

# Quality markers in cardiology: measures of outcomes and clinical practice—a perspective of the Spanish Society of Cardiology and of Thoracic and Cardiovascular Surgery

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## Introduction

The complexity of the individual patient and organization of medical practice results in important institutional and country quality of care variability.<sup>1–17</sup> Attempts to assess the quality of clinical practice have established rating systems that may yield completely different results and rating for the same hospital during the same period of time, adding confusion rather than help to prove their usefulness and, questioning whether existing measures can actually measure quality.<sup>18–35</sup> Most important, benchmarking may be associated with progressive improvement both in performance and outcomes,<sup>18,26,28,36–38</sup> highlighting the relevance of standardization of quality measures and the responsibility of scientific societies.

## Objectives

The Spanish Society of Cardiology (SSC) and the Spanish Society of Thoracic and Cardiovascular Surgery (SSTCS) organized a task force to identify and define two sets of quality metrics in hospital cardiology practice: (i) *outcome measures* (metrics of the final quality of the practice of cardiology) and (ii) *performance measures* (metrics of clinical practice which are known to positively influence desirable outcomes). Beyond this objective, Scientific Societies and Health Care Authorities should be responsible for the implementation of programmes to measure quality, ensure the quality of the data, benchmarking, and certification/accreditation of cardiology services.

## Methods

All European Society of Cardiology (ESC)<sup>32</sup> and American Heart Association/American College of Cardiology<sup>33</sup> guidelines were reviewed and recommendations related to quality standards were included in the document.

### Grading of quality markers

Three levels were established both for class recommendation and level of evidence considering (i) clinical and practical relevance, (ii) source and difficulty to obtain the information, (iii) difficulty to audit and ascertain the information, and (iv) evidence in the literature (Table 1). Mortality and stroke were considered as self-evident. To avoid confusion with general clinical practice guidelines nomenclature, Class of recommendation was graded in 1, 2, and 3 grades instead of I, II, and III.

### Type of hospital

For quality benchmarking, the task force established three types of hospitals defined as low, intermediate, and high complexity according to their organization, resources, and the need to transfer patients to other hospitals.

### Clusters to assess overall quality in clinical practice

Quality of care parameters may be grouped in clusters including institution characteristics, available technologies, staffing of the hospital and cardiac unit, organization, certification and accreditation, reputation and patients opinion.<sup>17,39,40</sup> All of them may influence outcomes, most are clearly identified in guidelines for clinical practice and all should be taken in consideration in every hospital.

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**Table 1** Grading of quality markers/metrics

Class of recommendation				Level of evidence	
Class	Relevance	Data source. Reliability and difficulty to obtain	Auditable	Level	Evidence
1	<ul style="list-style-type: none"> <li>• Major outcomes (usual outcomes in clinical trials)</li> </ul>	<ul style="list-style-type: none"> <li>• Data available in all hospitals by law (e.g. minimal health care database)</li> <li>• Obligatory registries</li> </ul>	<ul style="list-style-type: none"> <li>• Data public, available on file</li> <li>• Obligatory registries</li> </ul>	A	<ul style="list-style-type: none"> <li>• Self-evident</li> <li>• Level A in ESC/AHA-ACC guidelines</li> <li>• Recommendations of regulatory agencies</li> </ul>
2	<ul style="list-style-type: none"> <li>• Outcome surrogates</li> <li>• Class I in guidelines other than major outcomes in clinical trials</li> </ul>	<ul style="list-style-type: none"> <li>• Voluntary registries including all patients</li> <li>• Difficult to obtain; may be unreliable</li> </ul>	<ul style="list-style-type: none"> <li>• Voluntary disclosures</li> <li>• Difficult to audit</li> </ul>	B	<ul style="list-style-type: none"> <li>• Level B in guidelines</li> </ul>
3	<ul style="list-style-type: none"> <li>• Class &lt; I in guidelines</li> <li>• Opinions</li> </ul>	<ul style="list-style-type: none"> <li>• Voluntary registries (not including all consecutive patients)</li> <li>• Opinions, surveys</li> </ul>	<ul style="list-style-type: none"> <li>• Data on file but difficult to obtain</li> <li>• Data impossible to obtain in majority of hospitals</li> </ul>	C	<ul style="list-style-type: none"> <li>• Level C in guidelines</li> <li>• Opinion surveys</li> <li>• Recommended by other agencies for quality grading</li> </ul>

