Quality indicators for the care and outcomes of adults with atrial fibrillation

Task Force for the development of quality indicators in atrial fibrillation of the European Heart Rhythm Association (EHRA) of the European Society of Cardiology (ESC): Developed in collaboration with the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), and the Latin-American Heart Rhythm Society (LAHRS)

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Aims
To develop quality indicators (QIs) that may be used to evaluate the quality of care and outcomes for adults with atrial fibrillation (AF).

Methods and results
We followed the ESC methodology for QI development. This methodology involved (i) the identification of the domains of AF care for the diagnosis and management of AF (by a group of experts including members of the ESC Clinical Practice Guidelines Task Force for AF); (ii) the construction of candidate QIs (including a systematic review of the literature); and (iii) the selection of the final set of QIs (using a modified Delphi method). Six domains of care for the diagnosis and management of AF were identified: (i) Patient assessment (baseline and follow-up), (ii) Anticoagulation therapy, (iii) Rate control strategy, (iv) Rhythm control strategy, (v) Risk factor management, and (vi) Outcomes measures, including patient-reported outcome measures (PROMs). In total, 17 main and 17 secondary QIs, which covered all six domains of care for the diagnosis and management of AF, were selected. The outcome domain included measures on the consequences and treatment of AF, as well as PROMs.

Conclusion
This document defines six domains of AF care (patient assessment, anticoagulation, rate control, rhythm control, risk factor management, and outcomes), and provides 17 main and 17 secondary QIs for the diagnosis and management of AF. It is anticipated that implementation of these QIs will improve the quality of AF care.

Keywords
Atrial fibrillation • Quality indicators • Outcome measures

Abbreviations
AF atrial fibrillation
EORP EURObservational Research Programme
ESC European Society of Cardiology
INR international normalized ratio
LV left ventricle
LVEF left ventricular ejection fraction
PRISMA Preferred Reporting Items for Systematic Review and Meta-Analyses
PROMs patient-reported outcome measures
PVs pulmonary veins
QI quality indicator
QoL quality of life
RCT randomized controlled trial

Introduction
Atrial fibrillation (AF) is a key public health challenge and a major source of morbidity, mortality, and economic burden for governments worldwide.1 Despite progress in the management of patients with AF, this arrhythmia is still a major cause of stroke, heart failure, and cardiovascular morbidity and mortality globally.2 Additionally, AF is associated with cognitive impairment,3–5 reduced quality of life (QoL),6,7 depression,8 and frequent hospital admissions.9–11 The magnitude of the economic burden of AF is increasing, mainly driven by AF-related complications and management costs, particularly those associated with hospitalizations.12,13

Data from the EURObservational Research Programme in AF (EORP-AF) found that adherence to guideline-recommended therapies in the treatment of AF is associated with lower mortality,14 yet large variability persists in the delivery of such therapies across Europe.15,16 To improve the implementation of evidence-based medicine,17 some professional organizations have developed quality standards, clinical indicators, and quality measures to evaluate and improve the quality of AF care.18–21,22 However, no AF quality indicators (QIs) have been specifically designed for the wider international community. Hence, the European Heart Rhythm Association (EHRA), in collaboration with the Asian Pacific Heart Rhythm Society (APHRS), the Heart Rhythm Society (HRS), and the Latin-American Heart Rhythm Society (LAHRS), established the AF QI Working Group, which was tasked with the development of QIs for the diagnosis and management of adults with AF. It is hoped that these QIs can serve as a mechanism to improve the quality of AF care, and be used by healthcare providers to evaluate care delivery at the patient, centre, and national levels.

To enhance the translation of guideline recommendations into clinical practice and give healthcare providers the tools to identify opportunities for improvement, a summary of the AF QIs has been embedded in the 2020 ESC Clinical Practice Guidelines for AF.23 Efforts were made to ensure alignment between the developed QIs and the ESC Guidelines for AF, which may differ from recommendations developed by other professional organizations.

Methods
The detailed methodology for the development of QIs for the quantification of cardiovascular care and outcomes for the ESC Clinical Practice Guidelines is published separately.24 This methodology consists of a four-step process: identification of the key domains of care; construction of candidate indicators; selection of a final QI set; and undertaking of a feasibility assessment. In this document, we have identified important domains of AF care, and developed QIs for each domain. The development process involved conducting a systematic review of the literature, and using a modified Delphi method25 to derive the final set of QIs and divide them into main and secondary QIs. The next step would be to conduct a feasibility assessment of the developed QIs using existing AF registries.24 Quality indicators may be divided into structural, process, and outcome indicators.26 For each proposed QI, we provided relevant specifications, including numerator, denominator, measurement period, and measurement duration. However, no care settings were suggested, because the proposed QIs are applicable in both the inpatient and outpatient care. It is, thus, important to determine locally the clinical setting...
Members of the Working Group

The Working Group comprised members of the ECG Clinical Practice Guidelines Task Force, as well as international experts in AF management, patients with AF, and representatives from patient organizations. Six domains of AF care were defined: (i) Patient assessment (baseline and follow-up), (ii) Anticoagulation therapy, (iii) Rate control strategy, (iv) Rhythm control strategy, (v) Risk factor management, and (vi) Outcomes measures, including patient-reported outcome measures (PROMs). The names, affiliations, and conflicts of interest of the AF QIs Working Group are provided in Supplementary material, Appendix 1.

