NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Atrial fibrillation

Date of Quality Standards Advisory Committee post-consultation meeting:
08 April 2015.

2 Introduction

The draft quality standard for atrial fibrillation was made available on the NICE website for a 4-week public consultation period between 13 February and 13 March 2015. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 27 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendix 1.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

3. For each quality statement what do you think could be done to support improvement and help overcome barriers?

Stakeholders were also invited to respond to the following statement specific questions:

4. For draft quality statement 1: Is the term manual pulse palpation widely understood to mean that it is done by hand or is a definition of this term required? If so, can a definition be provided?

5. For draft quality statement 6 (developmental): Does this reflect an emergent area of cutting-edge service delivery or technology? If so, does it indicate outstanding performance, currently found only in a minority of providers, which will need specific,

significant changes to be put in place, such as redesign of services or new equipment? Can you provide any evidence of current practice for this?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- In general support was received for this quality standard and the good practice it promotes. The 6 draft quality statements reflect key areas for quality improvement.
- A concern was raised that no responsibilities were outlined within the quality statements, that is who will deliver these statements.
- There were general comments on the introductory text to the quality standard regarding wording on morbidity and mortality that could be more explicit.
- A stakeholder felt that it needed to be clear if all people with atrial fibrillation will be covered in the quality standard, included valvular and non-valvular atrial fibrillation.

Consultation comments on data collection

- Generally stakeholders felt that if the appropriate systems and structures were available, collection of data would be possible, with the clinical audit tool referred to in the quality standard being a useful method to collect this data.
- Some concern that the use of ‘local data collection’ would incur resource implications.
- There would be challenges collecting data where there was overlap between primary and secondary care.
- Potential to use GRASP-AF tool for more data collection, though conflicting views about the availability of this tool and whether it should be used for data collection purposes.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

Adults with risk factors for atrial fibrillation have a manual pulse palpation.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- Stakeholders advised that this statement should cover those who are asymptomatic. This would include opportunistic screening of high risk groups such as those over 65 although there were other suggestions to target high risk populations including those over 60. The current list of risk factors also affects the ability to measure the statement.
- Stakeholders felt that the term risk factor is not being used correctly as the list presented is not something that clinicians would understand as risk factors, they felt that patient characteristics, symptoms or indicators could be used as alternative wording.
- Some stakeholders felt this statement should also cover what happens next and that an ECG is required to confirm a diagnosis of atrial fibrillation.
- Stakeholders felt that the statement does not state who needs to perform a manual pulse palpation, and some healthcare professionals may require additional training.

Consultation question 4

Stakeholders made the following comments in relation to consultation question 4:

- Stakeholders felt that ‘manual pulse palpation’ was widely understood by clinical colleagues, however the statement may need to use the term pulse check for a lay audience. No definition was provided as the term ‘manual pulse palpation’ was sufficient.

5.2 Draft statement 2

Adults with atrial fibrillation and a CHA_2DS_2-VAS_C stroke risk score of 2 or above are offered anticoagulation.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Stakeholders felt that this statement should also consider anticoagulation in the population with a CHA_2DS_2-VAS_C of 1 (not based on gender alone).
- Stakeholders stated that this statement should incorporate bleeding risk using the HASBLED score at statement and rationale level as well as being referred to in the definitions potentially adding "…taking bleeding risk into account".
- Stakeholders suggested that this statement could also address the fact that aspirin should not be used as a monotherapy to prevent stroke (as well as it being suggested as an additional area).
- Stakeholders felt that the statement did not suggest alternatives for people in whom anticoagulants are contraindicated and that this exclusion should also be addressed.
- Stakeholders felt that the GRASP-AF tool may not be suitable as a data collection tool and should be referenced as an implementation tool. Similar issues were raised regarding the reference to the Sentinel Stroke National Audit Programme (SSNAP).

5.3 Draft statement 3

Adults with atrial fibrillation prescribed anticoagulation are given a choice of anticoagulants.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Stakeholders felt that the statement should include detail on a discussion of the risk and benefits of all anticoagulants.
- Stakeholders added that patients should be part of the decision making process and have access to data to inform choice.

- Stakeholders suggested that patient feedback may be a better way to collect data for measuring this statement as a choice may not necessarily improve patient experience.
- A stakeholder felt it would be difficult to measure that a choice had been given, and even if this were possible without a definition of choice, measurement may be meaningless.

5.4 Draft statement 4

Adults with atrial fibrillation taking a vitamin K antagonist with a time in therapeutic range below 65% have their anticoagulation reassessed.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- In general there was agreement and support for this statement from stakeholders.
- Stakeholders added that time in therapeutic range was not the only parameter to measure anticoagulation control and that INR should also be referenced within this statement.
- Stakeholders felt it needed to be clearer that a time in therapeutic range is calculated over a 6 month period. However others felt that this may lead to patients being under/over coagulated if they have to wait.

5.5 Draft statement 5

Adults with atrial fibrillation whose treatment fails to control their symptoms are referred for specialised management within 4 weeks.

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- Stakeholders felt that the denominator in these measures i.e. all those whose treatment fails to control symptoms, would be difficult to measure and not possible to collect reliably.

- Stakeholders felt that this should focus particular on the statement avoiding heart failure and word the statement as such and not necessarily focus on linking to stroke as suggested in the audience descriptors.

5.6 Draft statement 6 (developmental)

Adults with atrial fibrillation taking a vitamin K antagonist are offered a coagulometer to self-monitor their coagulation status.

Consultation comments

Stakeholders made the following comments in relation to draft statement 6 (developmental):

- Stakeholders felt that the outcome measurements in this statement should be the same as those in draft statement 4, given the rationale to improve anticoagulation control.
- Stakeholders felt that the statement should only be applicable to those who wish to have this option and who are trained and competent to do so.

Consultation question 5

Stakeholders made the following comments in relation to consultation question 5:

- Stakeholders were mixed in their response to this question, with some suggesting that this is not a cutting edge service given that it has been available for some time. Alternatively other stakeholders stated that there is variation in the management of coagulometers and they are effective and warrant a developmental statement.
- A stakeholder felt that there is a move towards the newer oral anticoagulants for which coagulometers are not relevant.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Stakeholders felt that there should be a statement on not prescribing aspirin as a monotherapy to prevent stroke for people with atrial fibrillation.

- Stakeholders suggested a statement on personalised packages of care and information for patients.
- A stakeholder felt the use of audited care of management could be covered.
- A stakeholder suggested that ablation and cardioversion could be covered.
- A stakeholder suggested that there should be a statement on rate and rhythm control.
- A stakeholder suggested there should be a statement specifically covering paroxysmal atrial fibrillation.

Appendix 1: Quality standard consultation comments table

ID	Stakeholder	Statement No	Comments[1]
001	**Boehringer-Ingelheim**	General	Boehringer Ingelheim (BI) welcomes the opportunity to respond to this consultation. We have some general feedback on the Quality Standard in addition to comments on specific Quality Statements and questions.
002	**Boehringer-Ingelheim**	General	The Quality Standard does not demonstrate the patient safety concerns around the use of warfarin (NPSA/2007/18) compared to the new anticoagulants. This has been further highlighted recently as warfarin was positioned as one of the 7 classes of medicines causing half of all serious medication errors (NICE Medicines Awareness Weekly - 2nd February 2015 to 6th February 2015).
003	**Boehringer-Ingelheim**	General	The Quality Standard seems focused on supporting the use of vitamin K antagonists. This may be misunderstood as vitamin K antagonists being the first line option with non-vitamin K antagonist anticoagulants only recommended after warfarin has been tried, which is not the case (NICE Guideline CG180 1.5).
004	**Boehringer-Ingelheim**	General	The Quality Standard does not address the issue that some CCGs are currently displaying significantly higher rates of exception reporting against the Quality and Outcomes Framework (QOF) AF indicator than others. For example, NHS Nottingham West CCG, NHS Nottingham North and East CCG, NHS Nottingham City CCG, NHS Brighton and Hove CCG, NHS Lothian, NHS Birmingham South and Central CCG, NHS Haringey CCG and NHS Bradford City CCG all have exception rates of over 25% (QOF target AF004 - QOF target for patients with a CHA2DS2-VASc score of 2 or more). This could mean that there are groups of AF patients who may be at risk of a stroke as their anticoagulation needs are not being met. Such high rates of exception reporting should be a factor that the Care Quality Commission takes into account during investigations.
005	**Boston Scientific**	General	We welcome the development of Quality Standards for Atrial Fibrillation and the consistency between the draft Quality Standards and recently published Atrial Fibrillation Clinical Guidelines (CG180) published in June 2014.
006	**Boston Scientific**	General	We welcome the requirement that atrial fibrillation services should be coordinated across all relevant agencies encompassing the whole atrial fibrillation care pathway, and believe this will have a positive impact on patient care.
007	**British Heart Foundation**	General	We have no specific comments to make, other than to support the standard.
008	**Department of Health**	General	No substantive comments
009	**Digital**	General	No comments as part of the consultation

