

Anticoagulation Initiative 2013 - 2016

The Challenge of Moving From Linear Constructs to Solution Sets

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School of Medicine

Disclosures

- Biomedical Systems (Consultant)
- Biotie (DSMB)
- Cook MED Institute (Clinical Events Committee)
- Eli Lilly (DSMB, Consultant)
- NFL (Scouting Combine)
- TEVA (Consultant)

Happy Birthday 97th
Mrs. Elizabeth Kovacs
from the NCDR

October 22, 2015

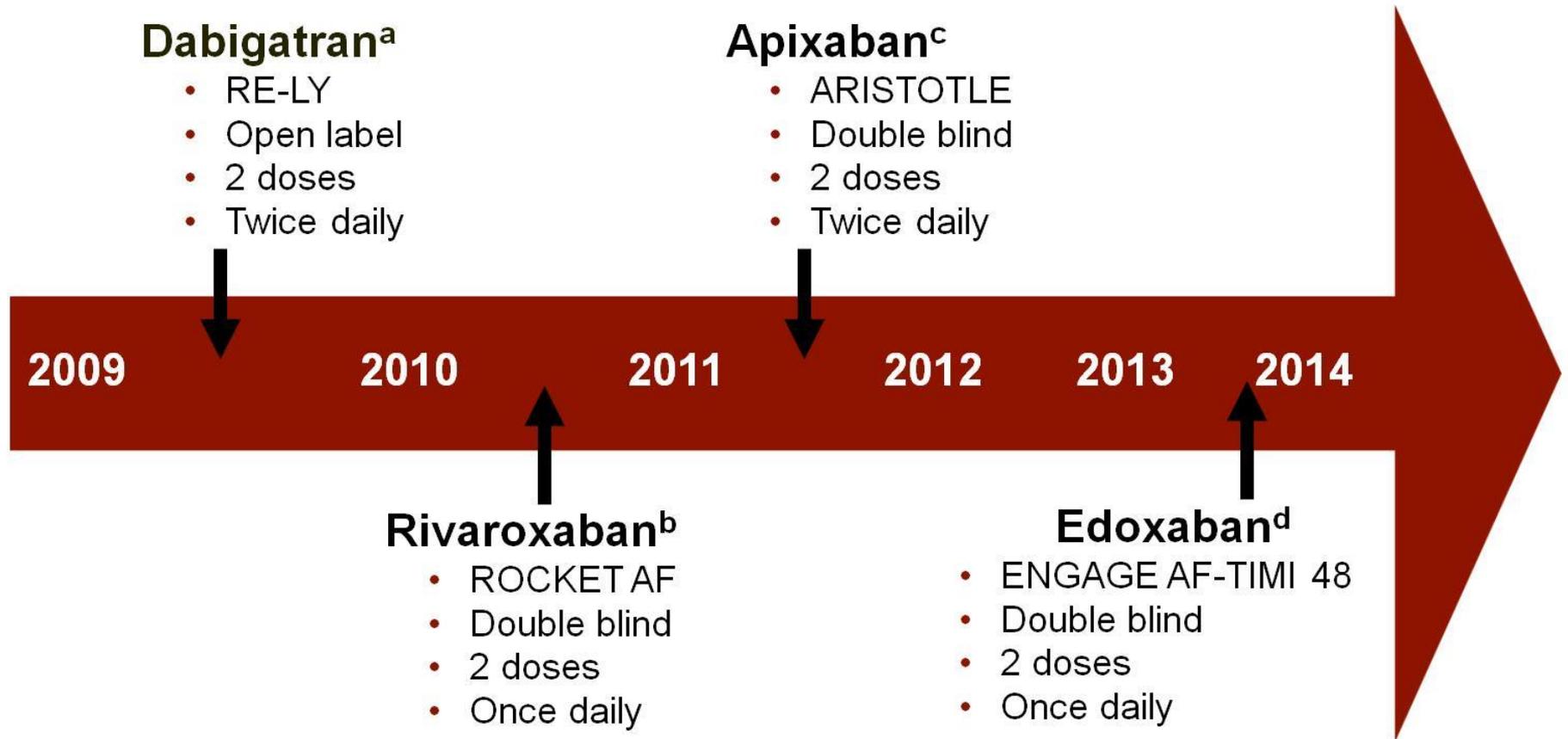




Linear Constructs

- Shortest distance between two points
- Easily followed

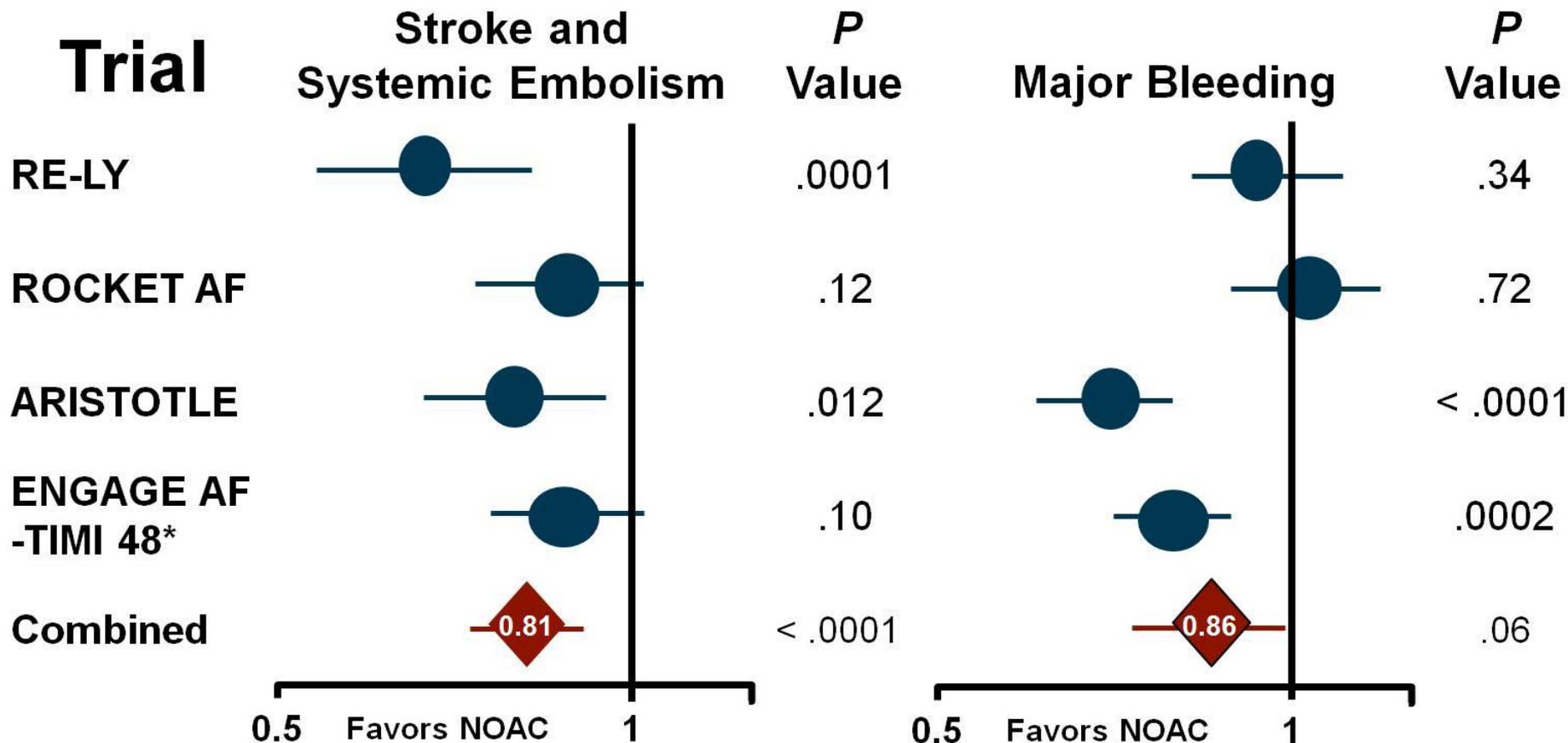
NOACs for Stroke Prevention in AF



a. Connolly SJ, et al. *N Engl J Med.* 2009;361:1139-1151^[4]; b. Patel MR, et al. *N Engl J Med.* 2011;365:883-891^[5]; c. Granger CB, et al. *N Engl J Med.* 2011;365:981-992^[6]; d. Giuliano RP, et al. *N Engl J Med.* 2013;369:2093-2104.^[7]

