AHA Scientific Statement

Impact of Percutaneous Coronary Intervention Performance Reporting on Cardiac Resuscitation Centers
A Scientific Statement From the American Heart Association

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Patients who experience out-of-hospital cardiac arrest (OHCA) have high mortality rates. Acute coronary occlusions and high-risk coronary obstructive disease are common in this population, especially in patients with ventricular tachycardia or ventricular fibrillation (VF) as the presenting cardiac arrest (CA) rhythm. In one recent series, 32% of patients with OHCA and sustained return of spontaneous circulation (ROSC) had ST-segment elevation on their first documented ECG.[1] The vast majority of patients are unable to give a history of prearrest symptoms on hospital arrival because they are comatose.

The "2010 American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC)" state that "appropriate treatment of ACS or STEMI, including PCI, should be initiated regardless of coma (Class I, LOE B)" and "coma and the use of induced hypothermia are not contraindications or reasons to delay PCI."[2] The 2010 AHA Guidelines for CPR and ECC also state that "PCI after ROSC in subjects with arrest of presumed cardiac etiology may be reasonable, even in the absence of a clearly defined STEMI (Class IIb, LOE B)." Quality postarrest care was thought to make such a significant contribution to overall survival after CA that the AHA added a fifth link to the Chain of Survival to emphasize the importance of care after resuscitation treatments.

The AHA recently issued a policy statement calling for the establishment of regional systems of care to manage OHCA patients.[3] The proposed model is patterned after similar successful major trauma, ST-segment elevation myocardial infarction (STEMI), and stroke programs. The policy statement recommends a comprehensive, regionalized approach to postresuscitation care that includes therapeutic hypothermia, multidisciplinary goal-directed management of critical physiological functions (ie, organ perfusion, ventilation, metabolic management), and early coronary angiography/percutaneous coronary intervention (PCI) when indicated.

The AHA policy statement defines 2 levels of cardiac resuscitation centers (CRCs). Level 2 hospitals receive OHCA patients and perform initial stabilization and then transfer patients to level 1 hospitals that perform comprehensive, multidisciplinary postarrest care, including but not limited to therapeutic hypothermia and coronary angiography. Accumulating clinical data now show that up to 70% of OHCA patients have coronary artery disease, and nearly half have an acute coronary occlusion.[4–18] These data underscore the importance of early coronary angiography, and reperfusion in these patients is likely similar to that in STEMI patients who have not had a CA.

The mortality in all STEMI patients after primary PCI is closely tracked by numerous registries, and this information is used for public reporting of outcomes and third-party payer

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reimbursement, as well as individual and hospital-level reward programs. Patients with OHCA have much lower survival rates than non-CA STEMI-PCI patients. Hospitals that care for moderate numbers of postarrest patients, such as the level 1 CRCs recommended by the AHA, take more of these typically comatose, systemically critically ill patients to the catheterization laboratory for emergency coronary angiography and PCI. Even under the best reported circumstances, mortality in the overall postarrest population who have been initially resuscitated is ≈50%.[13] This 50% survival is double the previous long-term survival rate before such aggressive bundled postarrest care was used.[13] Such an aggressive postarrest revascularization approach[5–10,12–21] has the unintended consequence of causing the centers that perform the type of high-volume, quality postarrest care that follows a Class I AHA guideline to have significantly higher mortality than hospitals that treat only a few postarrest patients annually. Appropriate subsets of postarrest patients being given immediate access to the catheterization laboratory involves treating many patients who will ultimately succumb to neurological or multiorgan failure rather than a cardiovascular death,[22] yet their deaths are reported simultaneously with all other STEMI patients, the majority of whom have a 10-fold lower periprocedural mortality. Because federal- and state-mandated public reporting of outcomes has been shown to influence physician decision making in choosing whether to take high-risk patients for lifesaving procedures, the potential exists for interventional cardiologists and hospitals to have to decide between protecting their publicly reported reputation or jeopardizing future reimbursement and providing what the evidence has demonstrated to be the best clinical care for their patient.[23]

The purpose of this scientific statement is to describe the potential impact of including OHCA patients with STEMI in the public reporting of PCI mortality and to make recommendations for modifications in the current outcomes-reporting procedures in this population.

