department Chair & Associate Professor for the Department of Family & Community Medicine at the Lewis Katz School of Medicine at Temple University and Temple University Hospital, and Chief Quality Officer for the Temple Faculty Practice Plan. She is an attending physician at Temple University Hospital (Philadelphia, PA) and Christiana Care Health System (Wilmington, DE). Dr. Savoy graduated from the University of Maryland School of Medicine in 2002, completed the Family Medicine Residency Program at the Crozer-Keystone Family Medicine Residency Program (Springfield, PA) in 2005, and graduated from the University of North Carolina Chapel Hill Gillings School of Global Public Health in 2008 with a Master's degree in Public Health in Public Health Leadership with a focus on Public Health Practice. She is certified by the American Board of Family Medicine, the Certifying Commission in Medical Management, and is a Fellow of the Advisory Board Company.

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Dr. Bhatt reports he is a consultant for Abbott; Afimmune; Amarin Corporation; Amgen Inc.; Astra Zeneca; Bayer Corporation; Boehringer Ingelheim; Bristol-Myers Squibb Company; Cardax, Inc.; Chiesi USA, Inc.; CSL Behring; Eisai Inc.; Ethicon USA, LLC; Ferring Pharmaceuticals: Forest Laboratories; Fractyl Laboratories, Inc.; Idorsia Pharmaceuticals Ltd; Ironwood Pharmaceuticals, Inc.; Ischemix; Lexicon Pharmaceuticals, Inc.; Lilly USA, LLC.; Medtronic; PhaseBio Pharmaceuticals, Inc.; Pfizer Inc.; PLx Pharma Inc.; Regeneron; Roche; Sanofi-Aventis U.S. LLC; Synaptic Pharmaceutical Corp.; and The Medicines Company.

Dr. Cannon reports that he receives research grants from Amgen Inc.; Boehringer-Ingelheim; Bristol-Myers Squibb Company; Daiichi Sankyo, Inc.; Janssen Pharmaceuticals, Inc.; Merck & Co., Inc.; and Pfizer Inc. He is a consultant for Aegerion Pharmaceuticals, Inc.; Alnylam Pharmaceuticals ,Inc.; Amarin Corporation; Amgen Inc.; Applied Therapeutics; Ascendia Pharmaceuticals; Boehringer-Inghelheim; Bristol-Myers Squibb Company; Corvidia; Eli Lilly and Company; HLS Therapeutics Inc.; Innocent Biologics, Inc.; Janssen Pharmaceuticals, Inc.; Kowa Pharmaceuticals America, Inc.; Merck & Co., Inc.; Pfizer Inc.; Rhoshan Pharmaceuticals, Inc.; and Sanofi-Aventis.

Dr. Savoy has no disclosures to report.

Jeffrey Helfand, DO (peer reviewer) has no disclosures to report.

Mae Ochoa, RPh (peer reviewer) has no disclosures to report.

Rachel Speer, PhD (planning committee) has no disclosures to report.

Evan Luberger (planning committee) has no disclosures to report.

Jan Perez (planning committee) has no disclosures to report.

Sharon Tordoff (planning committee) has no disclosures to report.

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Keeping the Beat: Screening and Management of High-Risk Patients with Non-Valvular Atrial Fibrillation

Supported by an educational grant from the Bristol-Myers Squibb and Pfizer Alliance.

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Learning Objective 1

Implement opportunistic and systematic screening in primary care settings to identify patients with NVAF who might benefit from anticoagulant therapy.

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Learning Objective 2

Integrate current guidelines into the management of patients with NVAF.

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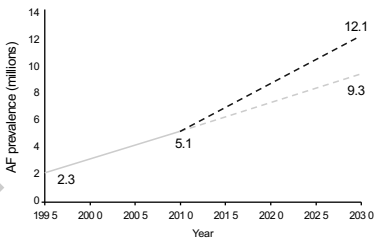
Learning Objective 3

Incorporate the latest resources and strategies to facilitate collaborative care and optimize patient outcomes.

Epidemiology of AF in the US: Rising Prevalence

- As of 2010, prevalence estimates for AF in the US ranged from ~2.7 million to 6.1 million[1]
- **AF prevalence is predicted to increase by up to two-fold by 2030 to 12.1 million[1,2]**

Projections assume no increase (red dashed line) or logarithmic growth (blue dashed line) in incidence of AF from 2007.



AF = atrial fibrillation

1. Benjamin EJ, et al. *Circulation*. 2018;137:e67-e492.; 2. Colilla S, et al. *Am J Cardiol*. 2013;112:1142:1147.

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Lifetime Risk of AF

Lifetime Risk for AF at Selected Index Ages by Sex

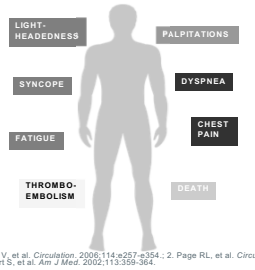
Index Age, yrs	Men	Women
40	**26.0%** (24.0 – 27.0)	**23.0%** (21.0 – 24.0)
50	**25.9%** (23.9 – 27.0)	**23.2%** (21.3 – 24.3)
60	**25.8%** (23.7 – 26.9)	**23.4%** (21.4 – 24.4)
70	**24.3%** (22.1 – 25.5)	**23.0%** (20.9 – 24.1)
80	**22.7%** (20.1 – 24.1)	**21.6%** (19.3 – 22.7)

1 in 4
Men & women ≥ 40 years old will develop AF

1 in 6
Lifetime risk if currently free of AF

Lloyd-Jones DM, et al. *Circulation*. 2004;110(9):1042-1046.

