# **European Society of Cardiology Quality Indicators for Cardiovascular Disease** Prevention: developed by the Working Group for Cardiovascular Disease Prevention Quality Indicators in collaboration with the European **Association for Preventive Cardiology of the European Society of Cardiology** Suleman Aktaa (1) 1,2,3\*, Baris Gencer<sup>4,5</sup>, Elena Arbelo (1) 6,7,8,

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**Aims** 

To develop a set of quality indicators (QIs) for the evaluation of the care and outcomes for atherosclerotic cardiovascular disease (ASCVD) prevention.

## **Methods** and results

The Quality Indicator Committee of the European Society of Cardiology (ESC) formed the Working Group for Cardiovascular Disease Prevention Quality Indicators in collaboration with Task Force members of the 2021 ESC Guidelines on Cardiovascular Disease Prevention in Clinical Practice and the European Association of Preventive Cardiology (EAPC). We followed the ESC methodology for QI development, which involved (i) the identification of the key domains of care for ASCVD prevention by constructing a conceptual framework of care, (ii) the development of candidate QIs by conducting a systematic review of the literature, (iii) the selection of the final set of QIs using a modified Delphi method, and (iv) the evaluation of the feasibility of the developed QIs. In total, 17 main and 14 secondary QIs were selected across six domains of care for ASCVD prevention: (i) structural framework, (ii) risk assessment, (iii) care for people at risk for ASCVD, (iv) care for patients with established ASCVD, (v) patient education and experience, and (vi) outcomes.

Conclusion We present the 2021 ESC QIs for Cardiovascular Disease Prevention, which have been co-constructed with EAPC using the ESC methodology for QI development. These indicators are supported by evidence from the literature, underpinned by expert consensus and aligned with the 2021 ESC Guidelines on Cardiovascular Disease Prevention in Clinical Practice to offer a mechanism for the evaluation of ASCVD prevention care and outcomes.

Keywords Cardiovascular disease • Atherosclerosis • Preventive cardiology • Quality indicators • Clinical practice guidelines

# Introduction

Atherosclerotic cardiovascular disease (ASCVD) is a leading cause of mortality globally. Evidence suggests that large proportions of individuals at high cardiovascular disease risk have unhealthy lifestyles and inadequate control of blood pressure, lipids, and diabetes.<sup>2,3</sup> Although the advent of effective treatments for ASCVD has led to a reduction in morbidity and mortality, 4 future challenges involve improving adherence to guideline-recommended therapies, optimizing patients' risk factors and modifying lifestyle behaviours to prevent the development and progression of ASCVD.<sup>5</sup> To that end, international registries such as the European Action on Secondary and Primary Prevention by Intervention to Reduce Events (EUROASPIRE) have demonstrated gaps in care delivery and geographic variation in clinical practice.<sup>6</sup>

Quality indicators (QIs) are tools that may provide a means to evaluate the implementation of guideline-recommended therapies. The US federal Agency for Healthcare Research and Quality (AHRQ) has developed prevention QIs for a range of clinical conditions, some of which are relevant to ASCVD.8 These indicators have been used to describe temporal and spatial patterns of the outcomes of preventive care. 9,10 However, they do not include structural and process components of care, which are known to be more relevant to the delivery of care. 11 Professional Societies including the European Association of Preventive Cardiology (EAPC) have also developed quality measures for aspects of ASCVD. 12-20 Each focus on particular elements of ASCVD prevention (primary prevention, <sup>16</sup> hypertension, <sup>15</sup> dyslipidaemia, <sup>17</sup> and cardiac rehabilitation <sup>12,14,18,20</sup>) or are directed to a particular clinical setting, such as primary care. 13,19 However, there is no single contemporary set of Qls that encapsulates the wider aspect of cardiovascular disease prevention to allow a holistic evaluation of care.

Therefore, in parallel with the development of the 2021 European Society of Cardiology (ESC) Guidelines on Cardiovascular Disease Prevention in Clinical Practice, the ESC Quality Indicator Committee formed the Working Group for Cardiovascular Disease Prevention Qls in collaboration with EAPC to develop a comprehensive set of Qls for the prevention of ASCVD. This document presents the 2021 ESC QIs for ASCVD prevention in line with other ESC Clinical

Practice Guidelines. 21,22 The ESC and EAPC anticipate that such Qls may facilitate the standardized evaluation of ASCVD prevention care and outcomes, and therefore identify where improvement initiatives may be used to reduce the burden of cardiovascular disease.

