NICE National Institute for Health and Care Excellence

Indicator development programme

Consultation report

Indicator area: Atrial fibrillation

Consultation period: 04 October 2022 to 18 October 2022

Date of Indicator Advisory Committee meeting: 07 November 2022

Executive summary

Overview

This paper presents consultation comments on a new indicator potentially suitable for inclusion in the Quality and Outcomes Framework (QOF):

- IND2022-131: Percentage of patients with atrial fibrillation and a last recorded CHA_2DS_2-VASc score of 2 or more who are currently prescribed a direct-acting oral anticoagulant (DOAC), or where a DOAC is declined or clinically unsuitable, a Vitamin K antagonist.

Anticoagulation in patients with atrial fibrillation (AF) can help prevent stroke, and DOACs are more effective than Vitamin K antagonists for people with atrial fibrillation at high risk of stroke. After committee consideration the next stage would be publication on the NICE menu.

Development

This indicator was a direct referral from NHS England in July 2021 as a possible replacement for AF007 in the QOF (NICE menu NM82) and is derived from CVD-05 in the Impact and Investment Fund (IIF). The proposal has not been previously discussed by the committee and has been subject to consultation only. Quantitative testing has not been undertaken because of the existence of CVD-05 in the IIF and similarity to QOF AF007.

Context

The QOF currently includes an indicator on anticoagulation for people with atrial fibrillation that does not require that DOACs are offered as first line treatment:

- AF007 (NICE menu NM82): In those patients with atrial fibrillation with a record of a CHA_2DS_2-VASc score of 2 or more, the percentage of patients who are currently treated with anticoagulation drug therapy.

AF007 QOF data for 2021/22 show national achievement at 92% with intervention at 89%. There is low reporting of personalised care adjustments:

4%. An average practice with 10,000 patients would have approximately 173 eligible patients.

The proposed new indicator is based on CVD-05 in the IIF 2022/23. Network Contract Directed Enhanced Service data for September 2022 show national achievement at 80% with intervention at 79%. There is low reporting of personalised care adjustments: 2%.

The Network Contract Directed Enhanced Service for 2021-22 also includes an indicator that examines DOAC provision for any patient prescribed an anticoagulant, not just those with atrial fibrillation (NCDMI021). Data from September 2022 shows an average of 85% of patients prescribed an anticoagulant were prescribed a DOAC.

Potential benefits

The current indicator on the NICE menu and in the QOF measures provision of anticoagulants and counts DOACs and Vitamin K antagonists equally. The proposed new indicator promotes DOACs as first line treatment for people with high risk of stroke in line with NICE's guideline on atrial fibrillation. Provision of a Vitamin K antagonist to people with contra-indications or choosing not to receive a DOAC will still count as a "success".

Validity concerns

In the absence of a record of mechanical prosthetic replacement, the prescription of a Vitamin K antagonist without a recorded personalised care adjustment for provision of a DOAC will count as a "fail". Stakeholders have commented that this could result in increased coding requirements with no additional clinical benefit.

Committee decision

The committee is asked to decide whether the indicator should progress to the NICE menu, either in addition to the existing indicator (NM82) or as a replacement.

IND2022-131 Atrial fibrillation: anticoagulation

Percentage of patients with atrial fibrillation and a last recorded CHA2DS2-VASc score of 2 or more who are currently prescribed a direct-acting oral anticoagulant (DOAC), or where a DOAC is declined or clinically unsuitable, a Vitamin K antagonist.

Rationale

Anticoagulation in patients with atrial fibrillation (AF) can help prevent stroke. Evidence from an analysis of several studies shows that DOACs are more effective than vitamin K antagonists for a number of outcomes and should be used as a first line treatment for people with an increased risk of stroke (NICE's guideline on atrial fibrillation).

For patients already established and stable on a vitamin K antagonist, the benefits of changing to a DOAC need to be discussed with the patient. Therefore, the risks and benefits of changing medication, the person's time in therapeutic range and the person's preferences should be explored at their next routine appointment.

This indicator aims to promote the use of DOACs over vitamin K antagonists unless DOACs are unsuitable or declined by the patient.

Specification

Numerator: the number in the denominator who are currently prescribed a DOAC, or where a DOAC is declined or clinically unsuitable, a vitamin K antagonist.

Denominator: the number of patients with atrial fibrillation and a last recorded CHA2DS2- VASc score of 2 or more.

Definition: Current treatment is defined as a prescription in the last 6 months of the reporting period.

Exclusions: People with resolved atrial fibrillation.