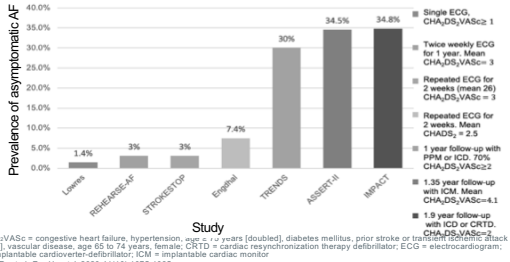
Clinical Presentation of AF



- AF presents with a wide range of symptoms[1]
  - May also be asymptomatic
- Impact of asymptomatic AF[2]
  - Potential for underlying electrical and structural damage to atrial myocardium
- While AF symptoms alone may not always be severe, untreated disease can result in significant morbidity and mortality[3]

1. Fuster V, et al. *Circulation*. 2006;114:e257-e354.; 2. Page RL, et al. *Circulation*. 2003;107:1141-1145.; 3. Stewart S, et al. *Am J Med*. 2002;113:359-364.

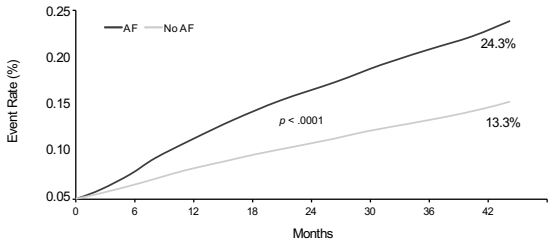
Prevalence of Asymptomatic AF by Screening Method and Stroke Risk Score



CHA_2DS_2VASc = congestive heart failure, hypertension, age ≥ 75 years [doubled], diabetes mellitus, prior stroke or transient ischemic attack [doubled], vascular disease, age 65 to 74 years, female; CRTD = cardiac resynchronization therapy defibrillator; ECG = electrocardiogram; ICD = implantable cardioverter-defibrillator; ICM = implantable cardiac monitor

Jones NR, et al. *Eur Heart J*. 2020;41(10):1075-1085.

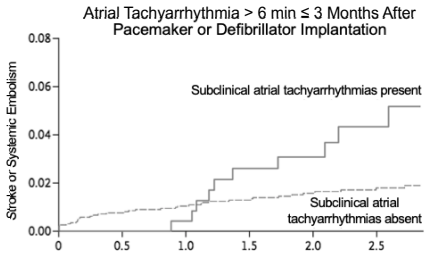
Cumulative Incidence of CV Death, MI, or Stroke After AF Diagnosis



CV = cardiovascular; MI = myocardial infarction

Ruff CT, Bhatt DL, et al. *Int J Cardiol*. 2014;170(3):413-418.

Subclinical AF and Stroke Risk



Asymptomatic AF increases the risk of stroke or systemic thromboembolism and all-cause mortality compared to no AF, and comparable to symptomatic AF in a meta-analysis.

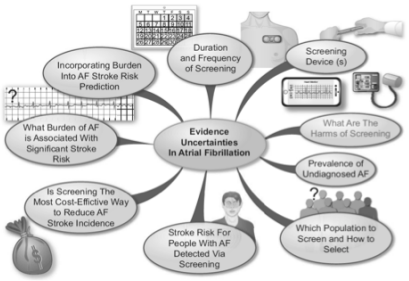
Healey JS, et al. *N Engl J Med*. 2012; 366:120-129.; Jones NR, et al. *Eur Heart J*. 2020;41(10):1075-1085.

U.S. Preventive Services Task Force Recommendation on Screening in AF

- The U.S. Preventive Services Task Force released a final recommendation statement on screening for atrial fibrillation with electrocardiography. The Task Force found insufficient evidence on screening for atrial fibrillation with ECG to prevent strokes.

US Preventive Services Task Force (USPSTF). *JAMA*. 2018;320(5):478-484.

Evidence Uncertainties in AF Screening



Jones NR, et al. *Eur Heart J*. 2020;41(10):1075-1085.

2020 ESC Guidelines: Recommendations for Screening for AF

Selected Recommendations	COR	LOE
Opportunistic screening for AF by pulse taking or ECG rhythm strip in patients ≥65 years of age	I	B
Interrogate pacemakers and implantable cardioverter defibrillators on a regular basis	I	A
Systematic ECG screening in patients aged ≥75 years or at high risk of stroke	I	B
Opportunistic screening for AF in hypertensive patients	I	B
Opportunistic screening for AF in patients with obstructive sleep apnea should be considered	IIa	C

ESC = European Society of Cardiology
Hindricks G, et al. *Eur Heart J*. 2020;ehaa612.

Potential Benefits From and Risks of Screening for AF

Benefits

Prevention of:
- Stroke/SE using OAC in patients at risk
- Subsequent onset of symptoms

Prevention/reversal of:
- Electrical/mechanical atrial remodeling
- AF-related haemodynamic derangements
- Atrial and ventricular tachycardia-induced cardiomyopathy

Prevention/reduction of:
- AF-related morbidity; hospitalization; mortality

Reduction of:
- The outcomes associated with conditions/diseases associated with AF that are discovered and treated as a consequence of the examinations prompted by AF detection

Risks
- Abnormal results may cause anxiety
- ECG misinterpretation results may lead to overdiagnosis and overtreatment
- ECG may detect other abnormalities (true or false positives) that may lead to invasive tests and treatments that have the potential for serious (e.g., angiography/revascularization with bleeding, contrast-induced nephropathy and allergic reactions to the contrast)

OAC = oral anticoagulant; SE = systemic embolism
Hindricks G, et al. *Eur Heart J*. 2020;ehaa612.

Why Screen for Undiagnosed AF?