## **Methods**

We followed the ESC methodology for the development of QIs for the quantification of cardiovascular care and outcomes. In brief, this involves (i) the identification of the key domains of ASCVD preventive care by constructing a conceptual framework of care delivery, (ii) the development of candidate QIs by conducting a systematic review of the literature, (iii) the selection of the final set of QIs using a modified Delphi method, and (iv) the evaluation of the feasibility of the developed Ols. The ESC Ols include main and secondary indicators. The main indicators were deemed to have higher validity and feasibility by the Working Group members and thus may be used for performance measurement across regions and over time. Both the main and secondary QIs may be used for local quality improvement activities.<sup>7</sup>

# **Members of the Working Group**

The Working Group comprised Task Force members of the 2021 Guidelines on Cardiovascular Disease Prevention in Clinical Practice, EAPC representatives, patients, and international experts in ASCVD prevention, as well as members of the ESC Quality Indicator Committee. A series of virtual meetings were convened between the members of the Working Group from December 2020 until June

# Target population and domains of care

The initial phase of the development process involved the identification of the 'target population' and the key domains of ASCVD preventive care. The 'target population' for whom the QIs are intended was defined as patients with established or high risk for ASCVD, and the key domains of care were selected accordingly by constructing a conceptual illustration of the multi-layered care pathway for this group of patients.<sup>7</sup> To facilitate the operationalization of the developed QIs, ASCVD was defined as 'atherosclerotic clinical conditions, including acute/chronic coronary syndrome, coronary artery disease documented by computed tomography (CT)/invasive coronary angiography, coronary or other arterial revascularization, stroke, transient ischaemic attack, documented carotid, aortic, peripheral artery disease, or atherosclerotic renovascular disease'. Patients at high risk for ASCVD were defined as those with no documented ASCVD diagnosis, but with diabetes mellitus, hypertension, moderate-severe renal disease, smoking history, familial hyperlipidaemia or other lipid disorder and who were deemed at high or very high risk for ASCVD according to the 2021 ESC Guidelines on Cardiovascular Disease Prevention in Clinical Practice.<sup>5</sup>

Specifications were defined for each of the Qls. These included a numerator, which is the group of patients for whom the Ql was delivered, and, with the exception of the structural Qls, a denominator, which is the group of patients eligible for the Ql. We also defined a measurement period (the time point at which the assessment is performed) and a measurement duration (the time frame needed for enough cases to be collected). Structural Qls are designed as binary measurements evaluating the availability of services in healthcare centres or units involved in the management of patients with established or high risk for ASCVD.

## 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 statement (Supplementary material online, *Appendix Table A1*).<sup>23</sup> We searched two online bibliographic databases; MEDLINE and Embase via OVID (Wolters Kluwer, Alphen aan den Rijn, Netherlands). The initial search strategy was developed in MEDLINE using keywords and medical subject headings (MeSH) terms, such as 'primary prevention', 'secondary prevention', 'cardiac rehabilitation', 'health education', 'smoking cessation', and 'exercise' (for full list see Supplementary material online, *Appendix Table A2*). Further potential articles were identified using citation-searching and hand-searching of the references of identified articles.

We only included the primary publication of randomized controlled trials, and included the main publications of major trials from which our search obtained only sub-studies. We excluded systematic reviews, meta-analyses, editorials, letters, and conference proceedings. The search was restricted to English language reports and publication dates between 01 January 2016 and 08 March 2021. The search was restricted to the period after 2016 because this year corresponds to the publication of the previous ESC Guidelines on Cardiovascular Disease Prevention in Clinical Practice, thus ensuring current validity and applicability.<sup>24</sup>

## Eligibility criteria

We included articles fulfilling the following criteria: (i) the study population was adult patients (≥18 years old) with established or with risk factors for ASCVD, (ii) the study defined an intervention (structural or process aspect of preventive care) for which at least one outcome measure was reported, (iii) the outcome measures were hard endpoints (e.g. mortality, re-admission) or patient-reported outcomes (e.g. quality of life), (iv) the study provided definitions for the

intervention and outcome measure(s) evaluated, and (v) the study was a peer-reviewed randomized controlled trial. No restriction was placed on sample sizes, but studies which reported surrogate outcomes (e.g. biomarkers) as the main endpoints were excluded.

#### Study selection

EndNote X9 (Clarivate Analytics, London, UK) was used for reference management and for duplicates removal. Each retrieved study was independent evaluated by two reviewers (S.A. and C.D., B.G. and I.D., or E.A. and M.H.) against prespecified inclusion criteria. Disagreements were resolved through discussions and full-text review of the article.

## Quality assessment and data extraction

Studies that met the eligibility criteria were included in the initial phase of the review. The broad inclusion was important to ensure that a list of initial (candidate) Qls was representative of a wide range of preventive care. For each included study, both the intervention studied and the outcome measure(s) that were evaluated were extracted. The variables were then classified according to their domain of care and to the type of the measurement (structural, process, or outcome). Definitions of the data items extracted were also obtained when provided in the studies.

#### Clinical practice guidelines and existing QIs

In addition to the systematic review, Clinical Practice Guidelines pertinent to the prevention of ASCVD were reviewed. The goal of the Clinical Practice Guidelines review was to assess the suitability of their recommendations with the strongest association with benefit and harm (Class I and III, respectively) against the ESC criteria for QIs (Supplementary material online, Appendix Table A3). Existing QIs and 'performance measures' relevant to ASCVD prevention 11–20 were considered as candidate QIs using the same criteria.

## **Data synthesis**

#### **Modified Delphi process**

The modified Delphi approach was used to evaluate the candidate QIs derived from the literature review. The Working Group members were made aware of the ESC criteria for QI development (Supplementary material online, Appendix Table A3) to standardize the voting process, and each candidate QI was ranked by each panellist on a 9-point ordinal scale for both validity and feasibility using an online questionnaire. In total, two rounds of voting were conducted, with a number of teleconferences after each round to discuss the results of the vote and to address any concerns, questions, or ambiguities.