The Role of Emergency PCI in OHCA Patients

Approximately 20% to 30% of OHCA patients who survive to hospital admission have evidence of STEMI (including new left bundle-branch block) on their presenting ECG. The 2010 AHA Guidelines for CPR and ECC state that "aggressive treatment of STEMI on the presenting ECG should begin as in non–cardiac arrest patients, regardless of coma or induced hypothermia." The 2010 AHA Guidelines for CPR and ECC also state that "because of the high incidence of acute coronary ischemia, consideration of emergent coronary angiography may be reasonable even in the absence of STEMI."[24] The basis for this recommendation is the recognized role of acute coronary ischemia as a dominant mechanism in the setting of OHCA. The potential contribution of coronary ischemia in OHCA was observed initially in postmortem case series and in angiography data obtained from survivors of sudden cardiac death.[4,25]

Immediate coronary angiography followed by successful coronary intervention has been shown to be an independent predictor for survival and improved neurological outcomes for patients with OHCA, irrespective of the presence or absence of STEMI on the presenting ECG. The supportive data for emergency coronary angiography are most compelling in patients who manifest ST elevation on the surface ECG, because the benefit of emergency reperfusion of the infarct-related artery is well established in this setting. In a retrospective study limited to CA cases, Garot et al[19] reported outcomes in 186 consecutive patients over a 10-year period undergoing immediate PCI after successful resuscitation for CA complicating acute myocardial infarction (AMI) with STEMI on the initial ECG. PCI was successful in 87% of the patients. Survival at 6 months was 54%, and survival free of neurological sequela at 6 months was 46%.

Bendz et al[26] compared 40 patients treated with primary PCI after OHCA with a reference group of 325 patients without CA also treated with primary PCI in the same time period. The in-hospital mortality rate was 27.5% in the CA group and 4.9% in the STEMI-without-CA group. The 2-year mortality rate was unchanged in the CA group and rose to 7.1% in the non-CA STEMI group. Gorjup et al[15] reported on 135 STEMI patients between 2000 and 2005 who were resuscitated after CA. Catheterization was performed in all patients, of whom 64% remained comatose during the initial evaluation. Primary PCI was performed in 79% of the comatose patients with a procedural success rate of 82%, which demonstrates that successful PCI can be accomplished urgently in comatose postarrest patients. The survival-to–hospital discharge rate was 51% for comatose postarrest patients, 100% for noncomatose postarrest patients, and 95% for patients with STEMI and no CA.

In an angiographic analysis by Spaulding et al[18] of 84 consecutive patients with OHCA aged 30 to 75 years, 60 subjects were noted to have a severe coronary stenosis, and 40 (48%) of these had an occluded coronary artery, irrespective of the presence or absence of STEMI on the initial ECG. On multivariate logistic regression analysis, successful angioplasty was noted to be an independent predictor of survival (odds ratio [OR], 5.2; 95% confidence interval [CI], 1.1–24.5; $P=0.04$). The same group of investigators confirmed their findings in the larger PROCAT (Parisian Region Out of Hospital Cardiac Arrest) Registry, which performed urgent angiography in 435 of 714 patients with OHCA without an obvious extracardiac cause.[27] Immediate coronary angiography in this population revealed a significant stenosis in 96% (128 of 134) of patients with ST elevation on the surface ECG after ROSC and in 58% (176 of 301) of patients without ST elevation. As in the prior study, multivariable analysis showed successful coronary angioplasty to be an independent predictive factor of survival, regardless of the postarrest ECG pattern (OR, 2.06; 95% CI, 1.16–3.66).

Strote et al[28] evaluated a retrospective cohort of 240 patients with OHCA with VF or pulseless ventricular tachycardia as the presenting rhythm. Survival was greater in those patients undergoing coronary angiography within 6 hours of presentation than in those undergoing coronary angiography later than 6 hours or not at all (72% versus 49%, $P=0.001$). Seventy-five percent of patients in the <6-hour group had STEMI on the presenting ECG, which led these authors to conclude that their data supported the idea that all patients resuscitated from OHCA caused by VF or pulseless ventricular tachycardia should receive early cardiac catheterization and PCI if indicated.

Dumas et al[29] performed a cohort investigation of 1001 adult, nontraumatic OHCA patients who were resuscitated and discharged alive from the hospital between 2001 and 2009, hypothesizing that the short-term survival benefit of the hospital interventions of PCI and hypothermia after OHCA would be associated with reduced long-term mortality. PCI was performed in 38.4% of patients and hypothermia in 25.6% of patients comatose on hospital admission, whereas 9% of patients received both PCI and hypothermia. PCI, when performed, occurred within 6 hours of hospital admission in 80% of the patients. Of those patients receiving PCI within 6 hours, 71% had evidence of STEMI on an initial ECG. Patients treated with PCI had a 5-year survival rate of 78.7%, whereas only 54.4% survived who were not treated with PCI ($P<0.001$). The survival rate in those patients treated with hypothermia was 77.5% compared with 60.4% in those not treated with hypothermia ($P<0.001$). Those patients who received neither treatment had the lowest 1- and 5-year survival rates, and patients who received both PCI and hypothermia had the highest survival rates at both time points. Both PCI and hypothermia were independently associated with a lower risk of death in a multivariate model (hazard ratio, 0.46 [95% CI, 0.34–0.61] and hazard ratio, 0.70 [95% CI, 0.50–0.98], respectively). These findings suggest that PCI performed at the clinician's discretion was associated with a long-term survival benefit in patients with and without STEMI on the presenting ECG.