- Prevent preventable stroke
- Data from Riks-Stroke and registry
  - Approximately 33% of ischaemic strokes due to AF
  - Only 16% of those had received an anticoagulant in the previous 6 months
  - 8% of patients in registry had AF that was not previously known
  - 8% - 28% of patients with ischemic stroke notice their symptoms when they wake (i.e., wake-up stroke)

Screening can find unknown AF and facilitate appropriate management

Friberg L, et al. *Stroke*. 2014;45:2599-2605.; Denny MC, et al. *J Neurol Disord*. 2014;pii:102.; Rubin MN, Barrett KM. *Neurohospitalist*. 2015;5(3):161-172.; Mackey J, et al. *Neurology*. 2011;76(19):1662-1667.

Screening is Effective

- Incidence of previously unknown AF was found to be 1.4% in ≥ 65 year olds; ~ 490,000 people in the US[1]
- Screening can increase detection rate of new cases of AF: 1.63% a year compared with 1.04% without systematic or opportunistic screening[2]

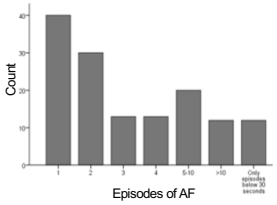
Systematic screening: invitation for electrocardiography
Opportunistic screening: pulse taking and invitation for electrocardiography if the pulse was irregular

1. Lowres N, et al. *Thromb Haemost*. 2013;110: 213-222.; 2. Fitzmaurice DA, et al. *BMJ*. 2007;335(7616):383.

Systematic Screening for AF with Intermittent ECG

- STROKESTOP study in 7,173 people aged 75–76
- Use of self-activated hand-held single lead ECG returned positive AF diagnosis in an additional 3% of all patients in 2 weeks
- In participants who received a new diagnosis of AF, the mean number of registrations with AF was 4.5

Number of AF Episodes Recorded by Intermittent ECG



Svennberg E, et al. *Circulation*. 2015;131(25):2176-2184.

Detection of AF After Cardiac Surgery (SEARCH-AF)

- Open-label, two-arm RCT in 396 post-cardiac surgical subjects at risk of stroke
  - Comparing a strategy of enhanced cardiac rhythm monitoring with a wearable adhesive patch device* vs. usual care
- Primary outcome: documentation of sustained atrial fibrillation or flutter within 30 days after randomization

*Medtronic SEEQ™ mobile cardiac telemetry system or the CardioSTAT (Icentia Inc.)
POAF/AFL = post-operative atrial fibrillation/flutter; RCT = randomized controlled trial
Detection of Atrial Fibrillation After Cardiac Surgery (SEARCH-AF). ClinicalTrials.gov Identifier: NCT02793895

Who to Screen for AF

- People over 65 years of age
- People at high CV risk
- People with predisposing conditions:
  - Hypertension
  - Heart failure
  - Coronary artery disease
  - Obesity
  - Diabetes mellitus
  - Chronic kidney disease
  - Obstructive sleep apnoea

Hindricks G, et al. *Eur Heart J*. 2020;ehaa612.

How to Screen for AF: New Technologies Offer Many Options

Type of technology	Example Device
Photoplethysmography via smartwatch	• AppleWatch • Technology compatible with wide range of smartphones
Blood pressure monitor to detect AF	• WatchBP Home A (Microlife) • Omron M6 (Omron)
Handheld device or smartphone-compatible ECG recorder	• Kardia (Alivecor) • Zenicor ECG (Zenicor) • MyDiagnostic (Applied Biomedical Systems BV)
Patch ECG monitors	• Zio (iRhythm) • Cardiostat (Icentia) • Nuvant (Corventis)

Jones NR, et al. *Eur Heart J*. 2020;41(10):1075-1085.

Techniques for AF Screening

Hindricks G, et al. *Eur Heart J*. 2020;ehaa612.

How Useful Are AF Screening Tools?

	Sensitivity	Specificity
Pulse taking	87% - 97%	70% - 81%
Automated BP measurements	93% - 100%	86% - 92%
Single lead ECG screening	94% - 98%	76% - 95%
Smartphone apps	91.5% - 98.5%	91.4% - 100%
Watches	97% - 99%	83% - 94%

"A role in screening for silent AF may also exist for remote electrocardiographic acquisition and transmission with a "smart" worn or handheld WiFi-enabled device with remote interpretation"
- AHA/ACC/HRS 2019 Focused Update of AF Guidelines

ACC = American College of Cardiology; AHA = American Heart Association; BP = blood pressure; HRS = Heart Rhythm Society
Hindricks G, et al. *Eur Heart J*. 2020;ehaa612.; January CT, et al. *Circulation*. 2019;140:e125–e151.

Which Screening Tools Will Reach Patients at Highest Risk of AF?

- Do high-risk patients have access to high-tech screening tools?
- How can we ensure that screening will narrow, rather than widen, disparities in care?

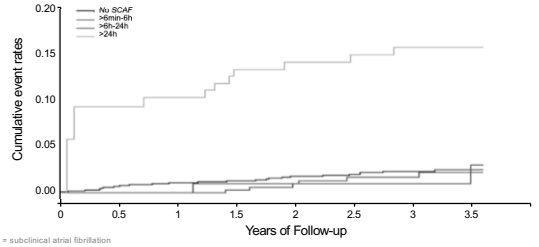
How Much AF is Enough to Increase Risk of Stroke?