[1]PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement No	Comments[1]
	Assessment Service, NHS Choices		
010	**Education for Health**	General	These quality statements are very clear and helpful to clinicians and public
011	**NHS England**	General	I welcome the development of these standards and commend the group who have produced this draft. It's not made clear in the title whether NICE considers this to be a QS for ALL people with AF (there is reference below to INR self monitoring in those with valve disease) or whether it is for non-valvular AF. I think this distinction is important to make clear at the outset of the document. Prevalence of AF increases greatly with age. Rather than simply expressing population prevalence it would be helpful to have this broken down by age cohorts.
012	**NHS England**	General	Reference is made throughout the document to 'local; arrangements. This is a vague concept and needs to be defined as to what you mean. Where would you go to look for evidence that this was being achieved?
013	**NHS Improving Quality**	General	Suggest it is worth mentioning that the strokes caused by AF are associated with significantly higher morbidity and mortality. Also that having AF increases a person's risk of stroke fivefold.
014	**NHS Improving Quality**	General	Just a note of clarification- the GRASP-AF audit toolkit is jointly owned by NHS IQ and PRIMIS, NHS IQ funds the support for the toolkit, enabling it to be provided free to GP practices in England. It is not the property of the AFA. The appropriate link for further information about the GRASP suite of toolkits, including GRASP-AF is www.nhsiq.nhs.uk/grasp
015	**Roche Diagnostics Limited**	General	The list is clear and reflects the key areas for quality improvement discussed by the committee. In our opinion it would be possible to collect the data for all the proposed quality measures.
016	**Royal College of Nursing**	General	No substantive comments to note.
017	**Stroke Association**	General	We welcome the development of these standards and the opportunity to comment on them. Question 1: We believe the QS does cover the important areas Question 2: We believe it would be possible to collect data on some of the proposed quality measures, we have commented on measures that we believe it would be difficult to collect data on, and have suggested alternatives. Question 3: Comments below.

ID	Stakeholder	Statement No	Comments[1]
			Question 4: As a patient organisation, we use the term 'pulse check'. However, we believe that 'pulse palpation' would be understood by clinicians. Question 5: We are not in a position to comment on the draft QS 6
018	**The Royal College of Emergency Medicine**	General	Not relevant to Emergency Medicine. However, there are concerns that there are no individuals responsible for delivery of standards, and no timeframe from point of diagnosis. It is felt inappropriate for these standards to be measured in the Emergency Department, and would expected them to be owned by the GP.
019	**Medtronic Limited**	Question 1	Question 1: Does this draft QS accurately reflect the areas for Quality Improvement? Medtronic welcomes the Quality Statements out lined in the Draft Quality Standard.
020	**NHS England**	Question 1	Question 1: The draft QS does cover the important areas.
021	**NHS England**	Question 1	Except the lack of a standard around identifying AF including PAF after stroke and TIA
022	**Boehringer-Ingelheim**	Question 2	There are a number of clinical audit tools to facilitate the identification of AF patients who would benefit from anticoagulation that exist across England, for example the GRASP-AF tool. However, these tools are not available throughout Wales, leaving undiagnosed AF patients significantly disadvantaged. The consistent collection and analysis of data throughout England and Wales would lead to better care for patients with AF.
023	**London Stroke Strategic Clinical Network**	Question 2	No. Many of the proposed collection measures are unspecified and would require audits that do not currently exist.
024	**London Stroke Strategic Clinical Network**	Question 2	'Local data collection' The document references 'local data collection' repeatedly without clarification. QOF will offer data about anticoagulation rates for those AF patients with a CHA2DS2-VASc of greater than 2, but the other data will be very difficult to obtain. In order to collect the majority of these, most CCGs will need to begin collecting large amounts of new data, which would be costly.
025	**Medtronic Limited**	Question 2	Question 2: If the systems and structures were available do you think it would be possible to collect the data for the proposed quality measures? Medtronic suggests that a QOF indicator for primary care physicians will allow data collection for this Quality Measure.
026	**NHS England**	Question 2	Question 2: Data collection will be challenging. Those who have ablation, or those who have a stroke or cardiac event, will likely be picked up in the relevant national clinical audits. However, a denominator such as "those at risk of AF" will be almost impossible to measure, unless one simply takes those in the different age cohorts as the denominator.

ID	Stakeholder	Statement No	Comments[1]
027	**NHS England**	Question 2	Many of the proposed measures are either vague or would require considerable additional resources to collect. Few of the measures could be obtained using routine datasets
028	**University Hospital Birmingham**	Question 2	The Quality standards laid out in this document are well founded and broadly represent current best practice as determined by national and international guidelines. However, as with all such standards, there are resource implications for the collection of data which do not appear to have been addressed.
029	**University Hospital Birmingham**	Question 2	Collection of some of the data will be challenging, especially where there is an overlap between primary and secondary care.
030	**Boehringer-Ingelheim**	Question 3	BI recommends that measures to improve the identification, treatment and management of AF, are included within Quality Premiums (CCG Outcomes Indicator Set), NHS Low Income Schemes, QOF, GP revalidation tools, the Medicines Optimisation Programme and the Academic Health Science Networks. BI also recommends the introduction of an equal incentive payment to support anticoagulation with non-vitamin K antagonists, as already exists with vitamin K antagonists. This should be offered to support GPs with annual reviews of patients to ensure their risk-benefit balance has not changed, and also to ensure appropriate renal function monitoring.
031	**London Stroke Strategic Clinical Network**	Question 3	Barriers Statement 2: A massive barrier to appropriate anticoagulation is that some clinicians (mostly GPs) overestimate the bleed risk in frail, elderly AF patients, when in reality the risk of stroke is higher and more catastrophic. A tactic would be to educate patients, carers, and GPs about the risks and effects of stroke compared to the risk and effects of a bleed. Statement 3: Recall all existing guidance which prefers warfarin over NOACs, such as exists in North West London currently. Statement 4: A fundamental barrier is that time in therapeutic range (TTR) is not being recorded. The yellow warfarin book, for example, does not have a place to record TTR. This issue could be addressed by mandating that TTRs are recorded in an accessible and standardised place, like the yellow booklet. Statement 6: Ensure that provision of coagulometers is not impeded by unnecessary bureaucratic hurdles, such as the requirement to fill in separate forms for each patient (as happens with diabetic pumps in London.)
032	**Medtronic Limited**	Question 3	Question 3: what do you think could be done to support improvement and help overcome barriers? Medtronic suggests that a QOF indicator Medtronic suggests that a QOF indicator for primary care physicians will drive

ID	Stakeholder	Statement No	Comments[1]
			prompt referral as defined by the GDG (The Guideline Development Group defined 'promptly' as no longer than 4 weeks after the final failed treatment or no longer than 4 weeks after recurrence of atrial fibrillation following cardioversion when further specialised management is needed
033	**NHS England**	Question 3	Question 3: Encouraging the use of GRASP-AF and any other GP identification tools will help, and pulse palpation as part of every blood pressure check within the NHS Health Checks programme will also pick up cases. Public awareness campaigns to increase awareness should be discussed. All those with diagnosed hypertension should be encouraged to monitor their own blood pressure and this offers another opportunity for 'automatic' detection of AF.
034	**AF Association**	Quality statement 1	• Although fully supporting routine pulse checks in high-risk population groups, AF Association suggests that QS1 should offer risk assessment and appropriate anticoagulation therapy within two weeks, as soon as AF is diagnosed. QS1 should be explicit in the phasing out of aspirin for the prevention of AF- related stroke (NICE Guideline CG180 1.5.15). • Pulse checks, hand held monitors and blood pressure monitors with an AF detector should all be used in AF opportunistic screening. • AF patients can be asymptomatic and should also be included for risk factors for AF. High-risk groups, especially over the age of 65 should routinely be checked for AF. • AF Association would like to see a personalised package of care for patients diagnosed with AF. • It is anticipated that AF will cost the NHS 1% of its annual budget and it is important that patients with AF are identified at the earliest possible stage, preventing the risk of AF-related stroke.
035	**AliveCor Ltd**	Quality statement 1	• AliveCor fully supports the use of pulse checks as Pulse checks can help detect atrial fibrillation (AF) but a recorded electrocardiogram (ECG) remains the gold standard1. • Using cell phone based ECG recording, AF detection is made simple2 • With the advent of new intelligent devices such as the AliveCor® Heart Monitor and others, Atrial Fibrillation can be automatically detected with a high degree of accuracy in one step • This automatic detection in just 30 seconds is superior to pulse check at sensitivity of 100% and specificity of 97%3 References: 1. 1. Camm A, Lip G, de Caterina R et al. 2012 focused update of the ESC guidelines for the management of atrial fibrillation. An update of the 2010 ESC guidelines for the management of atrial fibrillation. Developed with the special contribution of the European Heart Rhythm association. Eur Heart J 2012;33:2719–47. 2. March 2015 Br J Cardiol 2015;22:31–3 doi: 10.5837/bjc.2015.009 Authors: Pierre Le Page, Hamish MacLachlan, Lisa Anderson, Lee-Ann Penn, Angela Moss, Andrew R J Mitchell; from the Jersey International Centre for Advanced Studies 3. Using a Novel Wireless System in Monitoring patients After Atrial Fibrillation Ablation Procedure. The iTransmit Study Khaldoun G. Tarakji et al. HeartRhythm, The Official Journal of the Heart Rhythm Society. November 2014.
036	**AntiCoagulation Europe**	Quality statement 1	Pages 8 and 9 refer to shortness of breath etc as risk factors. These are symptoms of atrial fibrillation and not risk factors.
037	**Arrhythmia**	Quality	• Arrhythmia Alliance (A-A) fully supports routine pulse checks in high risk population groups, A-A suggests that QS1