Using established guidance for existing IIF Indicator CVD-05 this indicator has multiple success criteria that are evaluated sequentially. A personalised care adjustment (PCA) for the first success criterion (DOAC prescribing) moves the patient into the pool for evaluation against the second criterion (Vitamin K antagonist prescribing), rather than removing them from the denominator altogether. People with recorded mechanical prosthetic replacement are not evaluated against the first criterion and do not require a record of a PCA for DOACs before evaluation against the second criterion.

PCAs for success criterion 1 (moves the patient to evaluation under success criterion 2):

- DOAC clinically unsuitable (includes recordings of antiphospholipid syndrome).
- 'DOAC not indicated' plus last recording of 'Time in Therapeutic Range' >= 65% in the six months to the reporting period end date.
- DOAC declined.

PCAs for success criterion 2:

- Vitamin K antagonist / Warfarin clinically unsuitable.
- Vitamin K antagonist / Warfarin declined.

Possible grounds for exception reporting in the traditional sense (removal from the denominator altogether, unless a success is registered) are:

- First AF diagnosis in 3 months to reporting period end date
- Oral anticoagulant clinically unsuitable
- Oral anticoagulant declined
- A combination of PCAs applying to success criteria 1 and 2 individually.

Summary of consultation comments

The majority of stakeholders agreed with the clinical validity of promoting DOACs over Vitamin K antagonists for people with atrial fibrillation prescribed anticoagulants. However, one stakeholder did note that DOACs are not currently licensed for all patients with atrial fibrillation: additional risk factors

must usually be present that are not identical across the different medications. A CHA2DS2- VASc score of 2 or more does not guarantee the presence of a relevant risk factor.

Stakeholders highlighted that, unlike IIF CVD-05, the proposed indicator does not include men with a risk score of 1. This population was not included because NICE's guideline on atrial fibrillation only recommends that DOACs are "considered" for this population because of less certainty of benefit.

The impact on workforce capacity was raised: it was suggested that the indicator would primarily rely on GPs rather than the wider general practice workforce and patients on DOACs would require much more monitoring than those on Vitamin K antagonists. One stakeholder commented that there could be a considerable resource impact associated with switching medications and coding exceptions.

Some concerns were raised around over-use of the 'atrial fibrillation resolved' code.

Considerations for the advisory committee

The committee is asked to consider:

- Whether increasing the use of DOACs over Vitamin K antagonists outweighs the potential added resource impact of reviewing patients and coding of personalised care adjustments.
- In the absence of a record of mechanical prosthetic replacement, the prescription of a Vitamin K antagonist without a recorded PCA for provision of a DOAC will count as a "fail".
- The validity of using of "not indicated" personalised care adjustments to account for the licensing restrictions of DOACs.

Committee decision

The committee is asked to decide whether the indicator should progress to the NICE menu, either in addition to the existing indicator (NM82) or as a replacement.

Appendix A

Consultation comments

Organisation	Comments	Response
Bayer plc	Bayer welcomes this proposed new NICE indicator as an evolution of the existing QOF indicator (AF007*), recognising the clinical and economic benefits of the DOACs as oral anticoagulants of choice, in line with Atrial Fibrillation: diagnosis and management (NG196), recommendations 1.6.3 and 1.6.5. One observation however, is that the indicator does not capture those patients in NG196 recommendation 1.6.4 i.e.: "Consider anticoagulation with a direct-acting oral anticoagulant for men with atrial fibrillation and a CHA_2DS_2-VASc score of 1, taking into account the risk of bleeding" This group is captured in CVD-05 in the Investment and Impact Fund 2022/23, as referred to in the consultation document: CVD-05: Percentage of patients on the QOF Atrial Fibrillation register and with a CHA_2DS_2-VASc score of 2 or more (1 or more for patients that are not female), who were prescribed a direct-acting oral anticoagulant (DOAC), or, where a DOAC was declined or clinically unsuitable, a Vitamin K antagonist. We wonder if this is an omission, or whether instead it reflects the strength of the recommendations in NG196; "offer" in recommendation 1.6.3 and "consider in recommendation 1.6.4? We wonder however if the difference between the proposed NICE indicator and the indicator associated with the Investment and Impact Fund may lead to unintended confusion. * In those patients with atrial fibrillation with a record of a CHA_2DS_2-VASc score of 2 or more, the percentage of patients who are currently treated with anti-coagulation drug therapy	Thank you for your comment. As you note, the indicator does not include people with a risk score of 1 who are not female. This is not an omission: it does indeed reflect the strength of the recommendation in the underpinning guidance. The indicator has been progressed to the NICE menu as suitable for inclusion in the QOF. NICE would expect that if included in the QOF, the existing indicator in the IIF would be retired. NICE was asked to review IIF CVD-05 as NHS England were interested in the potential to replace AF007 in the QOF. We understand that one of the objectives of adding IIF indicators to the QOF menu is to enable rationalisation and elimination of overlaps between the schemes – not to create duplication between them. Any future relevant NICE consultations and documentation will make this clearer.

