

**Quality indicators for acute myocardial infarction: A position paper of the
Acute Cardiovascular Care Association**

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List of Abbreviations

ACC, American College of Cardiology

ACCA, Acute Cardiovascular Care Association

ACS, acute coronary syndrome

AHA, American Heart Association

AMI, Acute myocardial infarction

CCS: Canadian Cardiovascular Society

CQI, composite quality indicator

LVEF, Left ventricular ejection fraction

NSTEMI, non ST segment elevation myocardial infarction

PCI, percutaneous coronary intervention

PM, performance measure

QI, quality indicator

STEMI, ST segment elevation myocardial infarction

Abstract

Evaluation of quality of care is an integral part of modern healthcare, and has become an indispensable tool for health authorities, the public, the press and patients. However, measuring quality of care is difficult, because it is a multifactorial and multidimensional concept that cannot be estimated solely on the basis of patients' clinical outcomes. Thus, measuring the process of care through quality indicators (QIs) has become a widely used practice in this context. Other professional societies have published QIs for the evaluation of quality of care in the context of acute myocardial infarction (AMI), but no such indicators exist in Europe. In this context, the ESC Acute Cardiovascular Care Association (ACCA) has reflected on the measurement of quality of care in the context of AMI (STEMI and NSTEMI) and created a set of QIs, with a view to developing programmes to improve quality of care for the management of AMI across Europe. We present here the list of QIs defined by the ACCA, with explanations of the methodology used, scientific justification and reasons for the choice for each measure.

1. Introduction

In a report published in 2001, the Institute of Medicine stated that “in its current form, habits and environment, American healthcare is incapable of providing the public with the quality health care it expects and deserves”(1). Evaluation of the quality of care is an integral part of modern healthcare, and has become an indispensable tool, much sought after by health authorities, the general public, the press and even patients themselves. However, measuring the quality of care is difficult, because it cannot be estimated solely on the basis of patients’ clinical outcomes, even if achieving a favourable outcome for the greatest number of patients possible is the ultimate goal of high quality care.

Thus, measuring the process of care through quality indicators (QIs) or performance measures (PMs) has become a widely used practice in this context. The American College of Cardiology (ACC) and the American Heart Association (AHA) have considerable experience in the measurement of quality of care in the setting of AMI. Indeed, these two organisations have jointly published several Task Force documents and position papers with precise definitions of QIs and PMs that can be used to describe and evaluate management and outcomes of patients with acute coronary syndromes (ACS)(2). Furthermore, they have published several documents on the optimal methodology for defining QIs and PMs (3, 4), the statistics suitable for public reporting (5), and the use of composite indicators (6). The first set of PMs for AMI published by the ACC/AHA was released in 2006 (7), and updated in 2008 (8), and a position paper specific to coronary reperfusion published in 2008(9).

The lack of standard definitions of QIs validated by the ESC for clinical situations such as AMI or heart failure is in stark contrast with the professional societies of

cardiology in the USA. Thus, the question arises as to whether it is time for the ESC to define QIs for AMI, which would be in line with the ESC's own recommendations for the management of these conditions? The ESC Acute Cardiovascular Care Association (ACCA) has reflected on the measurement of quality of care in the context of AMI and aimed to create QIs, with a view to developing programmes to improve quality of care for the management of AMI across Europe.

1.1.Objectives

The objectives of the ACCA Quality of Care Working Group were to define suitable QIs for the management of AMI, with or without ST segment elevation.

1.2. Scope

Specifically, in an attempt to improve the management of patients hospitalised with AMI, the ACCA proposes standardisation of the evaluation of quality of care across all centres in Europe. Whilst the link between assessment and improvement of quality of care is a matter of debate, the hypothesis that improvement in quality partially relates to internal or external assessment is supported by observational data(10). Either way, the Quality of Care Working Group's scope was to select not only QIs based on existing guidelines, but also to incorporate measures whose implementation is deemed to be important, like centre facilities, or patient satisfaction. Lastly, a set of simple and reliable QIs can be used to evaluate the conformity of actual practices with the ESC guidelines for management in AMI.

The definition of QIs relies on the existence of treatments and strategies of proven efficacy, as well as on high-grade recommendations. These prerequisites are satisfied in several clinical situations, such as AMI, acute heart failure, pulmonary embolism, as well as chronic conditions including stable angina, coronary

revascularisation, atrial fibrillation, cardiovascular prevention, peripheral arterial disease and cardiac rehabilitation.

1.3.Membership of the “Quality of Care Working Group” and selection of the domains of care.

Under the supervision of the Board of the ACCA, a “Quality of Care Working Group” was formed and comprised international experts selected for their expertise in the management of patients with ACS. All members were invited to participate in the selection and definition of the QIs in the selected domains of management and were representative of the different European countries that comprise the ESC, and included members of the ACCA, members of the ESC Practice Guidelines Committee, and *ad hoc* members, experts in clinical practice, public health or statistics. The full list of the group leaders and members of the Quality of Care Working Group, with their respective area of expertise, is displayed in Table 1.

Seven different domains of care where quality should be assessed were defined, with one chairperson responsible for coordinating the discussions in each domain.

The aim of this selection was to extend the quality assessment beyond simply the process of care and its outcomes, by incorporating the full spectrum of the patient pathway, from organization of care, to outcomes and the patient experience. The seven domains selected are relevant to the clinical situation of AMI, namely: (i) centre organization, (ii) reperfusion/invasive strategy, (iii) in-hospital risk assessment, (iv) antithrombotic treatment during hospitalization, (v) discharge treatments, (vi) patient satisfaction, and (vii) composite QIs and outcomes.

2. Methodology

2.1. Selection of Candidate Quality Indicators

A set of 45 candidate QIs were identified, based on existing QIs and international guidelines for the management of STEMI and NSTEMI. These covered all seven pre-selected dimensions. The 45 candidate QIs were selected by the Quality of Care Working Group using an online survey circulated to the whole group and completed by all members. Each candidate QI was graded on a scale of 1 to 5 according to the following criteria: (1) supported by evidence / guidelines, (2) interpretability, (3) actionability and room for improvement, (4) feasibility of assessment and (5) global fit.

2.2. Definition of quality indicators

For each domain, one or more “main” QIs, as well as one or more “secondary” QIs were finally retained. The grading of the QIs and the final selection of those to be retained was based on the feasibility and reliability of the assessment of the QI. The main QIs were selected because they were considered an essential element, mandatory for basic assessment. Conversely, the secondary QIs were considered as complementary measures that could be used to perform more advanced assessment, and/or may only be suitable for use in certain centres. The list of the main and secondary QIs for each domain is presented in Table 2, with details of the numerator and denominator, rationale, support from guidelines and method of reporting. The figure presents a summary of the QI in each domain, with the corresponding ESC guidelines.

2.3. Support

The work is exclusively supported by the ACCA and the ESC. No commercial support was received for the development of the QIs.

3. Quality Indicators for STEMI / NSTEMI

3.1. Center Organization

3.1.1. Dimensions of care

For patients with AMI, early diagnosis, pre-hospital medical care, and quick access to revascularization through direct admission to cardiology centres with catheterization facilities available 24/7 have all been shown to reduce time to reperfusion, which in turn is associated with lower mortality(11). To this end, organized systems of care such as structured networks are needed to determine the optimal pathways of care based on local circumstances, centre characteristics and transfer capabilities in the area(12-14). Organization of networks of care has been shown to be effective in reducing times to reperfusion, through rapid diagnosis with expeditious ECG recording and interpretation, risk assessment, safe transfer and rapid access to reperfusion strategies(15-19). The main QI for network organization was based on four organizational points deemed to be the most important in clinical terms, as well as being easy to implement in practice, and easy to assess. Although non-written collaborations can be efficient in practice, the ACCA Quality of Care Working Group considers that only centres with a written protocol that has been discussed and signed by both the centre and the pre-hospital system should be regarded as participating in a network for the purposes of assessing quality of care.

3.1.2. Clinical relevance

Organization of care has an important impact on the implementation of recommendations for times to reperfusion (13). Depending on the local environment, bringing the patient to the centre in a timely manner or bringing the treatment to the patient through the administration of intravenous fibrinolytics in the pre-hospital setting have been extensively discussed. Both methods are not exclusive and a well-organized network organization should provide the most appropriate treatment in the shortest delay (20). Several reports relate network experiences, and all have shown an improvement in the proportion of patients reperfused in a timely manner thanks to a single call number, a physician-staffed or trained paramedic ambulance crew and direct transfer to a PCI-capable hospital with experienced cardiologists on call. The Vienna citywide system of care involves one academic and four non-academic centres, providing a physician-staffed ambulance and a guarantee that only experienced interventionists are on duty (21). The French SAMU organization has a physician-staffed ambulance on site and can start pre-hospital fibrinolytic therapy, antithrombotic therapy, resuscitation and transfer directly to PCI-capable centres (22). Based on similar organizations, numerous other networks have been established in large cities (23-25), regions (23) or nations (26).

3.1.3. Specific aspects for potential quality indicators

Optimal treatment delivered within a minimal time frame has been shown to reduce mortality in STEMI patients and is thus strongly recommended by guidelines(27-29). The main effective components of a STEMI network are pre-hospital ECG recording and interpretation(30-33), pre-hospital activation of the catheterization laboratory(34,

35) with a single call number(7, 36), adequate selection of the mode of transportation(37), and direct admission to the catheterization laboratory(19). All these strategies have been identified as predictors of short door-to-balloon times(38). This type of optimal collaboration within a STEMI network has been shown to increase both the proportion of patients treated by reperfusion, and the proportion of patients with timely reperfusion(20).

Prospective monitoring of the times to management in STEMI patients:

Since the time to reperfusion is clinically important and is used to define the QI for reperfusion, the different times to management need to be recorded. Although the most clinically important overall time span is the time from symptom onset to reperfusion (that is, the total ischemic time), several intermediate times are required, such as: time of the call, time to first medical contact, time of the first ECG, time of arrival at the PCI-capable centre (door), time of the balloon (guidewire or other device) that restores patency in the infarct-related artery. Additionally, for patients admitted to non-PCI centres, the interval between time of admission and time of discharge for transfer to a PCI-capable centre (door in - door out time) needs to be recorded.

The ESC guidelines recommend participation in a national or international registry or a quality program, such as the “Stent for Life” initiative (39), to record data regarding the actual management of patients admitted with AMI. Despite a lack of firm evidence that participation in a registry has an impact on quality of care, the ACCA Quality of Care Working Group considers that regular participation in a registry which assesses quality of care is an indicator of quality at a centre level.

3.1.4. Definition of the main and secondary quality indicator for “Center Organisation”

<p>Name of the Main QI</p>	<p>The centre should be part of a Network Organization with written protocols for rapid and efficient management covering the following points:</p> <ul style="list-style-type: none"> • <i>Single emergency phone</i> number for the patient to be connected with a medical system for triage • <i>Pre-hospital interpretation of ECG</i> for diagnosis and decision for immediate transfer to a centre with catheterization laboratory facilities • <i>Pre-hospital activation</i> of the catheterization laboratory
<p>Name of the Secondary QI (1)</p>	<p>Routine assessment of relevant times for the reperfusion process in STEMI patients (i.e. recording actual times in order to assess “call to first medical contact”, “first medical contact to door”, “door to device” and “door-in door-out” for centres without cath-lab on site).</p>

<p>Name of the Secondary QI (2)</p>	<p>The centre should participate in a regular registry or program for quality assessment</p>
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3.1.5. Agreement with guidelines and existing quality indicators

Main QI: The guidelines for the management of STEMI issued by the ESC explicitly recommend that each center receiving patients with suspected AMI should be part of

a Network Organization. According to the ESC guidelines, the main features of the network are (1) the existence of written protocols for risk stratification and adequate transportation, (2) pre-hospital triage with the aim of bypassing non-PCI hospitals, (3) immediate transportation to the catheterization laboratory for eligible STEMI patients, (4) monitoring and immediate transfer of STEMI patients admitted to non-PCI centres. In view of the guidelines recommendations, the components of the Structure-Network QI are strongly supported.

