University of Birmingham and University of York Health Economics Consortium (NCCID)

Development feedback report on piloted indicators

QOF indicator area: Atrial Fibrillation

Pilot period: 1st October 2016 – 28th February 2017

Potential output: Recommendations for NICE menu

Contents

Summary of recommendations

Indicator

1. The percentage of patients with atrial fibrillation, currently treated with an anticoagulant, who have had a review in the preceding 12months which included:
    a. Assessment of stroke/ VTE risk
    b. Assessment of bleeding risk
    c. Assessment of renal function, creatinine clearance, FBCand LFTs
    d. Any adverse events related to anticoagulation
    e. Assessment of compliance
    f. Choice of anticoagulant.

Acceptability recommendation:

Band 1: >70% of practices support inclusion.

Implementation recommendation:

Band 2: minor problems identified during piloting or anticipated to arise in wider implementation.

Cost effectiveness recommendation:

See summary report.

Issues to consider:

Issue	Detail	Mitigating activity
Availability of HAS-BLED tool on clinical systems	HAS-BLED tool is not built in to all clinical systems requiring practices to manually complete a form to calculate this score.	If adopted into QOF it is likely that system suppliers would integrate the tool into their clinical system.
Clarity of the renal functioning, creatinine clearance, FBC and LFT element of the review.	Practices commented that the wording of this element of the review needed to be more specific to the anticoagulant being prescribed.	Guidance could clarify the circumstances in which these tests should be performed.
Compliance element of the review	This could be a difficult aspect of care to measure, especially in patients prescribed NOACs.	This is captured under the read code for 'annual review' and does not require a specific test.
Outsourcing of monitoring and prescribing to anticoagulation clinics	Some practices explained that elements of the annual review were managed by external anticoagulation clinics, however the GP practice was responsible for prescribing so they felt responsible for monitoring this care. In two practices, anticoagulants were prescribed by a third party organisation and	

	one of these practices questioned whether completing annual reviews should be viewed as a marker of quality in general practice for this reason.	

Background

As part of the NICE-managed Quality and Outcomes Framework (QOF) process, all clinical and health improvement indicators are piloted, using an agreed methodology, in a representative sample of GP practices across England, Scotland, Wales and Northern Ireland.

The aim of piloting is to test whether indicators work in practice, have any unintended consequences and are fit for purpose.

Practice recruitment

Number of practices recruited:	29
Number of practices dropping out:	2
Number of practices unable to interview:	0
Number of practices interviewed:	27

[26 GPs, 6 practice nurses, 9 practice managers and 1 health care assistant = 42 primary care staff]

All percentages reported have been calculated using the 29 practices recruited to the pilot as the denominator.

Piloted indicators

1. The percentage of patients with atrial fibrillation, currently treated with an anticoagulant, who have had a review in the preceding 12 months which included:
    a. Assessment of stroke/VTE risk
    b. Assessment of bleeding risk
    c. Assessment of renal function, creatinine clearance, FBC and LFTs
    d. Any adverse events related to anticoagulation
    e. Assessment of compliance
    f. Choice of anticoagulant.

Assessment of clarity, reliability, feasibility, and acceptability

Clarity

During piloting some practices expressed concerns about the clarity of aspect c of the review: assessment of renal function, creatinine clearance, FBC and LFTs. For people prescribed warfarin only INR tests are needed and people prescribed NOACs need all of these tests. Practices felt this needed to be more clearly worded in the indicator.

Reliability and feasibility

We were able to develop business rules to support this indicator.

Issues to be resolved prior to implementation:

Issue	Detail	Mitigating activity
Exception reporting	Exception reporting criteria usually includes patient refused/ informed dissent. Are there any patient safety or medicolegal concerns arising from exception reporting patients who refuse medication reviews?	
Elements of the review	Do each of the elements that make up the indicator need to be considered discretely?	For the pilot certain elements of the review were considered as being within a more general code e.g. as part of the atrial fibrillation review rather than specifically looking for assessment of renal function for example. Consideration may be required as to if this would suffice should the indicator go forward to the NICE menu (keeping as is would minimise coding burden for practices) or if the Business Rules should look for each element separately. If the latter then new codes would be required.

Acceptability

All practices felt that this was a suitable topic area for quality measurement. Twenty-four practices (82.8%) were supportive of this indicator being considered for QOF, one of whom agreed to the inclusion only of the assessment of stroke and bleeding risk and did not feel the other elements of the review should be included. Most practices explained that anticoagulation reviews were already conducted as standard practice because they were important to reduce stroke risk and monitor other potential cardiovascular problems.