**Table 2** Principal markers frequently used to assess overall quality of results in clinical practice

Metric	Relevance	Difficulty	Auditable	Evidence	Comments
All-cause mortality	1	1	1	A	<ul style="list-style-type: none"> <li>• Self-evident. Reliable only in auditable registries/databases</li> </ul>
Cardiovascular mortality	1	2	2	A	<ul style="list-style-type: none"> <li>• Difficult to ascertain. Needs adjudication</li> </ul>
Number of days in hospital	1	2	2	A	<ul style="list-style-type: none"> <li>• Reason for hospitalization dependent of health care systems, individual preferences and co-morbidities</li> <li>• Number of days in any hospital 30 days after index hospitalization preferred to days in hospital until discharge</li> </ul>
Stroke	1	2	2	A	<ul style="list-style-type: none"> <li>• Difficult to ascertain. Needs adjudication</li> <li>• No reliable risk scores for corrections between different hospitals</li> </ul>
Re-infarction	1	2	2	A	<ul style="list-style-type: none"> <li>• Difficult to ascertain. Needs adjudication</li> </ul>
Safety (major bleeding, severe infections, medical errors, etc.)	1	2	2	A	<ul style="list-style-type: none"> <li>• Difficult to ascertain. Needs adjudication</li> </ul>

## Main markers to measure quality of results (measures of outcomes) in clinical cardiology practice

Clinical outcomes are the ultimate measure of quality of care in cardiology and there is no excuse to ignore them. The main outcomes in cardiology trials (mortality, hospitalization, myocardial infarction/re-infarction, and stroke) constitute the strongest reference for guideline recommendations.<sup>29,30,32,33,41–47</sup> Ideally, an outcome at a pre-defined follow-up (e.g. 30 days after index hospitalization) is preferred instead of during hospitalization, but this may be difficult or impossible to ascertain except in well-organized dedicated registries. Outcomes should be measured in uniform groups of patients and need corrections for case mix complexity (Table 2).

## Mortality

Mortality constitutes the first and most important metric recommended by this task force to measure quality results in clinical practice. The relevance of mortality is self-evident, remains the most important outcome measure in clinical trials designed to change clinical practice, and is the most powerful evidence to support recommendations in practice guidelines. In many clinical settings, it is related to guideline adherence as well as performance measures,<sup>2,47</sup> it is included in different programmes that evaluate quality of care,<sup>3–7,10,13,16,19,21,31</sup> and certainly it can be audited (Class of recommendation 1 and Level of evidence A). All-cause mortality during the index hospitalization is the recommended metric by this Task Force, as different causes of mortality need adjudication for uniformity and this will not be possible except in dedicated registries. Mortality,

particularly in acute coronary syndromes (ACS), is not evenly distributed, i.e. mortality for stable patients is currently around 3–5%, while resuscitated or intubated patients have a lethality of 35–50%. Thus, mean mortality rates have to be adjusted for case complexity to be fair for centres with a large number of ACS patients in shock or after cardiopulmonary resuscitation.

### Length of hospitalization stay and re-admission rates

Length of hospitalization stay and re-admission rates constitute the second metric recommended by this Task Force. Hospitalization reflects quality of care, impacts health care cost, is commonly used in quality programmes,<sup>2,41–47</sup> and is also included in many quality control databases. On the other hand, length of stay may not be reliable as an outcome metric to compare results of practice in different countries/areas where hospitalization may be driven not only by medical but also by administrative and social reasons. In addition, it may be dependent of other conditions or comorbidities, always difficult to properly determine. For this reason, hospitalization is recommended as a quality metric only when hospitals participate in a prospective, dedicated registry, where criteria for admission and discharge are pre-defined or the cluster of hospitals is uniform (Class of recommendation 2 and Level of evidence B).