In summary, there are multiple observational studies that support the Class I AHA recommendation to take all postarrest patients with STEMI for emergency coronary angiography, irrespective of the presence or absence of coma. In addition, there is increasing evidence that patients without evidence of STEMI on a presenting ECG may also benefit from early intervention.

STEMI-PCI Quality-Reporting Systems and CA

Data on outcomes from PCI performed in the setting of an STEMI have been collected, compared, and reported publicly for more than a decade in numerous regional, state, and national databases. The purpose of this public reporting is to monitor the quality of invasive cardiac procedures to assess any differences in the risk-adjusted mortality among hospitals and individual PCI operators.[30] The potential benefits of this scrutiny of outcomes are to encourage best practices among peers, drive better performance, and inform the public about the quality of care they will receive at a given hospital by a specific provider. Unfortunately, there are potential unintended consequences from public reporting of STEMI-PCI mortality, despite the best intentions.

It is instructive to look at how STEMI-PCI quality-reporting systems address risk adjustment and how CA is dealt with as a covariate. We have chosen examples of prominent national and statewide PCI-reporting systems to demonstrate how CA is considered and to illustrate the impact of postarrest patients treated with PCI on publicly reported outcomes.

The National Quality Forum

The National Quality Forum (NQF) is a private, nonprofit organization whose mission is to improve the quality of health care

in the United States. One central role of NQF is in the development, endorsement, and maintenance of contemporary quality standards for a variety of common, high-impact disease groups through a consensus development process. These standards define the methods of measurement, reporting, and, in many cases, risk adjustment for these various conditions. A broad variety of governmental and nongovernmental healthcare organizations assist with the consensus development process, and each standard has an organization that serves as its steward.

The Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, and a variety of state-level and private-sector benchmarking groups use these NQF-maintained standards for their public reporting and quality comparison programs. The general public has access to detailed comparative hospital-level information on the Centers for Medicare & Medicaid Services Web site (http://www.hospitalcompare.hhs.gov). Entities such as The Joint Commission and the University Health System Consortium also use the NQF quality standards in their benchmarking analysis and reporting.

In 2009, the NQF entered into a contract with the US Department of Health and Human Services to help establish the quality standards for 20 "high-impact" conditions, including AMI, identified by the Centers for Medicare & Medicaid Services that accounted for >95% of Medicare's costs. Current NQF standards related to the treatment of patients with AMI, and by extension AMI patients who have had an OHCA, are listed in Table 1.

In 2011, the US Department of Health and Human Services formed the Measure Applications Partnership as a public-private partnership composed of >60 organizations representing major stakeholder groups, 40 individual experts, and 9 federal agencies. The Measure Applications Partnership derives its statutory authority from the Affordable Care Act and represents an important innovation in the regulatory process. The Measure Applications Partnership program was convened by the NQF and will eventually include both hospital and individual provider pay-for-reporting and value-based purchasing characteristics that will affect provider and hospital reimbursements. Quality standards and metrics for the treatment of AMI and for performance of PCI are currently under review. More than half of all standards being proposed for use are already NQF endorsed. More information about this program can be found at http://www.qualityforum.org/map/.

The Centers for Medicare & Medicaid Services partnered with the Yale–New Haven Health System Corporation Center for Outcomes Research and Evaluation to develop and modify risk-adjusted standardized measures for reporting on outcomes for AMI. In the latest 2011 version, the standard for reporting and risk adjustment was developed "using hierarchical generalized linear modeling to create a risk-standardized mortality rate at the hospital level that reflects hospital quality" (https://www.qualitynet.org). Although heart failure and cardiogenic shock at the time of presentation were considered, analysis of the impact of OHCA was not included in the model, and OHCA was not an exclusion from the derivation or validation groups.