Systematic review

Search strategy

We conducted a systematic review of the published literature in accordance with the Preferred Reporting Items for Systematic Review and Meta- Analyses (PRISMA) statement27,28 (Supplementary material, Appendix 2). We searched two online bibliographic databases: MEDLINE and Embase via OVID29. The initial search strategy was developed in MEDLINE using keywords and, when available, Medical Subject Headings (MeSH) based on three main terms: ‘atrial fibrillation’, ‘quality indicators’, and ‘outcome measures’ (Supplementary material, Appendix 3). The final search strategies were then developed using an iterative process, which also included citations search, grey literature, and a hand search of the reference lists of the selected studies.

We included randomized controlled trials (RCTs) and observational studies, including local, national, and international registries. We excluded systematic reviews, meta-analyses, editorial letters, and conference proceedings. We only included the main publications of major trials and registries from which our search obtained only their sub-studies. The search was restricted to full-text articles published in the English language with a publication date between 1 January 2014 and 5 October 2019, to capture QIs and outcome measures for AF from contemporary practice.

Eligibility criteria

We included articles that fulfilled the following criteria: (i) the study population was adult patients (≥18 years old) with AF, (ii) the study explicitly stated at least one QI or outcome measure to define best practice for AF diagnosis and/or management, (iii) the study provided specifications for the QI or outcome measure (e.g. definition, data collection source, method of reporting), (iv) RCT or registry, and (v) full-text publication. No restrictions were applied to the presence of, or the type of, intervention or comparison in the study.

Study selection

A reference manager software (Zotero) was used for duplicates removal and data management. Two authors (Suleman Aktaa and Elena Arbelo) independently examined the abstracts of the studies retrieved from the search against the inclusion criteria. Disagreements were resolved through discussion and review of the full text of the article when required.

Data extraction

The full texts of the included studies were independently reviewed by two authors (Suleman Aktaa and Elena Arbelo). All QIs relevant to the agreed six domains of AF care, namely: (i) Patient assessment (baseline and follow-up), (ii) Anticoagulation therapy, (iii) Rate control strategy, (iv) Rhythm control strategy, (v) Risk factor management, and (vi) Outcomes measures (including PROMs) were extracted and listed on an Excel spreadsheet. When available, the following information was obtained for the extracted QIs: definition (including numerator, denominator, and exclusions), objective, type of QI (structural, process, outcome, or PROM), domain of application, and potential data collection source.

Clinical practice guidelines and existing QIs

In addition to the systematic review outlined earlier, we reviewed relevant clinical practice guidelines and existing QIs from different professional organizations (Table 1). The goal of the clinical practice guidelines review was to identify the recommendations with the strongest association with benefit or harm and to assess these recommendations against the ESC criteria for QIs (Table 2).30 Additionally, existing publications on QIs for patients with AF were also reviewed and, when applicable, information about the feasibility and/or validity of these measures was obtained.

Data synthesis

Candidate QIs

A list of candidate QIs was derived from the aforementioned systematic review and classified into structural, process, or outcome measures depending on the aspect of care being measured31. For each QI, a detailed definition was provided in order to facilitate the evaluation process.

Modified Delphi process

We used the modified Delphi process24, 29 to evaluate the candidate QIs and arrive at the final set of QIs. Instructions on the voting process, including QIs criteria (Table 2) were sent to the Working Group before the vote. All measures were independently graded by each member of the Group using the SurveyMonkey platform. Three rounds of voting were conducted, with a teleconference after each round to discuss the results of the vote. In the first voting round, we used a 9-point ordinal scale, where ratings of 1 to 3 signified that the QI was not valid; ratings of 4 to 6 meant that the QI was of uncertain validity; and ratings of 7 to 9 indicated that the QI was valid. Candidate QIs were included if ≥75% of the Working Group members ranked them between 7 and 9, and were excluded if ≥75% of the Working Group members ranked them between 1 and 3. Indicators that did not fall in the two categories above were carried forward to the second voting round, where a 3-point scale (should not be included, maybe, and should be included) was used, and the percentage agreement (≥75% of the Working Group members) cut-off was used. The final round comprised a binary, ‘yes’ or ‘no’ questionnaire to obtain the Working Group members’ agreement on the proposed final set of QIs.

Results

Search results

The literature search retrieved 2954 articles, of which 441 met the inclusion criteria (Figure 1). These articles were used to extract a total of 352 candidate QIs (17 related to structure, 162 to process, and 173 related to outcomes) before the first voting round. Of these 34 QIs (19 related to process and 15 related to outcomes) were selected by the end of the second round (Table 3). Over 93% of the Working Group members agreed on this final set of QIs in the third voting round.

The domains for AF care identified by the Working Group were: (i) Patient assessment (baseline and follow-up), (ii) Anticoagulation therapy, (iii) Rate control strategy, (iv) Rhythm control strategy, (v) Risk factor management, and (vi) Outcome measures (including PROMs). For each domain, main, and for some secondary, QIs have been developed. Figure 2 shows the main QIs according to their
Table 2  Criteria for the development and evaluation of the ESC quality indicators for cardiovascular disease