ID	Stakeholder	Statement No	Comments[1]
	Alliance	statement 1	should recommend that if AF is subsequently diagnosed, risk assessment and appropriate anticoagulation therapy should be offered within two weeks. Crucially, the Quality Standard does not help to support the phasing out of aspirin for the prevention of AF- related stroke (NICE Guideline CG180 1.5.15). • Opportunistic screening should involve manual pulse checks as well as using new NICE approved technology such as hand held ECG monitors which can identify and diagnosis AF (such as AliveCor) and blood pressure monitors with an AF detector (Watch BP MicroLife for example) • The rationale behind QS 1 equates risk factors for AF to symptoms of AF. However, the risk factors of AF should not just be based on the symptoms, as AF patients can be asymptomatic. In some instances, the first presence of AF may be detected only after the patient has suffered an AF-related stroke. A measure should be introduced to ensure that groups of patients at risk of AF (for example individuals over the age of 65), who may be asymptomatic, should be checked for AF as part of other touch points with the NHS, for example flu jab clinics, diabetes clinics and other health checks. • A-A would recommend for a personalised package of care and information for patients with AF (NICE Guideline CG180 1.2) • Early detection, diagnosis and appropriate medical management leads to fewer appointments and admissions, saving the NHS money, and individual's ill-health, in the long term. • It is anticipated that AF will cost the NHS 1% of its annual budget and it is important that patients with AF are identified at the earliest possible stage, preventing the risk of AF-related stroke.
038	**Boehringer-Ingelheim**	Quality statement 1	The rationale behind Quality Statement 1 equates risk factors for AF to symptoms of AF. However, the risk factors of AF should not just be based on the symptoms, as AF patients can be asymptomatic. In some instances, the first presence of AF may be detected only after the patient has suffered a stroke. A measure should be introduced to ensure that groups of patients at risk of AF (for example individuals over the age of 65), who may be asymptomatic, should be checked for AF as part of other touch points with the NHS for example flu jab clinics, diabetes clinics and other health checks.
039	**Boston Scientific**	Quality statement 1	In regards to your question on quality statement 1, we believe the wording is sufficiently clear. We would be interested to know if NICE have considered other sources of information to identify adults with risk factors for stroke (e.g., remote patient monitoring for adults who have an implantable cardiac device) and whether it would be appropriate (or not) to reference them here.
040	**Education for Health**	Quality statement 1	Very important to have this here and spelt out the importance of
041	**London Stroke Strategic Clinical Network**	Quality statement 1	'Risk factors' Pages 8-9 inaccurately list symptoms or indicators as risk factors for atrial fibrillation (AF). Suggestion 1: Create a new category titled 'indicators of atrial fibrillation' and follow it with the list previously called 'risk factors.' Suggestion 2: Under 'risk factors' add the following: hypertension, increased age, coronary heart disease, heart failure,

ID	Stakeholder	Statement No	Comments[1]
			valvular disease, rheumatic heart disease, structural heart defects including mitral valve prolapse, pericarditis, congenital heart defects, previous heart attacks, family history of AF, obesity, excessive alcohol consumption (in some), and some chronic conditions including thyrotoxicosis, diabetes, sleep apnea, metabolic syndrome, chronic kidney disease, and lung disease.
042	**London Stroke Strategic Clinical Network**	Quality statement 1	Provision of pulse checks The document as it stands does not specify who should administer pulse checks or in what circumstance. Embedding this practice will be easier if the standard is clarified, particularly given that the UK National Screening Committee decided in June 2014 not to recommend AF screening in over 65 year olds. Suggestion 3: Clarify where pulse checks are expected to be performed and by whom. (Is the assumption that only GPs and primary care nurses will carry out pulse checks when a patient presents with the symptoms or risk factors listed? Or is the assumption that pulse checks will be carried out by any healthcare professional, at any point?) Recommend that pulse checks be performed opportunistically with blood pressure checks and at flu clinics, and be embedded within Health Checks. Suggestion 4: Recommend that all patients with symptoms of AF receive a manual pulse palpation upon presentation to a healthcare professional.
043	**London Stroke Strategic Clinical Network**	Quality statement 1	Training If the recommendation is that all healthcare professionals administer pulse checks, presumably some will never have received training to deliver manual pulse palpations. Suggestion 5: All staff administering pulse checks to patients with suspected AF should receive training in how to do so properly.
044	**London Stroke Strategic Clinical Network**	Quality statement 1	Following a pulse palpation There is no guidance on what happens after a pulse check indicates AF. Furthermore, there is no mention that AF can be intermittent and thus may be missed from one pulse check alone. Suggestion 6: Require that patients whose pulse palpation positively indicates AF, and who have a CHA2DS2-VASc score of 1 or greater, are referred for an ECG within 4 hours, as they are now identified as at risk of stroke. Patients whose pulse palpation positively indicates AF, and who have a CHA2DS2-VASc score of 0, must be referred for an ECG within 24 hours. Suggestion 7: Require that upon diagnosis of AF, patients receive a stroke assessment and bleeding risk assessment immediately, or at most within 24 hours of diagnosis. Suggestion 8: Recommend that manual pulse palpations are performed at regular intervals with at risk patients over the age of 65, and with all patients over the age of 75.

ID	Stakeholder	Statement No	Comments[1]
045	**NHS England**	Quality statement 1	See note above regarding the difficulty in determining the denominator for this QS.
046	**NHS England**	Quality statement 1	The description of "adults with risk factors for AF" is obviously not comprehensive. It is true that some of those with AF, particularly younger people, may have some of these symptoms (and certainly those who have a cardiovascular event), but in many people, particularly those in older groups, AF is often asymptomatic. If one was to adopt targeted screening for AF an argument could be made for selecting certain age groups for routine pulse checking (eg: all those above the age of 65, or those with any suggestive symptoms whatever their age). As you know, the National Screening Committee has looked at AF screening and rejected a national screening programme, but opportunistic and targeted detection could be valuable.
047	**NHS England**	Quality statement 1	One could consider developing a requirement that all providers undertake a pulse check on, for instance, all those admitted who are over the age of 60, in a manner similar to the requirement to undertake a DVT/PE risk assessment.
048	**NHS England**	Quality statement 1	The term 'risk factors' is not I think being used in a way that a clinician would immediately understand. What I understand by risk factors are those things that increase the risk of a patient developing AF e.g. hypertension, valvular heart disease, thyrotoxicosis etc. You are I think referring to those patient characteristics in terms of symptoms that might raise the suspicion that AF would be found if looked for. Please clarify what you do mean. Either way if you are going to be trying to measure the denominator you need to be more explicit about precisely which factors should be included. This is going to be very difficult to measure.
049	**NHS Improving Quality**	Quality statement 1	Pulse palpation –disagree with the definition of risk factors in the draft. What the draft has given is a collection of symptoms which will almost certainly mandate a clinical examination of the patient in any case. We need to be focusing on risk factors in asymptomatic patients – ie patients with known hypertension, mitral valve disease and obstructive sleep apnoea and age > 65. Also manual pulse palpation must be followed by ECG in patients deemed to have an irregular pulse ie the ECG must be mandated in any patient found to have an irregular pulse. Would remove the words "with risk factors for atrial fibrillation".
050	**NHS Improving Quality**	Quality statement 1	It appears that symptoms of AF have been confused with risk factors for AF. Risk factors for AF would include CVD, diabetes, CCF, hyperthyroidism, age , high alcohol consumption, chronic lung disease etc.
051	**PMS (Instruments) Ltd**	Quality statement 1	In order to determine with certainty whether AF is present it is necessary to record an ECG . The Alivecor heart monitor is a low cost (£74.99) validated device which can be used with a smart phone or tablet. The advantage of this new technology recently available is that within 30 seconds a visual ECG can be recorded and automatically analysed. With the current recommendation the accuracy of a manual palpation is determined by the user and maybe subjective with no confirmatory evidence at that moment in time. The guideline recommendation for the investigation of palpitations pre-dates the introduction of this low cost AliveCor