"The reason I'd like AF to be added in (and certainly put in this way) is certainly stroke management could be better, in terms of costings and what they actually spend on stroke management afterwards". (GP, Practice ID10)

"We have a fair few patients with AF linked to other cardiovascular problems, and a lot of the indicators are kind of relevant to support the other problems that they have" (GP, Practice ID24)

"I think what isn't on there that we'd be adding is also patients with atrial fibrillation who are not on anything because otherwise where are they getting monitored?" (GP, Practice ID05)

Only a small number of practices did not already have a formal approach to recalling these patients for an annual review but they felt including this in QOF would be beneficial to providing more structured anticoagulation care. It was viewed as important to encourage all practices to do this and adding this to QOF may achieve this aim.

"I think it's a good thing to introduce but no, I don't think there was any formal recall set up for it at all" (GP, Practice ID12)

"This means that we're using the structured approach. So if maybe an odd clinician who's not using that, I think it helps them to bring on board so it standardises the approach." (GP, Practice ID04)

Practices generally reported that there was usually a standard process for monitoring people who were prescribed warfarin. At some practices a similar approach was not currently in place for reviewing patients taking novel oral anticoagulants (NOACs) but this was described as important and introducing this in to QOF may encourage it.

"I think a very few number of patients on the NOAC case, but that may shift actually over the next few years…and I think the need for formal assessment may well be more important in practice" (GP, Practice ID20)

A benefit of having an annual review reported by a small number of practices was patient safety and monitoring potential adverse reactions in patients who were prescribed anticoagulants.

"I think in general it's extremely important because the whole treating atrial fibrillation has been enormously heavily promoted by drug companies and NICE. I think it would be fair to say there hasn't been the same emphasis on safety and monitoring and that side of things hasn't been as emphasised and obviously the drugs responsible are the top causes of iatrogenic harm so the monitoring's extremely important." (GP, Practice ID05)

Some practices who chose to include this indicator described potential problems with some aspects of the review. Seven practices reported that the HAS-BLED tool was not integrated in to their clinical system meaning they used an external web link to calculate this score during the pilot. This was not generally viewed as a barrier to inclusion because it was assumed the tool would be built in to clinical systems if the indicator was in QOF.

"The HAS-BLED can't be done in EMIS and I had a look. You can put a code in to say that you've calculated HAS-BLED but you can't press a button and EMIS do it for you and I phoned EMIS and they said, 'Oh yes, we've been asked this question before and it can't be done and it's not even on the

horizon for being done. So then you have to go into a website and do the calculation separately...to go back through our over 100 patients and do that retrospectively... that's quite a big piece of work to go back and put in all the HAS-BLED scores." (PN, Practice ID10)

A small number of practices questioned the value of measuring the HAS-BLED score and CHA_2DS_2-VASc annually. It was felt that this was not useful once anticoagulation treatment had been started because these patients were still viewed as being at sufficient risk to require anticoagulation.

"I think if you're already on maximum treatment and you're not going to be changing that treatment then I think to do the CHADSVASC again every year is not particularly helpful." (GP, Practice ID14)

"I really think that that's more of a relevant at the start of therapy with a new atrial fibrillation patient rather than a follow-up one because if they're on anticoagulant and their HASBLED comes up a big high we're probably not going to still stop the anticoagulant judging by the current recommendation. Basically it's treatment because there's more risk of the problems if you don't anticoagulate them." (GP, Practice ID27)

It was also commented that the element of the review concerning assessment of renal functioning, creatinine clearance, FBC and LFT's needed to be more specific to the anticoagulant being prescribed. Practices commented that although all of these tests were needed for NOACs, only the INR tests were required for warfarin which could be explained more clearly in the indicator. Parts c, d, e and f of the indicator are currently read coded on clinical systems using a single annual review code. This does not highlight whether or not each individual element of the review has been completed.

"We wouldn't suggest that's in QOF because for example if they're just on Warfarin then you don't really need to know renal function or full blood count or LFTs you know it's fine just to carry on just doing INR but if they're on a NOAC then you'd be doing those through blood tests or certainly the renal function so I would say all of it is okay apart from the blood because you're better of using the right blood tests to monitor the right drugs…You could ... say if you're going to use say like a NOAC or anticoagulant then you know which specific blood test you do for which drug." (GP, Practice ID16)

Different methods of measuring anticoagulant compliance were discussed. Most practices felt blood tests were useful for patients prescribed warfarin, however some reported the issue of NOACS because compliance couldn't be detected through a blood test. This was described by one practice as being particularly challenging from a measurement perspective.

"We haven't got a way of monitoring how effective the newer ones are because there's no blood test as such or there's no way to know." (GP, Practice ID04)

A further two practices (6.9%) were unsure as to whether this was suitable for inclusion in QOF. One of these practices regarded this as standard care and adding it to QOF is potentially unnecessary.