<table>
<thead>
<tr>
<th>Domain</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Importance</td>
<td>QI reflects a clinical area that is of high importance (e.g. common, major cause for morbidity, mortality, and/or health-related quality of life impairment).</td>
</tr>
</tbody>
</table>
|                  | QI relates to an area where there are disparities or suboptimal care.  
|                  | QI implementation will result in an improvement in patient outcomes.                           |
|                  | QI may address appropriateness of medical interventions.                                                                                   |
| Evidence base    | QI is based on an acceptable evidence consistent with contemporary knowledge.  
|                  | QI aligns with the respective ESC Clinical Practice Guideline recommendations.                                                               |
| Specification    | QI has a clearly defined patient group to whom the measurement applies (denominator), including explicit exclusions.  
|                  | QI has clearly defined accomplishment criteria (numerator).                                                                                   |
| Validity         | QI is able to correctly assess what it is intended to, adequately distinguishes between good and poor quality of care, and compliance with the indicator would confer health benefits. |
| Reliability      | QI is reproducible even when data is extracted by different people, and estimates of performance on the basis of available data are likely to be reliable and unbiased. |
| Feasibility      | QI may be identified and implemented with reasonable cost and effort.  
|                  | Data needed for the assessment is (or should be) readily available and easily extracted within an acceptable time frame. |
| Interpretability | QI is interpretable by healthcare providers, so that practitioners can understand the results of the assessment and take actions accordingly.    |
| Actionability    | QI is influential to the current practice, where a large proportion of the determinants of adherence to the QI, are under the control of healthcare providers.  
|                  | This influence of QI on behaviour will likely improve care delivery.  
|                  | QI is unlikely to cause negative unintended consequences.                                                                                   |

QI, quality indicator.
respective domain of care. The full set of main and secondary QIs, alongside their definitions, proposed measurement period (the time point at which the assessment is performed), measurement duration (the time frame needed for enough cases to be collected), and when applicable, the corresponding ESC Clinical Practice Guidelines recommendations are illustrated in APPENDIX 4. For each QI, a unique code was developed using the domain number and indicating whether the QI is main or secondary.

Quality indicators

Domain 1: Patient assessment (baseline and follow-up)
Stroke prevention is the cornerstone of the AF patient management pathway, and ‘avoid stroke/anticoagulation’ is the ‘A’ of the ABC pathway32, within the 2020 ESC guidelines23. Stroke risk in AF is not homogeneous and depends on the presence of various stroke risk factors33. The CHA2DS2-VASc score is recommended to assess stroke risk where the default should be to offer stroke prevention, unless the patient is low risk; hence use the

**Figure 1** PRISMA flow diagram for selection of included studies.

**01MQI1: Proportion of patients with cardio-embolic risk assessment using CHA2DS2-VASc score**

**Numerator:** Number of patients with AF who have their CHA2DS2-VASc score documented at the time of diagnosis and at every follow-up appointment.

**Denominator:** Number of patients with AF.

**01MQI2: Proportion of patients with bleeding risk assessment using a validated method, such as the HAS-BLED score**

**Numerator:** Number of patients with AF who have their bleeding risk assessment documented at the time of diagnosis and at every follow-up appointment using a validated bleeding risk score.

**Denominator:** Number of patients with AF.

**01MQI3: Proportion of patients with a measurement of their serum creatinine (or creatinine clearance)**

**Numerator:** Number of patients with AF who have their serum creatinine checked at the time of diagnosis and at every follow-up appointment.

**Denominator:** Number of patients with AF.
Table 3  Primary (green) and secondary (yellow) quality indicators for AF diagnosis and management