The National Cardiovascular Data Registry

The National Cardiovascular Data Registry (NCDR) is an initiative of the American College of Cardiology Foundation with

Table 1. Current NQF Standards Related to the Treatment of AMI Patients

NQF No.	Title	Steward
0161	AMI inpatient mortality (risk adjusted)	Joint Commission on Accreditation of Healthcare Organizations
0230	Hospital 30-day, all-cause RSMR after AMI hospitalization for patients ≥18 years old	CMS
0505	Hospital 30-day, all-cause RSRR after AMI hospitalization	CMS
0530	Mortality for selected conditions	AHRQ
0535	30-Day all-cause RSMR after PCI for patients without STEMI and without cardiogenic shock	CMS
0536	30-Day all-cause RSMR after PCI for patients with STEMI or cardiogenic shock	CMS
0730	AMI mortality rate	AHRQ

AHRQ indicates Agency for Healthcare Research and Quality; AMI, acute myocardial infarction; CMS, Centers for Medicare & Medicaid Services; NQF, National Quality Forum; PCI, percutaneous coronary intervention; RSMR, risk-standardized mortality rate; RSRR, risk-standardized readmission rate; and STEMI, ST-segment elevation myocardial infarction.

the stated mission "to improve the quality of cardiovascular patient care by providing information, knowledge, and tools; implementing quality initiatives; and supporting research that improves patient care and outcomes." The NCDR was launched in 1997 and encompasses a set of clinical quality data registries covering a wide spectrum of cardiovascular disease with >2200 participating hospitals. Two of the NCDR registries, the American College of Cardiology/AHA Acute Coronary Treatment and Intervention Outcomes Network (ACTION) Registry–Get With The Guidelines (ACTION Registry-GWTG) and CathPCI, deal extensively with AMI and PCI outcomes. Data collected through the ACTION Registry-GWTG and the CathPCI registry are used by various public reporting and benchmarking venues. Notably, the quality metrics and risk-adjustment methodology for PCI in AMI that were developed by investigators based on CathPCI data are currently used in NQF standards 0535 and 0536.

Through multivariate analysis, investigators with NCDR CathPCI have determined ORs of precatheterization clinical variables and developed a scoring system to help determine risk-adjusted categories. Myocardial infarction with cardiogenic shock on presentation had an OR for mortality of 9.21 (95% CI, 6.95–12.22) in a recent validation of 16226 AMI patients. The most recent publication of NCDR CathPCI methodologies by Chin et al[31] acknowledges that "information regarding resuscitated CA at presentation is not collected in ACTION Registry-GWTG, and therefore we could not assess its significance." The current data collection system for NCDR CathPCI (version 4.4) does include the field "CA within 24 hours." Inclusion of this data element was meant to improve the ability to risk stratify patients who had experienced a CA, but the metric is too crude to account accurately for the severity of illness associated with the spectrum of patients arriving at hospitals after OHCA with ROSC. Included in the same category are patients with witnessed VF arrest in the catheterization laboratory who receive immediate defibrillation and are neurologically normal and patients with out-of-hospital, unwitnessed asystolic arrest with an unknown duration of circulatory collapse who present in coma. There is a substantial difference in the odds of surviving the event among these differing clinical scenarios. It is arguable that patients with brief witnessed VF in the hospital setting who awaken immediately after rapid defibrillation are a different population

pathophysiologically from patients with OHCA who present in coma after a prolonged ischemia interval. A subsequent death in the former category is likely to be cardiovascular in origin and may well reflect the quality of cardiovascular care received. A deceased patient in the latter group who manifests a systemic inflammatory response with multiorgan injury and failure is not likely to reflect the quality of the PCI at all.

Gupta et al[32] analyzed a subset of patients in the CathPCI registry with CA within 24 hours of admission and STEMI on ECG and found a 25% mortality rate. This mortality rate is far in excess of survival rates expected from OHCA and demonstrates that even the risk-adjusted model using "CA within 24 hours" currently being designed by NCDR does not adequately represent the severity of illness for the majority of OHCA patients.

Peterson et al[33] evaluated whether taking "extreme risk cases" to the catheterization laboratory impacted hospitals' risk-adjusted PCI mortality ratings by reporting on 614746 PCI procedures in the CathPCI Registry. They found no evidence that treatment of high-risk PCI case patients adversely affected hospital risk-adjusted mortality. It is unknown how many comatose OHCA patients received immediate angiography and PCI in the participating hospitals. It is also unknown how many OHCA patients were treated at individual hospitals and what impact volume has on institutional risk adjustment. Given that dedicated CA centers may treat multiple times the volume of these patients than noncenter hospitals, the extrapolation of these conclusions cannot be made to centers that treat significant numbers of OHCA patients.