## **Analysing voting results**

The 9-point ordinal scale used for voting implied that ratings of 1-3 meant that the QI is not valid/feasible; ratings of 4-6 meant that the QI is of an uncertain validity/feasible; and ratings of 7-9 meant that the QI is valid/feasible. For each candidate QI, the median and the mean deviation from the median were calculated to evaluate the central tendency and the dispersion of the votes. Indicators, with median scores  $\geq 7$  for validity,  $\geq 4$  for feasibility, and with minimal dispersion, were included in the final set of QIs. The candidate QIs that met the numerical threshold fo inclusion in the first voting round were

defined as main Qls, whilst those that met the inclusion criteria after the second round of voting were defined as secondary indicators.

## **Results**

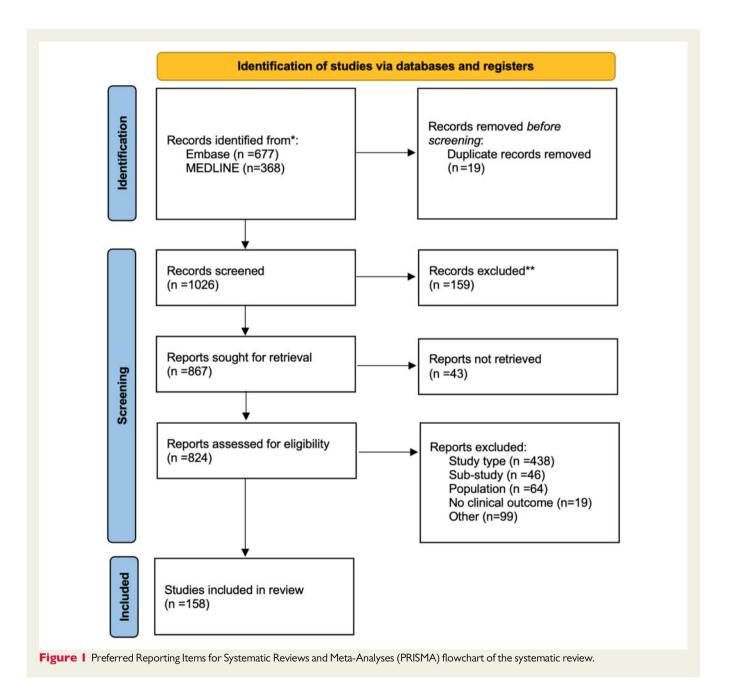
## **Domains of ASCVD prevention**

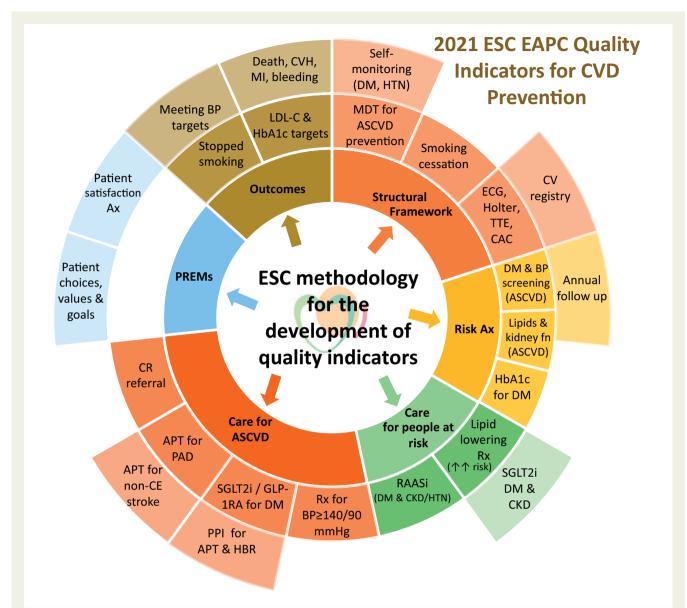
The Working Group identified six domains of preventive care for ASCVD during the early phases of the development process. These domains capture the spectrum of ASCVD prevention care and outcomes irrespective of the healthcare institution at which the performance measurement is taking place, and in line with the EAPC Core Curriculum for Preventive Cardiology.<sup>31</sup> The domains are:

(i) structural framework, (ii) risk assessment, (iii) care for people at risk for ASCVD, (iv) care for patients with established ASCVD, (v) patient education and experience, and (vi) outcomes.

## Systematic review results

The literature search retrieved 1026 articles, of which 158 met the inclusion criteria (*Figure 1*). In total, 75 potential Qls were extracted from the included studies. Of those, 51 candidate Qls were included in the first Delphi round. The remaining 24 indicators overlapped with other ESC Qls, such as those for acute myocardial infarction, <sup>32</sup> atrial fibrillation, <sup>33</sup> heart failure, or cardiac pacing, <sup>34</sup> and were, thus, removed.