ID	Stakeholder	Statement No	Comments[1]
			smartphone technology. There should be an appraisal of smartphone based recording systems like the AliveCor in the identification of AF. The recorded ECG provides a visual recording of the incidence of AF or not. [1] 1. Camm A, Lip G, de Caterina R et al. 2012 focused update of the ESC guidelines for the management of atrial fibrillation. An update of the 2010 ESC guidelines for the management of atrial fibrillation. Developed with the special contribution of the European Heart Rhythm association. Eur Heart J 2012;33:2719–47. [1] March 2015 Br J Cardiol 2015;22:31–3 doi: 10.5837/bjc.2015.009 Authors: Pierre Le Page, Hamish MacLachlan, Lisa Anderson, Lee-Ann Penn, Angela Moss, Andrew R J Mitchell; from the Jersey International Centre for Advanced Studies
052	**UCLPartners**	Quality statement 1	Adults aged 65 years and over with pre-existing cardiovascular or cerebrovascular disease, diabetes or renal disease or age 75 and over should have a manual pulse palpation or automated pulse rhythm check annually and adults age 65 years and over without pre-existing CVD or diabetes should have a manual pulse palpation or automated pulse rhythm check every 5 years.
053	**UKCPA, Cardiac Group**	Quality statement 1	Adults aged 65 years and over with pre-existing cardiovascular or cerebrovascular disease, diabetes or renal disease or age 75 and over should have a manual pulse palpation or automated pulse rhythm check annually and adults age 65 years and over without pre-existing CVD or diabetes should have a manual pulse palpation or automated pulse rhythm check every 5 years.
054	**Stroke Association**	Quality statement 1	We are aware that the National Screening Committee does not recommend an AF screening programme. However there is an argument for opportunistic pulse checking as part of routine clinical practice, as well as targeted pulse checking in people with one or more risk factors for AF, e.g. people over a certain age or those with another cardiovascular condition.
055	**Stroke Association**	Quality statement 1	A pulse check every time a patient has their blood pressure checked would improve detection rates, for example within the NHS Health Check and during regular monitoring for other long term conditions.
056	**Stroke Association**	Quality statement 1	The denominator for this QS will be difficult to measure, perhaps use age or population estimates for prevalence of risk factors such as blood pressure as a denominator
057	**Stroke Association**	Quality statement 1	The list of risk factors for AF included in this guidance may be better described as symptoms. Our understanding of risk factors for atrial fibrillation include (but are not limited to) age, high blood pressure, diabetes, kidney disease and other cardiovascular conditions. Also, AF often does not present with any symptoms, or if symptoms do present, they can come and go, as with paroxysmal AF. It would be useful to have some recognition of this in the QS, particularly regarding selecting groups of people with risk factors such as age or high blood pressure.
058	**London Stroke Strategic Clinical**	Quality statement 1 & 2	SSNAP question 2.1 Both statement 1 and statement 2 suggest SSNAP question 2.1 as a data source. This question asks whether a stroke patient had AF prior to admission, and whether that patient was on antiplatelets and/or anticoagulants.

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	Network		• Given statement 1 aims to increase case-finding, a better indicator would be a reduction in the percentage of stroke patients with previously undiagnosed AF, rather than the percentage of patients with known AF on admission. • This data source is also inappropriate for statement 2, as one cannot calculate a CHA2DS2-VASc score using SSNAP question 2.1 (since the SSNAP does not ask about history of vascular disease.)
059	**Digital Assessment Service, NHS Choices**	Question 4	Question 4 – manual pulse palpation is a widely understood term in mine and a colleagues experience.
060	**London Stroke Strategic Clinical Network**	Question 4	This term is widely understood by medical and nursing professionals, and possibly by all healthcare professionals. It is less widely understood by members of the public. Using 'manual pulse palpation' versus 'pulse check' should depend on the intended audience.
061	**NHS England**	Question 4	Question 4: I think the term 'manual pulse palpation' will be widely understood without further definition.
062	**NHS England**	Question 4	I think manual pulse palpation would be widely understood. However maybe some guidance as to what to do next would be useful
063	**University Hospital Birmingham**	Question 4	The term manual pulse palpation seems adequate
064	**Yorkshire and Humber SCN**	Question 4	Manual Pulse Palpation is widely understood How Frequently?. Opportunistically, every consultation or annually
065	**AF Association**	Quality statement 2	Specialist commissioning exists for Left Atrial Appendage. For a minority of AF Patients, this is the only option and therefore AF Association believes this should be included.
066	**Arrhythmia Alliance**	Quality statement 2	NICE guidance exists for Left Atrial Appendage (LAAO) where anticoagulation is contraindicated and yet it is not included in QS2. Specialist Commissioning exists for this therapy and for a minority of AF patients this is the only therapy option left. A-A believes this should be included in QS2
067	**Bayer PLC**	Quality statement 2	As well as 'offer[ing] anticoagulation to people with a CHA2DS2-VASc score of 2 or above', the NICE clinical guideline on the management of atrial fibrillation also recommends 'consider[ing] anticoagulation for men with a CHA2DS2-VASc score of 1'. We suggest that this should form part of the quality statement. Proposed quality statement: Adults with atrial fibrillation and a CHA2DS2-VASc stroke risk score of 2 or above are offered anticoagulation. Men with a CHA2DS2-VASc risk score of 1 or above are considered for anticoagulation.
068	**Boehringer-Ingelheim**	Quality statement 2	The quality statement does not entirely embody NICE Guideline CG180 which states that anticoagulation should also be considered for men with a CHA2DS2-VASc score of 1 (NICE Guideline CG180 1.5.2). The current wording of the quality

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			statement could lead to the unintended consequence of certain patients at risk of a stroke not being appropriately anticoagulated. In the rationale behind Quality Statement 2, it would be helpful to highlight the use of the HAS-BLED score to assess the risk of bleeding in people who have started or who are starting anticoagulation. It should be noted that most people are at a higher risk of having a stroke than a bleed, and the HAS-BLED score should not be used as a reason not to anticoagulate.
069	**Bristol-Myers Squibb**	Quality statement 2	Issue: There is no reference to bleeding, or the use of bleeding risk scores (such as HAS-BLED), in the main body of the quality statement, only in the 'Definitions of terms' section at the end. The assessment of bleeding risk is crucial when determining whether and how to anticoagulate: the NICE AF Guideline CG180 states 'Offer anticoagulation to people with a CHA2DS2-VASc score of 2 or above, taking bleeding risk into account' (section 1.5.3). Proposal: Add 'taking bleeding risk into account.' to the end of the quality statement. It would then read, 'Adults with atrial fibrillation and a CHA2DS2-VASC stroke risk score of 2 or above are offered anticoagulation, taking the bleeding risk into account.'
070	**Bristol-Myers Squibb**	Quality statement 2	Issue: Data suggest a significant proportion of patients remain on aspirin for stroke prevention in atrial fibrillation. May 2014 data from the GRASP-AF toolkit reported by AFA1 "Grasp the initiative: Action Plan" suggests that 33.98 per cent of AF patients at high risk of stroke (CHADS2> 1) have been prescribed an antiplatelet but not an anticoagulant. However, the NICE AF Guideline CG180 states 'Do not offer aspirin monotherapy solely for stroke prevention to people with atrial fibrillation.' (section 1.5.15) [new 2014]. Quality statement 2 measures the proportion of adults with atrial fibrillation and a CHA2DS2-VASC score of 2 or above who receive anticoagulation. Proposal: In the 'Rationale' section of this quality statement, emphasise that aspirin monotherapy should not be used solely for stroke prevention in AF (CG180). Where aspirin is being used solely to treat patients with AF, it should be replaced with an effective and evidence-based anticoagulant . References 1 Grasp the initiative: Action plan. Atrial Fibrillation Association (2014).
071	**Education for Health**	Quality statement 2	Would it be appropriate to have anticoagulation considered if CHA2DS2 VASc above 1 depending on clinical picture?
072	**London Stroke Strategic**	Quality statement 2	Antiplatelets Although it's implied, the document does not specifically recommend revaluating AF patients currently on antiplatets or