"It's a very important condition, atrial fibrillation and prevention of stroke is very important. But, as I say, I think we're doing most of it already without making it a new domain...I'm fairly ambivalent. If it comes fine; it won't make much difference to me." (GP, Practice ID32)

The other practice was unsure because their warfarin prescribing is managed by an outside NHS provider who also monitor compliance and discussion of the choice of anticoagulant. For this reason the practice did not view this area as a marker of quality in general practice.

"Be an easy one if it was 'cause I think most of it gets done so depends if I've got my sort of political commissioning hat on otherwise I've got my cold-faced GP hat on 'cause yeah, it wouldn't be too difficult to do, to get our QOF point to the practice but whether it's worth incentivising GPs to do more of it 'cause they do it already 'cause that was my feelings…I'd be getting the QOF rewards for checking that someone has done their work" (GP, Practice ID11)

Anticoagulation monitoring and prescribing is not always the responsibility of the GP practice. Two practices who chose to include the indicator explained that their reviews were conducted by the anticoagulation clinic, however the GP practice were responsible for prescribing. For this reason and due to the importance of monitoring anticoagulation they felt it should be included in QOF. However, a further practice who chose to include the indicator said that a third party provider prescribed warfarin and monitored compliance and the choice of anticoagulant. Some elements of the review were the responsibility of the GP so they felt the indicator should still be included.

"Although it's outsourced, only part of the service is outsourced but ultimate responsibility lies with the GP...It's a service where you delegate, so we're still accountable for the service. I mean here, that's how it works....If we weren't prescribing the drugs, then it probably wouldn't be our responsibility to review it but if we are prescribing, then we have this duty." (GP, Practice ID26)

"It's third party anti coagulation prescribing so they're taking the responsibility for a little bit of the patient management, the rest is still in the hand of the GP...I'm quite happy with that, I mean in fact that this is a joint assessment and bleeding risk score, you do the score which is a good thing." (GP, Practice ID21)

Only one practice (3.4 %) chose not to include this indicator in QOF. They viewed the indicator as good quality of care, however they did not choose to include any of the piloted indicators because they did not feel any further indicators should be added to QOF at this time due to local workload pressures.

Assessment of implementation

Assessment of piloting achievement

	Baseline	Final
Number of practices uploading	14	14
Practice population (from NHAIS)	118,341	119,968
Register	1,981	2,128
Excluded		
Rule 1: patients not prescribed an anticoagulant in the preceding 6 months	636	606
Exception reported		
Rule 3: AF exception code recorded in preceding 12 months	9	9
Rule 4: Recent registration	9	16
Rule 5: recent diagnosis	34	55
Total exceptions	**688**	**686**
Exceptions as a % of eligible population	**34.73**	**32.24**
Denominator	1,293	1,442
Numerator	5	19
Numerator as a percentage of denominator	**0.39**	**1.32**
Prevalence	**1.67**	**1.77**

Cohort prevalence was comparable to reported QOF prevalence for 2015/16 (latest available data). Baseline and final achievement figures are lower than those which would be expected given participating practices self reported behaviours. In order to be counted as a success and included in the numerator patients needed to have a HAS-BLED, a CHA_2DS_2-VASC AND an annual review coded during the relevant time period. In the absence of a clinical template, it is likely that inadequate coding contributed to the apparent poor achievement rates. Individual practice achievement ranged from 0 to 32.7% at the final upload.

Changes in practice organisation

Some practices did not currently complete the HAS-BLED score for AF patients. However, this was not viewed as an issue if this tool was integrated in to their clinical systems.

Resource utilisation and costs

Most practices completed annual reviews with these patients as standard practice. Some practices commented that they conducted some aspects of the review opportunistically. It was acknowledged that calculating the HAS-BLED and CHA2DS2-VASc scores created additional administrative work that may need to be completed outside the consultation. Also, some practices did not currently complete reviews for patients prescribed NOACs. Although this was viewed as useful, it would create additional work.

Barriers to implementation

No potential barriers to implementation were identified.

Assessment of exception reporting

The main driver of exception reporting at both data extraction points was patients not having been prescribed an anticoagulant in the preceding 6 months. At the final upload this accounted for 28.5% of patients.

Assessment of potential unintended consequences

No potential unintended consequences were identified.

Assessment of overlap with and/or impact on existing QOF indicators

There is some overlap with this existing indicator for atrial fibrillation:

AF006: The percentage of patients with atrial fibrillation in whom stroke risk has been assessed using the CHA_2DS_2-VASc score risk stratification scoring system in the preceding 12 months (excluding those patients with a previous CHA_2DS_2 or CHA_2DS_2-VASc score of 2 or more).

