Overview of NICE AF Guidelines and their impact on anticoagulant services

Windermere, October 2014
Atrial Fibrillation

Atrial fibrillation: the management of atrial fibrillation

Clinical guideline
Methods, evidence and recommendations
June 2014

Commissioned by the National Institute for Health and Care Excellence
Why did we need a guideline revision?
Leeds Primary Care Stroke Prevention in AF Audit

- Combined practice population of 151000
- 2119 (1.4%) patients with AF
- 1106 (52%) CHADS ≥ 2
- 512 46% CHADS ≥ 2 not on warfarin
GRASP – AF

Practice Name: Any Practice
Date of Audit: 7th July 2008
Total Practice Population: 9824
No. with Atrial Fibrillation: 130 (0.32%)
No. over 65 with AF: 0.85%

Risk Profile for Thrombo-embolism

Warfarin use in High Risk Patients

Breakdown of Warfarin and Antiplatelets use by CHADS score

Risk of Stroke v CHADS2 Score (95% CI)

Strokes Expected Annually in untreated group of 33

2.0
(95% CI 1.4 to 2.6)

Atrial Fibrillation rate per 1000 patients

Risk Factors

- Stroke or TIA
- Over 75
- Diabetes
- Hypertension
- Heart Failure

ADVICE
REFERENCES
PODCAST
Anticoagulant uptake – CHADS$_2$ ≥ 2

<table>
<thead>
<tr>
<th>Description</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients with CHADS$_2$ ≥ 2</td>
<td>132,099</td>
</tr>
<tr>
<td></td>
<td>(57.0%)</td>
</tr>
<tr>
<td>Number on OAC</td>
<td>72,211</td>
</tr>
<tr>
<td></td>
<td>(54.7%)</td>
</tr>
<tr>
<td>Number with OAC contra-indicated</td>
<td>12,128</td>
</tr>
<tr>
<td></td>
<td>(9.2%)</td>
</tr>
<tr>
<td>Number with OAC declined</td>
<td>2,859</td>
</tr>
<tr>
<td></td>
<td>(2.2%)</td>
</tr>
<tr>
<td>No OAC and not contra-indicated / declined</td>
<td>44,901</td>
</tr>
<tr>
<td></td>
<td>(34.0%)</td>
</tr>
<tr>
<td>Estimate for England, no OAC and not contra-indicated or declined</td>
<td>169,000</td>
</tr>
</tbody>
</table>

Heart 2013;99:1166-1172
Anticoagulation deficit in patients with known AF and CHADS$_2$ $> 2$

- Estimate of 169,000 patients in England
- Based on a relative risk reduction of 25 to 50 to prevent 1 stroke
- Estimate that treating these patients with OAC could prevent 3380 - 6760 strokes annually
Sentinel Stroke National Audit Programme (SSNAP)

Clinical audit first pilot public report

National results

August 2013
Based on stroke patients admitted to hospital between January – March 2013

Prepared by
Royal College of Physicians, Clinical Effectiveness and Evaluation Unit on behalf of the Intercollegiate Stroke Working Party
Sentinel Stroke Audit

• 11939 patients with stroke
• 2465 known to be in AF prior to admission
  – 1272 on oral anticoagulant (51.6%)
  – 1193 not on oral anticoagulant (48.4%)
  – 296 contraindicated (12.0%)
• By extrapolation up to 4772 preventable strokes each year in England, Wales and N.Ireland
Algorithm 1: Stroke prevention of people with non-valvular AF

1. Assess stroke risk stratification using CHA₂DS₂-VASc
   - Discuss risks and benefits of anticoagulation
     - Identify low risk patients i.e. CHA₂DS₂-VASc=0 (men) or 1 (women)
       - CHA₂DS₂-VASc=1 (in men)
         - Consider oral anticoagulant
       - CHA₂DS₂-VASc≥2
         - Offer oral anticoagulant
     - Anticoagulation contraindicated

2. Assess bleeding risk stratification using HAS-BLED
   - No anti-thrombotic therapy

3. Discuss the options for anticoagulation with the person and base the choice on their clinical features and preferences
   - Vitamin K antagonists (VKA)
   - Non-VKA oral anticoagulant
     - Poor control
       - Non VKA oral anticoagulant
         - Non VKA contraindicated or not tolerated
           - Left atrial appendage occlusion
   - Annual review for all patients
Assess stroke risk stratification using CHA\textsubscript{2}DS\textsubscript{2}-VASc

