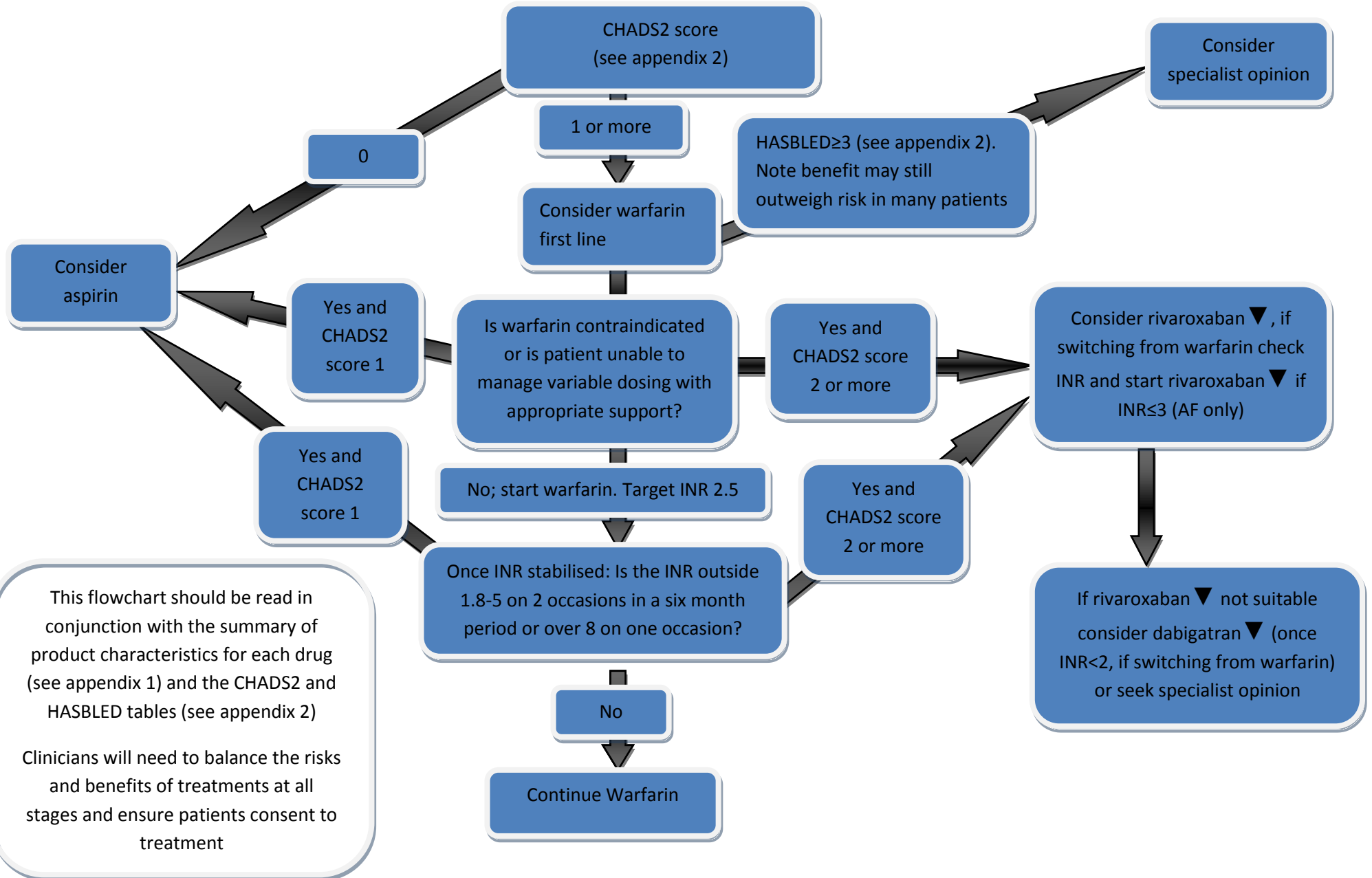


NORCOM primary care flowchart for the prevention of stroke and systemic embolism in Non Valvular Atrial Fibrillation: July 2012



Appendix 1: Indications and Contraindications for warfarin and non vitamin K antagonists as specified in the summary of product characteristics (SPC) for each drug