**Figure 2** 2021 ESC EAPC Quality Indicators for ASCVD Prevention. ACR, albumin creatinine ratio; APT, antiplatelet therapy; ASCVD, atherosclerosis cardiovascular disease; Ax, assessment; BP, blood pressure; CAC, coronary calcium scoring; CE, cardioembolic; CKD,chronic kidney disease; CR, cardiac rehabilitation; CV, cardiovascular; CVH, cardiovascular hospitalization; DM, diabetes mellitus; ECG, electrocardiogram; eGFR, estimated glomerular filtration rate; GLP-1 RA, glucagon-like peptide-1 receptor agonists; HbA1c, glycated haemoglobin; HBR, high bleeding risk; HTN, hypertension; LDL-C, low-density lipoprotein cholesterol; MDT, multidisciplinary team; MI, myocardial infarction; PAD, peripheral artery disea; PPI, proton pump inhibitors; PREMs, patient-reported experience measures; RAASi, renin–angiotensin–aldosterone system inhibitors; Rx, treatment; SGLT2i, sodium/glucose cotransporter-2 inhibitors; TTE, transthoracic echocardiogram.

# **Modified Delphi results**

Following the first round of voting, 23/51 (45%) candidate QIs were excluded; 17/51 (33%) met the inclusion threshold and thus were included as main QIs. The remaining 11/51 (22%) were deemed inconclusive and were carried to the second voting round. The excluded QIs (N = 23) were reviewed by the Working Group in subsequent meetings and agreement reached to reconsider modified versions of 16/23 (70%) in the second round of voting. As such, a total of 27 QIs (11 inconclusive and 16 modified) were included in the second

Delphi round, following which 14/27 (52%) were included as secondary QIs. Figure 2 shows the main and the secondary indicators of the 2021 ESC EAPC Quality Indicators for ASCVD Prevention across six domains of care.

# **Quality indicators**

#### Domain 1: Structural framework

This domain evaluates the characteristics of the centres that provide preventive care for patients with established or high risk for ASCVD. While the association between structural Qls and favourable patient

## Table I 2021 European Society of Cardiology quality indicators for cardiovascular disease prevention

#### Domain 1. Structural framework

**Main 1.1** Healthcare centres should have access to a multidisciplinary team dedicated to CVD prevention who deliver lifestyle modification (including diet, exercise, and alcohol consumption) advice and medication adherence counselling for patients with risk factors for or established ASCVD.

**Numerator**: Healthcare centres or units involved in the management of patients with established or high risk for ASCVD that have a dedicated multi-disciplinary team.

Main 1.2 Healthcare centres should have access to a smoking cessation programme for patients with risk factors for or established ASCVD.

**Numerator**: Healthcare centres or units involved in the management of patients with established or high risk for ASCVD that have access to a smoking cessation programme.

Main 1.3 Healthcare centres should have access to 12-lead ECG, ambulatory ECG Holter monitoring, transthoracic echocardiogram, and CT calcium scoring to facilitate the assessment of patients with established or high risk for ASCVD.

**Numerator**: Healthcare centres or units involved in the management of patients with established or high risk for ASCVD that have access to 12-lead ECG, ambulatory ECG Holter monitoring, transthoracic echocardiogram, and CT calcium scoring.

**Secondary 1.1** Healthcare centres should participate in a registry or common database to record clinical data relevant to cardiovascular risk (BMI, BP, LDL-C, HbA1c, and renal function) for patients with established or high risk for ASCVD.

**Numerator**: Healthcare centres or units involved in the management of patients with established or high risk for ASCVD that participate in a registry or common database to record patients' BMI, BP, LDL-C, HbA1c, and renal function.

**Secondary 1.2** Healthcare centres should have available written protocols that encourage and facilitate disease self-measurement for patients with hypertension and/or diabetes.

**Numerator**: Healthcare centres or units involved in the management of patients with established or high risk for ASCVD that have available written protocols to encourage and facilitate disease self-measurement for patients with hypertension and/or diabetes.

#### Domain 2. Risk assessment

Main 2.1 Proportion of patients with established ASCVD who have their kidney function (eGFR and albuminuria) checked at least once and if had new treatment or event.

Numerator: Patients with established ASCVD who have their eGFR and albuminuria checked at least once and if had new treatment or event.

**Denominator**: Patients with established ASCVD.

Main 2.2 Proportion of patients with established ASCVD who have their lipid profile checked at least once and if had new treatment or event.

Numerator: Patients with established ASCVD who have their lipid profile checked at least once and if had new treatment or event.

**Denominator**: Patients with established ASCVD.

Main 2.3 Proportion of patients with established ASCVD who are screened for diabetes (with fasting blood glucose and/or HbA1c) at least annually.

**Numerator**: Patients with established ASCVD who are not known to have diabetes and have their fasting blood glucose and/or HbA1c checked at least annually.

**Denominator**: Patients with established ASCVD who are not known to have diabetes.

Main 2.4 Proportion of patients with established ASCVD who are screened for hypertension at least annually.

**Numerator**: Patients with established ASCVD who are not known to have hypertension and have their BP measured<sup>a</sup> at least annually.