Assess bleeding risk stratification using HAS-BLED

Discuss risks and benefits of anticoagulation
<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congestive heart failure/LV dysfunction</td>
<td>1</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1</td>
</tr>
<tr>
<td>Age $\geq$75</td>
<td>2</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1</td>
</tr>
<tr>
<td>Stroke/TIA/thrombo-embolism</td>
<td>2</td>
</tr>
<tr>
<td>Vascular disease $^a$</td>
<td>1</td>
</tr>
<tr>
<td>Age 65–74</td>
<td>1</td>
</tr>
<tr>
<td>Sex category (i.e. female sex)</td>
<td>1</td>
</tr>
<tr>
<td>Maximum score</td>
<td>9</td>
</tr>
<tr>
<td>Letter</td>
<td>Clinical characteristic(^a)</td>
</tr>
<tr>
<td>--------</td>
<td>---------------------------------------------------</td>
</tr>
<tr>
<td>H</td>
<td>Hypertension</td>
</tr>
<tr>
<td>A</td>
<td>Abnormal renal and liver function (1 point each)</td>
</tr>
<tr>
<td>S</td>
<td>Stroke</td>
</tr>
<tr>
<td>B</td>
<td>Bleeding</td>
</tr>
<tr>
<td>L</td>
<td>Labile INRs</td>
</tr>
<tr>
<td>E</td>
<td>Elderly (e.g. age $&gt;$ 65 years)</td>
</tr>
<tr>
<td>D</td>
<td>Drugs or alcohol (1 point each)</td>
</tr>
</tbody>
</table>

Maximum 9 points

\(^a\) Clinical characteristics are determined based on individual patient assessment.
Bleeding risk Assessment

Use the HAS-BLED score to assess the risk of bleeding in people who are starting or have started anticoagulation and to highlight, correct and monitor the following modifiable risk factors:

– uncontrolled hypertension
– poor control of INR (‘labile INRs’)
– concurrent medication, for example concomitant use of aspirin or an NSAID
– harmful alcohol consumption.
Stroke versus bleeding risk

When discussing the benefits and risks of anticoagulation, tell the person that:

– for most people the benefit of anticoagulation outweighs the bleeding risk
– for people with an increased risk of bleeding the benefit of anticoagulation may not always outweigh the bleeding risk, and careful monitoring of bleeding risk is important.

NICE June 2014
2014 NICE Patient Decision Aid

- Emphasises the importance of informed decision making
- Patient decision aid to help patients (and doctors) make a more informed judgement.
- Calculate CHADSVASC and HASBLED scores together
- Patient takes booklet away to read about risks and benefits of anticoagulation
Example of CHADSVASC=3, HASBLED =3

<table>
<thead>
<tr>
<th>Stroke risk</th>
<th>No Treatment</th>
<th>Anticoagulant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding risk</td>
<td><img src="image1.png" alt="Green circles with red and yellow dots" /></td>
<td><img src="image2.png" alt="Green circles with red and yellow dots" /></td>
</tr>
</tbody>
</table>
 Assess stroke risk stratification using CHA²DS₂-VASc

Assess bleeding risk stratification using HAS-BLED

Discuss risks and benefits of anticoagulation

Identify low risk patients i.e. CHA²DS₂-VASc=0 (men) or 1 (women)

No anti-thrombotic therapy

CHA²DS₂-VASc=1 (in men)
Consider oral anticoagulant

CHA²DS₂-VASc≥2
Offer oral anticoagulant
Warfarin or NOAC?