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	Clinical Network		nothing. Suggestion 9: State that all non-contraindicated AF patients with a CHA2DS2-VASc greater than or equal to two, who are on aspirin or no antithrombotic treatment, should be offered anticoagulation.
073	**London Stroke Strategic Clinical Network**	Quality statement 2	Men The document omits the NICE guidance for men with a CHA2DS2-VASc of 1. Suggestion 10: Reword to include “men with a CHA2DS2-VASc of 1 should be considered for anticoagulation.”
074	**London Stroke Strategic Clinical Network**	Quality statement 2	Contraindications The document does not address patients for whom anticoagulation is not a suitable treatment. Suggestion 11: Recommend that patients with a CHA2DS2-VASc of 2 or greater who are contraindicated to anticoagulation treatment should be referred to a specialist anticoagulation clinic.
075	**London Stroke Strategic Clinical Network**	Quality statement 2	GRASP-AF Statement 2 recommends GRASP-AF as a data source. GRASP-AF has a database comprised of voluntary uploads from GP practices. NHS IQ does not monitor how many practices have GRASP-AF installed, and there is no requirement to upload data for those practices which use it. As of October 2014, 79.4% of GP practices in London have never uploaded to GRASP-AF, and only 6.2% have uploaded more than once. Hence, GRASP-AF data will not be a representative sample of London, and potentially other regions as well. (This is of course completely separate GRASP-AF’s primary purpose – to help GP's assess the risk of AF-related stroke and effective management of AF in patients – and has no bearing on that function.)
076	**NHS England**	Quality statement 2	I agree with the emphasis on offering anticoagulation but would like to see some mention of a prior assessment of bleeding risk and discussion with the patient. Those who already have deranged clotting (such as those with liver disease or high alcohol intake) may still be appropriate for anticoagulation but clinicians may prefer warfarin, with INR monitoring, or indeed in a few cases may feel anticoagulation contraindicated, without additional specialist input. As drafted the QS assumes that everyone with AF and a CHADSVASC score of 2 or more should be expected to be anticoagulated, and whilst I support completely the attempt to reverse the years of inadequate intervention in the past, perhaps there should be some mention of balancing risk against benefit. The denominator should probably be all those with AF and a CHADVASC scoe of 2 or more who are not exclusions (even though one would hope the exclusions are few). On subsequent reading I see that the issue of bleeding risk is referred to on page 12, which is helpful, but I suggest should appear before the statement (QS2) is made, or at least referred to as part of the statement. Standing alone, and before the reader has reached page 12, the implication is that everyone with AF and a CHADSVASC of 2 or more should be anticoagulated and after reading page 12 obviously the expectation is that this number will be less than 100% because of exclusions.

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077	**NHS England**	Quality statement 2	Under the heading 'Outcome' I think the use of the term primary diagnosis of AF is unclear. Does it mean for example that you would ignore those patients who had hypertension as well
078	**NHS Improving Quality**	Quality statement 2	Anticoagulation to reduce stroke risk - no issue with this proposed standard What about patients with a CHA2DS2VASC score of one??? Should there be a discussion about anticoagulation?
079	**Roche Diagnostics Limited**	Quality statement 2	We agree with the statement to increase anticoagulation in people most at risk of strokes. However, it should be made more explicit that AF patients currently receiving aspirin only for the prevention of strokes would need to be re-assessed and possibly offered anticoagulation treatment. These patients seem the most likely to benefit from re-assessment of their stroke risk and anticoagulation. The need to re-assess AF patients on 'aspirin only' should therefore be at least stated in the 'Rationale' of this statement.
080	**Stroke Association**	Quality statement 2	Anecdotally, we have heard that risk of bleeding is still a concern for GP's when managing stroke risk in patients with AF, and is one of the main reasons for the inadequate stroke risk management of many people with AF. We welcome this QS for the clarity we hope it will bring to GP's on managing stroke risk in people with AF. We suggest addressing bleeding risk upfront and also adding detail on how the CHADS-VASC and HAS-BLED risk scores interplay when considering management options for people with AF.
081	**Stroke Association**	Quality statement 2	We suggest promoting GRASP-AF in general practice as a means for GP's to identify people who should be offered anticoagulation, not just as a data collection tool.
082	**UCLPartners**	Quality statement 2	Adults with atrial fibrillation and a CHA2DS2-VASC stroke risk score of 2 or above are offered and those with CHA2DS2-VASC of 1 (except female gender alone) or more are considered for anticoagulation, with consideration of HASBLED score to optimise/correct any factors to minimise the risk of major bleeding.
083	**UKCPA, Cardiac Group**	Quality statement 2	Adults with atrial fibrillation and a CHA2DS2-VASC stroke risk score of 2 or above are offered anticoagulation and those with CHA2DS2-VASC of 1 (except female gender alone) or more are considered for anticoagulation, with consideration of HASBLED score to optimise/correct any factors to minimise the risk of major bleeding.
084	**Yorkshire and Humber SCN**	Quality statement 2	The wording would be more precise if it read 'Adults with atrial fibrillation and a CHA2DS2-VASC stroke risk score of 2 are Assessed for anticoagulation using a face to face consultation.
085	**AF Association**	Quality statement 3	All anticoagulation choices should be included in QS3.
086	**AntiCoagulation Europe**	Quality statement 3	Page 14 refers to Healthcare professionals discussing options of anticoagulation. Wording should include discuss risks and benefits.
087	**Arrhythmia Alliance**	Quality statement 3	A-A suggest the wording for QS3 should be expanded to ensure inclusion of all anticoagulation choices
088	**Bayer PLC**	Quality statement 3	Under choice of anticoagulants we suggest that the wording should be amended slightly from 'A decision aid such as NICE's Atrial fibrillation: patient decision aid can be used to help people make choices' to 'NICE have created a decision

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			aid which can be used to help people make choices.' We suggest that this may help to ensure that local processes do not duplicate work already undertaken by NICE in creating such an aid.
089	**Boehringer-Ingelheim**	Quality statement 3	BI welcomes the proposal of this quality statement. However the current wording does not provide patients with sufficient choice in managing their anticoagulation. The statement may be subject to misinterpretation in that patients may be offered anticoagulation therapy without any further specific choice of anticoagulant, including the non-vitamin K antagonist anticoagulants. BI would suggest that the wording of the quality statement is altered to; adults with atrial fibrillation prescribed anticoagulation are given an equal choice of all oral anticoagulants with unrestricted NICE HTA approval.
090	**Bristol-Myers Squibb**	Quality statement 3	Issue: The only reference in this quality statement to informed patient choice is at the end of the description: 'Adults with atrial fibrillation who are prescribed anticoagulants are offered a choice of anticoagulants after a discussion with their doctor about the types of anticoagulants they could have and the advantages and disadvantages of each type.' The role of informed patient choice does not appear to have sufficient prominence in this quality statement as it stands. In 2014 the NICE AF Guideline CG180 was updated to include this text, 'Discuss the options for anticoagulation with the person and base the choice on their clinical features and preferences.' (section 1.5.4) [new 2014]. Proposal: Add 'and their preferences are taken into account' to the end of the quality statement. It would then read, 'Adults with atrial fibrillation prescribed anticoagulation are given a choice of anticoagulants and their preferences are taken into account.'
091	**Bristol-Myers Squibb**	Quality statement 3	Issue: Not all patients with NVAF have access to, or choice of, all NICE-recommended anticoagulants. Proposal: Ensure that NICE-approved medicines are included on all Clinical Commissioning Group and Trust formularies. Review local guidance and protocols for anticoagulant use in AF, identify those which deviate from NICE guidance, and take appropriate remedial action.
092	**London Stroke Strategic Clinical Network**	Quality statement 3	Agree
093	**NHS England**	Quality statement 3	I'm not sure whether measuring the number offered a choice of anticoagulant is likely to produce meaningful information which outweighs the efforts made to try and collect the data in the first place. Quite what is meant by "offering a choice" would have to be defined, or perhaps assessed from patient feedback because a practitioner simply mentioning that there are different drugs available could be construed as 'offering a choice' whereas in reality such choice is rather meaningless. I think the intention is to be supported, but I suspect measurement will be difficult or meaningless. I suppose it would be possible to audit how frequently relevant patients used the NICE patient decision aid – I'm just not sure the efforts that would need to be made to collect these data would be all that helpful in improving quality. Better, in