**Denominator**: Patients with established ASCVD who are not known to have hypertension.

Main 2.5 Proportion of patients with diabetes who have their HbA1c checked at least annually.

Numerator: Patients with diabetes who have their HbA1c checked at least annually.

**Denominator**: Patients with diabetes.

**Secondary 2.1** Proportion of patients with established or high risk for ASCVD who have follow up at least annually to assess and address cardiovascular risk factors.

Numerator: Patients with established or high risk for ASCVD who have follow-up at least annually to assess and address cardiovascular risk factors.

**Denominator**: Patients with established or high risk for ASCVD.

#### Domain 3. Care for people at risk for ASCVD

**Main 3.1** Proportion of patients 40–70 years of age with very high risk for ASCVD and a baseline LDL- $C \ge 1.8 \, \text{mmol/L}$  ( $\ge 70 \, \text{mg/dL}$ ) who are prescribed lipid lowering therapy.

**Numerator**: Patients between 40 and 70 years of age with very high risk for ASCVD and a baseline LDL-C  $\geq$  1.8 mmol/L ( $\geq$ 70 mg/dL) who are prescribed lipid lowering therapy.

**Denominator**: Patients between 40 and 70 years of age with very high risk for ASCVD and a baseline LDL-C ≥ 1.8 mmol/L (≥70 mg/dL) who have no contraindication, refusal, or history of intolerance to lipid lowering therapy.

**Main 3.2** Proportion of patients with diabetes and chronic kidney disease or hypertension who are prescribed renin–angiotensin–aldosterone system inhibitors.

#### Table I Continued

Numerator: Patients with diabetes and chronic kidney disease or hypertension who are prescribed renin-angiotensin-aldosterone system inhibitors.

**Denominator**: Patients with diabetes and chronic kidney disease or hypertension who have no contraindication, refusal, or history of intolerance to renin—angiotensin—aldosterone system inhibitors.

Secondary 3.1 Proportion of patients with type 2 diabetes and chronic kidney disease who are prescribed SGLT2 inhibitors.

Numerator: Patients with type 2 diabetes and chronic kidney disease who are prescribed SGLT2 inhibitors.

**Denominator**: Patients with type 2 diabetes and chronic kidney disease who have no contraindication, refusal, or history of intolerance to SGLT2 inhibitors.

#### Domain 4. Care for patients with established ASCVD

Main 4.1 Proportion of patients with established ASCVD and type 2 diabetes who are prescribed SGLT2 inhibitor or GLP-1RA.

Numerator: Patients with established ASCVD and type 2 diabetes who are prescribed SGLT2 inhibitor or GLP-1RA.

**Denominator**: Patients with established ASCVD and type 2 diabetes who have no contraindication, refusal, or history of intolerance to SGLT2 inhibitor and GLP-1RA.

Main 4.2 Proportion of patients with symptomatic peripheral artery disease who are prescribed appropriate antiplatelet therapy.

Numerator: Patients with symptomatic peripheral artery disease who are prescribed appropriate antiplatelet therapy.<sup>b</sup>

**Denominator**: Patients with symptomatic peripheral artery disease who have no contraindication, refusal, or history of intolerance to antiplatelet therapy, no indication for anticoagulation, and have not undergone a revascularization procedure within 1 month.

Main 4.3 Proportion of patients with established ASCVD and BP ≥140/90 mmHg who are prescribed BP lowering treatment.

Numerator: Patients with established ASCVD and documented BP ≥140/90 mmHg who are prescribed BP lowering treatment.<sup>c</sup>

**Denominator**: Patients with established ASCVD and documented BP ≥140/90 mmHg who have no contraindication, refusal, or history of intolerance to BP lowering treatment.<sup>c</sup>

**Main 4.4** Proportion of patients with established ASCVD who participate in a cardiac rehabilitation programme following an acute cardiovascular event or an elective revascularization procedure.

**Numerator**: Patients with established ASCVD who are referred to cardiac rehabilitation programme at the time of hospital discharge following an acute cardiovascular event or an elective revascularization procedure.

**Denominator**: Patients with established ASCVD following an acute cardiovascular event or an elective revascularization procedure who have not refused referral to cardiac rehabilitation programme.

**Secondary 4.1** Proportion of patients with a non-cardioembolic ischaemic (or embolic of undetermined source) stroke or TIA who are prescribed appropriate antiplatelet therapy.

**Numerator**: Patients with non-cardioembolic ischaemic (or embolic of undetermined source) stroke or TIA who are prescribed appropriate antiplate-let therapy.<sup>d</sup>

**Denominator**: Patients with non-cardioembolic ischaemic (or embolic of undetermined source) stroke or TIA who have no contraindication, refusal, or history of intolerance to antiplatelet therapy, have no indication for anticoagulation, and have not undergone a revascularization procedure within 1 month

Secondary 4.2 Proportion of patients on antiplatelets therapy for ASCVD who have high bleeding risk and are prescribed a proton-pump inhibitor.

Numerator: Patients on antiplatelets therapy for ASCVD and have high bleeding risk<sup>e</sup> who are prescribed a proton-pump inhibitor.