<table>
<thead>
<tr>
<th>Code</th>
<th>Quality indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>01MQI1</td>
<td>Proportion of patients with cardio-embolic risk assessment using CHA2DS2-VASc score</td>
</tr>
<tr>
<td>01MQI2</td>
<td>Proportion of patients with bleeding risk assessment using a validated method, such as the HAS-BLED score</td>
</tr>
<tr>
<td>01MQI3</td>
<td>Proportion of patients with a measurement of their serum creatinine (or creatinine clearance)</td>
</tr>
<tr>
<td>01SQI1</td>
<td>Proportion of people ≥65 years of age with risk factors for AF who have pulse check</td>
</tr>
<tr>
<td>01SQI2</td>
<td>Proportion of patients with AHREs detected on implantable cardiac devices who undergo further cardiovascular evaluation</td>
</tr>
<tr>
<td>01SQI3</td>
<td>Proportion of cryptogenic stroke patients who have been screened for AF</td>
</tr>
<tr>
<td>01SQI4</td>
<td>Proportion of patients with an ECG documentation of AF</td>
</tr>
<tr>
<td>01SQI5</td>
<td>Proportion of patients who have been engaged in shared decision making when deciding treatment strategy</td>
</tr>
<tr>
<td>02MQI1</td>
<td>Proportion of patients who are appropriately prescribed anticoagulation according to CHA2DS2-VASc score</td>
</tr>
<tr>
<td>02MQI2</td>
<td>Proportion of patients with a CHA2DS2-VASc score of 0 for men and 1 for women who are inappropriately prescribed long-term anticoagulation</td>
</tr>
<tr>
<td>02MQI3</td>
<td>Proportion of patients with ‘appropriate anticoagulation’ at every follow-up visit, defined as:</td>
</tr>
<tr>
<td></td>
<td>a. TTR*** &gt;70% for vitamin-K antagonist.</td>
</tr>
<tr>
<td></td>
<td>b. Appropriate dose for NOAC according to manufacturer recommendations.</td>
</tr>
<tr>
<td>03MQI1</td>
<td>Proportion of patients with permanent AF (i.e. where no attempt to restore sinus rhythm is planned), who are inappropriately prescribed antiarrhythmic drugs</td>
</tr>
<tr>
<td>03SQI1</td>
<td>Proportion of patients with LVEF&lt;40% who are inappropriately prescribed non-dihydropyridine calcium-channel blockers</td>
</tr>
<tr>
<td>04MQI1</td>
<td>Proportion of patients with structural heart disease who are inappropriately prescribed class IC antiarrhythmic drugs</td>
</tr>
<tr>
<td>04MQI2</td>
<td>Proportion of patients with end-stage kidney disease who are inappropriately prescribed dofetilide or sotalol</td>
</tr>
<tr>
<td>04MQI3</td>
<td>Proportion of patients with symptomatic paroxysmal or persistent AF who are offered AF catheter ablation after failure of, or intolerance to, one class I or class III antiarrhythmic drug</td>
</tr>
<tr>
<td>04SQI1</td>
<td>Proportion of patients with complete electrical isolation of the PVs during AF catheter ablation procedures</td>
</tr>
<tr>
<td>04SQI2</td>
<td>Proportion of patients with new-onset persistent AF who are offered cardioversion</td>
</tr>
<tr>
<td>05MQI1</td>
<td>Proportion of patients who have their modifiable risk factors identified</td>
</tr>
<tr>
<td>06.1MQI1</td>
<td>Annual rate of all-cause mortality***</td>
</tr>
<tr>
<td>06.1MQI2</td>
<td>Annual rate of ischaemic stroke or transient ischaemic attack***</td>
</tr>
<tr>
<td>06.1SQI1</td>
<td>Annual rate of cardiovascular mortality ***</td>
</tr>
<tr>
<td>06.1SQI2</td>
<td>Annual rate of cardiovascular hospitalization ***</td>
</tr>
<tr>
<td>06.1SQI3</td>
<td>Annual rate of overall thrombo-embolic event ***</td>
</tr>
<tr>
<td>06.1SQI4</td>
<td>Annual rate of clinician-reported symptom status assessment</td>
</tr>
<tr>
<td>06.2MQI1</td>
<td>Annual rate of life-threatening or major bleeding events</td>
</tr>
<tr>
<td>06.2MQI2</td>
<td>Annual rate of procedure-related 30-day mortality</td>
</tr>
<tr>
<td>06.2MQI3</td>
<td>Annual rate of procedure-related major complications or drug-related serious adverse events</td>
</tr>
<tr>
<td>06.2SQI1</td>
<td>Annual rate of haemorrhagic stroke</td>
</tr>
<tr>
<td>06.3MQI1</td>
<td>Proportion of patients with health-related quality of life assessment</td>
</tr>
<tr>
<td>06.3SQI1</td>
<td>Proportion of patients with patient-reported symptom status assessment</td>
</tr>
<tr>
<td>06.3SQI2</td>
<td>Proportion of patients with physical function assessment</td>
</tr>
<tr>
<td>06.3SQI3</td>
<td>Proportion of patients with emotional well-being (including anxiety and depression) assessment</td>
</tr>
<tr>
<td>06.3SQI4</td>
<td>Proportion of patients with cognitive function assessment</td>
</tr>
</tbody>
</table>

AF, atrial fibrillation; AHRE, atrial high-rate episodes; CHA2DS2-VASc, Congestive heart failure, Hypertension, Age ≥75 years, Diabetes mellitus, Stroke, Vascular disease, Age 65–74 years, Sex category (female); ECG, electrocardiogram; HAS-BLED, Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile INR, Elderly (≥65 years), Drugs/alcohol concomitantly; LVEF, left ventricular ejection fraction; NOAC, non-vitamin K antagonist oral anticoagulants; PVs, pulmonary veins; TTR, time in therapeutic range.

*Appropriateness of anticoagulation prescription is defined as CHA2DS2-VASc score of ≥1 for men and ≥2 for women in the 2020 ESC Guidelines. The 2014 ACC/AHA Guidelines (and 2019 focused update) define anticoagulation prescription appropriateness and CHA2DS2-VASc score of ≥2 for men and ≥3 for women.

**TTR calculated using Rosendaal method.

***Crude and risk-adjusted rates (risk adjustment should, as a minimum, consider age, sex, and comorbidities).
CHA2DS2-VASc score to initially define low risk patients (CHA2DS2-VASc score 0 in males, 1 in females) who do not need antithrombotic therapy (indicator 01MQI1). The subsequent step is to offer stroke prevention in those with 1 or more risk factors (CHA2DS2-VASc score ≥1 in males, ≥2 in females). Since stroke risk is dynamic, and influenced by ageing and incident risk factors, risk reassessment should occur at every follow-up visit.

Bleeding risk changes over time as well and should also be assessed at every patient contact, initially to identify modifiable bleeding risks that should be mitigated, and to identify the ‘high bleeding risk’ patient who should be scheduled for early follow-up (indicator 01MQI2).

Based on a Patient-Centered Outcomes Research Institute (PCORI) systematic review and evidence appraisal, the best validated bleeding risk score is the HAS-BLED score. While stroke and bleeding risks track each other, the evidence shows that a formal bleeding risk score (HAS-BLED) is superior to stroke risk scores (e.g. CHADS2, CHA2DS2-VASc) for assessing bleeding risk. A strategy for dynamic bleeding risk assessment using the HAS-BLED score has been shown to reduce bleeding risk and to increase oral anticoagulation (OAC) use.