Organisation	Comments	Response
British Cardiovascular Society	Do you think there are any barriers to implementing the care described by these indicators? No Do you think there are potential unintended consequences to implementing/ using any of these indicators? No Do you think there is potential for differential impact (in respect of age, disability, gender and gender reassignment, pregnancy and maternity, race, religion or belief, and sexual orientation)? If so, please state whether this is adverse or positive and for which group. No If you think any of these indicators may have an adverse impact in different groups in the community, can you suggest how the indicator might be delivered differently to different groups to reduce health inequalities? Yes. The AF numerator includes a 'clinically unsuitable' group. It's hard to get away from that approach completely but BCS is concerned that inappropriate use of this category may explain much of the variation in anticoagulant prescribing. Unless tightly defined, there is a risk that certain groups will be disadvantaged by overuse of this exemption from the target.	Thank you for your comment.
British Medical Association	Respondents queried the overlap that this has with IIF indicators (CVD-05 AND CVD-06), and existing QOF indicators AF006 and AF007. In an environment where GPC is seeking to reduce non-essential or bureaucratic work, this has the appearance of 'incentive clutter' and should be streamlined.	Thank you for your comment. NICE was asked to review IIF CVD-05 as NHS England were interested in the potential to replace AF007 in the QOF. We understand that one of the objectives of adding IIF indicators to the QOF menu is to enable rationalisation and elimination of overlaps between the schemes – not to create duplication between them. Any future relevant NICE consultations and documentation will make this clearer.

Organisation	Comments	Response
British Medical Association	Regarding barriers, respondents: • raised concerns about the feasibility of this indicator with reference to variable local arrangements, particularly with respect to conversion to DOACs and TTR (often managed in anticoagulation clinics/hospital). Some respondents were not at all familiar with TTR, which may reflect that it is not universally understood and available. • noted that, unlike other chronic conditions, work associated with this indicator will be 'GP-heavy'. Given existing low workforce capacity there are concerns this will add to the workload burden, especially due to the existing backlog associated with AF. • raised concerns about identifying patients who are on warfarin not just for AF (e.g., for valvular lesion).	Thank you for your comment. The requirement for a TTR greater than 65% has been removed from the personalised care adjustment rules. The committee noted the benefits of DOACs over Vitamin K antagonists could outweigh the potential added resource impact of reviewing patients and coding of personalised care adjustments. The guidance has been amended to specify that people with valvular atrial fibrillation are not evaluated against the first criterion (provision of a DOAC).
British Medical Association	Regarding unintended consequences, respondents noted: • that this will increase workload of monitoring from a DOAC point of view, e.g.: requirement for GFR check and weight compared to a patient on warfarin who may be monitored in secondary care. • that this may inadvertently destabilise existing treatment regimens with patients by incentivising a change to DOAC, and that existing treatment has the advantage of regular touchpoints with general practice and patient trust in 'familiar' treatment.	Thank you for your comment. The committee noted the benefits of DOACs over Vitamin K antagonists could outweigh the potential added resource impact of reviewing patients and coding of personalised care adjustments. Personalised care adjustment codes can be used if the provision of DOACs is not indicated, contraindicated or declined by the patient. The committee noted that some patients are stable on vitamin K antagonists, but discussion of the benefits of switching to a DOAC should still take place.

Organisation	Comments	Response
British Medical Association	Regarding differential impact, respondents said: • that it becomes more challenging to get an accurate weight for patients as they become older with either being housebound or bedbound. Not all patients have scales at home to measure themselves (e.g., due to deprivation), which carries a risk of 'guessing a weight' which may lead to CrCl being calculated inaccurately. This weight figure needs to be checked for accuracy on a fairly regular basis. • concerns around accurate weight become more pronounced with respect to elderly patients, who are at risk of increased bleeding.	Thank you for your comment.
Cochrane Heart	I am not sure if atrial fibrillation can ever be considered "resolved". Even after a successful ablation procedure, atrial fibrillation can always relapse after a while. Using this designation may be dangerous as it can lead GPs to consider that AF is "resolved" and stop anticoagulants in patients at risk and consequently lead to stroke and incapacity/death. Atrial fibrillation patients could also benefit from influenza vaccination. Please see Chang et al. 2016 https://pubmed.ncbi.nlm.nih.gov/26850784/ It would be important to include monitoring of usage of mineralocorticoid receptor antagonists, sabubitril/valsartan and dapagliflozin/empagliflozin for patients with heart failure and systolic dysfunction.	Thank you for your comment. The exclusion of people with an 'atrial fibrillation resolved' code mirrors the construction of QOF register AF001.QOF guidance acknowledges that patients can continue to be at higher risk of stroke that people with no previous AF diagnosis. The suggestions for additional indicators will be logged for future committee consideration.