**Denominator**: Patients who are on antiplatelets therapy for ASCVD and have high bleeding risk<sup>e</sup> with no contraindication, refusal, or history of intolerance to proton-pump inhibitor.

## Domain 5. Patient education and experience

**Secondary 5.1** Proportion of patients with established or high risk for ASCVD who have a documented discussion with a member of the multidisciplinary team about their treatment goals, preference, and values at least annually.

**Numerator**: Patients with established or high risk for ASCVD who have a documented discussion about their treatment goals, preference, and values with a member of the multidisciplinary team at least annually.

**Denominator**: Patients with established or high risk for ASCVD.

**Secondary 5.2** Proportion of patients with established or high risk for ASCVD who have their satisfaction about risk factor control captured at least annually.

Numerator: Patients with established or high risk for ASCVD who have their satisfaction about risk factor control captured at least annually.

**Denominator**: Patients with established or high risk for ASCVD.

#### **Domain 6. Outcomes**

#### **Treatment outcomes**

Main 6.1 Proportion of patients with established or high risk for ASCVD who have LDL-C levels at or below that recommended for their estimated cardiovascular risk.

#### Table I Continued

Numerator: Patients with established or high risk for ASCVD who have LDL-C levels at or below that recommended for their estimated cardiovascular risk.

**Denominator**: Patients with established or high risk for ASCVD who have no contraindication, refusal, or history of intolerance to statins, ezetimibe and PCSK9 inhibitors.

Main 6.2 Proportion of patients with established ASCVD and diabetes who have HbA1c levels <7.0% (53 mmol/mol).

Numerator: Patients with established ASCVD and diabetes who have their HbA1c levels <7.0% (53 mmol/mol).

Denominator: Patients with established ASCVD and diabetes who have no contraindication, refusal, or history of intolerance to optimal glycaemic control.

Main 6.3 Proportion of patients with established or high risk for ASCVD who stop smoking.

Numerator: Patients with established or high risk for ASCVD who self-identify as non-smokers.

**Denominator**: Patients with established or high risk for ASCVD who previously self-identified as smokers.

Secondary 6.1 Proportion of patients with established ASCVD who have their BP well-controlled.

**Numerator**: Patients with established ASCVD and hypertension who achieve their target BP levels.<sup>g</sup>

Denominator: Patients with established ASCVD who have hypertension and no contraindication, refusal, or history of intolerance to optimal BP control.

Disease outcomes

Secondary 6.2 Annual rate of all-cause mortality.

Secondary 6.3 Annual rate of cardiovascular mortality.

**Secondary 6.4** Annual rate of cardiovascular hospitalization.

**Secondary 6.5** Annual rate of non-fatal myocardial infarction.

**Treatment complications** 

**Secondary 6.6** Annual rate of bleeding resulting in hospital admission.

<sup>a</sup>Screening for hypertension involves office BP measurement, ambulatory BP monitor, and/or home-measurements using a validated device.

<sup>C</sup>Supplementary material online, *Appendix Table A4*. Blood pressure lowering drugs, with absolute and relative contraindications.

eAccording to the Academic Research Consortium criteria for high bleeding risk.

<sup>f</sup>LDL\_C targets for patients with established ASCVD is <1.4 mmol/L (55 mg/dL) and >50% reduction from baseline. LDL\_C targets for patients with high risk for ASCVD is <1.8 mmol/L (70 mg/dL) and >50% reduction from baseline.

<sup>g</sup>Controlled BP is defined as home-measured/mean ambulatory BP between 120–129/70–80 mmHg for those <65 years of age, and between 130–139/70–80 mmHg for those ≥65 years of age.

ASCVD, atherosclerosis cardiovascular disease; BP, blood pressure; BMI, body mass index; CT, computed tomography; CVD, cardiovascular disease; ECG, electrocardiogram; eGFR, estimated glomerular filtration rate; GLP-1 RA, glucagon-like peptide-1 receptor agonists; HbA1c, glycated haemoglobin; LDL-C, low-density lipoprotein cholesterol; PCSK 9, proprotein convertase subtilisin/kexin type 9; SGLT2i, sodium/glucose cotransporter-2 inhibitors; TIA, transient ischaemic attack.

outcomes is less established compared with process QIs, they may provide a qualitative assessment of the allocations of resources which are needed for the delivery of optimal care. As such, three main and two secondary QIs were included in this domain. The main QIs capture the availability of a multidisciplinary team that is dedicated for the delivery of lifestyle modification advice and medication adherence counselling (Main 1.1), smoking cessation programmes (Main 1.2) and investigations including a 12-lead electrocardiogram, Holter monitoring, transthoracic echocardiography, and CT calcium scoring (Main 1.3) for patients with established or high risk for ASCVD, which are fundamental aspects of cardiovascular disease protection (*Table* 1). 5.21,22

The **Secondary 1.1** QI within the structural framework domain evaluates the healthcare centre's participation in a registry that allows the capture of data relevant to ASCVD given the vital role longitudinal databases have in monitoring patterns of ASCVD risk factors<sup>2</sup> and outcomes.<sup>35</sup> Moreover, disease self-monitoring for patients with diabetes and/or hypertension has a role in improving treatment adherence and control (**Secondary 1.2**) (*Table 1*).<sup>28,29</sup>