Given that renal function has implications for both stroke and bleeding risk, as well as prescriptions of OAC (choice of agent and dose),
Asymptomatic AF is associated with higher risk of stroke and mortality compared with symptomatic AF. An observational study investigated that the application of standard care treatments for subclinical AF are likely to represent a cost-effective use of resources. Thus, screening programmes for AF should be considered for thromboprophylaxis (indicator 01SQI1).

To that end, atrial high-rate episodes (AHRE) detected by implantable cardiac devices, which may represent asymptomatic AF, should be investigated. Ideally, AHRE detection should be performed at every device interrogation, including home monitoring transmission as it determines whether or not subclinical AF is confirmed and whether anticoagulation and/or regular follow-up is warranted (indicator 01SQI2). Furthermore, the detection of previously unknown AF following has relevant implications for secondary prevention. Thus, it is recommended to screen for AF following a cryptogenic stroke (indicator 01SQI3).

However, screening for AF should be accompanied by confirming the diagnosis by traditional means, such as by 12-lead ECG or >30 s recording of a single-lead ECG, Holter monitor, or event recorder (indicator 01SQI4). Following the diagnosis, a dialogue between treating physician and patient to ensure patient involvement in decision making is recommended. Thus, the indicator 01SQI5 captures shared decision making when deciding on the treatment strategy.

Domain 2: Anticoagulation

Oral anticoagulation is an essential part of AF management, and the ESC 2020 Guidelines recommend oral anticoagulation for stroke prevention in males with CHA2DS2-VASc scores of ≥1, and in females with scores of ≥2. Accordingly, it is important that a set of QIs to regularly assess the proportion of patients with CHA2DS2-VASc score ≥1 in males, >2 in females who are offered stroke prevention (indicator 02MQI1), as well as the inappropriate use of long-term antithrombotic therapy in low-risk patients (CHA2DS2-VASc score 0 in males, and 1 in females) (indicator 02MQI2).

Assessment of the quality of anticoagulation is also important. If patients are taking a non-vitamin K antagonist oral anticoagulant (NOAC), the label-adherent dose of the respective NOAC should

Domain 2: Anticoagulation

Oral anticoagulation is an essential part of AF management, and the ESC 2020 Guidelines recommend oral anticoagulation for stroke prevention in males with CHA2DS2-VASc scores of ≥1, and in females with scores of ≥2. Accordingly, it is important that a set of QIs to regularly assess the proportion of patients with CHA2DS2-VASc score ≥1 in males, >2 in females who are offered stroke prevention (indicator 02MQI1), as well as the inappropriate use of long-term antithrombotic therapy in low-risk patients (CHA2DS2-VASc score 0 in males, and 1 in females) (indicator 02MQI2).

Assessment of the quality of anticoagulation is also important. If patients are taking a non-vitamin K antagonist oral anticoagulant (NOAC), the label-adherent dose of the respective NOAC should
be prescribed and the proportion appropriately dosed is indicative of quality of care. Regular audits should be performed to ensure that under- or over-dosing of the respective NOAC does not occur, given the association with worse outcomes. Oral anticoagulation can also be offered as a well-managed vitamin K antagonist (VKA) (e.g. warfarin, acenocoumarol, phenprocoumon, etc.), with a high (>70%) time in therapeutic range (TTR) calculated using the Rosendaal method, with international normalized ratio (INR) 2.0–3.0. High TTR has been associated with low rates of stroke and bleeding, as well as reduced mortality. Thus, the proportion of patients with TTR ≥ 70% is a good QI of anticoagulation control for patients on VKA.

**Domain 3: Rate control**

Rate control is an integral part of AF management, and may be sufficient to improve AF-related symptoms. In patients for whom a decision has been made not to restore or maintain sinus rhythm (permanent AF), rate control can be achieved by rate-limiting medications (e.g. beta-blockers, digoxin, diltiazem, or verapamil). The use of antiarrhythmic drugs, such as amiodarone, dronedarone, or sotalol, for rate control is not recommended when no attempt to restore sinus rhythm is planned. The use of certain types of rate control drugs, such as nondihydropyridine calcium-channel blockers can influence outcomes in patients with heart failure and/or left ventricular ejection fraction (LVEF) <40%<sup>36–44</sup>. Thus the indicator 03SQI1 evaluates the inappropriate use of nondihydropyridine calcium-channel blockers in AF patients with concomitant reduced LVEF.<sup>65</sup>

### 03MQI1: Proportion of patients with permanent AF (i.e. where no attempt to restore sinus rhythm is planned), who are inappropriately prescribed antiarrhythmic drugs

**Numerator:** Number of patients with permanent AF who are prescribed one or more antiarrhythmic drugs for rhythm control.

**Denominator:** Number of patients with permanent AF.

### 03SQI1: Proportion of patients with LVEF <40% who are inappropriately prescribed non-dihydropyridine calcium-channel blockers

**Numerator:** Number of patients with AF who have LVEF <40% and/or decompensated heart failure, and are inappropriately prescribed non-dihydropyridine calcium-channel blockers.

**Denominator:** Number of patients with AF who have LVEF <40% and/or decompensated heart failure.

**Domain 4: Rhythm control**

Rhythm control therapy is central for the reduction and/or relief of AF symptoms and improvement of patients’ quality of life (QoL). Given that the safety profile of an antiarrhythmic agent is a major determinant of treatment choice, the Working Group selected QIs based on this notion. Certain antiarrhythmic drugs have major contraindications that increase the likelihood of adverse events, such as the presence of structural heart disease (for instance, ischaemic heart disease, LV dysfunction, and/or significant cardiomyopathy) for class IC antiarrhythmic drugs (indicator 04MQI1), and advanced chronic kidney disease for dofetilide and sotalol (indicator 04MQI2) (REF ESC 2020 GLs).