The ACC/AHA PM for STEMI and Non-STEMI do not include any Structure-Network QI. The Canadian Cardiovascular Society (CCS) PM refers to “system indicators” that contain a pre-hospital 12 lead ECG (40).

Secondary QIs: The ESC guidelines for both STEMI and NSTEMI-ACS recommend participation in a survey or registry, both to record times to reperfusion among STEMI patients(28) and to record the degree of application of guidelines for all patients with STEMI and NSTEMI-ACS, as is already undertaken by a number of national initiatives, such as in Sweden (through the Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies, SWEDEHEART), the UK (Myocardial Infarction National Audit Project, MINAP) registry), Germany, Italy and Israel on a regional basis, or through intermittent programs in other countries (French Registry on Acute ST-elevation and non ST-elevation Myocardial Infarction, FAST-MI). The underlying justification for this recommendation is that continuous monitoring of actual patient management may enhance the quality of treatment and minimize unwarranted variation in evidence-based care.

3.2. Reperfusion/invasive strategy

3.2.1. Dimensions of Care

Invasive strategy, myocardial revascularisation, and the speed with which it is achieved, are key elements in the management of patients with ACS. However, the approach is different depending on the clinical presentation of the ACS, namely STEMI or NSTEMI, the myocardium at risk and the ischemic time.

In patients with STEMI admitted during the first few hours after symptom onset, the choice of reperfusion strategy and the speed with which it is implemented have a major impact on clinical outcomes(41, 42). Given this, coronary reperfusion performed within a short time frame is recommended (29, 42, 43). Both the use of reperfusion (either by fibrinolytic therapy in eligible patients or by PCI) and its timely implementation have previously been used as indicators of quality of care (8, 9). Many opportunities exist to reduce the proportion of patients who do not receive reperfusion, and the delay with which this is provided. This requires active involvement from all partners involved along the management pathway, and includes high quality organisation of care within a network organisation (7, 25). Accountability is an important factor in measuring quality of care, and measuring the different components of the overall time to reperfusion (such as time of call, time of first medical contact, time of arrival, transfer, arterial puncture, time at which artery patency is achieved) makes it possible to rank the quality of each in the overall pathway of care, and identify areas where there may be room for improvement (44).

In patients with NSTEMI, an invasive strategy using coronary angiography with a view to myocardial revascularisation is also related to lower mortality in moderate-to-high and in high risk patients (45, 46). In NSTEMI, appropriate use of an invasive

strategy is linked to the assessment of the patient's ischemic and bleeding risks. In practice, according to the risk profile, invasive strategy must be immediate (<2 hours), early (<24 hours), <72 hours or conditional. Avoiding the risks of an invasive strategy for patients at low ischemic risk is equally as important as ensuring access to invasive strategy for patients at high ischemic risk.

3.2.2. Clinical relevance

For patients with STEMI, the relation between shorter times to reperfusion and mortality has previously been established, particularly within the first 3-4 hours after onset of infarction. Beyond 12 hours, the benefit of reperfusion is less well established, and although PCI is recommended within the first 24 hours, measures of quality of care are limited to patients admitted less than 12 hours since the onset of symptoms(47, 48). The benefit is greater when reperfusion is performed early. The advantage of earlier reperfusion is seen more in the first 3-4 hours after onset of symptoms. The estimated times to reperfusion also contribute largely to the choice of reperfusion strategy. PCI is the technique of choice except if it is estimated that it cannot be performed within 120 minutes after the diagnosis of STEMI has been established(29, 42, 49). A time to reperfusion therapy \leq 30 minutes (diagnosis to injection) is recommended when fibrinolytic therapy is the strategy of choice; and when PCI is the chosen strategy, the recommended time to PCI is \leq 120 minutes between diagnosis and opening of the infarct-related artery. When the door to balloon (or to first device that open the artery) time is considered, ESC guidelines for revascularization propose a recommended time < 60 mins.

For patients with NSTEMI, the benefit of an invasive strategy is established only in patients at risk of ischemia(45, 46, 50). An invasive strategy is needed to confirm the diagnosis of ACS, identify the culprit coronary lesion, establish the indication for revascularization (by PCI or surgery) and assess the long-term risk. The timing of the invasive strategy also depends on risk assessment; a small proportion of patients require an immediate invasive strategy (within 2 hours), an early invasive strategy (within 24 hours) is indicated for high risk patients, while an invasive strategy can be performed within 72 hours in NSTEMI patients without high risk criteria. Lastly, a selective invasive strategy can be used among patients at low ischemic risk, according to the results of their non-invasive stress test. A decision for an early invasive strategy (i.e. performance of a coronary angiography and revascularization if appropriate) versus a conditional invasive or medical strategy should take into account the risk-benefit ratio. Invasive treatment is recommended in the presence of ischemic risk factors, and conversely, is not recommended in the absence of ischemic risk factors(27, 29).

3.2.3. Specific aspects for potential quality indicators

For the QIs relating to reperfusion and invasive strategy, the numerator and denominator should comprise all patients hospitalized with STEMI or NSTEMI. Only patients eligible for the invasive approach should be included, and form both the numerator and the denominator. Therefore, the numerators and denominators should not include patients who have contraindications, such as patients with STEMI who present after the first 12 hours, or those who have clinical, allergic, arterial access, or hemorrhagic problems, or patient-related reasons for exclusion (refusal to provide

consent for angiography or PCI). Patients with clinical or patient-related reasons for exclusion are considered ineligible.

In STEMI patients, measuring time to reperfusion requires that the different times of the various stages along the management pathway be measured. Both the use of reperfusion (either by fibrinolytic therapy in eligible patients or by PCI) and its timely implementation can be used as indicators of quality of care (8, 9). In case of fibrinolysis, the time interval to initiation of fibrinolysis is counted from first medical contact to injection, which is in line with recommendations for pre-hospital fibrinolysis. Conversely, in case of reperfusion by primary PCI, if the patient is admitted directly to a PCI-capable centre, the door to balloon time is preferred over other starting time points, in order to better reflect internal hospital organization, and also because it is easier to measure. Finally, if the patient is admitted to a centre without PCI facilities and primary PCI is chosen as the reperfusion strategy, the door-in-door-out time in the non-PCI-capable centre has been selected, as it is independent of geographical constraints that may affect transfer times.

Lastly, the median time from FMC to passage of the device that achieves reperfusion of the infarct-related artery has been chosen as a secondary QI.

In NSTEMI, appropriate use of an invasive strategy is linked to the assessment of the patient's ischemic and bleeding risks. Thus, according to the risk profile, invasive strategy must be immediate (<2 hours), early (<24 hours), <72 hours or conditional. To avoid excessive complexity, only the decision to perform an invasive strategy

within the first 72 hours in NSTEMI patients without contraindication has been retained as a QI.

3.2.4. Definition of the main and secondary quality indicators:

<p>Name of the Main QI (STEMI 1)</p>	<p>Proportion of STEMI patients reperfused among those eligible (onset of symptoms to diagnosis <12h)</p>
<p>Name of the Main QI (STEMI 2)</p>	<p>The proportion of patients reperfused within the timeframe recommended by the ESC guidelines; these time frames vary according to whether fibrinolysis or PCI is chosen as the strategy of choice.</p> <ul style="list-style-type: none"> ○ For fibrinolysis, a maximum time delay of 30 minutes between first medical contact (diagnosis) and the start of injection is retained. ○ For primary PCI, a maximum door to balloon time of <60 minutes is retained for patients admitted to centres with PCI facilities on site. ○ For transferred patients, an additional QI is defined, namely a “door-in, door-out” time of less than 30 minutes.

Name of the Secondary QI	Diagnosis to passage of wire time (absolute value) for primary PCI.
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Name of the Main QI (NSTEMI 1)	Proportion of patients with NSTEMI, and no contra-indication, who receive coronary angiography within 72 hours after admission
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3.2.5. Agreement with guidelines and existing quality indicators:

STEMI patients. The ESC guidelines stipulate that all patients with STEMI of onset <12 hours should receive reperfusion therapy as early as possible. In addition, the ESC guidelines recommend measuring the time from the onset of symptoms, FMC, diagnosis, and initiation to reperfusion, stating that an invasive strategy should be performed within 90 minutes in early presenters with a large area at risk(49).

Two main QIs and one secondary QI have been defined for myocardial reperfusion:

- Main QI (STEMI 1) is the percentage of patients reperfused among patients admitted with STEMI of <12 hours duration. This QI is identical to the PM defined by the ACC/AHA Task Force in 2008(8, 9).
- Main QI (STEMI 2) is the percentage of patients reperfused within the timeframe recommended by the ESC guidelines; these time frames vary according to whether fibrinolysis or PCI is the strategy of choice.

- For fibrinolysis, a maximum time delay of 30 minutes between FMC (diagnosis) and the start of injection is retained, in accordance with the ESC guidelines.
- For primary PCI, a maximum door to balloon time of <60 minutes is retained for patients admitted to centres with PCI facilities on site.
- For transferred patients, an additional QI is defined, namely a “door-in, door-out” time of less than 30 minutes.

The 2008 ACC/AHA PM related to reperfusion in STEMI were: (1) time to fibrinolytic therapy, (2) time to primary PCI, (3) proportion of patients who received reperfusion therapy, (4) time from emergency department arrival at STEMI referral facility to emergency department discharge for transfer to PCI centre and (5) time from emergency department arrival in PCI-centre to PCI. In the most recent ACC/AHA Task Force defining PM for reperfusion, five other PMs for reperfusion were defined. The main PM was the time to device use for PCI and four proposals for future PM relating to time to reperfusion were also defined: (1) time to reperfusion among patients transferred for PCI, (2) proportion of reperfusion-eligible patients receiving therapy, (3) diagnosis to reperfusion and (4) time to reperfusion for patients developing STEMI in the hospital(8, 9). The ACCA Quality of Care Working Group QIs are in agreement with these indicators from the ACC/AHA, but only three are retained in our document. Times are used with threshold values, according to the type of reperfusion and the need for transfer. The diagnosis to balloon time was left as an absolute value, because even though this measure depends on numerous factors, it is the most important in clinical terms(43).

NSTEMI patients: Although international guidelines concur in their recommendations of an invasive strategy among patients with high-risk features(27, 29), this aspect of

management has never before been used in measures of quality of care. To avoid excessive complexity, the decision to perform an invasive strategy within the first 72 hours in NSTEMI patients without contraindication was selected as a QI.

3.3. In-hospital risk assessment

3.3.1. Dimensions of care

Clinical outcomes following AMI are highly variable, and are, in part, due to the wide spectrum of baseline clinical risk levels. Therefore, risk assessment is a key step in the management of patients with AMI, particularly their risk of death and recurrent MI (to determine the need for a more aggressive approach), the risk of iatrogenic complications such as bleeding (to modify the use of antithrombotic treatments) and the short- or long-term risk of heart failure (to enable tailoring of clinical review, investigations and guideline-indicated therapies).

Establishing the risk of in-hospital or short-term death from the ischemic process will better inform clinicians of necessary changes to an invasive strategy, namely its timing. Indeed, for NSTEMI, the clinical benefit of an early invasive strategy has been shown to be related to the level of ischemic risk, with greater clinical benefits seen in higher risk patients.

Bleeding is one of the main iatrogenic complications among patients with AMI and is associated with an adverse prognosis. Bleeding risk estimation can help define the best diagnostic and therapeutic strategy and should affect the type, dose and duration of antithrombotic treatments, as well as the choice of arterial access for invasive procedures.