Warfarin	Rivaroxaban ▼	Dabigatran ▼
<p>Indication Prophylaxis of systemic embolism in patients with atrial fibrillation</p> <p>Contraindications Known hypersensitivity to warfarin or to any of the excipients</p> <ul style="list-style-type: none"> ○ Haemorrhagic stroke ○ Clinically significant bleeding ○ Within 72 hours of major surgery with risk of severe bleeding ○ Within 48 hours postpartum ○ Pregnancy ○ Drugs where interactions may lead to a significantly increased risk of bleeding 	<p>Indication Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack.</p> <p>Contraindications Hypersensitivity to the active substance or to any of the excipients.</p> <ul style="list-style-type: none"> ○ Clinically significant active bleeding. ○ Hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C ○ Pregnancy and breast feeding ○ Patients with CrCl <15ml/min, reduce dose to 15mg daily in CrCl 15-49ml/min ○ Concomitant systemic treatment with azole-antimycotics (such as ketoconazole, itraconazole, voriconazole and posaconazole) or HIV protease inhibitors (e.g. ritonavir) 	<p>Indication Prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation with one or more of the following risk factors:</p> <ul style="list-style-type: none"> ○ Previous stroke, transient ischemic attack, or systemic embolism ○ Left ventricular ejection fraction < 40 % ○ Symptomatic heart failure, \geq New York Heart Association (NYHA) Class 2 ○ Age ≥ 75 years ○ Age ≥ 65 years associated with one of the following: diabetes mellitus, coronary artery disease, or hypertension <p>Contraindications Hypersensitivity to the active substance or to any of the excipients</p> <ul style="list-style-type: none"> ○ Patients with severe renal impairment (CrCL < 30 ml/min) ○ Active clinically significant bleeding ○ Organic lesion at risk of bleeding ○ Spontaneous or pharmacological impairment of haemostasis ○ Hepatic impairment or liver disease expected to have any impact on survival ○ Concomitant treatment with systemic ketoconazole, cyclosporine, itraconazole and tacrolimus
<p>This table should be read in conjunction with the SPC for each drug available at http://www.medicines.org.uk/EMC/default.aspx</p> <p>Clinicians should use their clinical judgement where cautions rather than contraindications are listed in the SPC as to the risks vs. the benefits of starting a particular agent and ensure appropriate monitoring is carried out if required.</p> <p>Falls or being at risk of falls is not a contraindication to any of the agents. A history of injurious falls especially those falls leading to fracture may be seen as a contraindication to anticoagulants in general.</p>		

Appendix 2: Risk assessment tables

Table 1: CHADS2 risk index

	Condition	Point
C	Congestive Heart Failure	1
H	Hypertension	1
A	Age \geq 75	1
D	Diabetes Mellitus	1
S2	Stroke/TIA (History of)	2

Gage BF et al. Validation of clinical classification schemes for predicting stroke: results from the National Registry of Atrial Fibrillation. JAMA 2001;285:2864-70.

Table 2: CHADS2 score and stroke rate

CHADS2 score	Adjusted stroke rate (% / year)	Adjusted stroke rate on aspirin (20% RRR)	Adjusted stroke rate on warfarin (60% RRR)
0	1.9%	1.5%	0.76%
1	2.8%	2.24%	1.12%
2	4.0%	3.2%	1.6%
3	5.9%	4.7%	2.36%
4	8.5%	6.8%	3.4%
5	12.5%	10.0%	5.0%
6	18.2%	14.56%	7.28%

Table 3: Clinical characteristics comprising the HAS-BLED bleeding risk score

Letter	Clinical characteristic ^a	Points awarded
H	Hypertension	1
A	Abnormal renal and liver function (1 point each)	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile INRs	1
E	Elderly (e.g. age >65 years)	1
D	Drugs or alcohol (1 point each)	1 or 2
		Maximum 9 points

^a'Hypertension' is defined as systolic blood pressure > 160 mmHg. 'Abnormal kidney function' is defined as the presence of chronic dialysis or renal transplantation or serum creatinine \geq 200 μ mol/L. 'Abnormal liver function' is defined as chronic hepatic disease (e.g. cirrhosis) or biochemical evidence of significant hepatic derangement (e.g. bilirubin > 2 x upper limit of normal, in association with aspartate aminotransferase/alanine aminotransferase/alkaline phosphatase > 3 x upper limit normal, etc.). 'Bleeding' refers to previous bleeding history and/or predisposition to bleeding, e.g. bleeding diathesis, anaemia, etc. 'Labile INRs' refers to unstable/high INRs or poor time in therapeutic range (e.g. < 60%). Drugs/alcohol use refers to concomitant use of drugs, such as antiplatelet agents, non-steroidal anti-inflammatory drugs, or alcohol abuse, etc. INR = international normalized ratio. Adapted from Pisters et al.⁶⁰

Table 4: Adapted from the first validation of HAS-BLED [2], number of bleeds relating to score in a European AF population

HAS-BLED score	n	Bleeds, n	Bleeds/100 patients*
0	798	9	1.13
1	1286	13	1.02
2	744	14	1.88
3	187	7	3.74
4	46	4	8.70
5	8	1	12.50
Any score	3071	48	1.56

*p for trend of increasing bleeding risk with increasing score=0.007

References / Further reading

NICE CG36: Atrial fibrillation <http://publications.nice.org.uk/atrial-fibrillation-cg36>

NICE TA256: Rivaroxaban for atrial fibrillation, available at <http://publications.nice.org.uk/rivaroxaban-for-the-prevention-of-stroke-and-systemic-embolism-in-people-with-atrial-fibrillation-ta256>

NICE TA249: Dabigatran for atrial fibrillation, available at <http://publications.nice.org.uk/dabigatran-etexilate-for-the-prevention-of-stroke-and-systemic-embolism-in-atrial-fibrillation-ta249>

Summary of product characteristics for each drug available at <http://www.medicines.org.uk/emc/>

NPC patient decision aid for antithrombotic therapy in atrial fibrillation, available at http://www.npc.nhs.uk/therapeutics/cardio/atrial/resources/pda_af.pdf

European society of cardiology guidelines for the management of atrial fibrillation (2010), available at <http://www.escardio.org/guidelines-surveys/esc-guidelines/GuidelinesDocuments/guidelines-afib-FT.pdf>

Adapted from NORCOM statement: Non Vitamin K antagonists for the Prevention of stroke and transient ischaemic attack (TIA) in patients with atrial fibrillation (AF) at increased risk of stroke by:

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