Catheter ablation is effective in maintaining sinus rhythm and improving symptoms in patients with AF<sup>58–80</sup>. Ablation is generally recommended in symptomatic patients after failure or intolerance to one class I or class III antiarrhythmic drugs (indicator 04MQI3). Several factors may influence the decision between conservative and invasive treatment for AF, including age, AF duration, left atrial size, comorbidities, and substrate visualization by cardiac magnetic resonance<sup>81–87</sup>. Ultimately, patient preference supported by treating physician recommendation are the main determinants of the type of rhythm control strategy employed.<sup>23,30</sup>
A QI to assess the complete electrical isolation (entrance and exit block) of the pulmonary veins (PVs) during AF catheter ablation procedures (indicator 04SQI1) was developed given that this is the desired outcome of AF ablation. In addition, the indicator 04SQI2 assesses the consideration of cardioversion for patients with new-onset persistent AF.

**Domain 5: Risk factor management**

The Working Group considered the role of risk factors in AF and developed a QI accordingly (indicator 05MQI1). Recent research has highlighted the potential benefits of risk factor management as upstream non-invasive therapy to lower the risk of AF progression and recurrence. A large proportion of these risk factors are lifestyle related and, therefore, are amenable to be targeted and modified. It is recommended that in the assessment of AF patients, practitioners actively evaluate and document these modifiable risk factors, such as smoking, obesity, physical inactivity, alcohol intake, sleep apnoea, hypertension, and poor glycaemic control. Where necessary, appropriate education, support, and intervention (e.g. smoking cessation options, continuous positive airway pressure (CPAP), exercise prescription, etc.) can be provided to the patient to address the risk factors that may improve health outcomes.

**05MQI1: Proportion of patients who have their modifiable risk factors identified**

- **Numerator:** Number of patients with AF who have their modifiable risk factors (e.g. blood pressure, obesity, obstructive sleep apnoea, alcohol excess, lack of exercise, poor glycaemic control, and smoking) identified.
- **Denominator:** Number of patients with AF.

**Domain 6: Outcome measures**

**Consequences of the disease**

Reducing the risk of death is one of the primary aims of AF management, and healthcare in general. As such, annual assessment of crude and risk-adjusted rates of all-cause mortality is recommended (indicator 06.1MQI1). Risk adjustment should, as a minimum, consider age, sex, and comorbidities. In addition, the inclusion of lifestyle factors (e.g. smoking status, body mass index, physical activity, and alcohol intake) provides a better insight to the adjustment process. Given that ischaemic stroke is a major complication of AF and that most AF patients (CHA2DS2-VASc score of ≥1 in men and ≥2 in women) will be eligible for stroke prevention, the overall and risk-adjusted annual incidence of stroke and, separately, transient ischaemic attack should be recorded as a QI (indicator 06.1MQI2). Other outcomes measures, which may provide an illustration of the quality of AF care, include the rate of cardiovascular mortality (indicator 06.1SPQ1), cardiovascular hospitalization (indicator 06.1SQI2), overall thrombo-embolic events (indicator 06.1SQI3), and clinician-reported AF symptom status (indicator 06.1SQI4).

In the ABC pathway of AF management mentioned earlier, the ‘B’ component pertains to ‘better’ symptom management. Many AF patients may not be overtly symptomatic. However, assessment of AF-related symptoms can be a useful subjective measure of both the clinical consequences of AF and the success of rate- and rhythm control treatment from the patients’ perspective. Using a validated method, such as the modified European Heart Rhythm Association (EHRA) score, is recommended to assess symptom status (indicator 06.1SPQ1).

**Complications of treatment**

OAC treatment conveys an increased risk of major bleeding. However, bleeding complications can also occur in the absence of OAC treatment. The incidence of life-threatening or major bleeding events, defined by the International Society of Thrombosis and Haemostasis criteria, should be reported annually as a QI (indicator 06.2MQI1). The annual rate of haemorrhagic stroke is of particular importance (indicator 06.2SQI1) and should be documented as a QI.
### Quality indicators for the care and outcomes of adults with atrial fibrillation

**Patient-reported outcomes**

PROMs are important determinants of the patients’ perceived quality and success of treatment. The 2020 ESC Guidelines recommend that patient-reported outcomes should be routinely collected to measure treatment success and improve patient care. Health-related quality of life (HRQoL) is considered the main QI and should be assessed at baseline and at follow-up visits.

Several validated tools are available to measure general HRQoL, such as the Short-Form 12 (SF-12) and the Atrial Fibrillation Effect on Quality of Life (AFEQT) or the Atrial Fibrillation Severity Scale (AFSS). Both the SF-12 and the AFEQT are validated, psychometrically robust assessments of HRQoL, and are recommended by the International Consortium of Healthcare Outcome Measures (ICHOM) for AF.

Regardless of which validated tool is employed, it is important that the same PROM is used consecutively to assess HRQoL to permit temporal comparison of scores and allow the determination of response to treatment.