Ellis et al[34] highlighted the problem of accurate mortality prediction among OHCA patients in their report of the importance of considering general and neurological indicators after PCI in predicting long-term mortality. They found that prediction of in-hospital mortality after PCI is enhanced by the inclusion of variables that describe the patient's general and neurological status at the time of coronary intervention. Indeed, the model's accuracy of prediction is most improved among those with the highest decile of risk. They note that STEMI patients resuscitated from OHCA are an example of a subpopulation whose post-PCI mortality is high and is greatly influenced by such noncardiac factors. Recognition of the importance of these noncardiac variables, which are not included in any current performance reporting system,

is crucial for systems designed for mortality comparison and public disclosure.

As a result, the use of current standards may substantially underestimate the impact of CA on expected mortality predictions of AMI and PCI patients. The variables that alter this risk in these situations (eg, time to CPR, presenting rhythm, time to defibrillation for shockable rhythms, bystander CPR, and time to ROSC), although well recognized, are among a multitude of variables not captured in current PCI data sets. As a result, no degree of modeling can result in adequate adjustment and fidelity.

The Massachusetts Data Analysis Center

The Massachusetts Data Analysis Center (Mass-DAC) registry has reported on hospital-specific in-hospital mortality rates for PCI patients since 2003. Patient-specific risk factor and outcomes data are collected at each hospital and reported quarterly to the Mass-DAC. Mass-DAC has created risk-adjustment models by dividing PCI admissions into 2 groups: (1) admissions for patients who are in cardiogenic shock at initiation of PCI, or patients having an STEMI within 24 hours of arrival at the hospital or at the time of the first PCI procedure, and (2) admissions for patients without cardiogenic shock at initiation of PCI and patients without STEMI within 24 hours of arrival at the hospital or at the time of the first PCI. These models are applied to institutions using 1 year of data and to individual providers using a rolling 3-year period of data. Any hospital or operator found to be an outlier is notified. The hospital-specific outcomes are reported publicly and can be found at http://www.massdac.org. For patients with cardiogenic shock or STEMI, factors including age, renal failure, left main PCI, emergency or salvage procedure, ejection fraction <30%, and cardiogenic shock were noted to be significant predictors.

As a result of the recognition of the limitations of risk modeling in some patients, compassionate use criteria were added in 2006 for patients who present for a PCI with a very high expected risk of death. Most of these patients would be thought to be suboptimal candidates for PCI, but PCI may represent the only option for improvement of cardiac status or ultimate survival despite the high anticipated risks. Compassionate use criteria were initially defined as use of a percutaneous ventricular assist device or cardiopulmonary bypass or PCI performed in a patient with ongoing CPR or with coma (Glasgow Coma Scale [GCS] score <7) in the absence of sedatives before the procedure.[35] GCS frequently is not documented before intubation, which often occurs during resuscitation and frequently involves the use of sedatives or paralytic agents, making these patients ineligible to meet compassionate use criteria. Even if OHCA patients meet criteria to be categorized as compassionate use, these patients are still included in the analysis with "compassionate use status" included as a factor in the analysis for predicted mortality. Models that predict outcomes after PCI for OHCA that use compassionate use criteria are subject to unmeasured confounding because they do not include many prognostic features that predict neurological or multiorgan failure. Between 2005 and 2007, patients with the previously uncaptured compassionate use variable accounted for 1.7% of the overall population but accounted for 21% of the observed mortality, with an adjusted OR of 27.8. The adoption of these unique variables resulted in an improvement in the area under the receiver-operating characteristic from 0.87 to 0.90 (*P*<0.001) and significantly impacted the individual hospitals' publicly reported risk-adjusted mortality. Models predict a 75-year-old STEMI patient resuscitated after CA with a GCS score >6 without shock would have a predicted mortality of 2.63%. The same patient with a GCS score <7, which fulfills compassionate use criteria, would have a predicted mortality of 54.9%. Each year, an adjudication committee reviews and further defines the compassionate use criteria to ensure that the variable is capturing the correct elevated risk factors for mortality. Every patient classified as having received compassionate use PCI was reviewed by an adjudication committee to determine whether the case met the established criteria. Compassionate use was coded 128 times in 2009 and denied 37 times. However, the possibility of being denied the compassionate use designation is a factor considered by the operators when criteria are not met after OHCA (eg, sedative administration or GCS not documented after prolonged arrest), and models can only be constructed for the patients actually selected for PCI.