#### Domain 2: Risk assessment

The estimation of risk is the cornerstone of ASCVD prevention because it determines the appropriateness of the preventive

interventions needed.<sup>5</sup> For patients with established ASCVD, the annual measurement of kidney function (**Main 2.1**)<sup>36,37</sup> and lipid profile (**Main 2.2**),<sup>27</sup> as well as the screening for diabetes (**Main 2.3**),<sup>28</sup> and hypertension (**Main 2.4**)<sup>29</sup> can help identify those with suboptimal risk factor modification and requiring treatment optimization.<sup>38</sup> Furthermore, glycaemic control in patients with diabetes mellitus who have no history of established ASCVD has prognostic implications on the development of cardiovascular complications, and thus regular monitoring to glycated haemoglobin (HbA1c) in this group of patients may be used as an indicator of care quality (**Main 2.5**).<sup>28</sup> The provision of systems that allow the follow up of patients with established and those with high risk for ASCVD facilitates the implementation of these monitoring/screening measures, but may not be feasible in all healthcare systems (**Secondary 2.1**) (*Table 1*).

#### Domain 3: Care for people at risk for ASCVD

A number of primary preventive measures have a role in delaying the onset of cardiovascular events and in improving clinical outcomes in individuals at high or very high risk for ASCVD.<sup>5</sup> For patients between 40 and 70 years of age at a very high risk for the development of ASCVD (e.g. with diabetes) who have low-density lipoprotein cholestrol levles  $\geq$  1.8 mmol/L ( $\geq$ 70 mg/dL), lipid lowering therapy has shown to be effective in reducing major vascular events (**Main** 

<sup>&</sup>lt;sup>b</sup>Peripheral artery disease is defined as carotid artery stenosis irrespective of clinical symptoms, carotid/lower extremity artery revascularization, or symptomatic lower extremity artery disease. Appropriate antiplatelet therapy is defined as aspirin 75–100 mg daily or Clopidogrel 75 mg daily in case of aspirin intolerance.

<sup>&</sup>lt;sup>d</sup>Appropriate antiplatelet therapy for non-cardioembolic ischaemic (or embolic of undetermined source) stroke or TIA is defined as aspirin 75–100 mg daily or Clopidogrel 75 mg daily in case of aspirin intolerance.

**3.1**).<sup>27,39</sup> In addition, the prescription of renin-angiotensinaldosterone system inhibitors for patients with diabetes who have a concomitant chronic kidney disease and/or hypertension has been shown to improve cardiovascular outcomes (**Main 3.2**).<sup>28,29</sup> Furthermore, sodium–glucose cotransporter 2 (SGLT2) inhibitors have recently emerged as cardioprotective agents for patient with diabetes who have chronic kidney disease (**Secondary 3.1**) (*Table 1*).<sup>28,40,41</sup>

## Domain 4: Care for patients with established ASCVD

For patients with established ASCVD, intensive measures are needed to prevent further cardiovascular events.<sup>5</sup> Whilst these measures are initially based on lifestyle modification such as smoking cessation, pharmacotherapies play a role in slowing and/or delaying disease progression and preventing unfavourable outcomes. As such, the QIs within this domain focus on medical interventions for patients with established ASCVD. That is the prescription of: (i) SGLT2 inhibitors or glucagon-like peptide-1 receptor agonist for patients with diabetes (Main 4.1),<sup>21</sup> (ii) appropriate antiplatelet therapy for patients with symptomatic peripheral artery disease (Main 4.2), 30 (iii) blood pressure lowering treatment for patients with readings ≥140/90 mmHg (Main 4.3),<sup>29</sup> (iv) appropriate antiplatelet therapy following a noncardioembolic ischaemic (or embolic of undetermined source) stroke (**Secondary 4.1**), <sup>42</sup> and (v) proton pump inhibitors for those on antiplatelet therapy and who have high risk for gastrointestinal bleeding (**Secondary 4.2**). <sup>43</sup> Furthermore, cardiac rehabilitation has an important role in secondary prevention following an acute cardiovascular event and elective coronary revascularization (Main 4.4) (Table 1).12

## **Domain 5: Patient education and experience**

Shared decision-making about treatment benefit, risk modifiers, and lifestyle changes in accordance to patient preferences is an essential element of ASCVD prevention.<sup>5</sup> Thus, recording the delivery of patient education for those with established or high risk for ASCVD about their treatment goals, preference is a QI (**Secondary 5.1**). In addition, the assessment of patient satisfaction with care quality is also an indicator of care quality (**Secondary 5.2**) (*Table 1*).

#### **Domain 6: Outcomes**

The collection of outcome measures pertinent to ASCVD or its treatment provides information about the effectiveness and the safety of management strategy. For patients with established ASCVD, achieving the target levels of low-density lipoprotein cholesterol (Main 6.1),<sup>27</sup> the target level of HbA1c in the presence of diabetes (Main 6.2),<sup>44</sup> the cessation of smoking (Main 6.3),<sup>5</sup> and controlling blood pressure (Secondary 6.1)<sup>29</sup> have a role in determining the success of treatment and in improving clinical outcomes (*Table 1*). Achieving blood pressure control has been proposed as a secondary QI given concerns from the Working Group members on the feasibility of the measurement of this QI which carries the same level of clinical relevance as the other main QIs within this domain.