Year	Study	n	AF Burden Measure	HR for stroke
2003	MOST	312	5 min	6.7 $p = 0.02$
2005	Capucci	725	> 24 hrs	3.1 $p = 0.04$
2009	Botto	568	CHADS + AF burden	6.2 (5 vs. 0.8%)
2012	Home monitor CRT	560	3.8 hrs	9.4 $p = 0.006$
2012	TRENDS	2486	5.5 hrs	2.4 $p = 0.06$
2012	ASSERT	2580	6 min	2.5 $p = 0.008$

CRT = cardiac resynchronization therapy

Camm AJ, et al. *Am J Cardiol.* 2012;110(2):270-276.; Glotzer T. Presentation at Transcatheter Cardiovascular Therapeutics (TCT). 2013.

Subclinical AF and Stroke Risk in ASSERT



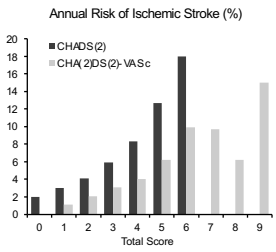
SCAF = subclinical atrial fibrillation

Van Gelder IC, et al. *Eur Heart J.* 2017;38(17):1339-1344.

Stroke Risk Stratification in AF

$CHADS_2$	
Risk Factor	**Score**
Cardiac failure	1
Hypertension	1
Age ≥ 75 years	1
Diabetes	1
Stroke	2

CHA_2DS_2-VASc	
Risk Factor	**Score**
Cardiac failure	1
Hypertension	1
Age ≥ 75 years	2
Diabetes	1
Stroke	2
Vascular disease (MI, peripheral arterial disease, aortic atherosclerosis)	1
Age 65-74 years	1
Sex category (female)	1



Lip GY, et al. *Am J Med.* 2010;123(6):484-488.; Camm AJ, et al. *Eur Heart J.* 2010;31(19):2369-2429.

Conclusions

- Screening for AF has been made easier by the development of new affordable technology and should be encouraged
- Screening may reduce stroke risk
- Reducing stroke risk in patients with AF is essential, regardless of whether a patient is symptomatic or not

Amerena JV, et al. *Med J Aust*. 2013;199(9):592-597.

CME Outfitters
CONTINUING MEDICAL EDUCATION

Learning Objective 2

Integrate current guidelines into the management of patients with NVAF.

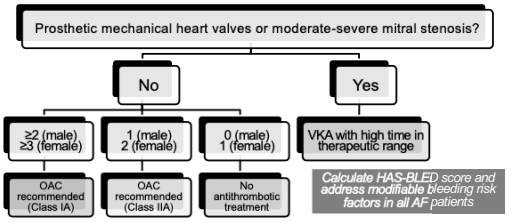
2019 ACC/AHA/HRS Guidelines for AF

Summary of Class I Recommendations	COR	LOE
For patients with AF and the CHA_2DS_2-VASc score of ≥ 2 in men or ≥ 3 in women, oral anticoagulants are recommended. Options include warfarin (LOE: A), dabigatran (LOE: B), rivaroxaban (LOE: B), apixaban (LOE: B), or edoxaban (LOE: B-R).	I	A, B, B-R
Non-vitamin K anticoagulants (NOACs) (dabigatran, rivaroxaban, apixaban, and edoxaban) are recommended over warfarin in NOAC-eligible patients with AF (except with moderate-to-severe mitral stenosis or a mechanical heart valve).	I	A
Among patients treated with warfarin, the international normalized ratio (INR) should be determined at least weekly during initiation of anticoagulant therapy and at least monthly when anticoagulation (INR in range) is stable	I	A
In patients with AF (except with moderate-to-severe mitral stenosis or a mechanical heart valve), the CHA_2DS_2-VASc score is recommended for assessment of stroke risk.	I	B
For patients with AF who have mechanical heart valves, warfarin is recommended.	I	B
Selection of anticoagulant therapy should be based on the risk of thromboembolism, irrespective of whether the AF pattern is paroxysmal, persistent, or permanent.	I	B
Renal function and hepatic function should be evaluated before initiation of a NOAC and should be reevaluated at least annually.	I	B-NR

January CT, et al. *J Am Coll Cardiol*. 2019;74(1):104-132.

ESC 2020 Updated Guidelines for AF Management

3-Step Pathway for Stroke Prevention Decision-Making For a Patient with AF Eligible for OAC

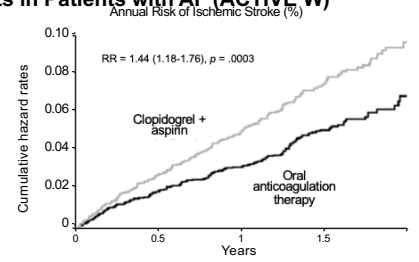


Non-vitamin K oral anticoagulants (NOACs), also called direct oral anticoagulants (DOACs), generally recommended as first line therapy for OAC

OAC = oral anticoagulant.
Hindricks G, et al. *Eur Heart J.* 2020;ehaa612.

Anticoagulation vs Antiplatelet Therapy for Prevention of Vascular Events in Patients with AF (ACTIVE W)

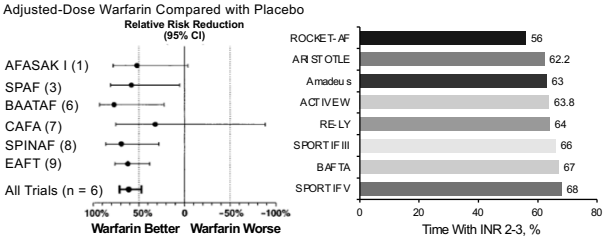
- Primary Outcome: first occurrence of stroke, non-CNS systemic embolus, myocardial infarction, or vascular death.
- The study was stopped early because of clear evidence of superiority of oral anticoagulation therapy.



