

CathPCI Registry®

Understanding the Reporting of Appropriate Use Criteria in the CathPCI Registry

The mission of the NCDR[®] is to improve the quality of cardiovascular patient CathPCI by providing information, knowledge and tools; implementing quality initiatives; and supporting research that improves patient CathPCI and outcomes.

The NCDR[®] is an initiative of the American College of Cardiology Foundation, with partnering support from the Society for Cardiovascular Angiography and Interventions for the CathPCI Registry.

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PCI Appropriate Use Criteria (AUC) for Revascularization Interpretation Guide

Percutaneous coronary intervention (PCI) Appropriate Use Criteria (AUC) metrics give sites feedback on selfassessment of the appropriateness of PCI procedures at the hospital level. They are located in two sections of the NCDR[®] CathPCI Registry[®] Outcomes report:

- 1. Executive summary, section III
- 2. Detail section, lines 1572 1592

These assessments are based on the <u>Appropriate Use Criteria for Coronary Revascularization Focused Update</u> developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies and published in the Journal of the American College of Cardiology (*J Am Coll Cardiol* 2012;59: 857-81). This was an unprecedented effort of professional societies to help guide clinical decision making, to help ensure high quality care and to critically evaluate the use of a major treatment in routine clinical practice. In your report you will find your institution's rate of appropriate, uncertain, and inappropriate procedures separately for PCIs in patients with acute coronary syndromes and non-acute presentations of coronary artery disease.

The ACC is dedicated to high-quality cardiovascular care and believes that implementation of the Appropriate Use Criteria can improve the efficient use of PCI in the U.S. In reporting institutional rates of procedural appropriateness, the ACC allows participating NCDR hospitals to become more informed about their use of PCI and determine whether there are opportunities to improve the patients selected for coronary revascularization.

Frequently asked questions on how to interpret your report:

What is an Appropriate Use Rating?

Appropriate Use Criteria categorize procedures as appropriate, uncertain, or inappropriate:

- <u>Appropriate PCI procedures</u> represent situations in which the procedure is acceptable and a *reasonable* approach for the indication and is likely to improve the patient's health outcomes or survival.
- <u>Uncertain PCI procedures</u> are cases where coronary revascularization may be acceptable and may be reasonable for the indication. There is *currently insufficient evidence* to conclude that the benefits of PCI outweigh the risks
- <u>Inappropriate PCI procedures</u> are those in which the risks of PCI are as great or greater than the benefits of PCI and also are cases in which coronary revascularization *is not generally a reasonable* approach for the indication and is unlikely to improve the patients' health outcomes or survival. While the term inappropriate is used, it is not a value judgment of the individual or institution that performed the procedure. Rather, it is a comparison to a population based standard and should be interpreted as measure of how well patients matched generally accepted criteria for the procedure (see appendix I).
- Additionally, some cases may be *unclassifiable* since we do not have enough data on those patients. We will be reporting back to the hospital the rate of those patients that we could not classify in the categories noted above.

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How were the Appropriate Use Criteria Developed?

Ratings of appropriateness were based upon trial evidence, clinical guidelines, expert opinion, and a consensus building process. Specifically, a Technical Panel considered six domains in assessing the appropriateness of revascularization:

- Clinical indication of Acute Coronary Symdrome (ACS) vs. Non-ACS (with or without prior CABG);
- Severity of symptoms (CCS angina class);
- Extent of ischemia on noninvasive testing (for non-acute presentations) which is associated with cardiac mortality;
- Presence of high-risk clinical factors (e.g., depressed LVEF) which is associated with cardiac mortality or non-fatal MI;
- Use of anti-ischemic therapy pre-procedure (maximal anti-anginal medical therapy is defined as the use of at least 2 anti-anginal agents used within the past two weeks)
- Coronary anatomy (1, 2, or 3-vessel CAD with or without involvement of the proximal LAD, left main, and/or bypass grafts)

By combining these elements, a number of prototypical patient scenarios were created and rated by a Technical Panel as to their appropriateness for coronary revascularization. Through this process, algorithms were developed, implemented, and applied to the CathPCI Registry data.