Furthermore, recording annual rates of all-cause mortality (Secondary 6.2), cardiovascular mortality (Secondary 6.3), cardiovascular hospitalization (Secondary 6.4), non-fatal myocardial infarction (Secondary 6.5), and hospitalized major bleeding events

(**Secondary 6.6**) provides information about the outcomes of care (*Table 1*). However, adjustments for baseline risk and other patient characteristics may be needed when interpreting the results of such outcome Qls.<sup>45</sup> Furthermore, whilst the measurement duration for these Qls is 12 months, longer follow-up may be needed to capture sufficient events, especially in lower-risk population.

# **Discussion**

By way of a joint working group between the EAPC, members of the Task Force of the 2021 ESC Guidelines on Cardiovascular Disease Prevention in Clinical Practice and the ESC Patient Forum, 17 main and 14 secondary Qls for ASCVD prevention have been developed across 6 key domains of care. This work has been conducted under the auspice of the ESC Quality Indicator Committee using the ESC standardized methodology of Ql development. The Qls presented in this document align with recommendations of the 2021 ESC Guidelines on Cardiovascular Disease Prevention in Clinical Practice and do not overlap or conflict with published ESC Qls. 22-34 It is hoped that by developing such Qls and providing the specifications needed for their implementation, local, regional, national, or international initiatives aiming to improve the quality of ASCVD prevention can be created in accordance to the specific needs of individual centres or countries.

Monitoring and reporting the structure, process, and/or outcome of care has become a requirement for modern healthcare systems. 46 Qls provide a means by which this may be undertaken and performance evidenced. 47 Qls also help evaluate the effectiveness of quality improvement initiatives and may be used to ascertain if patient's perceptions of their care have been considered. Additionally, Qls can be used as an advocacy tool to demonstrate to health politicians the gaps of ASCVD prevention in different regions or countries. Although the literature describes a range of quality measures for ASCVD, 8,12–19 until now there has been no set of Qls that span the breadth of cardiovascular prevention. We believe this document describes a Ql set that covers the key domains of ASCVD prevention care.

We believe that our approach to the development of the ESC QIs for cardiovascular disease prevention will facilitate their implementation in clinical practice. First, the achievement of a systematic review of the literature ensured that the developed Ols are derived from, and supported by, evidence. Second, the inclusiveness of our Working Group provided far-reaching representation through the close working with patients, Task Force members of the 2021 ESC Guidelines on Cardiovascular Disease Prevention in Clinical Practice, and EAPC experts who have a track records in the field of preventive cardiology. 14,31 As such, our work integrates, and complements, current ESC and EAPC activities that aim to improve the quality of ASCVD prevention care across Europe. Third, the methodological approach used to develop these QIs enhances their incorporation into international registries that aim to capture key aspects of care delivery across a number of cardiovascular disease conditions, such as the ESC European Unified Registries On Heart Care Evaluation and Randomized Trials (EuroHeart) project.<sup>48</sup>

While our work has a number of strengths, it does, however, have several evident limitations. First, we acknowledge that it may be

difficult for a healthcare centre to adopt all the QIs given that fact that they cover many aspects of care, which may be delivered in different settings. Therefore, the Working Group opted not to design a composite QI because such an indicator could disadvantage centres that rely on community or smaller hospital services. Also, the Working Group believes that efforts should be made to ensure that performance is measured along the continuum of patient care pathway. This may be achieved through the integration of systems used across various clinical settings, such as electronic healthcare records, clinical registries and quality improvement projects.<sup>47</sup> Evaluating the quality of care based on data that do not span the full breadth of cardiovascular prevention may result in unintended consequences and system 'gaming' to improve the scores rather than the actual care quality. Second, the methodology used for the development relied on expert opinion. One may argue that this approach created subjectivity in the selection process. However, the use of the modified Delphi method, the involvement of patient representatives, and the application of the ESC criteria to guide the voting provided a level of standardization to the process. Third, the developed QIs will require continuous update and revision as new evidence arises, and feasibility data become available.

# **Conclusion**

This document defines the 2021 ESC QIs for Cardiovascular Disease prevention, which have been co-developed by the members of the Task Force of the 2021 ESC Guidelines on Cardiovascular Disease Prevention in Clinical Practice, the ESC Patient Forum, the Quality Indicator Committee, and EAPC. In total, 17 main and 14 secondary QIs have been defined across six key domains of ASCVD preventive care. These indicators cover the breadth of ASCVD prevention care, including: (i) structural framework, (ii) risk assessment, (iii) care for people at risk for ASCVD, (iv) care for patients with established ASCVD, (v) patient education and experience, and (vi) outcomes. Their implementation in clinical practice will standardize the evaluation of cardiovascular preventive care.

# Supplementary material

Supplementary material is available at European Journal of Preventive Cardiology online.

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# **Data Availability Statement**

The data underlying this article are available in the article and in its online supplementary material.

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