ACTIVE = Atrial Fibrillation Clopidogrel Trial with Irbesartan for prevention of Vascular Events. Patients eligible for and willing to take oral anticoagulation therapy were enrolled into ACTIVE W; CNS = central nervous system
ACTIVE Writing Group of the ACTIVE Investigators, et al. *Lancet.* 2006;367(9526):1903–1912.

Warfarin Efficacy Meta-Analyses

Adjusted-Dose Warfarin Compared with Placebo



Hart RG, et al. *Ann Intern Med.* 1999;131(7):492-501.; Agarwal S, et al. *Arch Intern Med.* 2012;172(8):623-31.

NOAC Eligibility

Condition	Eligibility for NOAC therapy
Mechanical prosthetic valve	Contraindicated
Moderate to severe mitral stenosis (usually of rheumatic origin)	Contraindicated
Mild to moderate other native valvular disease (e.g., mild-moderate aortic stenosis or regurgitation, degenerative mitral regurgitation etc.)	Included in NOAC trials
Severe aortic stenosis	Limited data (excluded in RE-LY) Most will undergo intervention
Bioprosthetic valve (after > 3 months post operatively)	Not advised if for rheumatic mitral stenosis Acceptable if for degenerative mitral regurgitation or in the aortic position
Mitral valve repair (after > 3 months post operatively)	Some patients included in some NOAC trials
PTAV and TAVI	No prospective data yet May require combination with single or dual antiplatelet therapy
Hypertrophic cardiomyopathy	Few data, but patients may be eligible for NOACs

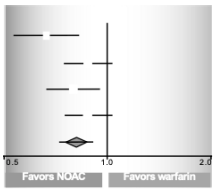
PTAV = percutaneous transluminal aortic valvuloplasty; TAVI = transcatheter aortic valve implantation
Steffel J, et al. *Eur Heart J.* 2018;38(16):1330-1393.

Efficacy of Novel OACs vs. Warfarin in Clinical Trials

Overall Reduction in Stroke or Systemic Embolic Events (SE) by 19% (~9% to 27%)

Meta-analysis of four phase III trials: stroke/SE events

	NOAC (events)	Warfarin (events)	RR (95% CI)	*p*-value
RE-LY Dabigatran 150 mg bid	134/6076	199/6022	0.66 (0.53–0.82)	.0001
ROCKET AF Rivaroxaban 20 mg qd	269/7081	306/7090	0.88 (0.75–1.03)	.12
ARISTOTLE Apixaban 5 mg bid	212/9120	265/9081	0.80 (0.67–0.95)	.012
ENGAGE AF-TIMI 48 Edoxaban 60 mg qd	296/7035	337/7036	0.88 (0.75–1.02)	.10
Combined (random)	911/29,312	1107/29,229	0.81 (0.73–0.91)	<.0001



Heterogeneity: I^2 = 83%; p = .001

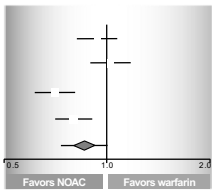
CI = confidence interval; RR = relative risk
Ruff CT, et al. *Lancet.* 2014;383(9921):955–962.

Safety of Novel OACs vs. Warfarin in Clinical Trials

Overall reduction in major bleeding events by 14% (~0% to 27%)

Meta-analysis of four phase III trials: major bleeding events

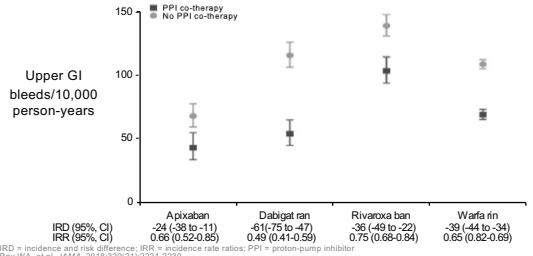
	NOAC (events)	Warfarin (events)	RR (95% CI)	*p*-value
RE-LY Dabigatran 150 mg bid	375/6076	397/6022	0.94 (0.82–1.07)	.34
ROCKET AF Rivaroxaban 20 mg qd	395/7111	386/7125	1.03 (0.90–1.18)	.72
ARISTOTLE Apixaban 5 mg bid	327/9088	462/9052	0.71 (0.61–0.81)	<.0001
ENGAGE AF-TIMI 48 Edoxaban 60 mg qd	444/7012	557/7012	0.80 (0.71–0.90)	.0002
Combined (random)	1541/29,287	1802/29,211	0.86 (0.73–1.00)	.06



Heterogeneity: I^2 = 83%; p = .001

Ruff CT, et al. *Lancet.* 2014;383(9921):955–962.

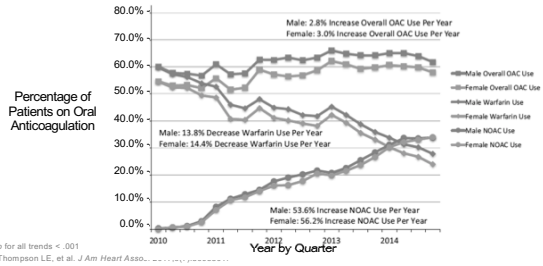
Upper GI Bleeding Risk with OACs With or Without PPI



IRD = incidence and risk difference; IRR = incidence rate ratios; PPI = proton-pump inhibitor

Ray WA, et al. *JAMA*. 2018;320(21):2221-2230.