Assessment of left ventricular function and the quantification of resting left ventricular ejection fraction (LVEF) before discharge from hospital are important for the selection of patients with severe left ventricular dysfunction who may benefit from additional treatments. Left ventricular systolic dysfunction is a key predictor of immediate and late episodes of heart failure, and ventricular arrhythmia(51). Patients with severe left ventricular dysfunction require specific secondary prevention therapies.

For STEMI, with the increasing use of primary PCI, risk assessment for ischaemia before discharge has become less important. This is because it can be assumed that the infarct-related coronary lesion has been treated and stabilized, and the presence or absence of significant lesions in other arteries has been assessed.

3.3.2. Clinical relevance

Observational studies support the use of established risk scores for ischaemic and bleeding risk.

Ischemic risk. Of the numerous ischaemic risk scores, the GRACE risk score is not widely used, but is strongly endorsed by ESC guidelines (27, 28). A recent update of the GRACE score (GRACE V2.0), calculated from 32,307 patients enrolled between 2001 and 2007 with suspected ACS, has shown, in an external population, adequate discrimination and calibration for in-hospital and 3 year mortality(52). Categorization of the patients into GRACE high risk, GRACE medium risk and GRACE lower risk may help physicians in their choice of whether to pursue an invasive strategy, since the invasive approach mainly benefits high risk patients(53, 54). Studies from registries have shown that the use of coronary angiography is higher in individuals at lower risk as compared to those at higher risk, defining the ‘treatment-risk paradox’(55, 56), Employing a facilitated GRACE score, like the updated one, has the

potential to favor a systematic and objective evaluation of the ischemic risk of NSTEMI patients and to increase the rate of revascularization in high-risk patients without contraindications. This means that, based on the impact of a systematic interventional strategy in the randomized trials, there would be between 30 and 80 fewer cardiovascular deaths or MIs for every 10,000 patients with NSTEMI (45, 57-60).

Bleeding risk can be predicted from baseline variables through a specific risk score.

Bleeding risk scores have also been developed from registry or trial cohorts in the setting of AMI and PCI. The Can Rapid risk stratification of Unstable angina patients Suppress ADverse outcomes with Early implementation of the ACC/AHA guidelines (CRUSADE) bleeding risk score (<http://www.crusadebleedingscore.org>) was developed from a cohort of 71,277 NSTEMI-ACS patients (derivation cohort) and further validated (61). The CRUSADE bleeding score has been demonstrated to have a good predictive accuracy also in STEMI patients treated by primary PCI(62).

Assessment of infarct size and post MI left ventricular systolic function can be performed by echocardiography, a technique available in almost all centres admitting patients with AMI.

3.3.3. Definition of the quality indicators:

<p>Name of the Main QI (1)</p>	<p>Proportion of ischemic risk assessment using the GRACE risk score for patients with NSTEMI. GRACE score should be assessed and the numerical value of the score recorded for all patients admitted with suspected NSTEMI.</p>
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Name of the Main QI (2)	Bleeding risk assessment using the CRUSADE risk score. CRUSADE bleeding score should be assessed and the numerical value of the score recorded for all patients admitted for NSTEMI.
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Name of the Main QI (3)	Assessment of LVEF before discharge. LVEF should be assessed and numerical value recorded for all patients admitted with STEMI and NSTEMI.
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3.3.4. Agreement with guidelines and existing quality indicators

Main QI (1): Ischaemic risk assessment. ESC NSTE-ACS guidelines recommend basing diagnosis and initial short-term ischaemic and bleeding risk stratification on a combination of clinical history, symptoms, vital signs, other physical findings, ECG and laboratory results. The quantitative assessment of ischaemic risk scores is superior to clinical assessment alone. The GRACE risk score provides the most accurate stratification of risk both on admission and at discharge and has a Class IA recommendation.

In the ACC/AHA PM set, risk assessment is used to measure the risk-adjusted 30-day mortality, but does not itself represent a PM.

Main QI (2): Bleeding risk assessment. The ESC NSTE-ACS guidelines stipulate that the use of the CRUSADE bleeding risk score may be considered in patients undergoing coronary angiography to quantify bleeding risk with a Class B IIb recommendation. Bleeding risk assessment is also recommended in the ESC STEMI

guidelines for antiplatelet therapy (like abciximab and prasugrel), without mention of any type of score for this assessment.

In the ACC/AHA PM for STEMI/NSTEMI, no assessment of bleeding risk is stated.

Main QI (3): Evaluation of left ventricular systolic function is recommended by the ESC guidelines for STEMI (Class I B) and for NSTEMI-ACS (Class I C). Assessment of left ventricular systolic function has been a part of the ACC/AHA PM set since 2008.

3.4. Anti-thrombotic treatment during hospitalisation

3.4.1. Dimensions of care

Anti-thrombotic treatment has a pivotal role in the management of AMI(63). Therefore, the combination of an anticoagulant with antiplatelet therapy is mandatory in the treatment of AMI(27-29). This approach has been shown to reduce mortality (both cardiovascular and total), (re)infarction and stroke(64-69). Moreover, many patients with AMI are treated with PCI and stent implantation, and in this case dual antiplatelet therapy (DAPT) has a key role in reducing stent thrombosis, both in the short (acute/subacute) and long term. Finally, antiplatelet therapy improves long-term outcomes following AMI. Prolongation of DAPT beyond the first year is currently a matter of debate(70, 71).

3.4.2. Clinical relevance

Antiplatelets: The benefit of aspirin for AMI has been demonstrated in four randomized studies, with the rate of ischaemic events reduced by half as compared to placebo. The benefit of the combination of aspirin with clopidogrel has also been

demonstrated, leading to a high-grade recommendation for DAPT(27-29). More potent P2Y₁₂ platelet receptor inhibitors (prasugrel and ticagrelor), in addition to aspirin, are linked to improved outcomes, with a reduction in the composite ischaemic outcome, including mortality from STEMI(72-74). The increase in bleeding is reasonable and sometimes negligible(75), with the exception of some high-risk subgroups. Based on trial design, prasugrel use has been limited to selected STEMI patients who receive PCI and who do not have previous stroke(73). Ticagrelor is suitable for use among a broader ACS population, irrespective of history, use of PCI or pre-treatment with clopidogrel(72). Whatever the drug chosen for P2Y₁₂ inhibition, DAPT should be initiated as soon as the diagnosis is established, and continued for a duration of 12 months, unless bleeding complications occur(76). The benefit of using glycoprotein GPIIb/IIIa inhibitors was established before the advent of DAPT, but since strong P2Y₁₂ platelet receptor inhibitors have become available, the use of GPIIb/IIIa inhibitors has been reserved for patients with peri-procedural thrombotic complications and patients with a high risk of thrombosis and a low risk of bleeding.

Anticoagulation: A parenteral anticoagulant is required during the acute phase, and continued until completion of revascularization or hospital discharge, whichever occurs first. Due to multiple comparisons of a variety of anticoagulants, at different doses, with or without arterial access and associated with different combinations of antiplatelets, no specific single anticoagulant regimen can be proposed for STEMI (unfractionated heparin, the low molecular weight heparin enoxaparin, and to some extent, bivalirudin have been investigated in prospective randomized trials). Conversely, for NSTEMI, fondaparinux at a dose of 2.5 mg/day is considered by guidelines to have a favorable efficacy/safety profile, except in those proceeding directly to PCI(27-29, 77-79).

3.4.3. Specific aspects for potential indicators

The complexity of selecting appropriate antithrombotic treatment, and the high-grade recommendations suggest that the selection of antiplatelet therapy and anticoagulants is an ideal field for the assessment of the quality of care.

Antiplatelet agents at admission: Aspirin, initiated as soon as possible in all patients without contraindication, has been used as a QI, both at admission and at discharge. Nevertheless, since the rate of use of aspirin is often higher than 95%, the interest of keeping this indicator is debatable. As regards P2Y₁₂ inhibitors, the choice between clopidogrel, prasugrel and ticagrelor is underpinned by clear contraindications, limitations of use, and risk assessment, and therefore might also reflect quality. Ticagrelor is recommended over clopidogrel unless the patient is at high risk of bleeding (patients with previous haemorrhagic stroke, chronic oral anticoagulation or fibrinolytic therapy, ongoing bleeding). Prasugrel is also recommended over clopidogrel in patients undergoing PCI, but also without a history of any type of cerebrovascular accident, age <75 years and body weight ≥60 kg (73). When neither ticagrelor nor prasugrel is possible, clopidogrel is the best option. The use of GPIIb/IIIa inhibitors is decided case by case, according to criteria that are not always recorded and, therefore, is less suitable for quality assessment.

Antiplatelet agents at discharge: The prescription of DAPT at discharge, for an expected duration of one year, is well supported by guidelines, and applicable to AMI irrespective of its management. The choice of P2Y₁₂ inhibitor follows the same rules as at admission. In addition, DAPT prescription at discharge was suggested as a potential QI in the recent ESC 2015 NSTEMI-ACS guidelines (27), without distinction of any single P2Y₁₂ inhibitor molecule. Only patients treated by chronic anticoagulants

are excluded, due to a high bleeding risk, a lack of scientific evidence, and a lack of strong recommendation regarding discharge antiplatelet treatment.

Anticoagulants. The use of fondaparinux in patients with NSTEMI (except those proceeding directly to PCI or those with severe renal dysfunction) can be used as a QI. If fondaparinux is not available, enoxaparin should be preferred. In STEMI patients, the use of anticoagulant prescription to assess quality is challenging, due to the multiplicity of drugs, doses and possible combinations. Dosing errors or inappropriate combinations of different anticoagulants are associated with thrombotic or haemorrhagic complications and could be tracked for quality assessment.

3.4.4. Definition of the main and secondary quality indicators for “antithrombotic treatments during hospitalisation”

<p>Name of the Main QI (1)</p>	<p>Proportion of patients (numerator and denominator detailed in appendix) with “adequate P2Y₁₂ inhibition” defined as: number of patients discharged with prasugrel or ticagrelor or clopidogrel / patients eligible. Eligible is defined as follows:</p> <ul style="list-style-type: none"> • For ticagrelor = AMI patients without previous haemorrhagic stroke, high bleeding risk, fibrinolysis or oral anticoagulation. • For prasugrel: PCI treated AMI patients without previous haemorrhagic or ischemic stroke, high bleeding risk (patients > 75 years and/or <60 kg body weight are also considered as high bleeding risk), fibrinolysis or oral anticoagulation.
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	<ul style="list-style-type: none"> • For clopidogrel: if no indication for prasugrel or ticagrelor and no high bleeding risk.
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Name of the Main QI (2)	Proportion of patients with NSTEMI treated with fondaparinux, unless candidate for immediate (≤ 2 hours) invasive strategy or with eGFR < 20 ml/min.
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Name of the Secondary QI	Proportion of patients discharged on dual antiplatelet therapy / patients with AMI, without clear and documented contraindication
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3.4.5. Agreement with guidelines and existing quality indicators

For STEMI patients who receive fibrinolysis, aspirin and clopidogrel have class IB and IA indications, respectively. Enoxaparin has the best indication with fibrinolysis (IA), followed by UFH (IC). In STEMI patients treated with primary PCI, prasugrel and ticagrelor both have a Class IB recommendation, while clopidogrel is indicated only if prasugrel and ticagrelor are not available or contraindicated (Class IC). The recommendations for parenteral anticoagulants are IC for UFH, IIaA for bivalirudin and IIaB for enoxaparin.

For NSTEMI patients, antiplatelet therapy with prasugrel or ticagrelor has a class IB recommendation, while clopidogrel is indicated in patients who cannot receive prasugrel or ticagrelor or who are treated with oral anticoagulants. In patients naive of

P2Y₁₂ inhibitors undergoing PCI, cangrelor has a lower level of recommendation (IIbA).