• Anticoagulation may be with apixaban, dabigatran etexilate, rivaroxaban or a vitamin K antagonist

• Discuss the options for anticoagulation with the person and base the choice on their clinical features and preferences.
Assess stroke risk stratification using CHA²DS²-VASc

Assess bleeding risk stratification using HAS-BLED

Discuss risks and benefits of anticoagulation

Identify low risk patients i.e. CHA²DS²-VASc=0 (men) or 1 (women)

No anti-thrombotic therapy

CHA²DS²-VASc=1 (in men)
Consider oral anticoagulant

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Offer oral anticoagulant

Discuss the options for anticoagulation with the person and base the choice on their clinical features and preferences

Vitamin K antagonists (VKA)

Non-VKA oral anticoagulant [See TA numbers 249, 256, 275]
Importance of quality of anticoagulation in patients on vitamin K antagonists
Calculate the person's time in therapeutic range (TTR) at each visit. When calculating TTR:

• use a validated method of measurement such as the Rosendaal method for computer-assisted dosing or proportion of tests in range for manual dosing

• exclude measurements taken during the first 6 weeks of treatment

• calculate TTR over a maintenance period of at least 6 months.
Reassess anticoagulation for a person with poor anticoagulation control shown by any of the following:

- 2 INR values higher than 5 or 1 INR value higher than 8 within the past 6 months
- 2 INR values less than 1.5 within the past 6 months
- TTR less than 65%.

NICE June 2014
When reassessing anticoagulation, take into account and if possible address the following factors that may contribute to poor anticoagulation control:

- cognitive function
- adherence to prescribed therapy
- illness
- interacting drug therapy
- lifestyle factors including diet and alcohol consumption.
If poor anticoagulation control cannot be improved, evaluate the risks and benefits of alternative stroke prevention strategies and discuss these with the person.
CHA₂DS₂-VASc=1 (in men)
Consider oral anticoagulant

CHA₂DS₂-VASc≥2
Offer oral anticoagulant

Discuss the options for anticoagulation with the person and base the choice on their clinical features and preferences

Vitamin K antagonists (VKA)

Assess anticoagulation control

Non-VKA oral anticoagulant
[See TA numbers 249, 250, 275]

Poor control

Non VKA oral anticoagulant
If CHA₂DS₂-VASc=1 (in men) or CHA₂DS₂-VASc=2:
- Consider oral anticoagulant
- Offer oral anticoagulant

Discuss the options for anticoagulation with the person and base the choice on their clinical features and preferences.

- Vitamin K antagonists (VKA) [See TA numbers 249, 258, 275]
- Non-VKA oral anticoagulant

Assess anticoagulation control:
- Poor control
- Non-VKA oral anticoagulant
- Non VKA contraindicated or not tolerated

Left atrial appendage occlusion
Algorithm 1: Stroke prevention of people with non valvular AF

1. Assess stroke risk stratification using CHA₂DS₂-VASc
2. Assess bleeding risk stratification using HAS-BLED
3. Discuss risks and benefits of anticoagulation
4. Identify low risk patients i.e. CHA₂DS₂-VASc=0 (men) or 1 (women)
5. CHA₂DS₂-VASc=1 (in men) Consider oral anticoagulant
6. CHA₂DS₂-VASc≥2 Offer oral anticoagulant
7. Discuss the options for anticoagulation with the person and base the choice on their clinical features and preferences
8. Vitamin K antagonists (VKA)
9. Assess anticoagulation control
10. Non-VKA oral anticoagulant [See TA numbers 249, 256, 275]
11. Poor control
12. Non-VKA oral anticoagulant
13. Non VKA contraindicated or not tolerated
14. Left atrial appendage occlusion
15. Annual review for all patients
Do not offer aspirin monotherapy solely for stroke prevention to people with atrial fibrillation. [new 2014]
Determine stroke/thromboembolic risk

- **High risk**
  - Consider anticoagulation
  - **Contraindications to warfarin?**
    - NO: Warfarin, target INR = 2.5 (range 2.0 to 3.0)
    - YES: Reassess risk stratification whenever individual risk factors are reviewed

- **Moderate risk**
  - Consider anticoagulation or aspirin

- **Low risk**
  - Aspirin 75 to 300 mg/day if no contraindications

Warfarin, target INR = 2.5 (range 2.0 to 3.0)

NICE 2006 Guideline
Overcoming Barriers

- The guideline has been simplified
- Aspirin removed
Overcoming Barriers

- The guideline has been simplified
- Aspirin removed
- “Faff factor” of warfarin
“Faff factor” of anticoagulation

- Need to make it easier for patients
- Reduce inconvenience of warfarin clinics
- Self monitoring
Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor)