Efficacy and Safety of NOACs

Pre-specified Meta-analysis of all 71,683 Patients

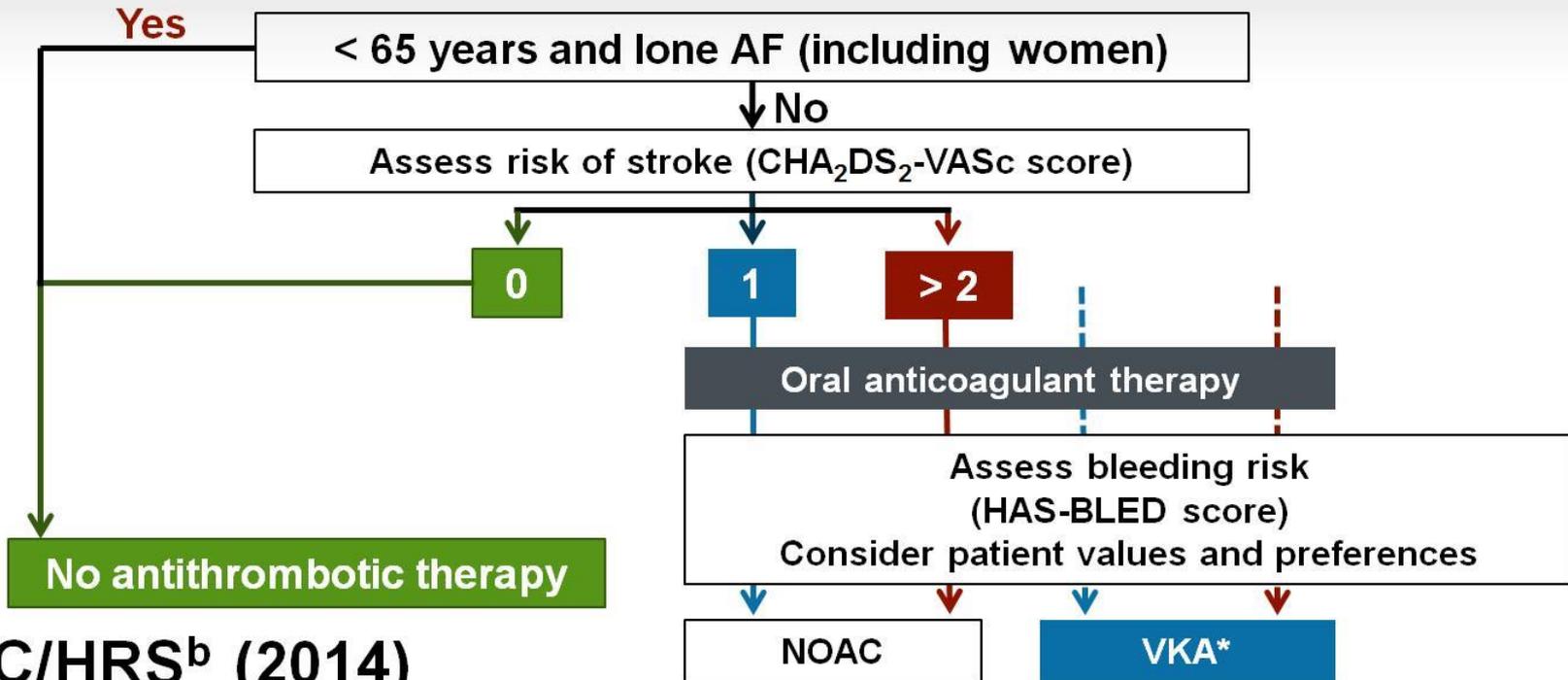


*Edoxaban is not approved for clinical use in AF

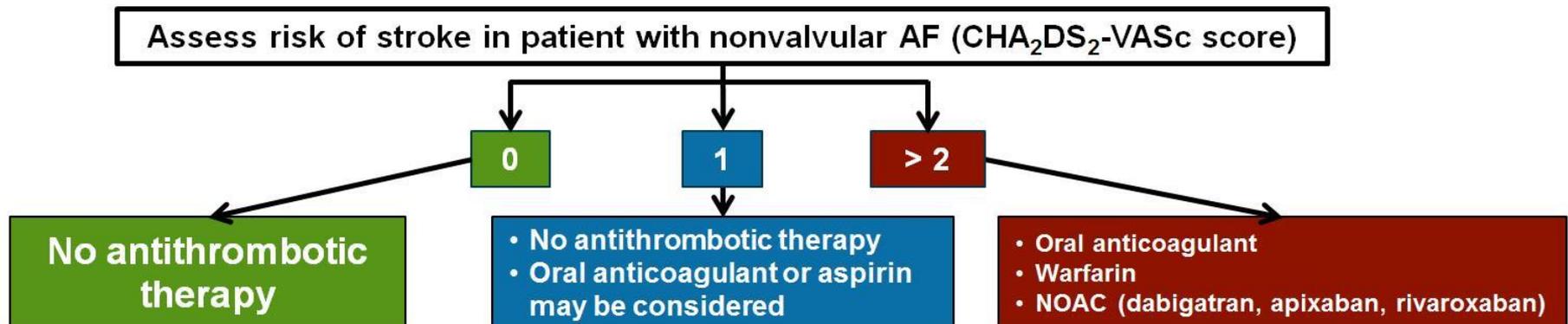
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Updated Guidelines for AF

ESC^a
(2012)



AHA/ACC/HRS^b (2014)



* NOAC should be considered over VKA

a. Camm AJ, et al. Europace. 2012;14:1385-1413^[20]; b. January CT, et al. J Am Coll Cardiol. 2014. [Epub ahead of print]^[21]

Guideline



Practice

ACC Anticoag Initiative Has Been Productive, and Not Always Linear

- Exemplary use of the think tank / roundtable format.
- Engagement of the entire CV team and a universe of specialties
- Major publications
- Apps and toolkits
- Flexibility
- Efficient use of volunteer time

THE PRESENT AND FUTURE

STATE-OF-THE-ART REVIEW

Practical Management of Anticoagulation in Patients With Atrial Fibrillation

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ABSTRACT

Anticoagulation for atrial fibrillation has become more complex due to the introduction of new anticoagulant agents, the number and kinds of patients requiring therapy, and the interactions of those patients in the matrix of care. The management of anticoagulation has become a "team sport" involving multiple specialties in multiple sites of care. The American College of Cardiology, through the College's Anticoagulation Initiative, convened a roundtable of experts from multiple specialties to discuss topics important to the management of patients requiring anticoagulation and to make expert recommendations on issues such as the initiation and interruption of anticoagulation, quality of anticoagulation care, management of major and minor bleeding, and treatment of special populations. The attendees continued to work toward consensus on these topics, and present the key findings of this roundtable in a state-of-the-art review focusing on the practical aspects of anticoagulation care for the patient with atrial fibrillation. (J Am Coll Cardiol 2015;65:1340-60) © 2015 by the American College of Cardiology Foundation.