### Myocardial infarction

In-hospital or post-discharge myocardial infarction is one of the components of the main outcomes in clinical trials and registries in patients with ischaemic heart disease. However, it may be a poor metric for outcomes due to the difficulties to standardize the diagnosis in large populations, in particular during the first few days after hospital admission for ACS,<sup>2,41–48</sup> and should only be used in dedicated, prospective controlled registries (Class of recommendation 2 and Level of evidence B).

### Stroke

Disabling stroke is self-relevant, is related with iatrogenia, percutaneous interventions (PCI) surgery, and the use of antithrombotic therapy. Stroke is a metric included in registries and some quality programmes.<sup>49</sup> However, minor forms of stroke are difficult to diagnose without the routine use of brain imaging techniques, there are not reliable scales for stroke risk in different clinical settings and this metric may represent a confounding factor for benchmarking if not centrally adjudicated.<sup>50–52</sup> Stroke is only recommended as a quality measure when considering well organized, controlled, and audited registries (Class of recommendation 2 and Level of evidence B).

### Safety

Safety parameters such as major bleeding, medical errors, infections, cardiac tamponade during PCI, and other relevant clinical complications of clinical practice should be considered in quality performance reports. Again, the complexity of achieving uniform diagnosis and reporting in large number of hospitals preclude the use of safety parameters for benchmarking of quality except when data are prospectively obtained in dedicated, controlled registries (Class of recommendation 2 and Level of evidence B).

## Adjustment of outcomes metrics

### Selection of uniform populations

Comparisons should be made only between similar hospitals and in selected, well-defined, high-risk-specific populations with prognosis known to be dependent on overall cardiology management (Groups of Related Diagnosis or GRDs).<sup>39,53–55</sup> Extreme high-risk and low-prevalence groups of patients should be excluded from analysis rather than corrected for risk.<sup>53,54</sup> Sometimes this information is not well reflected in registries or databases, stressing the importance of dedicated databases for the measurement of quality outcomes.<sup>54</sup> Table 3 shows the recommended populations for benchmarking.

### Risk adjustment

The use of specific and *validated* risk scores recommended in guidelines (GRACE or TIMI risk scores for ACS,<sup>70,71</sup> Euro2 risk score,<sup>72–74</sup> and others<sup>75–77</sup>) will provide further refinement and make the metrics reliable for benchmarking. Some are too complex and difficult to assess in large populations (e.g. including biological markers not universally used<sup>74–77</sup>). In such circumstances, adjusted models considering common risk factors are recommended.<sup>16,78</sup>

## Measures of the performance of the practice of clinical cardiology: quality markers related with better results in clinical practice (performance measures)

These metrics are the reference for a better health care organization but must not be considered as important as outcomes. Benchmarking of some of these parameters may be difficult, and obtaining the appropriate information may require a dedicated database very difficult to standardize or complete, and even more difficult to audit accurately. Accordingly, the most important use of these parameters is for internal quality controls, not for benchmarking different hospitals. Eight different sections have been identified:

### Clinical cardiology

Some quality markers are recommended for the accreditation of cardiology units of all hospitals (e.g. staffing, technology, volumes); others are directed to control internal quality or to identify problems and opportunities for improvement and are recommended for all hospitals.<sup>79–121</sup> The most relevant recommendations are the use of local protocols for diagnosis and treatment, based in the ESC/AHA or country-specific guidelines and approved by the hospital.<sup>32,33,89</sup> Teamwork with internal medicine and other related specialties, with special reference to primary care should constitute a priority.<sup>81–88</sup>