Issued: September 2014

NICE diagnostics guidance 14
www.nice.org.uk/dg14
Self monitoring of coagulation status in adults and children on long term vitamin K antagonist therapy who have AF or heart valve disease is recommended if:

- “the person prefers this form of testing and
- the person or their carer is both physically and cognitively able to self monitor effectively”
“Faff factor” of anticoagulation

- Make it easier for patients
- Reduce inconvenience of warfarin clinics
- Home monitoring
- NOACs
Overcoming Barriers

- The guideline has been simplified
- Aspirin removed
- “Faff factor” of warfarin
- Safety concerns
Safety concerns with anticoagulation

- Physicians are naturally concerned lest the therapy they initiate causes a serious bleed.
- Can’t identify patients who have been prevented from having a stroke – but can identify anticoagulant related bleeds.
- 2014 guidance represents a paradigm shift towards anticoagulation being the “norm” – 84% of AF patients are CHADSVASC ≥ 2.
Distribution of CHA$_2$DS$_2$VASc scores

Percentage of patients with AF

CHA2DS2VASc Score

0 1 2 3 4 5 6 7 8 9

0.00% 5.00% 10.00% 15.00% 20.00% 25.00%

84%
What is the potential increase in numbers as a result of the new guideline?
Total anticoagulation deficits

Conforming to 2006 recommendations, but currently untreated with oral anticoagulant (80% on aspirin)
Total anticoagulation deficits

Conforming to 2006 recommendations, but currently untreated

Conforming to new recommendations, currently untreated

169,000
Distribution of CHADS score
Warfarin treatment by CHADS Score

- Declined
- C / I
- Warfarin

Bar chart showing the distribution of Warfarin treatment by CHADS Score.
Total anticoagulation deficits

Conforming to 2006 recommendations, but currently untreated  
169,000

Conforming to new recommendations, currently untreated  
112,468
What else do we need to do to implement the 2014 guideline?
What else do we need to implement the 2014 guideline?

• Initial decision to commence anticoagulation

• Review recommendations
<table>
<thead>
<tr>
<th>Decision to commence anticoagulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Explanation of stroke in AF</td>
</tr>
<tr>
<td>• CHADSVASC evaluation</td>
</tr>
<tr>
<td>• HASBLED evaluation</td>
</tr>
<tr>
<td>• Discussion of risks and benefits with patient</td>
</tr>
</tbody>
</table>
## Decision to commence anticoagulation
- Explanation of stroke in AF
- CHADSVASC evaluation
- HASBLED evaluation
- Discussion of risks and benefits with patient

## Choice of anticoagulant
- Assessment of clinical features
- Explanation of advantages / disadvantages of NOAC / Vit K
  - Convenience / Monitoring requirements
  - Compliance issues
  - Quality of anticoagulation
  - Safety / reversibility
  - Side effects
- Patient decision
Extended anticoagulant clinic role

- Not just warfarin monitoring
- Initial clinical assessment and discussion to guide anticoagulant choice
- Continuing care for Vit K antagonist patients but NOAC care handed back to GP with advice on renal monitoring
Implications of NICE 2014 recommendations for annual review
– patients on an anticoagulant

• For people who are taking an anticoagulant, review the need for anticoagulation and the quality of anticoagulation at least annually, or more frequently if clinically relevant events occur affecting anticoagulation or bleeding risk.
Vitamin K antagonists annual review

Overall clinical care

Anticoagulant Control Clinic

Annual review of quality of anticoagulation and any recommendations for change
Vitamin K antagonists annual review

Overall clinical care

Anticoagulant Control Clinic
- Annual review of quality of anticoagulation
- Act to change anticoagulant when required

Inform GP of change and future monitoring requirements
The new NICE guidance helps address poor uptake of anticoagulation in AF in a number of ways

- Simplification of algorithms
- Removal of aspirin
- Change of paradigm so that anticoagulation is regarded as the norm
- Involvement of the patient in decision making
- Greater accessibility to NOACs
- Identifying low TTRs in warfarin patients and promoting change to NOACs
- Annual review of all patients with AF
Conclusions II

In addition there is a need for commissioners to address:

- Arrangements for commencing anticoagulation and choice of anticoagulant
- Arrangements for annual review of patients with AF most particularly those already receiving anticoagulants