Anticoagulation
Initiative

Anticoagulation Consortium Roundtable

Final Report

November 14, 2013



Europace

doi:10.1093/europace/euv309

EHRA PRACTICAL GU

Updated European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist anticoagulants in patients with non-valvular atrial fibrillation

Hein Heidbuchel^{1*}, Peter Verhamme², Marco Alings³, Matthias Antz⁴, Hans-Christoph Diener⁵, Werner Hacke⁶, Jonas Oldgren⁷, Peter Sinnaeve², A. John Camm⁸, and Paulus Kirchhof^{9,10}

The second ACC App



AMERICAN
COLLEGE of
CARDIOLOGY

AnticoagEvaluator

Calculate Risk

Review Therapy

Stroke Risk

CHA₂DS₂-VASc

Renal Function

SCr
mg/dL

CrCl
mL/min

i This app is for non-valvular atrial fibrillation patients only, and should not be used to guide therapy in patients with mechanical or bioprosthetic valves.

X

Calculate Risk

[Reset All](#)

Patient Information

Required to derive therapy options

Age

Yrs

Sex

1 Initiation of OAC to reduce stroke risk in patients with AF



- The CHA₂DS₂-VASc scoring system helps clinicians determine stroke risk and to choose oral anticoagulation (OAC) therapy
- OAC therapy options: New direct oral anticoagulants (DOAC) or vitamin K antagonists (VKA). The most commonly used VKA is warfarin
- Drug interactions should also be considered when prescribing

Risk factor	Points
C Congestive heart failure (or left ventricular systolic dysfunction)	1
H Hypertension (blood pressure consistently above 140/90 mmHg)	1
A ₂ Age ≥75 years	2
D Diabetes Mellitus	1
S ₂ Prior Stroke or TIA or thromboembolism	2
V Vascular disease (peripheral artery disease, MI, aortic plaque)	1
A Age 65-74 years	1
Sc Sex category (i.e. female sex)	1