Previous ACC/AHA PMs have not considered any PM related to anti-thrombotic therapy. However, in the 2008 update of PM for STEMI/NSTEMI, the use of clopidogrel in medically treated AMI patients only, as well as excessive initial dose of unfractionated heparin, enoxaparin, abxycimab, eptifibatide and tirofiban, were considered as “test measures”. In addition, the use of a standardized protocol for anticoagulants, and a tracking system for anticoagulation errors, were also considered as PMs in test(8).

3.5. Secondary prevention - discharge treatments

3.5.1. Dimension of care

The secondary prevention of cardiovascular events following index AMI is critical, because patients remain at high risk of mortality and recurrent cardiovascular events long after an AMI. Long-term cohort studies have shown that mortality after hospitalization with AMI is high (45). Moreover, secondary prevention pharmacotherapy has been shown to reduce long-term adverse clinical outcomes in this group (80-82). While the long-term management of patients with AMI is predominantly the responsibility of the general practitioner, secondary prevention medications will have a greater chance of being implemented if performed during the hospital stay. The caveat to this is that with declining lengths of hospital stay(83), there is less of a distinction between acute and chronic therapies and it is therefore the shared responsibility of primary and secondary care physicians to ensure that all eligible patients with AMI are prescribed and maintained on guidelines-indicated

medications. This domain encompasses the prescription of statins, angiotensin-converting enzyme inhibitors (ACEIs)/ angiotensin receptor blockers (ARBs) and beta-blockers.

3.5.2. Clinical relevance

The benefit of long-term treatment with beta-blockers among patients with AMI who have heart failure or left ventricular systolic dysfunction is well established(80). However, there are no contemporary randomized controlled trials testing the efficacy of beta-blockers among patients following AMI without HF. As such, current ESC guidance is to prescribe beta-blockers to hemodynamically stable patients who are eligible and who have a LVEF ≤ 0.40 . For ACEIs/ARBs, there is also strong evidence for their use as secondary prevention therapy among eligible patients with AMI who have heart failure or a LVEF ≤ 0.40 (81, 82, 84). Compelling evidence supports the use of high intensity statins for reducing recurrent cardiovascular events and mortality following AMI (85, 86), and although the rate of prescription of statins at discharge from hospital is high (83,88,89), a substantial proportion of patients are not discharged with high intensity statins after hospitalization for coronary heart disease (87). This is important when high intensity statins reduce low-density lipoprotein (LDL) cholesterol by around 50% and the efficacy of statins is apparent across a range of patient groups, including both sexes, the young and the elderly, as well as those with and without diabetes. As with statins, the opportunity to reduce premature cardiovascular death through increased prescription of ACEI/ARB and beta-blockers is clearly apparent (83, 88-90).

The magnitude of the relationship between high intensity statin therapy and mortality is strong. In 4162 patients hospitalized with an acute coronary syndrome, higher

intensity statins were associated with a 16% reduction in the risk of death at 2 years, over and above that of the reduction in risk of death associated with standard lipid therapy (85). The magnitude of the relationship between ACEIs/ARBs and mortality among patients with AMI is strong (81). For beta-blockers, the magnitude of the relationship for mortality among patients with AMI is weaker. That is, there are no contemporary randomized data testing the efficacy of beta-blockers among patients with AMI who do not have heart failure, and recent data from an observational study suggested no benefit among this group. In the CAPRICORN randomized trial of 1959 patients with AMI and a LVEF <0.40, the risk of all-cause mortality or non fatal AMI at a mean of 1.3 years was reduced by 29% among patients who received carvedilol (80). However, for patients with AMI and HF or a reduced LVEF, the magnitude of the evidence is strong. In a randomized trial of 2647 patients with heart failure, of which half had documented ischaemic heart disease, bisoprolol significantly reduced all-cause mortality by 34% at a mean of 1.3 years (91).

3.5.3. Specific aspects for potential quality indicators

For the secondary prevention medication QIs, the numerator and denominator should comprise all patients hospitalized with AMI. Only patients eligible to receive the medications should be included, and form both the numerator and denominator. Therefore, the numerators and denominators should not include patients who are allergic, have contraindications, refuse, or have side effects from the medications – these patients are ‘ineligible’.

Specifically, for the statins indicator, the numerator must only include patients who are prescribed a high intensity statin (such as atorvastatin 40-80 mg or rosuvastatin

20 mg) (92) at discharge. Consequently, patients who receive a low-intermediate intensity statin after hospitalization will be included in the denominator and not in the numerator. Patients with a history of intolerance to high-intensity statin therapy or have other characteristics that may influence safety should not be included in the numerator or denominator.

For ACEIs/ARBs, the numerator and denominator include all eligible patients with AMI who have heart failure or a LVEF ≤ 0.40 . Ineligibility criteria for the numerator and denominator include hypotension, acute renal failure and hyperkalemia (the contraindication must be documented in the patient's file). Specifically, the numerator is the number of patients with AMI and heart failure or a LVEF ≤ 0.40 who are prescribed an ACEI or an ARB.

Regarding beta-blockers, both STEMI and NSTEMI-ACS ESC guidelines are in alignment. Therefore, the numerator and denominator should comprise eligible patients with either heart failure or a LVEF ≤ 0.40 . Ineligibility criteria for beta-blockers include evidence of a low output state, increased risk for cardiogenic shock, PR interval > 0.24 seconds, second- or third-degree heart block, active asthma, or reactive airways disease. Therefore, the numerator will comprise the number of patients with AMI who have heart failure or a LVEF ≤ 0.40 , who have no ineligibility criteria, and who are prescribed a beta-blocker, whereas the denominator is defined as the number of patients with AMI who have heart failure or a LVEF ≤ 0.40 , and who have no ineligibility criteria.

3.5.4. Definition of the main and secondary quality indicators for “secondary prevention – discharge treatments”

Name of the Main QI	Proportion of patients with AMI discharged on statins, unless contra indicated, at high intensity (defined as atorvastatin \geq40 mg or rosuvastatin \geq20 mg).
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Name of the Secondary QI (1)	Proportion of patients with AMI and clinical evidence of heart failure or a LVEF \leq 0.40 who are prescribed, at discharge, an ACEI (or ARBs if intolerant of ACEI) unless contraindicated.
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Name of the Secondary QI (2)	Proportion of patients with AMI and clinical evidence of heart failure or an LVEF \leq 0.40 who are prescribed, at discharge, beta-blockers, unless contraindicated.
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3.5.5. Agreement with guidelines and existing quality indicators

Currently, the use of high intensity statins initiated early after admission to hospital (the main QI) is supported by the ESC guidelines (Class 1A) and ACC/AHA guidelines for STEMI (1B) and NSTEMI (Class1)(27, 28, 93, 94). The secondary QI, the use of an ACEi (or ARB if intolerant of ACEI) unless contraindicated, before discharge in patients with clinical evidence of heart failure or a LVEF \leq 0.40 is also

supported by the ESC and ACC/AHA guidelines (Class 1A). The other secondary QI, the use of a beta-blocker, unless contraindicated, before discharge in patients with clinical evidence of heart failure or a LVEF ≤ 0.40 is supported by the ESC guidelines (Class 1A) and ACC/AHA guidelines for STEMI (Class 1A) and NSTEMI (Class 1B).

3.6. Patient satisfaction

3.6.1. Dimensions of care

The Institute of Medicine has considered that being “respectful of and responsive to individual patient preferences, needs and values and [ensuring] that patients guide all clinical decisions” is a key element of the quality of care (1). Measuring patient satisfaction, as well as patient reported outcomes, provides information about symptoms, health-related quality of life, morbidity and satisfaction with care that are reported directly by the patient and not captured in medical records.

The ESC recognized the importance of including patient reported outcome measures (PROMs) in clinical trials and research to inform patients, clinicians, payers and policy-makers (95). PROMs provide information about health-related quality of life that can be used to assess how a treatment can improve symptoms or functional capacity, in association with other clinical endpoints such as clinical events or morbidity (96). This aspect of the quality has been measured through the patient satisfaction QI. Patient satisfaction informs about important aspects of the quality of management, such as fast access to reliable health advice, effective treatment and information delivered by health professionals, continuity of care and smooth transitions and emotional support, empathy and respect (97-99). Thus, patient satisfaction is an essential and complementary approach to conventional quality of

care indicators. This is the first time that PROMs have been considered in QIs for AMI.

3.6.2. Clinical relevance

Patient satisfaction measures a specific concept from the patient perspective that is obviously clinically relevant. Patient satisfaction can be assessed through specific questionnaires developed in the late 1970s (100), which explore multiple domains, such as symptoms and functional status, health perception, but also domains related to the relationship with nurses, physicians and other health professionals, to personal issues, admission, visitors, discharge, room, meals, tests and treatments (98). In the setting of ACS, patient information is a major component of patient satisfaction, whereby the more information patients receive, the more they report being satisfied (99). In a study using data from the CRUSADE registry and including 6467 patients with AMI, patient satisfaction was associated with guidelines adherence and with mortality rates(97).

3.6.3. Specific aspects for potential quality indicators

Given the complexity of assessment of patient satisfaction, the main QI is limited to the routine and continuous assessment of patient satisfaction through a specific scale. This scale should explore at least 3 domains: (1) pain control, (2) quality of information provided by the staff regarding the disease and treatment, and (3) quality of discharge explanations and education for secondary prevention and lifestyle.

3.6.4. Definition of the main and secondary QIs for “patient satisfaction”

Name of the	Feedback regarding patient’s experiences systematically collected in an organized way from all patients. It should
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Main QI (1)	<p>include the following points:</p> <ul style="list-style-type: none"> ▪ Pain control ▪ Explanations provided by health professionals about the coronary disease, the benefit/risk of discharge treatment, and medical follow-up ▪ Discharge information regarding what to do in case of recurrence of symptoms and recommendation to attend a cardiac rehabilitation program (including smoking cessation and diet counseling)
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3.6.5. Agreement with guidelines and existing quality indicators

The ESC NSTEMI-ACS guidelines recognized the need to consider patients' preferences for the decision regarding invasive strategy and revascularization, particularly in older patients. Pain control is usually not an issue for NSTEMI patients. In STEMI patients, relief of pain is considered of paramount importance, both for humane reasons but also to avoid excessive adrenaline activation and anxiety. Use of morphine, if needed, has a Class I C recommendation.

Patient information about the disease, need for treatment compliance, risk factor control (like smoking cessation, diet and weight control, physical activity) are recommended, as well as education about the recognition of symptoms.

No existing QI set has incorporated patient satisfaction. Conversely, a large number of hospitals routinely assess patient satisfaction. Centres from Medicare and Medicaid (CMS) in the United States have developed a national standardized survey instrument for measuring patient satisfaction: the Hospital Consumer Assessment of

Healthcare Providers and Systems (HCAHPS)(101-103). The United Kingdom's National Health Service Patient Survey also systematically gathers the views of the patients about the quality of care they have received (http://www.pickereurope.org/wp-content/uploads/2014/10/Inpatients_2015_spec_v12.pdf?gclid=COWclcmIk8oCFWoCwwodhRUC0Q).

3.7. Composite quality indicators and outcomes

3.7.1. Dimensions of care

Composite QI. In view of the growing interest in quality assessment among healthcare providers, insurances, agencies, press and the general public, composite quality indicators (CQI) have been developed. A CQI is a combination of two or more indicators into a single number to summarize multiple dimensions and to facilitate comparisons. In the field of assessment of quality of care, a CQI presents three potential advantages. Firstly, it comprehensively represents quality of care, making it possible to reduce the information into a single summary. Secondly, the information may contain a broader range of measures, including multiple dimensions of care. Thirdly, the presentation of the CQI as a single number facilitates its use by providers for decision-making, benchmarking or financial incentives. In addition, a CQI reduces the visible size of a set of indicators, allowing comparison and categorization of the centres, and it can be used to assess progress over time and facilitate communication and accountability. The disadvantage of the CQI is that it may be misinterpreted and invite simplistic policy conclusions. Another criticism leveled at

CQIs is that they can be like a “black box”, with loss of information; moreover, the selection of indicators and the models used to construct the CQI can be disputed.