Why was the revascularization AUC updated in 2012 and what was changed?

The document, first published in 2009, was updated to better address two areas:

- 1. Indications needed to be re-evaluated for the treatment of multi-vessel coronary artery disease with symptoms by PCI and CABG as a result of data from the SYNTAX trial, which came out after the original AUC were published, and,
- 2. Indications that represent gaps in rating patients with unstable angina (UA)/NSTEMI. The update created scenarios for patients with UA/NSTEMI and low- or intermediate-risk features as determined by the TIMI risk score.

With this update, all patients with UA/NSTEMI are reported in the metrics for patients with ACS.

What assumptions were made to match PCI procedures to the Appropriateness Ratings?

We made several assumptions in matching PCI procedures to the Appropriateness Ratings. These included:

- For PCI procedures that could match to more than one Appropriate Use Rating category, we classified that procedure's appropriateness based upon the highest rating to which it could be matched.
- For procedures with missing stenosis information on a given coronary artery, we assumed no significant stenosis (<70% for an epicardial artery and <50% for the left main artery) at that coronary artery if PCI was not performed on that artery.
- When immediate PCI was performed, we assumed it was for the culprit lesion and we treated all acute STEMI procedures as AUC scenario #1: (STEMI, ≤ 12 hours from onset of symptoms, with revascularization of the culprit artery)
- Staged PCIs during a non-index hospitalization, are classified as non-acute patients (in table 2 or 3)

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- If a stress or imaging test was performed and the result was negative or indeterminant, we classified it as "low risk findings" on non-invasive testing.
- If PCI was performed on a lesion of 50-70% stenosis and IVUS was used, we assumed that the IVUS result demonstrated obstructive CAD.
- All patients that are classified in indication #23 are rated as "inappropriate" regardless of the CCS classification (the guideline does not rate patients who are asymptomatic, but rates patients with CCS I-IV as inappropriate).
- Patients who did not have a stress test, but had an FFR or IVUS were classified in indication #22 and 23. This assumption was made to reduce the rate of unclassifiable patients.
- Patients with only a coronary calcium score and/or cardiac CTA d and no other stress or imaging studies do not qualify to have a stress or imaging study because these imaging tests do not assess the extent of ischemia like a stress test does.

How do I interpret the Appropriate Use Ratings for my hospital?

It is important to keep in mind that, unlike performance measures where the goal is to comply 100% of the time, **it is not expected that an institution would have 100% of their cases graded as appropriate or 0% of cases as inappropriate**. The Writing Committee developed the Appropriate Use Criteria based upon the six domains described above, but did not (and could not possibly) take into account the myriad of patient characteristics (e.g., age, comorbidities, etc . . .), patient preferences, or the presence of unique angiographic findings that might warrant PCI. Therefore, the AUC should be considered a framework for assessing appropriateness of the revascularization procedure realizing that some inappropriate procedures may be considered uncertain or appropriate in the context of an individual patient with extenuating factors. Likewise, cases classified as appropriate do not indicate the procedure *should* always be undertaken in similar patients. An appropriate rating merely means that the patient is a *reasonable* candidate for the procedure, but patient preferences and a discussion of the alternatives should be avoided, but rather the available evidence and patient characteristics require an approach that relies on evaluation of individual cases determine how reasonable an individual patient may be for the procedure.

While it may be difficult to interpret your Appropriate Use ratings in isolation, comparing your rates with other NCDR centers can be very informative. If you are doing far more cases rated as inappropriate compared to other centers, then an evaluation of the selection of patients for PCI at your institution is warranted. Although there may be unique patient characteristics that justify PCI in *some* cases, it would be unusual for a center to have such a unique population of patients that, on average, their rates would differ markedly from their peers.

Why are patient risk factors not included in the classification of appropriateness?