Total score	Anticoagulation therapy options
0 (low stroke risk)	No antithrombotic therapy (or aspirin 75-325 mg daily)
1 (moderate)	Either DOAC or warfarin at an international normalized ratio (INR) of 2.0-3.0
≥2 (high)	Either DOAC or warfarin at INR 2.0-3.0

2 Quality, cost and team-based management



- Patients taking OACs will require baseline and periodic lab monitoring to determine dose
- Coordinating care through anticoagulation clinics improves patient outcomes and reduces costs. Anticoagulation clinics need financial support from healthcare systems to be able to exist

3 Management of bleeding and emergency care



Even with coordinated care, bleeding complications can occur. Minor bleeding may predict major bleeding and may lead to stoppage of effective OAC therapy. Major bleeding is associated with higher mortality.

There are specific recommendations for managing these scenarios:

- Bleeding onset
- Major bleeding
- Clinically relevant non-major bleeding
- Minor bleeding or elevated INR values
- After bleeding

4 Management of complex disease

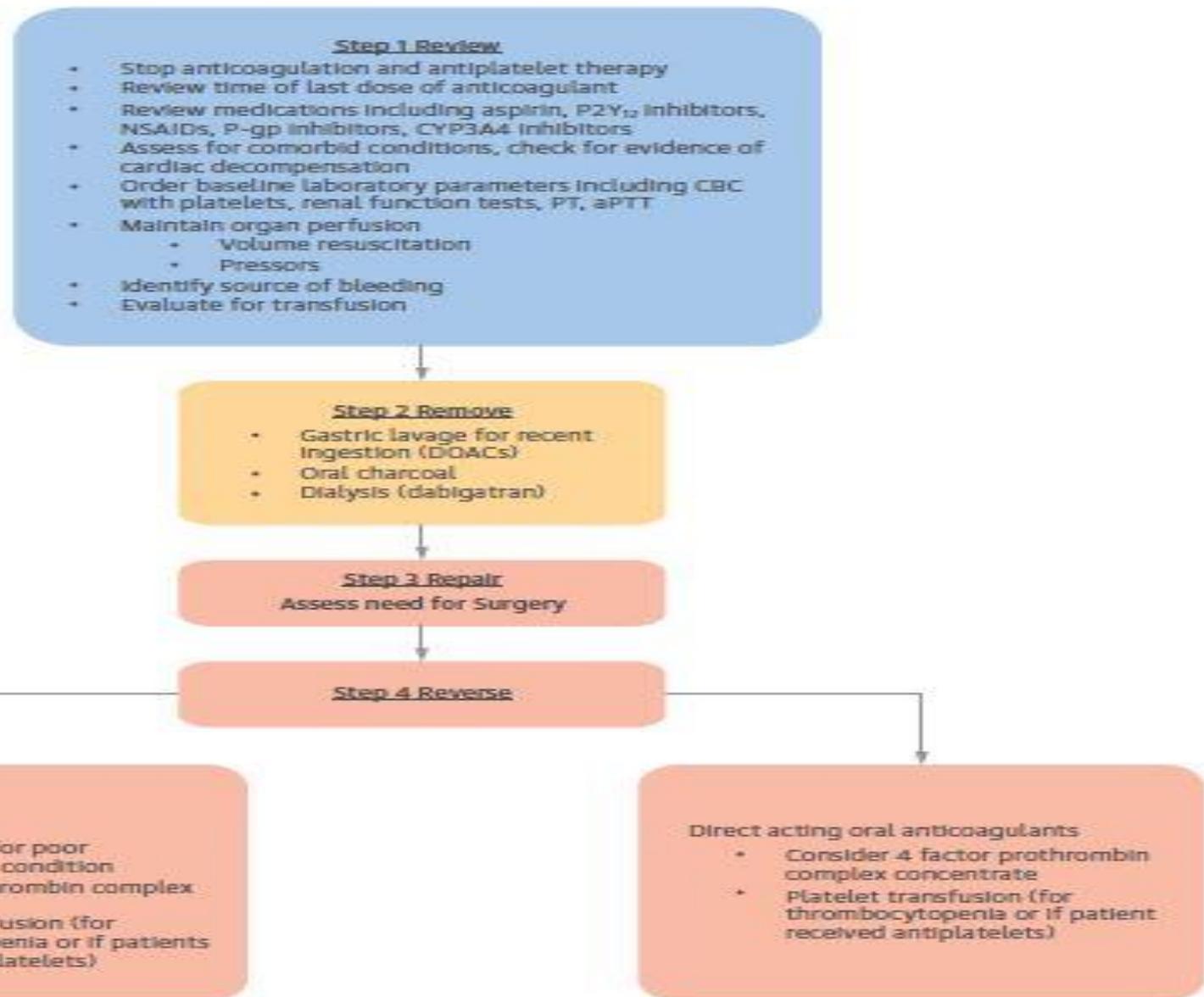


Patients with AF requiring anticoagulation therapy often have comorbid conditions

There are specific recommendations for OAC use for these patients:

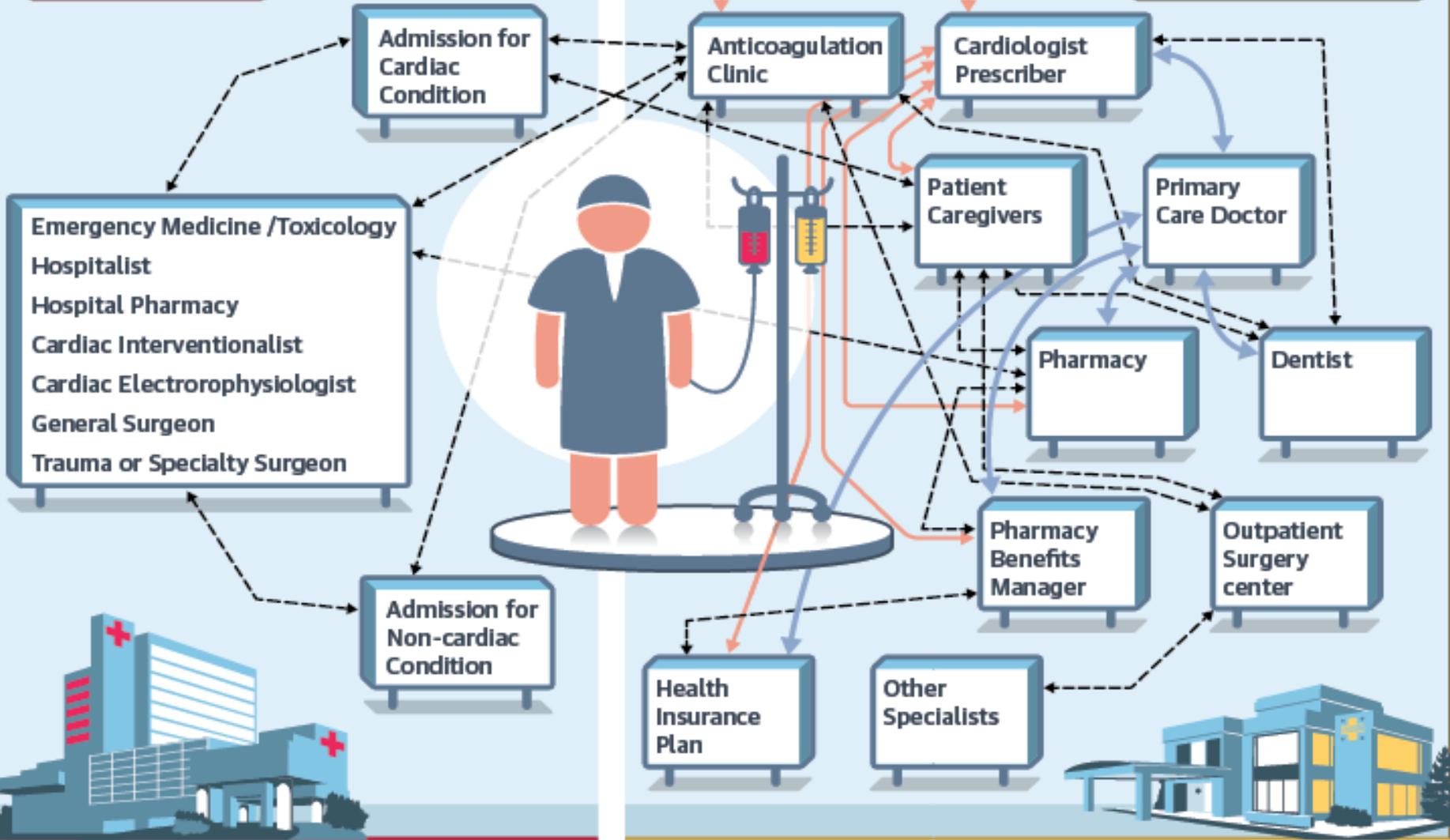
- Recent coronary stent and new onset AF
- Established AF, on OACs, requiring elective stenting
- Established AF, on OACs, who develop acute coronary syndrome
- Established AF, on OACs, with medically managed coronary disease
- Patients with stenting >1 month ago with a bare metal stent, or >6 months ago with a drug eluting stent, who develop AF
- Cerebral vascular disease and AF
- Previously on OACs, presenting with acute Ischemic stroke
- Ischemic stroke treated with vitamin K antagonist - convalescent phase
- Hemorrhagic stroke, on OACs
- Significant carotid stenosis and AF
- Peripheral artery disease and AF
- Mechanical heart valves and needing cardiac surgery
- Cardioversion
- AF ablation