Determining the impact of AF and its treatment on the patient are important considerations in the management of AF and may contribute to patient and healthcare provider decisions regarding continuation/cessation of certain treatments and/or initiating alternatives. In addition to HRQoL, the assessment of other PROMs, such as patient-reported symptom status, physical functioning, emotional well-being, and cognitive function, could also be considered. The assessment of cognitive function is recommended at baseline and once to twice annually, while the assessment of cognitive function is recommended at baseline and annually thereafter, given that it may show little variation over a shorter period of time. Validated tools, such as those recommended by the ICHOM for AF (PROMIS Global Health for physical and emotional well-being, and PROMIS for cognitive function) can be used.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Numerator</th>
<th>Denominator</th>
</tr>
</thead>
<tbody>
<tr>
<td>06.2MQI1: Annual rate of life-threatening or major bleeding events</td>
<td>Number of patients with AF on anticoagulation who had documented life-threatening or major bleeding events during the measurement duration.</td>
<td>Number of patients with AF on anticoagulation.</td>
</tr>
<tr>
<td>06.2MQI2: Annual rate of procedure-related 30-day mortality</td>
<td>Number of patients with AF who died due to an invasive procedure for AF management during the measurement duration.</td>
<td>Number of patients with AF treated with invasive procedures.</td>
</tr>
<tr>
<td>06.2MQI3: Annual rate of procedure-related major complications or drug-related serious adverse events</td>
<td>Number of patients with AF who had documented major procedural complications and/or drug-related serious adverse events during the measurement duration.</td>
<td>Number of patients with AF.</td>
</tr>
<tr>
<td>06.3SQI1: Proportion of patients with health-related quality of life assessment</td>
<td>Number of patients with AF who have their health-related quality of life assessed at the time of diagnosis and least annually afterwards using a validated instrument.</td>
<td>Number of patients with AF.</td>
</tr>
<tr>
<td>06.3SQI2: Proportion of patients with physical function assessment</td>
<td>Number of patients with AF who have their physical function assessed at the time of diagnosis and at every follow-up appointment using a validated instrument.</td>
<td>Number of patients with AF.</td>
</tr>
<tr>
<td>06.3SQI3: Proportion of patients with emotional well-being (including anxiety and depression) assessment</td>
<td>Number of patients with AF who have their emotional well-being (including anxiety and depression) assessed at the time of diagnosis and at every follow-up appointment using a validated instrument.</td>
<td>Number of patients with AF.</td>
</tr>
<tr>
<td>06.3SQI4: Proportion of patients with cognitive function assessment</td>
<td>Number of patients with AF who have their cognitive function assessed at the time of diagnosis and at least annually afterwards using a validated instrument.</td>
<td>Number of patients with AF.</td>
</tr>
</tbody>
</table>
Comparison with other quality metrics

Table 4 shows a comparison between the 2020 ESC QIs for AF and quality metrics from other professional organizations, such as the American College of Cardiology and the American Heart Association (ACC/AHA), the National Institute for Health and Care Excellence (NICE), the Canadian Cardiovascular Society (CCS), and ICHOM. There are major differences between the process QIs proposed here, and those developed by ACC/AHA, NICE, and CCS. These differences may be explained by the variation in clinical practice guidelines endorsed by different societies and/or local needs to address certain gaps in AF care. Outcome QIs were relatively similar compared to those proposed by ICHOM.

Discussion

Evaluating the quality of care delivered and measuring meaningful outcomes of both the condition and its treatment have become an essential element of modern healthcare. AF is the most common cardiac arrhythmia, affecting 2–4% of the population, and is a major cause of significant morbidity. Although evidence suggests that adherence to guideline-recommended therapies for AF is associated with improved outcomes, data from AF registries continue to show room for improvement and significant geographical variation in AF quality of care and outcomes. QIs have been developed to evaluate the quality of AF care, and significant geographical variation in AF quality of care and outcomes. QIs have been developed to evaluate the quality of AF care, and more recently, outcome QIs were proposed in the initial set of candidate QIs. The term ‘outcome measures’ was used separately and in different variations in the systematic review search strategy (APPENDIX 3). The outcome QIs selected are applicable to all domains of AF care, and are in line with the recent ICHOM recommendations.

One important type of outcome QIs is PROMs, which are increasingly used in everyday practice. Although a structured methodology for developing and reporting PROMs exists, there is uncertainty around the best instruments to collect such measures. By defining specific PROMs and recommending tools for their measurement, the Working Group hopes to promote PROMs use in a systematic manner. However, developing outcome QIs to measure the results of PROMs assessment, as well as their temporal trends may not be feasible in contemporary practice. Thus, process QIs to measure and encourage PROMs assessment were developed instead.

The Working Group acknowledges that high-quality evidence supporting PROMs use is limited, widely accepted tools to collect them are lacking, and little experience exists on how PROMs can guide AF treatment decisions. The same argument can be levelled at shared decision making in AF management. However, these aspects of AF care were deemed essential by the Working Group, thus QIs for PROMs and shared decision making were developed.

The patient’s perspective is a fundamental element of optimal AF care given that most therapies are aimed at improving patients’ symptoms, well-being, and overall QoL. Measuring patient-centred outcomes in a standardized way may allow comparison of performance, enable clinicians to learn from each other, and improve the care we provide to our patients. However, further validation of the tools and methods used to collect the patient’s perspective in routine clinical practice is needed. As such, these tools may be used to guide the development of, and the effect of, treatment strategies for AF patients.

The methodology used for the selection of QIs has limitations. We relied on expert opinion to arrive at the final set of QIs following the comprehensive systematic review of the literature. A different panel of experts may have selected different QIs. We addressed this challenge by using the modified Delphi method, and by involving AF specialists with different areas of expertise, as well as patients and representatives from AF patient associations.