### Cardiac imaging

Cardiac imaging constitutes the core for diagnosis in cardiology.<sup>122–137</sup> Transthoracic echocardiography performed by well-trained cardiologists is recommended in all patients, in all hospitals. More complex

**Table 3** Recommended measures to assess quality of results in clinical practice

Metric	Suggested reference value	Relevance	Difficulty	Auditable	Evidence	References
<i>Mortality<sup>a</sup></i>						
STEMI mortality (excluding Killip IV class patients and patients after cardiopulmonary resuscitation)	<5% (a)	1	1	1	A	41,42
Non-STE-ACS mortality (excluding Killip IV class patients and patients after cardiopulmonary resuscitation)	<3% (a)	1	1	1	A	43,44
Staged PCI mortality	<1% (a)	1	1	1	A	56
TAVI mortality	<6% (a)	1	1	1	A	57,58
VT after AMI and other complex catheter ablation mortality	<3% (a)	1	1	1	A	59–61
Pacemaker, ICD, CRT implant mortality	<1% (a)	1	1	1	A	62,63
Heart failure mortality	<7% (a)	1	1	1	A	67
Staged first aortic valve surgery replacement mortality (excluding TAVI)	<5% (a) <7% (b)	1	1	1	A	64–66
Staged first mitral valve surgery replacement mortality	<7% (a) <9% (b)	1	1	1	A	64–66
Staged first mitral valve surgery repair mortality	<3% (a) <5% (b)	1	1	1	A	64–66
Staged first CABG (without combined surgery) mortality	<3% (a) <5% (b)	1	1	1	A	64–66
Staged first combined CABG + AVR mortality	<6% (a) <8% (b)	1	1	1	A	64–66
Heart transplant	<15% (a)(c)	1	1	1	A	184
<i>Hospitalization<sup>b</sup></i>						
STEMI number of days in hospital	<10	2	2	1	A	41,42
Non-STE-ACS number of days in hospital	<10	2	2	1	A	43,44
Heart failure number of days in hospital	<9	2	2	1	A	5,11,18,67
Staged first CABG, aortic or mitral surgery number of days in hospital	<15	2	2	1	A	64,68,69
Rehospitalization after ACS, heart failure, or surgery as above <sup>c</sup>	Less than mean value in national registries					

Reference values are orientative. For benchmarking, a target reference value less than median value in participating hospitals is strongly suggested.

<sup>a</sup>Mortality: 30 days all-cause mortality is preferred over mortality before hospital discharge only if reliable data can be obtained.

<sup>b</sup>Hospitalization: the number of days in any hospital during the first 30 days after index hospitalization is preferred over number of days from hospitalization to discharge.

<sup>c</sup>Rehospitalization: unplanned readmission for any cause to any acute care hospital within 30 days of discharge from a hospitalization. (a) Observed mortality (mean value).

(b) Expected mortality corrected for the logistic euroscore for this population. (c) Mortality or re-transplant. CABG, coronary artery bypass-grafting; TAVI, transaortic valve implant.

techniques require specific training, accreditation and certification are highly recommended and may benefit from teamwork with radiologists (nuclear imaging, cardiac computed tomography, and cardiovascular magnetic resonance). Accreditation of image laboratories by the ESC or other official accreditation agencies is recommended. Quality controls include accreditation, low inter-observer variability, timely performed studies (waiting list's), and prompt systematic reports.

### Acute cardiac care measures related to better results in clinical practice

Acute cardiac care requires teamwork with out-of-hospital professionals, emergency departments, internal medicine, and intensive care physicians following well-defined protocols for common cardiac conditions such as acute myocardial infarction (AMI) and ACS.<sup>41–44,90,138</sup> Patients with ST elevation myocardial infarction

(STEMI) should be referred immediately and only to hospitals with available primary PCI. Well-trained nurses are of utmost importance in emergency departments, medical wards in type II and III hospitals, and intensive care units. Time do first medical contact to balloon or needle, risk score determinations, revascularization in intermediate and high-risk patients, and adherence to guidelines recommended medication are the most relevant quality performance measures. Outcomes include mortality in STEMI and ACS. Local safety controls should focus on antithrombotic complications.