FIGURE 2 Acute Management of Bleeding in a Patient Receiving Oral Anticoagulation



HOSPITAL

OUTPATIENT



Guideline



Practice

Knowledge



Solutions

Solutions Needed

- External obstacles to care
- Under and over-utilization
- Patient involvement
- Systems of care / Quality Improvement

Solution Sets Must Adapt to Change

CHA₂DS₂-VASc

The CHA₂DS₂-VASc score is an expansion of the original CHADS₂ score to include 3 additional stroke risk factors: age 65–74, female sex, and history of vascular disease. The additional risk factors are believed to more accurately determine stroke risk and the need for anticoagulation in patients with CHADS₂ scores of 0 or 1.

Condition	Points
Congestive heart failure	1
Hypertension	1
Age ≥ 75 years	2
Diabetes mellitus	1
Stroke/TIA or thromboembolism (prior)	2
Vascular disease (MI, PAD, or aortic plaque)	1
Age 65-74 years	1
Sex Category (Female)	1
Total score=	

Score	Risk	ESC Recommendation ³
>2	High	Anticoagulate
1	Intermediate	Anticoagulate
0	Low	Don't Anticoagulate

CHA ₂ DS ₂ -VASc Score	Yearly Stroke Risk (%)		
	No Warfarin	With Aspirin ²	With Warfarin ²
0	0	0	0
1	1.3	1.0	0.5
2	2.2	1.8	0.8
3	3.2	2.6	1.1
4	4.0	3.2	1.4
5	6.7	5.4	2.3
6	9.8	7.8	3.4

FDA Approved Anticoagulants
Comparison of warfarin and TSOACs/NOACs
Anticoagulant selection based on pt. characteristics
Identifying patients appropriate for TSOACs/NOACs

¹Lip GY, Nieuwlaat R, Pisters R, Lane DA, Crijns HJ. Refining clinical risk stratification for predicting stroke and thromboembolism in atrial fibrillation using a novel risk factor-based approach: the euro heart survey on atrial fibrillation. Chest. 2010 Feb;137(2):263-72. doi: 10.1378/chest.09-1584.

²Robert G. Hart, MD; Lesly A. Pearce, MS; and Maria I. Aguilar, MD. Meta-analysis: Antithrombotic Therapy to Prevent Stroke in Patients Who Have Nonvalvular Atrial Fibrillation. Ann Intern Med. 2007;146:857-8673. doi:10.7326/0003-4819-146-12-200706190-00007

³Camm, AJ et al. 2012 focused update of the ESC Guidelines for the management of atrial fibrillation. European Heart Journal (2012)33, 2719–2747. doi:



"At 3pm Friday, local autocrat C. Montgomery Burns was shot following a tense confrontation at Town Hall. Burns was rushed to a nearby hospital where he was pronounced dead.

--Kent Brockman
Newscaster, *The Simpsons*

Interdependency of ACC Efforts

- Science and Quality Committee
- Health Affairs Committee
- National Cardiovascular Data Registries
- Innovation Center

Advice

- Think about solution sets
- Use all of the resources of the ACC and collaborators
- Imagine adaptable and durable solutions
- Have fun