NOACs vs Warfarin Use in NCDR PINNACLE-AF Registry

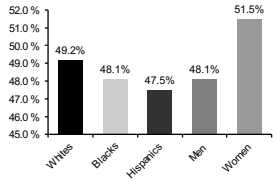


p for all trends < .001

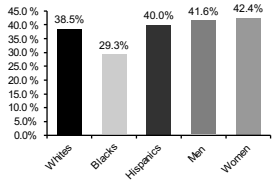
Thompson LE, et al. *J Am Heart Asso...*

Anticoagulation is Underutilized Among Medicare Patients

Among 42,952 patients with incident AF from 2012-2014, overall OAC initiation was low



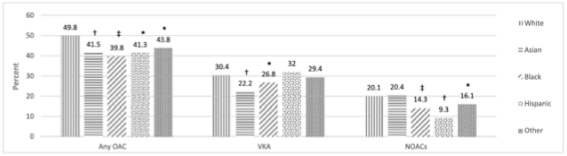
Among initiators of OAC, NOAC use was low



Essien UR, et al. *J Natl Med Assoc*. 2020;112(1):103-108.

Disparities in OAC Prescribing

Minority AF patients were less likely to receive any OAC and NOACs compared to whites even after adjusting for demographic factors, income, insurance status, and traditional stroke risk factors.

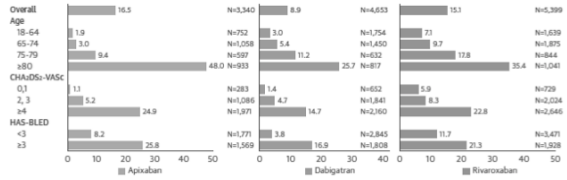


Percent of anticoagulant prescription by race in patients with atrial fibrillation CHA_2DS_2-VASc score greater than or equal to to 2. P-value: * < 0.05, † < 0.01, ‡ < 0.001 (reference group: white race). Other race includes American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, having 2 or more race, or indicated as other race.

VKA = vitamin K anticoagulant

Tedla YG, et al. *J Stroke Cerebrovasc Dis.* 2020;29(5):104718.

Under-Dosing of NOACs in AF



In a sample of 13,392 patients with no renal indication for dose reduction, 13.3% of patients receiving reduced doses of NOACs. Under-dosing increased in older, riskier patients.

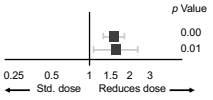
Yao X, et al. *J Am Coll Cardiol.* 2017;69(23):2779-2790.

Clinical Consequences of Under-Dosing of NOACs in AFS

- Among 8425 patients newly diagnosed with NVAF and initiating NOAC therapy, 39% received off-label dose-reduced treatment
- Underdosing was associated with increased risk of composite outcome of death/stroke/MI, with no mitigation of bleeding risk

Outcomes

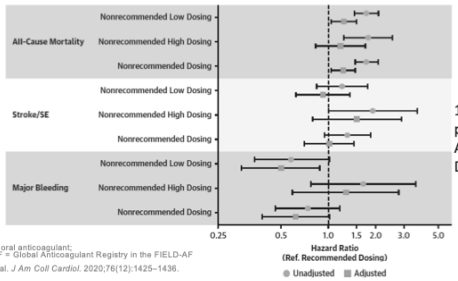
	Reduced dose Events/N (%)	Std. dose Events/N (%)	OR (95% CI)
Effectiveness	749/3285 (22.8)	447/5140 (8.7)	1.57 (1.34, 1.83)
Safety	101/3274 (3.')	80/5144 (1.6)	1.53 (1.14, 2.34)



NVAF = nonvalvular atrial fibrillation

Arbel R, et al. *Am J Med.* 2019;132(7):847-855.

Impact of Under- or Over-Dosing on 2-Year Outcomes: GARFIELD Registry



10,426 patients with AF receiving a DOAC

DOAC =direct oral anticoagulant; GARFIELD-AF = Global Anticoagulant Registry in the FIELD-AF

Camm, AJ. et al. *J Am Coll Cardiol.* 2020;76(12):1425–1436.

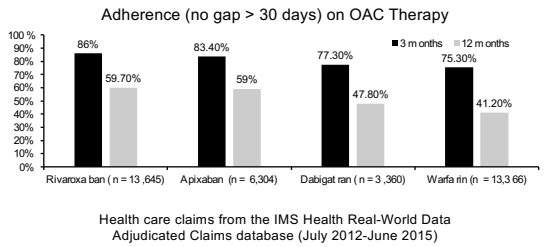
Case Study

A patient you treat in primary care is started on NOAC therapy while hospitalized and told to follow up with the cardiologist.

At the patient's next visit with you, while you are reviewing her current medications, you see that she is now taking a NOAC, but you are not sure whether the dose is appropriate.

What should a health care provider do in this situation?

Treatment Persistence and Time to Discontinuation



Health care claims from the IMS Health Real-World Data Adjudicated Claims database (July 2012-June 2015)

McHorney CA, et al. *J Manag Care Spec Pharm.* 2017;23(9):980-988.

Case Study

During a routine primary care office visit, your patient has BP 160/90. You want to adjust her medication to better control her hypertension. She is currently taking multiple medications, some of which were prescribed by her cardiologist.

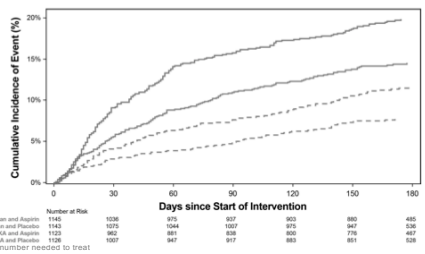
What should a health care provider do in this situation?

Case Study

Your patient's cardiologist performed a PCI and initiated antiplatelet therapy in addition to continuing the patient's NOAC therapy. You are considering whether to instruct the patient to continue taking aspirin (triple therapy) or use only dual therapy (NOAC + non-aspirin antiplatelet therapy).

What should a health care provider do in this situation?