Despite widespread enthusiasm for the development of CQIs, methodological controversies have arisen over their robustness, in the absence of an established model. In 2010, the AHA/ACC Task Force on Performance Measures published a Position Statement for the creation and interpretation of CQIs in healthcare assessment (6). The ACCA Quality of Care Working Group has decided to include two CQIs. A first CQI (opportunity-scoring), using a greater number of individual QIs, is suitable with a view to promoting high quality standards. The second (all or none) is based on discharge treatment, and is suitable for use in survivors and in all centres, irrespective of on-site facilities. These CQI can serve as a comparator between different healthcare systems or within centres to compare quality over time, and to determine categories of centres by comparison with the average value.

Outcome QI. Although clinical outcome is the final aim of quality of care, the use of outcome measures in quality assessment is the subject of controversy, since the variation in outcomes only partially depends on the quality of care. Furthermore, reporting outcomes might have adverse effects, such as restriction of admission for more severe patients. Nevertheless, since outcome measures are the most easily interpretable and also potentially important for patients (3), the Quality of Care Working Group has decided to include an outcome QI.

3.7.2. Clinical relevance

Whereas the relation between a single QI and clinical outcome is difficult to demonstrate, the relation between CQI and mortality has been established through different approaches. In early studies, a trend towards lower in-hospital mortality was observed across categories of centres defined according to the quartiles of a

composite indicator (104). Similarly, a significant trend towards lower 30-day mortality, adjusted for the GRACE risk score, was also observed at patient level, by quartiles of a composite score (105). The strength of association is higher with CQIs as compared to individual QIs (104, 106).

The association between CQIs and mortality has been observed in-hospital, but also at 30 days (105-108) and 1 year (106, 108). The magnitude of the relation between a CQI and mortality is usually modest, but significant. In a study from the National Registry of Myocardial Infarction, 6% of the variance in 30 day mortality after STEMI was explained by a CQI including “only” timely reperfusion and smoking measures (7). Similarly, the correlation between CQI and mortality (107) or risk adjusted mortality (105, 106, 109) is not strong. Indeed, the magnitude of the relation between a CQI and mortality depends on the individual QIs used, and on the type of QI.

3.7.3. Specific aspects for potential quality indicators

Explicit criteria exist for the development of composite performance measures so that they can accurately reflect healthcare quality, including explicit quantification of the numerator and denominator of potential measures and explicit evaluation of the interpretability, actionability, and feasibility of the proposed measure. Among the different methods of aggregation, the “opportunity-based” score (with or without weighting) and the “all or none” are the most frequently used in the assessment of quality of care. These two methods provide different results and the appropriate approach should be selected according to the purpose of the assessment (107, 108, 110, 111).

Opportunity Scoring: The main CQI includes all the individual QIs selected by the group, including structure, process and patient satisfaction QIs. However, since it is

possible that not all the components are available in all centres, the opportunity-based scoring method has been chosen for the calculation of this CQI, without weighting.

All or None: The secondary CQI included here uses discharge prescriptions, and is calculated using the “all or none” method. This method best reflects the interest of the patient, since even one missing component in the score may influence outcome. This CQI makes it possible to track excellence. For each patient, the CQI is rated 1 if all components of the CQI are present and it is rated 0 if one or more components are missing. In patients with heart failure or LVEF ≤ 0.40 , the CQI is calculated from five individual QIs, and for patients without heart failure or with LVEF >0.40 , the CQI is calculated using three individual QI.

30-day mortality rate, adjusted for GRACE risk score: Although there is no question as to the importance of outcome in quality of care, the use of outcome QIs is still controversial. Limitations on the use of outcomes as QI include the complex and multifactorial determinants of outcome, as well as the low proportion of variance in outcomes that can be explained by quality of care. The least controversial outcome QI in the setting of AMI is the adjusted 30-day mortality. Given the relatively low 30-day mortality rate after AMI in European countries, reliable assessment of mortality rate over a short period of time is challenging. In addition, the risk model used for adjustment can influence the results. In their latest position paper, the ACC/AHA recognized adjusted 30-day mortality as an acceptable outcome PM (3). Our writing group has selected the GRACE risk score for adjustment, since this score has been recently updated and validated in European registries and because guidelines recommend the calculation of GRACE risk score in patients with NSTEMI (52).

3.7.4. Definition of the main and secondary quality indicator for “composite quality indicators and outcomes”

<p>Name of the Main CQI</p>	<ul style="list-style-type: none"> • <u>Composite QI</u> = Main CQI: Opportunity-based CQI, with the following individual indicators: <ul style="list-style-type: none"> ○ The centre is part of a Network Organization ○ Proportion of patients reperfused among eligible (STEMI with FMC <12 hours after onset of pain). ○ Coronary angiography in STEMI and NSTEMI patients at high ischaemic risk and without contraindications ○ Ischaemic risk assessment using the GRACE risk score in NSTEMI patients ○ Bleeding risk assessment using the CRUSADE risk score in STEMI and NSTEMI patients ○ Assessment of LVEF before discharge. ○ Low dose aspirin (unless high bleeding risk or oral anticoagulation) ○ Adequate P2Y12 inhibition (as defined in treatment during hospitalization section) ○ ACEI (or ARBs if intolerant of ACEI, unless contra indicated) before discharge in patients with clinical
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	<p>evidence of heart failure or LVEF ≤ 0.40.</p> <ul style="list-style-type: none"> ○ beta-Blockers (unless clear contraindication) in patients with clinical evidence of heart failure or LVEF ≤ 0.40 ○ High intensity statins ○ Feedback regarding the patient's experience and quality of care is systematically collected for all patients
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<p>Name of the Secondary CQI (1)</p>	<ul style="list-style-type: none"> • Secondary CQI: All-or-none CQI based on 3 or 5 components, according to the LVEF. • <i>In patients without heart failure and with LVEF >0.40, CQI calculated on 3 individual QI:</i> <ul style="list-style-type: none"> • Low dose aspirin • P2Y₁₂ inhibitor (unless documented contraindication) • High intensity statins • <i>In patients with heart failure or with LVEF ≤ 0.40, CQI calculated on 5 individual QI:</i> <ul style="list-style-type: none"> • Low dose aspirin • P2Y₁₂ inhibitor (unless documented contraindication) • High intensity statins
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	<ul style="list-style-type: none"> • ACEI (or ARB if intolerant of ACEI) in patients with clinical evidence of heart failure or LVEF ≤ 0.40 • Beta-blockers (unless clear contraindication) in patients with clinical evidence of heart failure or LVEF ≤ 0.40
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Name of the secondary QI (2)	Outcome QI: Risk-adjusted 30-day mortality rate adjusted on the GRACE 2.0 risk score.
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3.7.5. Agreement with existing QI and guidelines:

Currently, no CQI is included in the ACC/AHA set of PM (8), or in the Canadian PM (112). Conversely, CQI are used for assessment of quality of care by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), the Myocardial Ischemia National Audit Project (MINAP) (108) and by the French National Authority for Health (Haute Autorité de Santé) (113).

Outcome QI: The use of the GRACE 2.0 risk calculator is recommended in the ESC guidelines for ischaemic risk assessment and for prognostic assessment in NSTEMI patients. The risk-adjusted 30-day mortality rate is recommended by the ACC/AHA task force, but is not included in the ACC/AHA QI set.

4. Discussion

The Acute Cardiovascular Care Association (ACCA) brought together the current Quality of Care Working Group with a view to defining a set of QIs for the management of AMI. This is the first such initiative undertaken within the ESC by one of its constituent associations. The absence of any official publication of QIs in STEMI and NSTEMI by the ESC to date is in contrast with the historical experience of the ACC and AHA in this area (8, 9), and with individual national initiatives. Among the missions of the ACCA, “improving the quality of care of patients with acute cardiovascular disease” is fundamental, thus justifying the creation of this Working Group to define QIs suitable for use in this clinical setting.

Specificities of the quality indicators defined by the ACCA:

Compared with previous QIs defined by the ACC-AHA (8, 9), the Canadian Cardiovascular Society (40), or the National Service Framework for Coronary Heart Disease (114), the selection of suitable QIs by the ACCA Quality of Care Working Group followed a methodology that is comparable in many respects, but different on a certain number of important points.

While the QIs developed by our group are in line with the official guidelines published by the ESC, they are not simply the reflection of high grade recommendations, but rather incorporate measures that have a grade II recommendation, or even no recommendation at all, because the Quality of Care Working Group feels that it is a critically measurable reflection of the quality of care. Indeed, therein lies the difference between guidelines and quality indicators (115). Conversely, some key features of management that hold a strong grade recommendation were not retained as QI, when it was judged that there was little room for improvement. A typical

example of this is the prescription of aspirin at admission or discharge, which is among the QIs issued by the ACC-AHA, but registry data show that the already widespread implementation of this measure leaves little room to further improve practices on this point. Although some of the QIs do not fulfil the criteria for PM, the ACCA Quality of Care Working Group decided to keep all selected QIs, even if the set of QI might not be suitable for public reporting, benchmarking or Pay for Performance. The main reason was that the QI focus on processes of care for which failure to follow the recommendations is likely to result in suboptimal patient outcomes.

Another point of divergence between the QIs defined here and previous publications from other societies concerns the wide spectrum of topics covered by the ACCA QIs. Indeed, seven domains were selected to define one or more main QIs as well as secondary QIs. Two domains are related to the organisation at the level of the centre, as opposed to the quality of individual management. In particular, the Structure-Network domain emphasises the importance of the working environment in each centre, as this has been clearly shown to have an impact on clinical outcomes in STEMI management. Patient satisfaction is the second domain that deals with centre organisation rather than individual patterns of care. To date, neither the ACC-AHA QIs nor those of the Canadian Cardiovascular Society have defined any indicators relating to centre organisation or patient satisfaction. The ACCA Quality of Care Working Group considered that certain contributors to patient satisfaction (e.g. pain management, respect, education) can reflect the quality of care better than medical criteria.

In the five other domains, the QIs selected by the ACCA Quality of Care Working Group present some differences and specificities as compared to existing QIs from

other sources. For example, in addition to a QI for reperfusion, a QI for “early invasive strategy” has been added, which is applicable to patients with NSTEMI. Estimation of the ischaemic and bleeding risks using the GRACE and CRUSADE risk scores respectively has been added as a QI, going beyond the simple measure of LVEF recommended by American PMs. The QIs related to secondary prevention focus on the use of high-intensity statins and on the treatment of patients with a LVEF ≤ 0.40 , which are two situations where these treatments are especially beneficial. Lastly, the composite criterion proposed in this paper is computed using the “opportunity-based” method, based on all the main QIs from all the domains, while a second “all or none” composite QI is proposed, with a limited number of QIs (108, 116).

Implementation of QIs

The QIs defined here by the ACCA Quality of Care Working Group are not intended for ranking, benchmarking, or pay-for-performance, but merely in the aim of monitoring and improving quality of care through meaningful surveillance, in line with the founding principles of quality of care first described by Donabedian in 1966 (10). A second major point is the wide spectrum of the care pathway that is covered by the different domains, namely centre organisation, risk assessment, acute management and secondary prevention through to outcome. A composite indicator is proposed to provide a summary indicator for all the information from these different domains.

In this document, we propose main QIs, and secondary level QIs. A total of 12 main QIs are proposed, representing criteria that we consider to be major, requiring preferential measurement. The eight secondary QIs are supplementary measures of quality that are suitable for use as a complementary approach. In the continuity of

this document, the Quality of Care Working Group plans to design a registry specifically intended for performance measurement, as well as annual updates of the QIs to reflect any changes in ESC guidelines.