Another challenge is that, if considered in isolation, QIs may cause some unintended consequences, such as anticoagulation prescription for patients with very high bleeding risk or recommending catheter ablation for frail patients with major risk factors for AF recurrence. We have sought to circumvent this issue by clearly defining eligible patients for each QI and specifying relevant exclusions. The suggested QIs are intended to drive holistic patient assessments and tailor treatments to individual patients to improve patient care. More refinement of these QIs and/or their definitions may be needed in the future when more ‘real-world’ and feasibility data become available.
### Table 4  Comparison between the 2020 ESC AF QIs and the ACC/AHA, NICE, CCS, and ICHOM indicators for AF

<table>
<thead>
<tr>
<th>Domain</th>
<th>2020 ESC QIs</th>
<th>2016 ACC/AHA</th>
<th>2017 NICE</th>
<th>2019 CCS</th>
<th>2020 ICHOM</th>
</tr>
</thead>
</table>
| Patient assessment (at baseline and follow-up) | CHA2DS2-VASc score risk assessment  
Bleeding risk assessment  
Serum creatinine  
Screening people ≥65 years of age with risk factors for AF  
Evaluating AHREs detected on implantable cardiac devices  
Screening for AF after cryptogenic stroke  
ECG documentation of AF diagnosis  
Shared decision making when deciding treatment strategy | | | | | |
| Anticoagulation                 | Anticoagulation with CHA2DS2-VASc score ≥1 for men and ≥2 for women  
Inappropriate anticoagulation with CHA2DS2-VASc score 0 for men and 1 for women  
Appropriate anticoagulation (TTR≥70% or appropriate NOAC dose) | | | | | |
| Rate control                    | Inappropriate AAD use for patients with permanent AF  
Inappropriate non-dihydropyridine CCBs use for patients with LVEF<40% | | | | | |
| Rhythm control                  | Inappropriate class IC AAD use for patients with structural heart disease  
Inappropriate dofetilide or sotalol use for patients with end-stage kidney disease  
Offering CA for symptomatic paroxysmal or persistent AF after single AAD failure  
Complete PVs electrical isolation during all AF CA procedures  
Cardioversion for patients with new-onset AF | | | | | |
| Risk factor management          | Identifying modifiable risk factors for AF patients | | | | | |
| Outcome: consequences of the disease | Rate of all-cause mortality  
Rate of ischaemic stroke or TIA  
Rate of CV mortality  
Rate of CV hospitalization  
Rate of overall thrombo-embolic event  
Rate of clinician-reported symptom status assessment | | | | | |
| Outcome: consequences of treatment | Rate of life-threatening or major bleeding events  
Rate of procedure-related 30-day mortality  
Rate of procedure-related major complications or drug-related serious adverse events  
Rate of haemorrhagic stroke | | | | | |
| Outcome: patient-reported outcomes | Assessment of health-related quality of life  
Assessment of patient-reported symptom status  
Assessment of physical function  
Assessment of emotional well-being (including anxiety and depression)  
Assessment of cognitive function | | | | | |

AAD, antiarrhythmic drug; ACC, American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; AHRE, atrial high-rate episodes; CA, catheter ablation; CCB, calcium-channel blockers; CCS, Canadian Cardiovascular Society; CV, cardiovascular; ECG, electrocardiogram; ESC, European Society of Cardiology; ICHOM, International Consortium of Healthcare Outcome Measures; LVEF, left ventricular ejection fraction; NICE, National Institute for Health and Care Excellence; NOAC, non-vitamin K oral anticoagulant; PVs, pulmonary veins; QI, quality indicator; TIA, transient ischaemic attack; TTR, time in therapeutic range.

*Green colour represents measures with similar definition; orange represents measures with different definitions; and white represents no corresponding measure.*
It is hoped that the developed set of QIs can be used in a wider quality assessment and improvement initiatives. As such, integration between different efforts (e.g., the ESC Clinical Practice Guidelines and registries), can be achieved and performance gaps addressed. Ongoing projects, such as the European UNified Registries On Heart care Evaluation And Randomized Trials (EuroHeart) of the ESC[160] or the Stroke prevention and rhythm control Therapy: Evaluation of an Educational Programme of the European Society of Cardiology in a cluster-randomized trial in patients with Atrial Fibrillation (STEEER-AF) study[161,164] may favour the use of systematically developed QIs for future AF registries in Europe, which this statement uniquely provides.

Conclusion

This document defines six domains of AF care (patient assessment, anticoagulation, rate control, rhythm control, risk factor management, and outcomes), and provides 17 main and 17 secondary QIs for AF diagnosis and management. For each QI, relevant specifications were described to enhance their use in practice. The recommended set of QIs may facilitate the implementation of, and assess the adherence to, clinical practice guidelines and enable institutions to monitor, compare, and improve quality of care in patients with AF.

Acknowledgements

The authors thank the EHRa Scientific Document Committee: Dr Nikolaos Dagres, Dr. Serge Boveda, Dr. Kevin Vernooij, Prof. Zbigniew Kalarus, Prof. Gulmira Kudaiberdieva, Dr. Georges H. Mairesse, Prof. Valentina Kutyifa, Prof. Thomas Denekel, Prof. Jesper Hastrup Svendsen, Dr. Vassil B. Traykov, Prof. Arthur Wilde, and Prof. Frank R. Heinzel.

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