Major / Clinically Relevant Non-Major Bleeding



VKA + Aspirin (18.7%)

Apixaban + Aspirin (13.8%)

VKA + Placebo (10.9%)

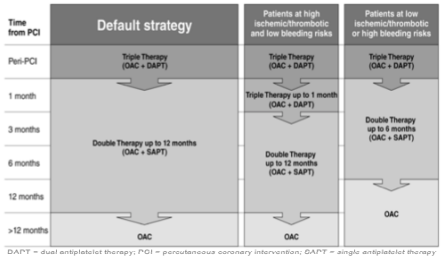
Apixaban + Placebo (7.3%)

Apixaban + Placebo vs. VKA + Aspirin: 11.4% absolute risk reduction (NNT = 9)

NN I = number needed to treat

Lopes RD, et al. *N Engl J Med*. 2019;380:1509-1524.

2018 Update: North American Expert Consensus Statement



DAPT = dual antiplatelet therapy; PCI = percutaneous coronary intervention; SAPT = single antiplatelet therapy

Angiolillo DJ, et al. *Circulation*. 2018;138(5):527–536.

'A **double therapy** approach (OAC + P2Y12 inhibitor) should represent the **default strategy** for most patients…

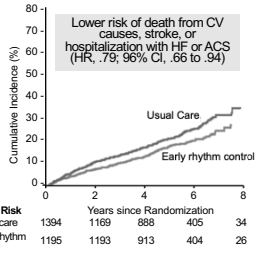
'An NOAC (rather than VKA) should generally be preferred..'

'If ticagrelor is chosen as the P2Y12 agent, concomitant aspirin should not be given (i.e. avoid triple therapy), as was done in the RE-DUAL PCI trial'

EAST-AFNET 4 Study of Early Rhythm Control

Patients randomized to rhythm control vs usual care within 1 year of AF diagnosis:

- Received catheter ablation (19%), class 1c antiarrhythmic drugs, dronedarone, amiodarone, or other antiarrhythmics
  - 65% still receiving rhythm control at 24 months
  - 15% of usual care group used rhythm control
- OACs used in ~90% in both groups

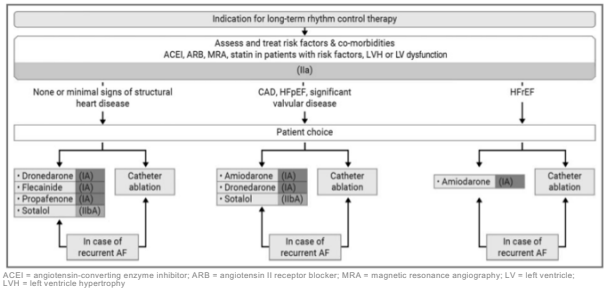


No. at Risk					
Usual care	1394	1169	888	405	34
Early rhythm control	1195	1193	913	404	26

HF = heart failure

Kirchhof P, et al. *N Engl J Med*. 2020 Aug 29. [Epub ahead of print].; Bunch TJ, Steinberg BA. *N Engl J Med*. 2020;383:1383-1384.

2020 ESC Guidelines: Long-term Rhythm Control



ACEI = angiotensin-converting enzyme inhibitor; ARB = angiotensin II receptor blocker; MRA = magnetic resonance angiography; LV = left ventricle; LVH = left ventricle hypertrophy

Hindricks G, et al. *Eur Heart J*. 2020;ehaa612.

Conclusions

- NOACs have demonstrated benefit in reducing stroke risk and death in AF
- Adequate dosing is necessary to achieve maximum benefit and reduce risk of harm
- In patients with AF who have undergone PCI, new consensus statements:
  - North American: Dual therapy should be the "default strategy"
  - NOAC preferred
- Rhythm control for recent onset Afib to be considered

CME Outfitters CONTINUING MEDICAL EDUCATION

Learning Objective 3

Incorporate the latest resources and strategies to facilitate collaborative care and optimize patient outcomes.

The Need for Shared Decision-Making (SDM) in AF Management

- Less than half of high-risk patients with AF receive anticoagulants[1]
- Of those who start anticoagulation, 30% - 50% stop treatment within 12 months[2,3]
- 2019 AHA/ACC/HRS guidelines recommend using SDM to individualize anticoagulation and note that SDM can improve adherence[4]

1. Ogilvie IM, et al. *Am J Med*. 2010;123(7):638-645.e4.; 2. Hylek EM, et al. *Circulation*. 2007;115(21):2689-2696;
3. Gallagher AM, et al. *J Thromb Haemost*. 2008;6(9):1500-1506.; 4. January CT, et al. *J Am Coll Cardiol*. 2019;74(1):104-132.

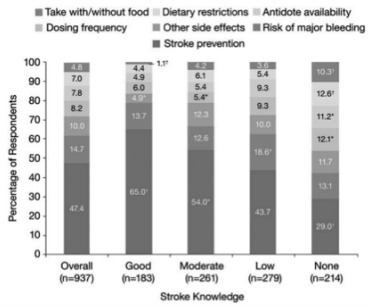
Guidelines Recommend SDM

2020 ECS/EACTS Recommendations	Class	Level
To optimize shared decision making about specific AF treatment option(s) in consideration, it is recommended that physicians: • Inform the patient about the advantages/limitations and benefit/risks associated with the treatment options(s) being considered and • Discuss the potential burden of the treatment with the patient and include the patient's perception of treatment burden in the treatment decision.	I	C
It is recommended to routinely collect PROs to measure treatment success and improve patient care.	I	C
Integrated management with a structured multidisciplinary approach including healthcare professionals, patients, and their family/carers, should be used in all AF patients to improve clinical outcomes.	IIa	B

2019 AHA/ACC/HRS Recommendations	Class	Level
In patients with AF, anticoagulant therapy should be individualized on the basis of shared decision-making after discussion of the absolute risk and relative risks of stroke and bleeding, as well as the patient's values and preferences.	I	C

PROs = patient reported outcomes
Hindricks G, et al. *Eur Heart J.* 2020;ehaa612.; January CT, et al. *J Am Coll Cardiol.* 2019;74(1):104-132.