Assessment of QIs and Perspectives

Among the main characteristics of a QI, feasibility and reliability of the assessment are important, and have an impact on the selection of the QI. The ACCA Quality of Care Working Group QI set has been defined in this view. To date, national initiatives for assessment of quality have used administrative databases, registries (specifically designed or not) or observational cohort studies. Across Europe, leading examples include the Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies (SWEDEHEART) registry, which is a comprehensive and voluntary database of all patients admitted for ACS in all Swedish hospitals and including approximately 80,000 new cases per year (117); the Myocardial Ischaemia National Audit Project (MINAP) in England and Wales (the participation of all institutions in England and Wales is mandatory and MINAP is used as a tool to improve quality of care (118); the French registries on Acute ST-elevation or non-ST-elevation myocardial infarction (FAST-MI), which consist in one-month snapshot surveys performed every 5 years since 1995 (119), Acute Coronary Syndrome Israeli Survey (ACSIS) (120) - biennial two-months registries in all Israeli ICCUs (119) and lastly, the German Maximal Individual Therapy in Acute Myocardial Infarction (MITRA) and Arbeitsgemeinschaft Leitender Kardiologischer Krankenhausärzte (ALKK) registries(121),(121). The Spanish Society of Cardiology and of Thoracic and Cardiovascular Care has defined quality markers for clinical cardiology, cardiac imaging acute care, interventional cardiology, cardiac rehabilitation and cardiac surgery (122). The proposed indicators

for AMI are in line with the ACCA selection, but not precisely defined, and limited to direct transfer for PCI and recording first medical contact to balloon time for STEMI patients, risk assessment, revascularization for high risk patients and adherence to guidelines for discharge treatment. Several other European countries have successfully implemented large-scale population-based registries to collect information about the incidence, management and outcome of ACS, such as the Acute Myocardial Infarction and Unstable Angina in Switzerland (AMIS plus) registry(123), the Italian BLITZ registry (124), the PRIAMHO I and II (125) in Spain and in the Central and Eastern European countries (126). Registries for assessment of quality have also been organized by the ESC, such as the Euro Heart Survey-ACS programme (88, 90, 127). Results from specific European national campaigns using quality indicators or QIs have also been reported (113).

5.Conclusions

In agreement with the missions of the ACCA, the Quality of Care Working Group has planned a quality assessment programme through a dedicated registry using the main and secondary QI developed here. Despite its limitations, the publication of this set of QI will offer the possibility to assess the quality of management of AMI, which in turn will provide a clear picture of the management of AMI in Europe and serve to identify the domains of care where improvements are most needed.

Table 1: List, area of expertise and participation in QI domains of the members of the Quality of Care Working Group (by order of authorship).

Table 2: Summary of the Quality Indicators: definition, numerator and denominator, rationale, support from guidelines and method of reporting.

Figure: Summary of the Quality Indicators: definition, and support from guidelines

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Appendix Table: List, area of expertise and participation in QI domains of the members of the Quality of Care Working Group (by order of authorship)

Members of the Quality WG	Country	Area of expertise	Participation in QI Domain
Francois Schiele	France	ICCU-Interventional Cardiology-Statistics-Cardiovascular Quality and Outcomes	Chair of the Quality of Care WG Composite and Outcomes (chair)
Christopher Gale	UK	Statistics-Cardiovascular Quality and Outcomes- Public Health	Secondary prevention, discharge treatment (chair)
Eric Bonnefoy	France	ICCU	Reperfusion-Invasive Strategies
Marc Claeys	Belgium	ICCU-Interventional Cardiology	Composite and Outcomes
Frederic Capuano	France	Statistics-Cardiovascular Quality- Public Health	Composite and Outcomes
Nicolas Danchin	France	ICCU-Statistics- Cardiovascular Quality and Outcomes-Public Health	Reperfusion-Invasive Strategies
Keith A. A. Fox	UK	ICCU- Statistics- Cardiovascular Quality and Outcomes, Public Health	Reperfusion-Invasive Strategies
Kurt Huber	Austria	ICCU-Interventional Cardiology	Center Organization (chair)
Zaza Iakobishvili	Israel	ICCU-Internal Medecine	Center Organization
Maddalena Lettino	Italy	ICCU- Clinical Cardiology Cardiovascular Quality and Outcomes	In-hospital risk assessment (chair)
Tom Quinn	UK	Emergency cardiovascular care, nursing	Patient's Satisfaction (chair)
Maria Rubini Gimenez	Swiss	Clinical Cardiology	Secondary prevention, discharge treatment
Hans Erik Bøtker	Denmark	ICCU-Statistics- Cardiovascular Quality and Outcomes-Public Health	Center Organization
Eva Swahn	Suede	Clinical Cardiology	Secondary prevention, discharge treatment
Adam Timmis	UK	Clinical Cardiology-Editor- Cardiovascular Quality and Outcomes	In-hospital risk assessment
Marco Tubaro	Italy	ICCU- Clinical Cardiology Cardiovascular Quality and Outcomes	Anti thrombotic during hospitalization (chair)
Christiaan Vrints	Belgium	Clinical Cardiology-Editor- Cardiovascular Quality and Outcomes	Center Organization
David Walker	Belgium	Emergency cardiovascular care	Centre Organization
Doron Zahger	Israel		Anti thrombotic during hospitalization
Uwe Zeymer	Germany	ICCU-Interventional Cardiology	Reperfusion-Invasive Strategies (chair)
Hector Bueno	Spain	ICCU-Interventional Cardiology Clinical Cardiology-Editor- Cardiovascular Quality and Outcomes	In-hospital risk assessment

Table 2: Summary of the Quality Indicators: definition, numerator and denominator, rationale, support from guidelines and method of reporting

1.1. Centre Organization. Main QI: The centre should be part of a Network Organization with written protocols for rapid and efficient management covering the following points:

- Single emergency phone number for the patient to be connected with a medical system for triage.
- Pre-hospital interpretation of ECG for diagnosis and decision for immediate transfer to a center with catheterization laboratory facilities.
- Pre-hospital activation of the catheterization laboratory.

Numerator: All centres that are part of a Network Organization

Denominator: All centres.

Clinical rationale: To improve speed and efficiency of pre-hospital care and reperfusion for STEMI patients

Sources of Data: Administrative data

Corresponding guidelines:

- Network organization: ESC STEMI GL Class I, level B,
- Written protocol: ESC STEMI GL Class I, level C.
- Single phone call: no recommendation.
- Pre hospital interpretation of ECG: ESC STEMI GL Class I, level B.
- Pre hospital activation of the catheterization laboratory: ESC STEMI GL Class IIa, level B.

Method of reporting: Qualitative measure per centre.

1.2. Centre Organization. Secondary QI (1): Routine assessment of relevant times for the reperfusion process in STEMI patients (i.e. times from “call to first medical contact”, “first medical contact to door”, “door to device”; and “door-in door-out” for centers without a catheterization laboratory on site).

Numerator: All centres with routine assessment of relevant intervals for the reperfusion process.

Denominator: All centres.

Clinical rationale: To identify system inefficiencies and steps where reduction in time for reperfusion for STEMI patients is possible.

Sources of Data: Administrative data.

Corresponding guidelines:

- Routine assessment of time to reperfusion for STEMI patients (time “call to first medical contact”, first medical contact to door”, door to device”): ESC STEMI GL, Class I, level C
- All hospital must record and monitor delay times: ESC STEMI GL, Class I, level B

Method of reporting: Qualitative measure (per centre).

1.3. Centre Organization. Secondary QI (2):The centre should participate in a regular registry or program for quality assessment.

Numerator: Centres participating in a registry.

Denominator: All centres.

Clinical rationale: To allow assessment of quality of care.

Sources of Data: Administrative data, Registry data.

Corresponding guidelines:

- The center should participate regularly in a registry for quality assessment: ESC STEMI GL, Class I, level C
- Development of regional or national programmes to measure performance indicators systematically and provide feedback to individual hospitals : proposed as PM by ESC GL NSTE-ACS

Method of reporting: Qualitative measure (per centre).

2.1. Reperfusion-Invasive Strategy. Main (STEMI 1):Proportion of STEMI patients reperfused among those eligible (onset of symptoms to diagnosis <12h)

Numerator: Number of STEMI patients with onset of symptoms to diagnosis <12h who receive reperfusion therapy

Denominator: All STEMI patients eligible for reperfusion (onset of symptoms to diagnosis <12h, without contraindication or patient refusal).

Clinical rationale: All STEMI patients (within the first 12 hours) should receive reperfusion therapy.

Sources of Data: Administrative data and medical records.

Corresponding guidelines: ESC STEMI GL:Reperfusion <12 hours: Class I, level A.

Method of reporting: Proportion (standard error).

2.2. Reperfusion-Invasive Strategy. Main QI (STEMI 2): Proportion of patients with timely reperfusion. Timely is defined as:

- **For patients treated with fibrinolysis: < 30 mins from diagnosis (FMC) to needle**
- **For patients treated with primary PCI and admitted to centres with catheterization laboratory facilities: < 60 mins from door to balloon (passage of wire) for reperfusion with PCI**
- **For transferred patients: door-in door-out time of < 30 mins**

Numerator: Number of STEMI patients treated with primary PCI within the above delays

Denominator: All STEMI patients eligible for reperfusion by primary PCI (onset of symptoms to diagnosis <12h, without contraindication or patient refusal).

Clinical rationale: Time to effective mechanical reperfusion should be reduced.

Sources of Data: Pre-hospital and hospital medical records, ECG, angiography.

Corresponding guidelines: Timely reperfusion:

- *For patients treated with fibrinolysis: < 30 min FMC to needle: ESC STEMI GL, class I, level B*
- *For patients admitted to centers with catheterization laboratory facilities: <60 min door to balloon (passage of wire) for reperfusion with PCI ESC STEMI GL, class I, level B*
- *For patients transferred to a non PCI-capable centre for primary PCI : should bypass the emergency department... : ESC STEMI GL, Class IIa, level B. <30 mins door-in-door out: ESC Revascularization GL, Class IIa, level B.*

Method of reporting: Proportion (standard error).

2.3. Reperfusion-Invasive Strategy. Main QI (NSTEMI): Proportion of patients with NSTEMI and no contra indication who receive coronary angiography within 72 hours after admission.

Numerator: Number of NSTEMI patients at high-intermediate ischemic risk undergoing coronary angiography within 72 hours after the diagnosis.

Denominator: All NSTEMI patients at high-intermediate ischemic risk without contraindications or patient refusal.

Clinical rationale: NSTEMI patients at high risk should be treated with early invasive strategy. Early is defined as ≤ 72 hours after admission

Sources of Data: Medical records, ECG, angiography.

Corresponding guidelines: Invasive strategy ≤ 72 hours for high-intermediate risk (in patients with NSTEMI and one intermediate-risk criteria (diabetes mellitus, renal dysfunction (eGFR<30 ml/min/1.72m²), LVEF ≤ 0.40 , congestive heart failure, recent PCI, prior CABG,

GRACE risk score >140) or recurrent symptoms or ischaemia on non invasive testing: ESC NSTEMI-ACS GL Class I, level A.

Method of reporting: Proportion (standard error).

2.4. Reperfusion-Invasive Strategy. Secondary QI (STEMI): The time between the diagnosis (FMC) and passage of wire (absolute value) for primary PCI.

Clinical rationale: Improve speed and efficiency of pre-hospital care and reperfusion for STEMI patients.

Sources of Data: Pre-hospital and hospital medical records, ECG, angiography.

Corresponding guidelines: ESC Guidelines for STEMI 2012: Routine assessment of times for reperfusion: Class I, level B

Method of reporting: Median time

3.1. In Hospital Risk Assessment. Main QI (1): The proportion of patients with NSTEMI in whom ischaemic risk assessment using the GRACE risk score is performed. GRACE score should be assessed and the numerical value of the score recorded for all patients admitted with suspected NSTEMI.

Numerator: Number of NSTEMI patients who have been stratified according to the GRACE risk score.

Denominator: Number of NSTEMI patients.