In 2009, exceptional risk criteria were created. Cases submitted as exceptional risk PCI had to meet the following criteria: (1) extremely high-risk features were not captured by current risk-adjustment covariates, and (2) the PCI was the only or best option for improving the chance of survival. All cases submitted as exceptional risk required additional documentation and were reviewed by an exceptional risk committee. All cases approved by the committee for exceptional risk were removed from analysis. Of cases submitted for exceptional risk consideration in 2009, 73% (19 of 26 cases) were denied. The Mass-DAC experience illustrates the importance of public reporting of PCI outcomes but also highlights that continued evaluation of risk-adjustment models is necessary with multidisciplinary input.

The New York State Registry

The New York State Registry also publicly reports aggregate hospital and individual provider mortality. Although it excludes all patients with shock, the registry has not excluded or performed risk adjustment for patients with CA. In response to multiple provider requests to have the CA population excluded from public reporting, the New York State Registry has recently provided guidelines for the exclusion of patients with proven anoxic encephalopathy as the cause of mortality after CA. The criteria for exclusion are many and specific and include the following:

- The PCI was performed for an AMI.
- CA occurred as part of the initial presentation of the AMI and before the patient was brought to the catheterization laboratory.
- The patient had normal consciousness before the arrest but became comatose, as defined by failure to exhibit adequate responsiveness to external stimuli.
- The death cannot have occurred in the catheterization laboratory.

- The patient must have been dependent on mechanical respiratory support until the time care was withdrawn.
- Neurology or critical care medicine (not including the PCI provider) consultation was performed and documented the presence of anoxic/hypoxic encephalopathy with the following findings:
  — GCS score <5
  — Tests that supported the consultant's diagnosis of persistent anoxic/hypoxic encephalopathy, particularly if death occurred within 72 hours of the PCI
  — Specific language by the consultant that the neurological condition was caused primarily by anoxic/hypoxic encephalopathy, indicating clearly that prognosis was poor for recovery from coma, and that the consultant supported withdrawal of care
  — Documentation that specified the people involved in the decision to withdraw care (including physicians, family, and proxies)
  — Documentation of the cardiac status as being hemodynamically stable (no shock or unstable hemodynamics with systolic blood pressure >90 mm Hg) without reinfarction or repeat CA while still being supported
  — A note in the chart that included the date and time and indicated that withdrawal was planned before it was actually performed. It is encouraged that the death certificate note anoxic/hypoxic encephalopathy as at least a contributing cause of death.
  — The patient survived a minimum of 72 hours after the index PCI, unless it can be documented that the patient met generally accepted criteria for brain death before this.
- The death cannot have occurred before planned withdrawal of support.

Although this is the largest step that any publicly reporting registry has taken to respond to clinician concerns about the exceptionally high and often noncardiovascular mortality in this population, there are few postarrest patients who go on to die after initial resuscitation who meet all of these criteria. Brain death is an uncommon cause of death in this group, with severe cerebral dysfunction (short of brain death) accounting for the majority of neurological deaths. It is difficult to separate hemodynamic instability that is primarily cardiac from that which is neurologically or systemically mediated after CA, so the inability to exclude a patient on the basis of hemodynamic instability still does not mean that the registry is capturing death attributable to a primary cardiac cause or one related to the PCI procedure. These exclusions do not account for any death that is secondary to multiorgan failure from a severe systemic inflammatory/injury response. These criteria are also, unfortunately, flawed in that they require withdrawal of care before death. The decision to withdraw care after CA is one that is personal for families and can be related to religious or cultural beliefs. Withdrawal of life-sustaining therapies typically does not occur in the United States without approval from the next of kin; therefore, if the patient's physicians all agree that additional care is futile but the family refuses to withdraw care, these patients will not be able to be excluded from the reporting. Any performance-reporting system that attempts to exclude patients after CA must take into account the many reasons for death and hemodynamic instability if its model is to fairly and comprehensively account for this population. In response to additional feedback, the New York State Registry is currently revising its exclusion criteria for CA patients once again; however, the specifics of the new criteria have not yet been determined.

Impact of Including OHCA Cases on STEMI-PCI Mortality

Table 2 illustrates the incremental effect of additional CA STEMI PCI volume on mortality. The model assumes 100 non-CA PCI-STEMI cases are performed per year, with an NCDR-reported average national mortality rate of 5%.

Even under the current best US practices, only ≈50% of patients with OHCA who are admitted to the hospital survive to hospital discharge; therefore, additional CA STEMI PCI cases were assumed to have an expected mortality rate of 50%.

The addition of only 15 CA STEMI cases, which is common for a high-volume CRC, results in a doubling of the reportable STEMI-PCI mortality for that hospital compared with a non-CRC hospital. Although small in number, these additional deaths are enough in many reporting systems to drop the hospital and provider from the highest to the lowest bracket for performance outcomes. This scenario has already occurred and has placed Beth Israel Deaconess Medical Center, a large-volume PCI-CRC hospital, in the local newspaper and under review for its publicly reported high PCI mortality associated with simply following the 2010 AHA Guidelines for CPR and ECC recommendations.