It is the intention that this indicator would sit alongside the existing indicator set rather than replace any of the existing indicators.

Suggested amendments to indicator wording

1. The percentage of patients with atrial fibrillation, currently treated with an anticoagulant, who have had a review in the preceding 12 months which included:
    a. Assessment of stroke/VTE risk
    b. Assessment of bleeding risk
    c. Assessment of renal function, creatinine clearance, FBC and LFTs (as appropriate for prescribed anticoagulation)
    d. Any adverse events related to anticoagulation
    e. Assessment of compliance
    f. Choice of anticoagulant.

Appendix A: Practice recruitment

We planned to recruit 34 practices in England and 2 in each of the Devolved Administrations. English practices were to be representative in terms of practice list size, deprivation and clinical QOF score. Given the limited variability in clinical QOF score we excluded practices with a score of ≤ 10th centile. Practice list size and IMD scores were divided into tertiles and a 3x3 matrix created with target recruitment numbers for each cell. These are detailed in the table below.

	List size		
IMD Score	Low	Medium	High
Low	3	4	5
Medium	3	4	4
High	4	4	3

As previously presented to the Committee, practice recruitment has been extremely challenging. At the beginning of this pilot we had recruited 28 practices in England and 3 in the Devolved Administrations (2 in Northern Ireland, 1 in Scotland). Practice recruitment by strata is shown in the table below with cells in bold where we failed to meet target numbers. We also over recruited in one strata which is shown by the numbers in the table. Two practices in England withdrew from the pilot prior to it starting reducing the total numbers of pilot practices to 26 in England, 2 in Northern Ireland and 1 in Scotland.

	List size		
IMD Score	Low	Medium	High
Low	**2/3**	**3/4**	**1/5**
Medium	3/3	4/4	**1/4**
High	5/4	4/4	3/3

Appendix B: Indicator development

Following the June 2016 Advisory Committee meeting the NCCID was asked to develop new indicators for anticoagulant monitoring in patients with atrial fibrillation.

GP focus group

A focus group to discuss potential indicators was held on 20th July 2016 where all potential indicators were discussed. Focus group attendees were volunteers recruited via our database of GPs who had responded to previous invitations. From the volunteers we purposively selected 15 GPs to attend the focus group to try to ensure a balance of men and women, representation from minority ethnic groups and a range of ages.

Of those invited, 14 attended the meeting. Nine (60%) were male. Approximately one third of the participants described themselves as being of white ethnicity (n=5). Participants were reimbursed £250 for their attendance.

Anneka Patel and Shaun Rowark attended on behalf of NICE. Gemma Ramsey and Ross Ambler attended on behalf of NHS Digital.

Two indicators were presented to the group: firstly, an annual review for all patients with a atrial fibrillation and secondly a review indicator focused upon those currently treated with an anticoagulant. The consensus amongst participants was that the focus should be upon patients currently treated with anticoagulants. However, participants noted that some proposed aspects of the review tended not to be in the control of general practice, such as, choice of anticoagulant, monitoring of compliance if patients attended an anticoagulant clinic. There were also queries as to how checking compliance could be evidenced. Overall, the proposed elements of the review seemed reasonable although it was suggested that creatinine clearance could also be considered, especially where patients are being prescribed NOACs.

One indicator was progressed to piloting.

Indicator wording as piloted

2. The percentage of patients with atrial fibrillation, currently treated with an anticoagulant, who have had a review in the preceding 12 months which included:
    a. Assessment of stroke/VTE risk
    b. Assessment of bleeding risk
    c. Assessment of renal function, creatinine clearance, FBC and LFTs
    d. Any adverse events related to anticoagulation
    e. Assessment of compliance
    f. Choice of anticoagulant.

Appendix C: Acceptability and Implementation recommendations

Acceptability recommendations

One of the following recommendations is made based upon reported acceptability of the indicator to pilot practices.

Band 1: ≥70% of practices support inclusion

Band 2: 60-69% of practices support inclusion

Band 3: 50-59% of practice support inclusion

Band 4: <50% of practices support inclusion.

Implementation recommendations

One of the following recommendations is made based upon an assessment of issues or barriers to implementation reported during piloting.

Band 1: no problems identified during piloting or anticipated to arise. Indicator terms precisely defined.

Band 2: minor problems identified during piloting or anticipated to arise in wider implementation. Problems resolvable prior to implementation through either 1) an amendment to indicator wording, 2) an amendment to the business rules and/or 3) by giving further clarification of indicator terms in associated guidance.

Band 3: major problems identified during piloting or anticipated in wider implementation. Possibly resolvable through the actions described in band 2 but indicator requires further development work and/or piloting.

Band 4: major problems identified during piloting. Not immediately resolvable. Indicator not recommended for wider implementation.