Clinical rationale: NSTEMI patients at high ischemic risk should be treated with early invasive strategy.

Sources of Data: Medical records.

Corresponding guidelines:

- Prognostic risk assessment: The use of risk scores for estimating prognosis is recommended:ESC NSTEMI-ACS GL, Class I, level A
- GRACE score: Recommendations Class IA depending on the value of the GRACE score.

Method of reporting: Proportion (standard error).

3.2. In Hospital Risk Assessment. Main QI (2): Proportion of patients admitted with STEMI or NSTEMI who have bleeding risk assessment using the CRUSADE bleeding score. The CRUSADE bleeding score should be assessed and the numerical value of the score recorded for all patients admitted with STEMI or NSTEMI.

Numerator: Number of STEMI or NSTEMI patients who have been stratified according to the CRUSADE bleeding score.

Denominator: Number of STEMI or NSTEMI patients.

Clinical rationale: STEMI and NSTEMI patients at high bleeding risk should be treated with caution regarding anti thrombotic treatment.

Sources of Data: Medical records.

Corresponding guidelines:

- Prognostic risk assessment: ESC NSTEMI-ACS GL Class I, level A.
- CRUSADE bleeding score: ESC NSTEMI-ACS GL: Class IIb, level B.

Method of reporting: Proportion (standard error).

3.3. In Hospital Risk Assessment. Main QI (3): Proportion of patients with assessment of LVEF before discharge. LVEF should be assessed and the numerical value recorded for all patients admitted with STEMI or NSTEMI.

Numerator: Number of AMI patients with measured LVEF.

Denominator: All AMI patients.

Clinical rationale: All AMI patients with LVEF ≤ 0.40 need specific medical treatment.

Sources of Data: Medical records, echocardiogram, ECG.

Corresponding guidelines:

- LVEF assessment: ESC STEMI GL Class I, level A.
- LVEF assessment: ESC NSTEMI-ACS GL Class I, level C.

Method of reporting: Proportion (standard error).

4.1. Anti thrombotics during hospitalization. Main QI (1): Proportion of patients with “adequate P2Y₁₂ inhibition” defined as: (number of patients discharged with prasugrel or ticagrelor or clopidogrel) / (patients eligible). Eligible is defined as follows:

- For ticagrelor: AMI patients without previous haemorrhagic stroke, high bleeding risk, fibrinolysis or oral anticoagulation.
- For prasugrel: PCI-treated AMI patients without previous haemorrhagic or ischemic stroke, high bleeding risk (patients ≥ 75 years and/or < 60 kg body weight are also considered as high bleeding risk), fibrinolysis or oral anticoagulation.
- For clopidogrel: no indication for prasugrel or ticagrelor and no high bleeding risk.

Numerator: Number of STEMI and NSTEMI patients with “adequate P2Y₁₂ inhibitor” at discharge.

Denominator:STEMI and NSTEMI patients alive at discharge and without contraindications to P2Y12 inhibitors

Clinical rationale: Superiority of prasugrel and ticagrelor over clopidogrel in selected patients.

Sources of Data: Medical records.

Corresponding guidelines: ESC STEMI, ESC NSTEMI-ACS and ESC revascularization GL:

- Eligibility for Ticagrelor: Class I, level B.
- Eligibility for Prasugrel: Class I, level B.
- Eligibility for Clopidogrel: Class I, level A.

Method of reporting: Proportion (standard error).

4.2. **Anti thrombotics during Hospitalization. Main QI (2): Proportion of patients with NSTEMI treated with fondaparinux, unless candidate for immediate (≤ 2 hours) invasive strategy or with eGFR < 20 ml/min.**

- **Numerator:** Number of NSTEMI patients with eGFR ≥ 20 ml/min, not candidates for urgent invasive strategy, treated with fondaparinux.

Denominator: All NSTEMI patients with eGFR ≥ 20 ml/min, not candidates for urgent invasive strategy.

Clinical rationale: Better risk / benefit profile of fondaparinux in NSTEMI patients.

Sources of Data: Medical records.

Corresponding guidelines: Fondaparinux most favorable risk benefit profile (for NSTEMI patients not candidate for urgent angiography): ESC NSTEMI-ACS and Revascularization GL Class I, level B.

Method of reporting: Proportion (standard error).

4.3. **Anti thrombotics during Hospitalization. Secondary QI: Proportion of patients discharged on dual antiplatelet therapy, defined as: (number of patients discharged on dual antiplatelet therapy) / (number of patients with AMI without clear and documented contraindication).**

Numerator: Number of STEMI and NSTEMI patients, without contra indication, discharged with dual antiplatelet therapy.

Denominator: All STEMI and NSTEMI patients, without contra indications to dual antiplatelet therapy.

Clinical rationale: Benefit of DAPT over single antiplatelet therapy for 12 months.

Sources of Data: Medical records.

Corresponding guidelines: Irrespective of the revascularization strategy, a P2Y₁₂ inhibitor is recommended in addition to aspirin for patients with AMI: ESC STEMI GL, Class I, level A; ESC NSTEMI-ACS GL, Class I, level A.

Method of reporting: Proportion (standard error).

5.1. **Secondary Prevention-Discharge Treatment. Main QI (1): Proportion of patients with AMI discharged on statins, unless contra indicated, at high intensity (defined as atorvastatin ≥ 40 mg or rosuvastatin ≥ 20 mg).**

Numerator: The number of patients with AMI who receive high intensity statin therapy at discharge

Denominator: STEMI and NSTEMI patients alive at discharge and without contraindications, refusal, side effects, allergy, or history of intolerance to high-intensity statin therapy.

Clinical rationale: The use of high intensity statins is associated with reduced risk of recurrent cardiovascular events and mortality following AMI.

Sources of Data: Medical records.

Corresponding guidelines: Statins high intensity as early as possible, unless contra indication: ESC STEMI GL, Class I, level A, ESC NSTEMI-ACS GL, Class I, level A

Method of reporting: Proportion (standard error).

5.2. **Secondary Prevention-Discharge Treatment. Secondary QI (1): Proportion of patients with AMI and clinical evidence of heart failure or a LVEF ≤ 0.40 who are discharged on ACEI (or ARBs if intolerant of ACEI) unless contraindicated.**

Numerator: The number of patients with AMI who have heart failure or a LVEF ≤ 0.40 , and who receive an ACEI/ARB before discharge.

Denominator: All AMI patients who have heart failure or a LVEF ≤ 0.40 , and who are eligible for ACEI/ARBs (no hypotension, acute renal failure, hyperkalemia, contraindications, refusal, side effects or allergy).

Clinical rationale: The use of ACEIs/ARBs is associated with reduced mortality following AMI in patients with heart failure or left ventricular systolic dysfunction.

Sources of Data: Medical records.

Corresponding guidelines: ACE inhibitor in patients with LVEF ≤ 0.40 or heart failure, hypertension or diabetes: ESC STEMI GL, class I, level A, ESC NSTEMI-ACS GL Class I, level A

Method of reporting: Proportion (standard error).

5.3. **Secondary Prevention-Discharge Treatment. Secondary QI (2): Proportion of patients with AMI and clinical evidence of heart failure or an LVEF ≤ 0.40 who are discharged on beta-blockers, unless contraindicated.**

Numerator: The number of patients with AMI who have heart failure or a LVEF ≤ 0.40 and receive a beta-blocker before discharge.

Denominator: All AMI patients who have heart failure or a LVEF \leq 0.40, and are eligible for beta-blockers (no evidence of a low output state, increased risk for cardiogenic shock, PR interval $>$ 0.24 seconds, second- or third-degree heart block, active asthma, or reactive airways disease).

Clinical rationale: The use of beta-blockers in patients with AMI and who have heart failure or left ventricular systolic dysfunction is associated with a mortality benefit.

Sources of Data: Medical records.

Corresponding guidelines: Beta-blocker therapy in patients with LVEF \leq 0.40, unless contraindicated: ESC STEMI GL, Class I, level A, ESC NSTEMI-ACS GL, Class I, level A

Method of reporting: Proportion (standard error).

6.1. **Patient satisfaction.** Main QI: **Feedback regarding the patient's experience systematically collected in an organized way from all patients. It should include the following points:**

- Pain control.
- Explanations provided by doctors and nurses (about the coronary disease, the benefit/risk of the discharge treatment, and medical follow-up).
- Discharge information regarding what to do in case of recurrence of symptoms and recommendation to attend a cardiac rehabilitation program (including smoking cessation and diet counseling).

Numerator: Number of STEMI and NSTEMI patients discharged alive with feedback collected.

Denominator: STEMI and NSTEMI patients discharged alive.

Clinical rationale: Patient satisfaction must be considered in assessment of quality of care. Relation between patient satisfaction and adherence to guidelines, and with mortality.

Sources of Data: Administrative data and medical records.

Corresponding guidelines: No ESC GL to support this QI. Review paper by Anker et al published in Eur Heart J in 2014

- Participation in a well-structured cardiac rehabilitation programme: ESC NSTEMI-ACS GL, Class IIa, level A
- Smoking cessation advice/counselling: ESC STEMI GL, class I, level C; proposed as PM by ESC GL NSTEMI-ACS 2015, no recommendation
- Enrollment in a secondary prevention /cardiac rehabilitation programme: : proposed as PM by ESC NSTEMI-ACS GL, 2015, no recommendation

Method of reporting: Proportion (standard error).

7.1. **Composite QI.** Main Composite QI: **Opportunity based CQI, with the following individual indicators:**

- The center is part of a network organization
- Proportion of patients reperfused among eligible (STEMI with FMC <12 hours after onset of pain)
- Coronary angiography in STEMI and NSTEMI patients at high ischaemic risk and without contraindications
- Ischemic risk assessment using the GRACE risk score in NSTEMI patients
- Bleeding risk assessment using the CRUSADE risk score in STEMI and NSTEMI patients
- Assessment of LVEF before discharge
- Low dose aspirin (unless high bleeding risk or oral anticoagulation)
- Adequate P2Y₁₂ inhibition (as defined in the treatment during hospitalization section)
- ACEI (or ARB if intolerant of ACEI) in patients with clinical evidence of heart failure or an LVEF ≤0.40
- Beta-blockers (unless clear contraindication) in patients with clinical evidence of heart failure or an LVEF ≤0.40
- High intensity statins
- Feedback regarding the patient's experience and quality of care is systematically collected for all patients.

Numerator: all AMI patients discharged: sum of points (one point for each individual indicator, all individual indicators are weighted equally)

Denominator: All AMI patients discharged: sum of points (one point for each applicable indicator, according to patient and centre characteristics).

Clinical rationale: Relation between CQI and mortality.

Sources of Data: Administrative data and Medical records, statistical computation.

Corresponding guidelines: no Recommendation.

Method of reporting: Mean value (95% confidence interval).

7.2. Composite QI. Secondary Composite QI: **All-or-none CQI based on 3 or 5 components, according to the LVEF.**

Calculated on 3 individual QIs in patients without heart failure and with LVEF >0.40.

- Low dose aspirin
- P2Y₁₂ inhibitor (unless documented contraindication)
- High intensity statins

Calculated on 5 individual QIs in patients with heart failure or with LVEF \leq 0.40.

- **Low dose aspirin**
- **P2Y₁₂ inhibitor (unless documented contraindication)**
- **High intensity statins**
- **ACEI (or ARB if intolerant to ACEI) in patients with clinical evidence of heart failure or LVEF \leq 0.40**
- **Beta-blockers (unless clear contraindication) in patients with clinical evidence of heart failure or LVEF \leq 0.40**

Clinical rationale: Relation between CQI and mortality.

Sources of Data: Medical records, Statistical computation.

Corresponding guidelines: no Recommendation.

Method of reporting: At patient level, can be 0 or 1. At centre level, mean value (95% confidence interval).