When Beth Israel Deaconess Medical Center created a CRC, the hospital immediately received more of these critically ill patients after ROSC from OHCA. Postarrest patients with STEMI on the initial ECG were taken directly to the cardiac catheterization laboratory soon after arrival in the emergency department, on the basis of the 2010 AHA Guidelines for CPR and ECC recommendation. Michael W. Donnino, MD, an author of the present scientific statement and a faculty member at Beth Israel Deaconess Medical Center, reported in December 2012, "the total number of postarrest patients

Table 2. Effect of Additional Cardiac Arrest STEMI PCI Cases on Catheterization Laboratory Site Mortality

No. of Additional CA STEMI PCI Cases/Yr	Site Mortality, %
0	5.0
5	7.1
10	9.1
15	10.9
20	12.5
25	14.0
30	15.4
35	16.7
40	17.9
45	19.0
50	20.0

CA indicates cardiac arrest; PCI, percutaneous coronary intervention; and STEMI, ST-segment elevation myocardial infarction.

in this hospital system and cardiac catheterization laboratory increased substantially after implementing a postarrest center, leading to increased overall catheterization laboratory mortality that was almost all associated with CA patients." Because overall cardiac catheterization laboratory mortality rates are very low, these few additional deaths gave Beth Israel Deaconess Medical Center the highest mortality rate in the state of Massachusetts. This information was released publicly, and an article criticizing the care at Beth Israel Deaconess Medical Center was published in *The Boston Globe*.[36]

Discussion

One of the main purposes of PCI performance reporting is to identify systems that provide "good-quality" or "poor-quality" cardiac catheterization laboratory services and PCI. In cases of STEMI without associated CA, there is a direct link between the PCI procedure, the underlying myocardial infarction, and a subsequent cardiovascular death. However, the majority of patients hospitalized after arrest who do not survive to hospital discharge die of neurological causes or multiorgan failure from massive reperfusion injury and not cardiovascular complications of the PCI. Patient deaths of brain damage or systemic injury after CA most often have little to do with the cardiovascular care they received, and their inclusion in a public performance-reporting program violates a key premise to all such registries that the mortality actually be related to the procedure. Because performance-ranking registries are tied to awards, reimbursement, performance recognition, and public reporting of hospital performance, the inclusion of patients taken to the cardiac catheterization laboratory immediately after CA is likely to give misleading perceptions about the quality of cardiovascular care at a hospital. If there is not a strong link between the PCI and the outcome, then the public is misinformed, and hospitals and providers are ranked inappropriately for the care they provide.

OHCA is not the first area to potentially suffer unintended consequences from public reporting and performance ranking. Public reporting of cardiac surgery outcomes began in 1986 with unadjusted mortality reporting by Medicare. This effort initially appeared to penalize hospitals and surgeons that performed surgery on high-risk patients, because their outcomes were compared with procedures performed on low-risk patients. Since then, performance reporting for cardiothoracic surgery has evolved to either exclude or adequately risk adjust, when possible, cases with expected high mortality so that the ranking is more representative of true performance.

Although the intent of public reporting and performance ranking has numerous benefits, including accelerating the adoption of best clinical practices, there are potential unintended consequences. Risk-avoidant behavior, in which clinicians do not offer high-risk patients potentially lifesaving procedures in an attempt to avoid negative outcome reporting, has been documented to have occurred in coincidence with public reporting programs.[37] The proportion of patients undergoing PCI in Massachusetts for cardiogenic shock between 2003 and 2005 declined 43% from 2.28% to 1.29%, which coincides with the first 3 years of the public reporting of PCI outcomes in the state.[35] Another example comes from the New York State Registry, in which there was a 30% decrease

in the number of patients with cardiogenic shock receiving PCI in New York State between 1997 and 2003 (http://www.health.state.ny.us/nysdoh/heart/heart_disease.htm) when public reporting of outcomes included this population. Despite the results of the SHOCK (Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock) trial,[38–40] observed rates of PCI in New York State lagged behind national trends because of the lack of physician confidence in the risk-adjusted model. This behavior eventually led to the ultimate exclusion of cardiogenic shock patients from this registry in 2008.[30,37] After cardiogenic shock was excluded from public reporting, the use of PCI in this high-risk population increased back to pre-reporting era levels. Although it is a challenge to apply variables that define risks associated with CA in a verifiable manner in a nationwide registry, failure to monitor and implement high-risk criteria effectively may result in gaming and other unintended consequences.