### Interventional cardiology

The results of percutaneous cardiac interventions are highly dependent on the expertise and training of interventional cardiologists, as well as on the volume of performed procedures at each hospital and by individual interventional cardiologists.<sup>41–44,56–58,139–149</sup>

Complex cases should be only treated in hospitals with cardiac surgery support.<sup>142</sup> Low volume, highly complex interventions [transcatheter aortic valve implant (TAVI) closure of left atrial appendage and foramen ovale, valvular and adult congenital heart disease interventions] should be considered only in selected type III hospitals with specific training and accreditation. Adherence to local protocols based on guidelines and heart team decisions for non-urgent interventions should be considered in all cases. Outcome metrics include STEMI and ACS mortality, as well as TAVI mortality and elective PCI mortality. The main safety control is focused on bleeding and vascular complications requiring surgery or extended length of stay.

## Electrophysiology and complex arrhythmia

Interventional treatment of complex arrhythmias (e.g. atrial fibrillation) requires accreditation of both laboratory and electrophysiologists.<sup>59–63,150–161</sup> Indication for ablation should be established after a Heart Team approach that adheres to the guideline recommendations. Outcome targets should include complex electrophysiological procedures and device implantation mortality. Safety should focus on complications requiring surgery, transfusions, or prolongation of hospitalization.

## Heart failure

Diagnosis and treatment of heart failure is rapidly changing and increasing in complexity and adherence to guidelines is likely to assure better outcomes including survival.<sup>5,18,45,46,67,162–164</sup> Cardiac care must be continued after discharge from hospital in all cases. Teamwork as opposed to admitting patients in cardiology or internal medicine is crucial and strongly recommended. A heart failure unit adapted to local characteristics of the hospital is always highly recommended. Outcomes include mortality and readmissions to the hospital.

## Cardiac rehabilitation

Cardiac rehabilitation is more than controlled exercise training.<sup>41–44,165–180</sup> The main objective should be the patient education for long-term changes related to life-style, adherence to medical treatment for the specific condition and use of appropriate secondary prevention strategies. Cardiac rehabilitation units or programmes should be implemented to offer all patients appropriate counselling and follow-up for secondary prevention. Teamwork especially with general physicians is essential. Quality controls should include access to rehabilitation programmes for patients with ischaemic heart disease and adherence to guidelines during long-term follow-up.

## Cardiac surgery

Quality controls in cardiac surgery have already been implemented in some countries.<sup>64–66,181–184</sup> Heart Team approach is recommended in all cases; hospital volumes, training and expertise of surgeons, anaesthesiologist, nurses and referring cardiologists highly impact outcomes. Outcomes are relatively easy to measure and should focus on mortality and length of hospitalization in prevalent, well-defined surgical procedures such as CABG, aortic and mitral valve staged, first time surgery.

## Current limitations

### Capture of information

Registries and databases currently used for benchmarking may not have the appropriate quality. Audited, dedicated, prospective mandatory reports would be arguably the best way of capturing simple but essential/core information.<sup>185</sup>

This document is based on the ESC and AHA-ACC guidelines recommendations. Nevertheless, the document is mainly intended for the health care system in Spain. It may not apply in other countries with different health care systems. There is a need for defining quality standards universally acceptable to compare quality of care between different health care systems and countries, within and out of the European Union and ESC.

### Future challenges

Unmet needs and opportunities for improvement include: (i) standardization of data (data capture and availability, risk corrections, target values and reporting); (ii) standardization of audits to ascertain data quality; (iii) universal participation; (iv) identification of quality metrics for outpatient clinical practice<sup>68,69,186</sup> and long-term follow-up; and (v) refinement of the quality metrics considering the feedback from participants in benchmarking programmes.

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