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			my opinion, that efforts are made to ensure that all suitable patients are on some anticoagulant, than that too much effort is expended on monitoring 'choice' of agent.
094	**NHS England**	Quality statement 3	Outcome 'patient experience'. What is the evidence that providing choice of anticoagulant improves patient experience? You also suggest collecting data on anticoagulation adherence. How will that be achieved for patients on NOACs where there is no blood test that enables such a check to be made?
095	**NHS Improving Quality**	Quality statement 3	Choice of anticoagulation – suggest go further than what is included in the draft. Ie Patients should not only be offered a choice of available treatment options they should be involved in the decision making process and be presented with objective data as to the likely benefit and harm of the options.
096	**Stroke Association**	Quality statement 3	Anticoagulant adherence can help prevent strokes, and we support informed patient choice in managing their risk of stroke. We are unsure whether a simple choice of anticoagulant is sufficient to promote informed decision making and anticoagulant adherence. We suggest including stronger wording in the QS about discussing the benefits and risks of anticoagulation (particularly that for most people the benefit of anticoagulation outweighs the bleeding risk), as well as discussing the risks and benefits of different types of anticoagulation. The personalised package of care referenced in the NICE guidelines for AF, which talks about other elements beyond a choice of particular therapy, would also be a means to promote informed decision making and patient empowerment.
097	**Stroke Association**	Quality statement 3	We welcome the use of a decision making aid to promote informed choice, however suggest that the NICE Atrial fibrillation decision making aid is recommended to be used by GP's alongside discussion of the management of stroke risk, rather than as a stand-alone guide given to patients. As above we suggest stronger wording about the need to discuss the risks and benefits of different AF management options with patients.
098	**Stroke Association**	Quality statement 3	The measure for the numerator in this QS would be difficult to collect data on. Collecting feedback from people prescribed anticoagulants may provide a more accurate picture of whether people are being offered a meaningful choice of stroke risk management options.
099	**UCLPartners**	Quality statement 3	After an informed discussion including the benefits and risks of newer oral agents versus warfarin, which includes the limited experience to date of routine use of newer agents, lack of full reversibility of bleeding at present, and dose adjustment requirement for those with impaired renal function.
100	**UKCPA, Cardiac Group**	Quality statement 3	After an informed discussion including benefits, dis-benefits and harms of newer oral agents versus warfarin which includes the limited experience to date of routine use of newer agents and impact of lack of reversibility of bleeding and inability to monitor individual levels of anticoagulation in people with impaired renal function (of whom around 30% of those over 75 years have some degree of impairment).
101	**AF Association**	Quality statement 4	Agree
102	**AntiCoagulation Europe**	Quality statement 4	Time in therapeutic range needs to be recorded and shown on the records given to the patient

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103	**Arrhythmia Alliance**	Quality statement 4	Agree
104	**Bayer PLC**	Quality statement 4	Strictly in accordance with the NICE clinical guideline on the management of AF, a TTR <65% is not the only reflection of poor anticoagulation control: '2 INR values higher than 5 or 1 INR value higher than 8 within the past 6 months' and '2 INR values less than 1.5 within the past 6 months' are also included in the clinical guideline. We suggest that these criteria are also included to ensure consistency with the clinical guideline. Excluding these criteria means that individuals with poor anticoagulation control may not have their anticoagulation reassessed potentially putting them at risk of having a stroke or major bleed. Proposed quality statement: Adults with atrial fibrillation taking a vitamin k antagonist with poor anticoagulation control have their anticoagulation reassessed. Quality measures Structure – Evidence of local arrangements and written protocols to ensure that adults with atrial fibrillation taking a vitamin k antagonist with either • 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% have their anticoagulation reassessed. Process b) - Proportion of adults with either • 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% who have their anticoagulation reassessed.
105	**Boehringer-Ingelheim**	Quality statement 4	Quality Statement 4 is not completely aligned with NICE Guideline CG180. The guideline lists instances in addition to TTR being less than 65% whereby a patient should have their anticoagulation assessed. Specifically if a patient demonstrates 2 INR values higher than 5 or 1 INR value higher than 8 within the past 6 months or 2 INR values less than 1.5 within the past 6 months, their anticoagulation should be assessed (NICE Guideline CG180 1.5.12). The statement should also be more specific to include the direction that as well as reassessment, measures should also be taken to improve the care patients are receiving following the reassessment of their anticoagulation (NICE Guideline CG180 1.5.13 and 1.5.14). It would be helpful to GPs if Quality Statement 4 included reference to the Warfarin patient safety audit tool which is a free tool to help practices to audit their clinical data to look at the appropriateness of warfarin prescribing. The tool assists

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			practices in examining whether patients are achieving the optimum benefit from taking warfarin by calculating the amount of time they are within therapeutic range.
106	**Bristol-Myers Squibb**	Quality statement 4	Issue: Lack of INR control over time is not specifically captured in this quality statement. The quality statement proposes two measures: 1. % of patients on VKA who have TTR calculated at each visit; and 2. % of patients with TTR<65% who have their anticoagulation reassessed. However, the NICE AF Guideline CG180 states 'Calculate TTR over a maintenance period of at least 6 months', and also proposes a reassessment based not just on TTR<65% but also if two INR values are less than 1.5 within the past 6 months. As such, we believe the quality statement could do more to improve patient care. Proposal: Re-draft the quality statement to include a time period over which INR values should be measured to realistically assess the quality of patient care.
107	**Daiichi-Sankyo UK**	Quality statement 4	Calculate TTR over a maintenance period of at least 6 months: This definition potentially forces patients to be under/over coagulated for a period of 6 months before their anticoagulation options are reviewed. This is in stark contrast to Quality statement 5, where a specialist review would occur within 4 weeks. Just because an incorrect TTR is asymptomatic does not mean that the patient should be placed at risk. As an example, a 66 year old lady with a history of CHF, Hypertension and diabetes, has a CHA2DS2-VASc score of 5 meaning that her annual risk of a stroke if not anticoagulated is 7.65% over 6 months, i.e. one in thirteen patients with uncontrolled anticoagulation could develop a stroke while a decision to review anticoagulation is awaited. Patients started on a NOAC would be protected within 36-48 hours in contrast. This definition should be reworded so that it cannot be used simply as a way of delaying patients having their anticoagulation options reviewed and putting some of them at unnecessary risk. There are well scores that allow prediction of compliance with warfarin such as the SAMe-TT2R2 score (Apostolakis et al 2013) which has been prospectively validated (Poli et al 2014) in a population with comparable TTR control as in the UK. Such a measure would enhance patient choice and improve confidence in prescribing physicians. References Apostolakis et al Chest. 2013 Nov;144(5):1555-63. doi: 10.1378/chest.13-0054. Poli D et al Intern Emerg Med. 2014 Jun;9(4):443-7. doi: 10.1007/s11739-014-1065-8
108	**Education for Health**	Quality statement 4	Really important that this is highlighted as a quality standard

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109	**London Stroke Strategic Clinical Network**	Quality statement 4	Agree
110	**NHS England**	Quality statement 4	I don't think there is any evidence to show that having symptoms from AF is an any way linked to the risk of having a stroke
111	**NHS Improving Quality**	Quality statement 4	Anticoagulation control – the draft needs to specify clearly that the TTR needs to be measured over a 6 month period and there also needs to be inclusion of the other parameters that would trigger a review ie INR > 8, x2 INRs < 1.5 and x2 INRs > 5
112	**NHS Improving Quality**	Quality statement 4	The document states that a validated method of measurement such as the Rosendaal method be used. I wondered whether other methods have had the same usage and whether the 65% TTR applies to them also. If not, then the Rosendaal method should be specified.
113	**Stroke Association**	Quality statement 4	We are broadly supportive of this QS, however are not in a position to comment in detail.
114	**UCLPartners**	Quality statement 4	Agree
115	**UKCPA, Cardiac Group**	Quality statement 4	Agree
116	**Yorkshire and Humber SCN**	Quality statement 4	Add INR Values either above 5 or below 1.5 x twice in last 6 months
117	**Education for Health**	Quality statement 5	Again important that this is emphasised as in practice the importance of is not always followed up.
118	**London Stroke Strategic Clinical Network**	Quality statement 5	Agree
119	**NHS England**	Quality statement 5	With regards QS5 it should be possible to collect data on the numerator, but I'm not sure how the denominator (all those whose treatment fails to control symptoms) can be collected reliably. There is a danger that the denominator will be the same as the numerator, since GPs are unlikely not to refer the truly symptomatic and if they don't refer it will be on the basis that the GP (and patient) don't feel the symptoms warrant referral (and this level of perception of symptom control will vary between doctors and their individual patients).
120	**NHS Improving Quality**	Quality statement 5	Referral for specialised management – agree in principle with this but will be hard to gauge the denominator – ie exactly when a patient is deemed to have failed symptom control.