7.3. **Outcome QI.** Secondary Outcome QI: **30-day mortality rate adjusted for the GRACE 2.0 risk score.**

Numerator: All AMI patients who died within 30 days after admission, with assessment of the GRACE risk score.

Denominator: All AMI patients with assessment of the GRACE risk score and 30 day follow-up.

Sources of Data: Medical records, registry data.

Clinical rationale: 30 day adjusted mortality is an established criterion for quality of care in AMI patients.

Corresponding guidelines: no Recommendation.

Method of reporting: Proportion (standard error).

Figure

Domain of Care	Quality Indicator	Support from ESC guidelines
<p>Center Organization</p>	<p>Main QI: The centre should be part of a Network Organization with written protocols for rapid and efficient management covering the following points:</p> <ul style="list-style-type: none"> •Single emergency phone number for the patient to be connected to a medical system for triage •Pre-hospital interpretation of ECG for diagnosis and decision for immediate transfer to a center with catheterization laboratory facilities •Pre-hospital activation of the catheterization laboratory <p>Secondary QI (1): Routine assessment of relevant times for the reperfusion process in STEMI patients (i.e. times from “call to first medical contact”, “first medical contact to door”, “door to device” and “door-in door-out” for centers without a catheterization laboratory on site).</p> <p>Secondary QI (2): The center should participate in a regular registry or program for quality assessment.</p>	<p>Network: ESC GL, Class I, level B Written protocol: ESC STEMI GL Class I, level C</p> <p>Single phone number : No ESC GL to support this QI.</p> <p>Pre hospital interpretation of ECG: ESC STEMI GL, Class I level B</p> <p>Pre hospital easy activation of the catheterization laboratory : ESC STEMI GL, level B</p> <p>Routine assessment of time to reperfusion for STEMI patients (time “call to first medical contact”, first medical contact to door”, door to device”): ESC STEMI GL, Class I, level C All hospital must record and monitor delay times: ESC STEMI GL, Class I, level B</p> <p>The center should participate regularly in a registry for quality assessment: ESC STEMI GL, Class I, level C Development of regional or national programmes to measure performance indicators systematically and provide feedback to individual hospitals : proposed as PM by ESC GL NSTE-ACS 2015</p>
<p>Reperfusion-Invasive Strategy</p>	<p>Main QI (STEMI 1): Proportion of STEMI patients reperfused among eligible (onset of symptoms to diagnosis <12h)</p> <p>Main QI (STEMI 2): Proportion of patients with timely reperfusion. Timely is defined as:</p> <ul style="list-style-type: none"> • For patients treated with fibrinolysis: < 30 mins from diagnosis (FMC) to needle • For patients treated with primary PCI and admitted to centres with catheterization laboratory facilities: < 60 mins from door to balloon (passage of wire) for reperfusion with PCI • For transferred patients: door-in door-out time of < 30 mins <p>Secondary QI (STEMI): the time between the diagnosis (FMC) and passage of wire time (absolute value) for primary PCI.</p> <p>Main QI (NSTEMI): Proportion of patients with NSTEMI, and no contra-indication, who receive coronary angiography within 72 hours after admission.</p>	<p>Reperfusion STEMI patients Onset up to 12h: ESC STEMI GL, Class I, level A</p> <p>Timely reperfusion:</p> <ul style="list-style-type: none"> • For patients treated with fibrinolysis: < 60 min FMC to needle: ESC STEMI GL, class I, level B • For patients admitted to centres with catheterization laboratory facilities: <60 min door to balloon (passage of wire) for reperfusion with PCI ESC STEMI GL, class I, level B • For patients transferred to a non PCI-capable centre for primary PCI : should bypass the emergency department... : ESC STEMI GL, Class IIa, level B <30 mins door-in-door out: ESC Revascularization GL, Class IIa, level B. <p>All hospitals must record and monitor delay times: ESC STEMI GL, Class I, level B</p> <p>Invasive strategy in moderate-high risk patients: ESC NSTEMI-ACS GL, Class I, level A</p>
<p>In Hospital Risk Assessment</p>	<p>Main QI (1): Proportion of patients with NSTEMI who have ischaemic risk assessment using the GRACE risk score. GRACE risk score should be assessed and the numerical value of the score recorded for all patients admitted with suspected NSTEMI.</p> <p>Main QI (2): Proportion of patients admitted with STEMI and NSTEMI who have bleeding risk assessment using the CRUSADE bleeding score. The CRUSADE bleeding score should be assessed and the numerical value of the score recorded for all patients admitted with STEMI and NSTEMI.</p> <p>Main QI (3): Proportion of patients with STEMI and NSTEMI who have assessment of left ventricular ejection fraction. Left ventricular ejection fraction should be assessed and the numerical value recorded for all patients admitted with STEMI and NSTEMI.</p>	<p>The use of risk scores for estimating prognosis is recommended: ESC NSTEMI-ACS GL, Class I, level A</p> <p>Use of the CRUSADE score...in patients undergoing coronary angiography: ESC NSTEMI-ACS GL Class IIb, level B</p> <p>Assessment of left ventricular ejection fraction: ESC STEMI GL class I, level B ESC NSTEMI-ACS GL class I, level B</p>

Domain of Care	Quality Indicator	Support from ESC guidelines
Anti thrombotics during Hospitalization	<p>Main QI (1): Proportion of patients with “adequate P2Y₁₂ inhibition” defined as: number of patients discharged with prasugrel or ticagrelor or clopidogrel / patients eligible. Eligible is defined as follows: For ticagrelor: AMI patients without previous haemorrhagic stroke, high bleeding risk, fibrinolysis or oral anticoagulation For prasugrel: PCI treated AMI patients without previous haemorrhagic or ischaemic stroke, high bleeding risk (patients ≥75 years or <60 kg body weight are also considered as high bleeding risk), fibrinolysis or oral anticoagulation For clopidogrel: No indication for prasugrel or ticagrelor and no high bleeding risk</p> <p>Main QI (2): Proportion of patients with NSTEMI treated with fondaparinux, unless candidates for immediate (≤ 2 hours) invasive strategy, or with eGFR ≥ 20 ml/min .</p> <p>Secondary QI : Proportion of patients with AMI discharged on dual antiplatelet therapy / patients with AMI without clear and documented contra-indication</p>	<p>Ticagrelor in absence of contra indication for all patients regardless of initial strategy (i.e. patients without previous hemorrhagic stroke, high bleeding risk, oral anticoagulation) ESC NSTEMI-ACS GL, Class I, level B</p> <p>Prasugrel: in patients without previous hemorrhagic or ischemic stroke, high bleeding risk (patients ≥75 years, <60 kg body weight are also considered as high bleeding risk), oral anticoagulation, treated with PCI. ESC NSTEMI-ACS GL, Class I, level B</p> <p>Clopidogrel.... for patients who cannot receive ticagrelor or prasugrel or who require oral anticoagulation: ESC NSTEMI-ACS GL, Class I, level B</p> <p>Fondaparinux is recommended as having the most favourable efficacy/safety profile regardless of the management strategy ESC NSTEMI-ACS GL, Class I, level B</p> <p>Irrespective of the revascularization strategy, a P2Y₁₂ inhibitor is recommended in addition to aspirin for patients with AMI....ESC STEMI GL, Class I, level A, ESC NSTEMI-ACS GL, Class I, level A.</p>
Secondary Prevention- Discharge Treatment	<p>Main QI: Proportion of patients with AMI discharged on statins, unless contra indicated, at high intensity (defined as atorvastatin ≥40 mg or rosuvastatin ≥20 mg).</p> <p>Secondary QI (1): Proportion of patients with AMI and clinical evidence of heart failure or a LVEF ≤ 0.40 who are discharged on ACEI (or ARBs if intolerant of ACEI) unless contraindicated.</p> <p>Secondary QI (2): Proportion of patients with AMI and clinical evidence of heart failure or a LVEF ≤ 0.40 who are discharged on β-Blockers, unless contraindicated.</p>	<p>Statins high intensity as early as possible, unless contra indication: ESC STEMI GL, Class I, level A, ESC NSTEMI-ACS GL, Class I, level A</p> <p>Betablocker therapy in patients with LVEF ≤ 0.40, unless contraindicated: ESC STEMI GL, Class I, level A, ESC NSTEMI-ACS GL, Class I, level A</p> <p>ACE inhibitor in patients with LVEF ≤ 0.40 or heart failure, hypertension or diabetes: ESC STEMI GL, class I, level A, ESC NSTEMI-ACS GL Class I, level A</p> <p>Use of aspirin, ticagrelor/prasugrel/clopidogrel, statins, betablocker and ACE inhibitor (in patients with LVEF≤0.40 or heart failure), enrollment in cardiac rehabilitation at discharge : proposed as PM by ESC GL NSTEMI-ACS 2015, no recommendation</p>
Patient satisfaction	<p>Main QI: Feedback regarding the patient’s experience is systematically collected for all patients. This should include the following points:</p> <ul style="list-style-type: none"> •Pain control •Explanations provided by doctors and nurses (about the coronary disease, the benefit/risk of the discharge treatment, and medical follow-up) •Discharge information regarding what to do in case of a recurrence of symptoms and recommendation to attend a cardiac rehabilitation program (including smoking cessation and diet counseling) 	<p>No ESC GL to support this QI.</p> <p>Review paper from Anker et al published in Eur Heart J in 2014</p> <p>Participation in a well-structured cardiac rehabilitation programme: ESC NSTEMI-ACS GL, Class IIa, level A</p> <p>Smoking cessation advice/counselling: ESC STEMI GL, class I, level C; proposed as PM by ESC GL NSTEMI-ACS 2015, no recommendation</p> <p>Enrollment in a secondary prevention /cardiac rehabilitation programme: : proposed as PM by ESC NSTEMI-ACS GL, 2015, no recommendation</p>

Domain of Care	Quality Indicator	Support from ESC guidelines
<p>Composite and outcome QI</p>	<p>Main CQI : Opportunity based CQI, with the following individual indicators:</p> <ul style="list-style-type: none"> •The center is part of a network organization •Proportion of patients reperfused among eligible (STEMI with FMC <12 hours after onset of pain) •Coronary angiography in STEMI and NSTEMI patients at high ischaemic risk and without contraindications •Ischemic risk assessment using the GRACE risk score in NSTEMI patients •Bleeding risk assessment using the CRUSADE risk score in STEMI and NSTEMI patients •Assessment of LVEF before discharge •Low dose aspirin (unless high bleeding risk or oral anticoagulation) •Adequate P2Y₁₂ inhibition (unless documented contraindication) •ACEI (or ARB if intolerant of ACEI) in patients with clinical evidence of heart failure or an LVEF ≤0.40 •β-Blockers (unless clear contraindication) in patients with clinical evidence of heart failure or an LVEF ≤0.40 •High intensity statins •Feedback regarding the patient’s experience and quality of care is systematically collected for all patients. <p>Secondary CQI: All or none CQI based on 3 or 5 components, according to the LVEF.</p> <p>-In patients without heart failure and with LVEF >0.40, CQI calculated on 3 individual QI.</p> <ul style="list-style-type: none"> •Low dose aspirin •P2Y₁₂ inhibitor (unless documented contraindication) •High intensity statins <p>-In patients with heart failure or with LVEF ≤0.40, CQI calculated on 5 individual QI.</p> <ul style="list-style-type: none"> •Low dose aspirin •P2Y₁₂ inhibitor (unless documented contraindication) •High intensity statins •ACEI (or ARB if intolerant of ACEI) in patients with clinical evidence of heart failure or an LVEF ≤0.40 •β-Blockers (unless clear contraindication) in patients with clinical evidence of heart failure or an LVEF ≤0.40 <p>Secondary Outcome QI: 30 day mortality rate, adjusted for the GRACE 2.0 risk score</p>	<p>No ESC GL to support this QI. ESC NSTEMI-ACS GL proposes “Performance Measures”, but only individual indicators, no composite indicator.</p>