Organisation	Comments	Response
Leadgate Surgery (North Durham CCG)	It is worthwhile pointing out that this indicator does not mirror the IIF indicator as you have only included patients at high risk (CHADSVASc greater than or equal to 2). The IIF indicator also includes patients with moderate risk (CHADSVAsc greater than or equal to 1 in males). It is worth noting that some AF patients do not have a licensed indication for DOACs because all the DOAC require an age category or a risk factor. So, there are some patients for whom anticoagulation is indicated but who do not fit the licensing criteria for DOACs.	Thank you for your comment. As you note, the indicator does not include people with a risk score of 1 who are not female. This is not an omission: it does indeed reflect the strength of the recommendation in the underpinning guidance. The guidance has been amended to specify that people with valvular atrial fibrillation are not evaluated against the first criterion (provision of a DOAC). A personalised care adjustment code of 'DOAC not indicated', can be used if for patients with a risk score of 2 or more but without the relevant risk factors outline in the marketing authorisations for DOACs.
NHS England	We are already doing AF 006 and AF 007 in primary care, challenges with this Indicator would be the increasing workload on general practice, as this would involve considerable move to encourage the patients to move from Vit K antagonist over to DOAC or getting exceptions. In an already stressed system with challenges with access, we would have to bear in mind the impact of bringing in another indicator on access. Would bringing in another indicator and benefits from it outweigh decreased access for patients.	Thank you for your comment. NICE was asked to review IIF CVD-05 as NHS England were interested in the potential to replace AF007 in the QOF. We understand that one of the objectives of adding IIF indicators to the QOF menu is to enable rationalisation and elimination of overlaps between the schemes – not to create duplication between them. Any future relevant NICE consultations and documentation will make this clearer.
Primary Care Cardiovascular Society	We agree with this indicator which supports the uptake of anticoagulation (with DOACs as the preferred option) in patients at high risk of stroke. The period for excluding patients from the denominator should be reduced. Time from first diagnosis of AF to prescription of anticoagulation should be minimised. It is not acceptable to allow a period of three month from diagnosis to starting anticoagulation. It should be done much sooner - ideally on the day the patient is assessed. Need to avoid using the AF resolved code - it is arguably over-used and may lead to adverse clinical outcome (see NICE 2021)	Thank you for your comment. Business rules for QOF indicators routinely include the use of personalised care adjustment codes for patients newly diagnosed in the 3 months prior to the end of the reporting period. The intention is not to promote delays to treatment, it is to provide a fair window for intervention within general practice.

Organisation	Comments	Response
Daiichi Sankyo UK	Daiichi Sankyo UK Ltd agrees with the proposed wording for IND2022-131. This aligns with the wording of Investment and Impact Fund (IIF) indicator CVD-05 and thus ensures consistency across both QOF and IIF indicators at both an individual practice and primary care network level. Daiichi Sankyo UK Ltd would recommend NICE considers incorporating IIF indicator CVD-06: Number of patients who are currently prescribed Edoxaban, as a percentage of patients on the QOF Atrial Fibrillation register with a CHA2DS2-VASc score of 2 or more (1 or more for patients that are not female) and who are currently prescribed a direct-acting oral anticoagulant (DOAC) – into a corresponding QOF indicator for 2023. This would adhere to NHS England's commissioning recommendations on the use of DOACs and the national recommendations on DOAC prescribing, which followed the publication of NICE Clinical Guidance NG196 and the national procurement in 2021.1 NHS England outlines through these recommendations the best value treatment choices and if followed, will make it more affordable to treat these additional patients. Therefore, incorporation of both IIF anticoagulation indicators into General Practice indicators for use in the QOF would help to harmonise objectives, consistency, and targets at different organisational levels in the NHS. NHS England, 2022. Operational note: Commissioning recommendations for national procurement for DOACs. Available: https://www.england.nhs.uk/wp-content/uploads/2022/01/B1279-national-procurement-for-DOACs-commissioning-recommendations-v1.pdf	Thank you for your comment.

Organisation	Comments	Response
Royal Arsenal Medical Centre	The main problem currently is the delivery of the service. Covid has affected existing hospital-based resources (warfarin), and the contemporary changes over to DOAC means that local commissioners need to offer Primary Care based funding to provide the service. The spec also tampered with other Atrial fibrillation treatment – cardioversion.	Thank you for your comment.