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121	**Stroke Association**	Quality statement 5	As for QS 4, We are broadly supportive of this QS, however are not in a position to comment in detail.
122	**UCLPartners**	Quality statement 5	Adults with atrial fibrillation whose treatment fails to control their symptoms should be considered for consultant referral within 4 weeks or earlier advice, in particular to avoid heart failure ensuing.
123	**UKCPA, Cardiac Group**	Quality statement 5	Adults with atrial fibrillation whose treatment fails to control their symptoms should be considered for consultant referral within 4 weeks or earlier advice, in particular to avoid heart failure ensuing.
124	**AF Association**	Quality statement 6 (developmental)	There should be an option for suitable and willing patients to use home-testing after discussion with the wider choice of all anticoagulant therapies.
125	**AF Association**	Quality statement 6 (developmental)	Patient and GP education is critical to ensuring early diagnosis, anticoagulation and appropriate treatment of AF.
126	**AliveCor Ltd**	Quality statement 6 (developmental)	• This QS seems limited to self monitoring of anticoagulation but many benefits can be derived from Patients self monitoring of the AF condition1 • Simple app based tools are emerging with multiple functions for aiding the self management of their AF condition with medication tracking, AF event capture and logging, AliveCor® Hearth Monitor is at the forefront of this self care movement1 • These self-care tools can improve the communication with the Medical Care Providers and may improve outcomes2 • Post AF ablation patients can better understand their condition and share data remotely with their Cardiologist or other healthcare professional1,3 References: 1. BMJ Innov doi:10.1136/bmjinnov-2014-000029 Commentary, Living with the handheld ECG Andrew R J Mitchell1, Pierre Le Page 2. Ubiquitous Wireless ECG Recording: A Powerful Tool Physicians Should Embrace Leslie A. Saxon, Journal of Cardiovascular Electrophysiology, Volume 24, Issue 4, pages 480–483, April 2013 3. Using a Novel Wireless System in Monitoring patients After Atrial Fibrillation Ablation Procedure. The iTransmit Study Khaldoun G. Tarakji et al. HeartRhythm, The Official Journal of the Heart Rhythm Society. November 2014.
127	**AntiCoagulation Europe**	Quality statement 6 (developmental)	Coagulometers should be regularly checked against a professional model. There needs to be a recommendation as to how often this should take place. At present it can vary between four weeks to once a year. There is no need to check at monthly intervals
128	**Arrhythmia Alliance**	Quality statement 6 (developmental)	Clarification is required in QS6 as not all patients will be suitable for home-testing however those that are should be offered it as an option, together with the wider choice of anticoagulant therapies. Patient and GP education is critical to ensuring early diagnosis, anticoagulation and appropriate treatment of AF.

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129	**Bayer PLC**	Quality statement 6 (developmental)	Strictly in accordance with the NICE guidance on self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 OT/INR monitor) 2014, statement 6 should only relate to people who prefer and are able to effectively use this type of monitoring. We suggest that the wording of the quality statement is adjusted to bring it into line with the published guidance. Proposed quality statement: Adults with atrial fibrillation taking a vitamin K antagonist who prefer and are able to effectively use this type of monitoring are offered a coagulometer to self-monitor their coagulation status.
130	**Boehringer-Ingelheim**	Quality statement 6 (developmental)	The logistical support and resources required for the service re-design to maintain good quality assurance and patient training is an obstacle to the widespread uptake of coagulometers.
131	**Daiichi-Sankyo UK**	Quality statement 6 (developmental)	As this statement is based on guidance in patients with heart valve disease, the statement should reflect that this only applies to this restricted population.
132	**London Stroke Strategic Clinical Network**	Quality statement 6 (developmental)	Training No discussion of training for patients and carers is made. Suggestion 12: Eligible patients and their carers should be provided with training to properly use their coagulometers. Competency using the device should be demonstrated to the prescribing clinician to avoid inaccurate monitoring.
133	**NHS England**	Quality statement 6 (developmental)	See comments earlier about self-monitoring which, for those able to do it and who wish to do it I would certainly support. Discussion with GP leaders may be needed regarding governance issues.
134	**NHS England**	Quality statement 6 (developmental)	Under the process quality measures you state that the proportion receiving a coagulometer should be measured. What is the correct figure and without having a sense for this figure how is a practice/CCG to know whether too few or too many are being prescribed?
135	**NHS England**	Quality statement 6 (developmental)	Why are you using admission rate as the outcome for this standard. A coagulometer will be primarily improving rates of control so why not use stroke rate, proportion of patients being adequately anticoagulated etc?
136	**Roche Diagnostics Limited**	Quality Statement 6 (developmental)	We agree with this statement: INR self-monitoring has been recently recommended by NICE (http://www.nice.org.uk/guidance/dg14) due to significant improvements in TTR and reductions in thromboembolic events for people who self-monitor their INR compared to people attending anticoagulation clinics for monitoring (NICE DG 14 and Heneghan et al. Lancet 2012:79(9813):322-34). Implementation of INR self-monitoring requires changes in services provision and commissioning that are described in the NICE implementation resources for the diagnostic guidance (available at http://www.nice.org.uk/guidance/dg14/resources). These resources highlight that all necessary information is

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			available for further adoption of self-monitoring in the NHS. The insights from the services that have implemented INR self-monitoring indicate outstanding performance in terms of anticoagulation control (TTR improvement) and patient satisfaction (examples available at http://www.nice.org.uk/guidance/dg14/resources). However, INR self-monitoring is only available in a minority of service providers. This quality statement therefore has the potential to increase patient access to INR self-monitoring across the NHS and achieve significant quality improvements for people with AF.
137	**Roche Diagnostics Limited**	Quality Statement 6 (developmental)	We agree with the statement and suggest to mention the improvement in TTR associated with INR self-monitoring as well: " to optimise anticoagulation treatment and improve TTR. As well as reducing the frequency of hospital or clinic visits,"
138	**Roche Diagnostics Limited**	Quality Statement 6 (developmental)	This is an appropriate measure & process. This measure will be able to highlight significant local variation in the offer of INR self-monitoring.
139	**Roche Diagnostics Limited**	Quality Statement 6 (developmental)	We cannot understand the rationale for this outcome. As mentioned under 'Rationale', the main benefits of INR self-monitoring are the reduction in thromboembolic events and increased patient satisfaction. The outcomes for Statement 6 should be the same as in Statement 4: a) Rates of thromboembolic complications and, b) Patient experience. An additional outcome could be reduced visits to anticoagulation clinics for INR monitoring.
140	**Stroke Association**	Quality statement 6 (developmental)	As for QS's 4 & 5, We are broadly supportive of this QS, however are not in a position to comment in detail.
141	**UCLPartners**	Quality statement 6 (developmental)	Adults with atrial fibrillation taking a vitamin K antagonist are offered a coagulometer to self-monitor their coagulation status, provided appropriate education and training is available and utilised and sufficient competency can be demonstrated and confirmed to minimise risks of monitoring failure.
142	**UKCPA, Cardiac Group**	Quality statement 6 (developmental)	Adults with atrial fibrillation taking a vitamin K antagonist are offered a coagulometer to self-monitor their coagulation status, provided appropriate education and training is available and utilised and sufficient competency can be demonstrated and confirmed to minimise risks of monitoring failure.
143	**University Hospital Birmingham**	Quality statement 6 (developmental)	The outcome will not be measured in admission rates
144	**Bayer PLC**	Question 5	We do not believe that this quality statement meets the criteria of a 'developmental' quality statement. It neither represents 'cutting edge' service delivery having been available in the UK since 20021 and having been recommended in a similar population in NICE clinical guideline 36 since 2006,2 nor does it deliver outstanding performance; a recently published systematic review that stratified results by indication showed that whilst participants with a mechanical heart valve who self-monitored had significant reductions in thromboembolic events compared to usual care, effects for atrial