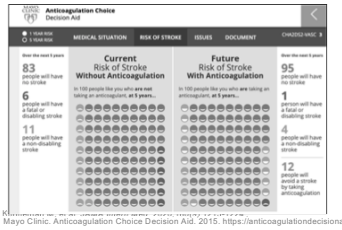
Patient Preferences for OAC Therapy



Lane DA, et al. *Clin Cardiol.* 2018;41(6):855-861.

Can Digital Tools Facilitate SDM?

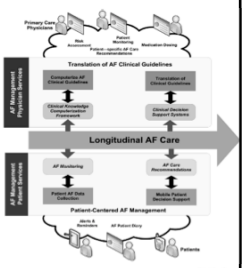
The Anticoagulation Choice tool was shown to improve patient involvement in decision-making, clinician satisfaction, and several measures of SDM quality, with no significant effect on treatment decisions or visit duration.



Mayo Clinic. Anticoagulation Choice Decision Aid. 2015. https://anticoagulationdecisionaid.mayoclinic.org/.

Can Digital Tools Improve Health Outcomes?

- The IMPACT-AF clinical decision support tool was designed to support guideline-based AF management
  - Includes a patient app for patients to record HR, BP, and other data to share with HCP
- Compared to usual care in primary care settings over 1 year
  - Primary efficacy outcome: composite of unplanned CV hospitalizations and AF-related ED visits
  - Primary safety outcome: major bleeding
- No impact on outcomes was observed

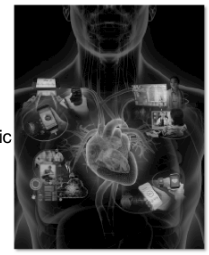


ED = emergency department; HCP = health care practitioner; HR = heart rate; IMPACT-AF = Integrated Management Program Advancing Community Treatment of AF

Cox JL, et al. *Am Heart J*. 2018;201:149-157.

Benefit of Digital Health Tools in Cardiovascular Medicine

- Digital health tools allow:
  - monitoring AF symptoms between visits
  - point-of-service information about medications and possible side effects
- Consistent benefit for:
  - "Communication and counseling"
  - "Remote monitoring of patients with chronic conditions"
  - "Improving outcomes, including mortality, QoL and reduced hospital admissions"
- Really?



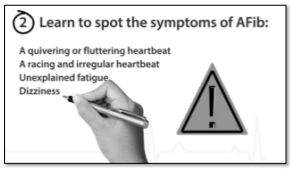
QoL = quality of life

Totten AM, et al. *Telehealth: Mapping the Evidence for Patient Outcomes From Systemic Reviews*. 2016.

NVAF Whiteboard for Patient Education

~ 2-minute free animation educating patients on:

- Description of NVAF
- Risk factors for NVAF
- Symptoms of NVAF
- Treatment options
- Downloadable "Questions to Ask Your HCP" document
- Available at https://www.cmeoutfitters.com/cardiology



SMART Goals

Specific, **M**easurable, **A**ttainable, **R**elevant, **T**imely

- Choose an appropriate screening strategy to identify patients at risk for NVAF
- Match the screening technology to the patient
- Use appropriate anticoagulation at the appropriate dose in at-risk patients. Don't overestimate the risk of anticoagulation vs the risk of undertreatment
- Consider rhythm control for early intervention
- Engage patients in SDM and reinforce the importance of adherence and persistence

To Ask a Question

Please click on the *Ask Question* tab and type your question. Please include the faculty member's name if the question is specifically for him/her.

CME Outfitters

AFTER THE SHOW

Questions & Answers

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To receive CME/CE credit click on the *Evaluations* tab to complete the post-test and evaluation online.

Be sure to fill in your **ABIM ID number** and **DOB** (MM/DD) on the evaluation so we can submit your credit to ABIM

Participants can print their certificate or statement of credit immediately.

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CME for MIPS IMPROVEMENT ACTIVITY

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Visit the
Cardiology Hub

Free resources for clinicians and patients on atrial fibrillation and other cardiology topics

https://www.cmeoutfitters.com/cardiology

This continuing education activity is provided by CME Outfitters

TV-120-100720-90

Attendance Form for Groups

Please complete and FAX to **614.929.3600**

Activity Title and Faculty:

Keeping the Beat: Screening and Management of High-Risk Patients with Non-Valvular Atrial Fibrillation

with Deepak L. Bhatt, MD, MPH, FACC, FAHA, FSCAI, FESC (Co-Moderator); Christopher P. Cannon, MD (Co-Moderator); Margot Savoy, MD, MPH, FAAFP, FABC, CPE, CMQ, FAAPL

Site/Institution Name: ______________________________

Practice Setting: ❑ Office-Based ❑ Hospital ❑ Clinic ❑ Managed Care ❑ Small Group Practice (less than 5) ❑ Large Group Practice (more than 5) ❑ Other: ______________________________

Address: ______________________________

City: ______________________________ State: ________ ZIP: ______________

Site Coordinator: ______________________________ Phone: ______________________________

Fax: ______________________________ Email: ______________________________

Completion Date: ____________ We participated in: ______________________________

Attendee Name (please print)	Please Circle Discipline
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Please FAX completed form to 614.929.3600 and use additional sheets as necessary.
Questions? Call 877.CME.PROS. Thank you for participating in this continuing education activity!