Recognizing that it is impossible to create scenarios capturing all possible clinical variables (including clinical risk factors), the writing group that developed the indications focused on several key factors in a patient's clinical presentation which were chosen based on practice guidelines and other coronary revascularization literature. Indications and classifications look at the risk/benefit of performing the procedure based on acuity (ACS or stable) and four key elements for stable patients that impact mortality and quality of life (severity of angina, extent of disease, extent of ischemia on stress test, and use of medical/anti-anginal therapy). While additional clinical factors (such as diabetes) can impact outcomes, these other factors often were considered likely to influence the approach to revascularization (PCI or CABG) rather than driving the primary decision about selecting revascularization. Additional risk factors are considered in the AUC document for diagnostic catheterization. These additional risk factors are assumed to be considered prior to the PCI in the clinical decision making process.

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Can an EF be used to as a stress test equivalent?

An ejection fraction cannot be used as an equivalent to define non-invasive stress/imaging results of high, medium or low risk/extent of ischemia.

If a patient had a stress test and it was negative or indeterminant, how is that classified?

Negative or indeterminant stress or imaging studies are classified as low risk for ischemia.

Why are patients unclassifiable?

A proportion of PCI procedures at your institution may not be matched to an Appropriate Use Criteria indication. The two most common reasons for this are that the patient did not undergo a stress test prior to PCI *or* a stress test was performed but the amount of ischemia was not documented or submitted to the Cath/PCI Registry. Since the extent of functional ischemia is integral in the adjudication of appropriateness, these procedures could not be mapped.

While clinical decisions to take a patient directly to cardiac catheterization may be scientifically sound (although, again, you may want to compare your rates with those of other institutions), high rates of missing information on stress testing may compromise the quality of data on appropriateness for your hospital. Making stress test results available is a process improvement that can contribute to the accuracy of your hospital's appropriateness ratings.

Important note! If more than 40% of a facility's PCIs are not able to be classified or calculated using the AUC model (Line 1589 in the detail section), the participant's data is not displayed in the "My Hospital R4Q" column, and is not included in the national benchmark (the "All Hospital Pts R4Q" column) for the detail lines that report AUC (starting on 1572), and is not displayed in the Executive Summary Metrics 31-36.

Can we receive feedback on individual patient record classifications?

Yes, the dashboard e-reports at ncdr.com provide feedback on individual patient records within each metric. While assessment of inappropriate or unclassifiable records is an important step in quality improvement, the main purpose of Appropriate Use Criteria is to evaluate populations of patients and reflect patterns of use at institutions. Justification of individual cases is not required and review is most useful in the context of overall patterns of use.

Why did I have a patient with a STEMI that was not classifiable?

There are some indications that require an ejection fraction to classify the patient. In these cases, when an EF is not available, the patient record can be unclassifiable.

How is the TIMI risk score calculated in the CathPCI Registry data elements?

For purposes of providing a TIMI Risk Score for Revasularization AUC, the NCDR calculates an "approximate" TIMI risk score. This score is used for patients with suspected acute coronary syndrome to predict risk of death or ischemic event through 14 days and is described as follows:

- 1. Low risk: 0-2 (<8.3% event rate)
- 2. Intermediate: 3-4 (<19.3% event rate)
- 3. High: 5-7 (41% event rate)

NCDR CathPCI Registry v4.4 dataset "approximate" TIMI risk score calculation

TIMI variable	Registry element and selection
Age >=65	Age is determined by Birth Date (Seq 2050 and Arrival
	Date (Seq 3000)
>=3 risk factors (hypertension, diabetes mellitus, family	>=3 of the following risk factors captured on arrival:
history, lipids, smoking)	
	Hypertension (Seq 4005)
	Diabetes (Seq 4085)
	FamilyHxCAD (Seq 4015)
	Dyslipidemia (Seq 4010)
	Smoker (Seq 4000)
Known CAD (stenosis >=50%)	At least one of the following variables captured on
	arrival:
	PriorMI (Seq 4020)
	PriorPCI (Seq 4035)
	PriorCABG (Seq 4045)
Aspirin use in past 7 days	Administration of aspirin within 24 hours pre-procedure
	(9500 and 9510)
Severe angina (>=2 episodes within 24 hours)	Anginal Class of III or IV (Seq 5020)
ST-segment deviation >=0.5 mm	CADPresentation (Seq 5000) of STEMI
Elevated cardiac markers	CADPresentation (Seq 5000) of STEMI or NSTEMI