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			fibrillation were not significant.3 This is the group relevant to this quality standard. Also, the introduction of this technology does not require significant changes to be made to current anticoagulation services, the only additional resources included in the NICE costing statement for DG14,4 are training (2 hours for self-testing and 4 hours for self-management), and additional staff time to call in each test result (5 mins of band 5 nurse time for each test). In addition, the costing statement does suggest that for both of these aspects where staff time is already available to provide this service along with current responsibilities, there may be no additional cost. 1. AntiCoagulation Self-Monitoring Alliance (July 2014). Anticoagulation services and patient access to INR self-monitoring in the NHS in England. Available at: http://heartrhythmcharity.org.uk/www/media/files/News_and_Events/FOI_report_Executive_Summary_FINAL_010914.pdf 2. National Institute for Health and Clinical Excellence. Clinical Guideline 36. Atrial fibrillation: the management of atrial fibrillation. 2006. 3. Heneghan, C. et al. Self-monitoring of oral anticoagulation: systematic review and meta-analysis of individual patient data. Lancet. 2012 Jan 28;379(9813):322-34. doi: 10.1016/S0140-6736(11)61294-4. Epub 2011 Nov 30. 4. National Institute for Health and Care Excellence. NICE Diagnostics Guidance DG14. Costing statement: Atrial fibrillation and heart valve disease: selfmonitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor). Published: September 2014
145	**Bristol-Myers Squibb**	Question 5	Issue: 'Developmental' quality statements set out an emergent area of cutting-edge service delivery or technology currently found in a minority of providers and indicating outstanding performance It is unclear that the evidence for the coagulometers supports 'outstanding performance': the recent NICE Diagnostics Guidance DG14 states 'Evidence indicates that the precision and accuracy of both monitors are comparable to laboratory-based INR testing'. We therefore believe that the clinical evidence presented does not warrant the inclusion of this quality statement as part of this quality standard. Proposal: Remove quality statement 6 from the draft atrial fibrillation quality standard.
146	**London Stroke Strategic Clinical Network**	Question 5	Anecdotally, these devices are not widely used in all areas of London, which indicates an emergent area. However these devices are commonly used in London in patients with artificial heart valves and in young, working age patients.
147	**NHS England**	Question 5	Question 5: There is likely to be a continuing move towards newer oral antithrombins (for which 'coagulometers' are not relevant) but for those who continue or are started on a Vitamin K antagonist, self monitoring and dosing has been shown to result in better INR control and I believe should be encouraged and supported. Concern has been expressed by GPs that some are reluctant to take "responsibility" for patients running their own anticoagulation control so this governance issue would need to be addressed and resolved.
148	**NHS England**	Question 5	I think this is an important area that is currently not managed well. The use of coagulometers should be encouraged as

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			an alternative to NOACs
149	**AntiCoagulation Europe**	Additional area	There is no mention of provision of information and education for patients and carers
150	**AntiCoagulation Europe**	Additional area	There is not mention of the need to review those patients taking aspirin
151	**Bayer PLC**	Additional area	We suggest that an additional quality statement related to aspirin monotherapy should be considered for inclusion in the quality standard. The NICE clinical guideline on the management of AF includes the following recommendation which is designated as a key priority for implementation: “Do not offer aspirin monotherapy solely for stroke prevention to people with atrial fibrillation.” As acknowledged in the full guideline, “the evidence was consistent with no clinical benefit of aspirin in reducing mortality and systemic emboli” and “…although there was a modest benefit in reducing ischaemic stroke it was partially offset by a modest harm in increased bleeding and haemorrhagic stroke.” The GDG concluded that “there was limited benefit in offering aspirin as the benefit was not outweighed by the associated harms.” They agreed that “it was important that patients at increased stroke risk should not be offered aspirin for stroke prevention.” Several recent publications suggest that there is “an over-reliance on anti-platelets for stroke prevention in AF”.1 A study investigating use of anticoagulants in the management of atrial fibrillation among 1857 general practices in England showed that 36.2% of AF patients with CHADS2≥2 were prescribed anti-platelets without anticoagulation,1 The SSNAP clinical audit public report also found that 38.6% of patients admitted in AF were taking anti-platelet medication prior to admission (Jul-Sept 2014),2 and data from the GRASP-AF toolkit found that 33.98% of AF patients with a CHADS2 score greater than one were prescribed anti-platelets to help reduce their risk of stroke (at May 2014).3 Therefore this is a high-priority area for quality improvement in atrial fibrillation and should be included in the quality standard. Proposed quality statement: ‘Adults with atrial fibrillation are not offered aspirin monotherapy solely for stroke prevention’ (key priority for implementation from the clinical guideline). 1. Cowan C, Healicon R, Robson I, Long WR, Barrett J, Fay M, et al. The use of anticoagulants in the management of atrial fibrillation among general practices in England. Heart 2013 Aug;99(16):1166-72. 2. Royal College of Physicians (2015). Sentinel Stroke National Audit Programme (SSNAP). Clinical uudit July-September 2014 public report. National results. Available at: https://www.strokeaudit.org/Documents/Results/National/JulSep2014/JulSep2014-PublicReport.aspx 3. Atrial Fibrillation Association (2014). Grasp the initiative. Action plan. Available at: http://www.atrialfibrillation.org.uk/files/file/Publications/140901-GRASP%20the%20Initiative%20Action%20Plan.pdf
152	**Boehringer-**	Additional area	Whilst the Quality Standard goes some way in highlighting measures to improve the identification, treatment and

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	Ingelheim		management of atrial fibrillation (AF), it is missing some markers of poor anticoagulation control. Crucially, the Quality Standard does not help to support the phasing out of aspirin for the prevention of stroke for patients with AF (NICE Guideline CG180 1.5.15).
153	**Boehringer-Ingelheim**	Additional area	The Quality Standard does not explicitly support the recommendation for a personalised package of care and information for patients with AF (NICE Guideline CG180 1.2).
154	**Boston Scientific**	Additional area	We noticed that the draft QS does not include any statements or comments related to the new rate and rhythm control guidance included in the recently published Atrial Fibrillation Clinical Guidelines (CG180) published in June 2014 and would support the inclusion of statements about these recommendations in the QS document.
155	**HQT Diagnostics**	Additional area	Atrial Fibrillation is improved if Fatty Acids are tested and adjusted via diet and supplements so that: Omega-3 Index >8% Omega-6/3 Index <3:1 Re-test after 3 months Sources: http://www.expertomega3.com/omega-3-study.asp?id=13 http://www.hqt-diagnostics.com/ http://www.omegaquant.com/publications/ http://omegametrix.eu/wissenschaftlicherhintergrund.html?lang=EN
156	**HQT Diagnostics**	Additional area	Atrial Fibrillation and overall heart failure are improved if Vitamin D 25(OH)D is tested and supplemented to be between 100-150nmol/L General Practitioners should test and supplement Vitamin D, followed by a re-test after 3 months Sources: http://www.vitamindwiki.com/Overview+Cardiovascular+and+vitamin+D
157	**HQT Diagnostics**	Additional area	Atrial Fibrillation is improved if Magnesium is given, either by infusion or by oral supplement Sources: http://www.afibbers.org/magnesium.html http://www.lef.org//Protocols/Heart-Circulatory/Arrhythmias/Page-04
158	**London Stroke**	Additional area	Although probably outside the scope of this document, an equally important emergent area of innovation is research into

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	Strategic Clinical Network		a reversal agent for novel oral anticoagulants (NOACs), and the systems that providers currently have in place to reverse the effects of bleeding.
159	**London Stroke Strategic Clinical Network**	Additional area	Almost. The document makes no mention of AF patients who are not applicable for pharmacological treatment however. The document also fails to advocate for engaging and sharing information with patients and carers. Suggestion 13: Recommend that patients unsuitable for pharmacological treatment be considered for non-pharmacological treatments such as left atrial appendage occlusion. Suggestion 14: Embed patient-focussed messages throughout the document, including recommendations for properly educating patients and carers, providing support, and engaging with patients to create and co-design the best local solutions to implement these quality standards.
160	**NHS England**	Additional area	No acknowledgement is made anywhere in the document that AF can be intermittent. I would encourage you to have a QS that addresses the issue of identifying these patients where there is a very high risk that the diagnosis of PAF might be present. This is particularly important after stroke where no other cause is found. We know that this group frequently are found to have AF if looked for hard enough. A standard setting out to encourage the use of prolonged monitoring would be of great value
161	**NHS Improving Quality**	Additional area	I would have liked to have seen a quality statement about the use of audited care of the management of patients with AF, not only within individual practices but also within CCGs using one of the many available audit tools.
162	**NHS Improving Quality**	Additional area	The document mentions ablation and cardioversion once only. Surely these techniques need to be included properly?

Stakeholders who submitted comments at consultation

- AF Association
- AliveCor Ltd
- Anticoagulation Europe
- Arrhythmia Alliance
- Bayer PLC
- Boehringer-Ingelheim

- Boston Scientific
- Bristol-Myers Squibb
- British Heart Foundation
- Daaichi-Sankyo UK
- Department of Health
- Education for Health
- HQT Diagnostics
- London Stroke Strategic Clinical Network (LSSCN)
- Medtronic Limited
- NHS Choices
- NHS England
- NHS Improving Quality
- PMS Instruments Ltd
- Roche Diagnostics
- The Royal College of Emergency Medicine
- Royal College of Nursing
- Stroke Association
- UK Clinical Pharmacy Association (UKCPA)
- University of Birmingham

- UCL Partners
- Yorkshire and Humber SCN