Narins et al[41] surveyed interventional cardiologists and determined that 79% "agreed or strongly agreed that the publication of mortality statistics has influenced their decision regarding whether or not to perform angioplasty on individual patients." Physicians expressed an increased reluctance to intervene in critically ill patients with high expected mortality rates, and 85% agreed or strongly agreed that "patients who might benefit from angioplasty may not receive the procedure as a result of public reporting of physician-specific patients' mortality rates." Eighty-five percent believed that the risk-adjustment model used in the "Percutaneous Coronary Interventions (PCI) in New York State 1998–2000" report is "not sufficient to avoid punishing physicians who perform higher-risk interventions."

Most recently, Joynt and colleagues[42] reported on a retrospective observational cohort using data from fee-for-service Medicare patients and determined that patients with AMI were less likely to receive PCI in public reporting states (New York, Massachusetts, and Pennsylvania) than in nonreporting states (Maine, Vermont, New Hampshire, Connecticut, Rhode Island, Maryland, and Delaware), with a risk-adjusted OR of 0.82 (95% CI, 0.71–0.93; $P=0.003$). The differences were greatest in patients with STEMI (61.8% versus 68.0%; OR, 0.73; 95% CI, 0.59–0.89; $P=0.002$) and those with cardiogenic shock or CA (41.5% versus 46.7%; OR, 0.79; 95% CI, 0.64–0.98; $P=0.03$). They further evaluated the change in PCI rates after initiation of public reporting in the state of Massachusetts, because this was the only state that initiated public reporting during the time frame analyzed. They found that the pattern of PCI rates began to diverge the year that public reporting was implemented. Patients in Massachusetts underwent similar rates of PCI as in nonreporting states before the implementation of public reporting, with an adjusted OR of 1.00. In the postreporting period, the odds of receiving PCI in Massachusetts decreased relative to the other nonreporting states (41.1% versus 45.6%; OR, 0.81; 95% CI, 0.47–1.38; $P=0.03$), which demonstrates that the public reporting of PCI outcome measures influences clinical decision making. Once again, the impact in Massachusetts was greater in patients with cardiogenic shock or CA ($P<0.001$ for the association).

However, although public reporting of outcomes after PCI may result in unintended consequences such as risk-avoidance

behavior, declining to perform an invasive procedure in the setting in which futility is rightfully expected is completely appropriate. There are several known factors associated with high mortality after CA, regardless of whether PCI is performed. The presenting rhythm during CA offers prognostic information at the time of CA. Compared with patients presenting with unshockable rhythms (pulseless electrical activity/asystole), those patients with shockable rhythms have significantly improved survival. Meta-analysis and systematic review of 79 studies involving 142 740 patients showed that the OR for survival to hospital discharge among patients found in asystole versus other rhythms ranged from 0.10 (95% CI, 0.03–0.31) in the studies with the lowest baseline rates of survival to 0.15 (95% CI, 0.09–0.25) in studies with the highest baseline rates. Conversely, the OR for survival to hospital discharge among those patients with VF/ventricular tachycardia compared with all other rhythms ranged from 2.91 (95% CI, 1.10–7.66) in the studies with the highest baseline rates of survival to an OR of 20.62 (95% CI, 12.61–33.72) in the studies with the lowest baseline rates of survival.[43] Detailed models predicting outcomes after CA have been developed using prognostic indicators such as initial rhythm, estimated no-flow interval and low-flow interval, blood lactate, and creatinine levels at admission, as well as time from collapse to ROSC and the presence of ROSC under prehospital conditions, witnessed arrest, and administration of bystander CPR.[44,45] The value of risk-adjustment models that evaluate PCI in CA would increase substantially if such variables were included. The ongoing challenge is to better define the predictors of mortality in these critically ill patients so that data-driven outcome predictions can be made.

Ethical Considerations

The primary goals of guidelines and registries are to ensure the optimal care of patients, both now and in the future. As such, they comport with the ethical obligations of clinicians, institutions, and payers to provide the best possible medical care that is expected to yield the best outcomes overall. Registries can facilitate meeting these obligations by making information about quality transparent, thereby encouraging compliance by clinicians and institutions with best practices. In some cases, such publicly available data also permit patients to select institutions where they might expect to receive quality care. Nevertheless, the current approach used for measuring quality of PCI care of patients who have had an OHCA, which centers on mortality, may misrepresent the quality of care actually provided, assuming quality rests with compliance with the best practices outlined in the 2010 AHA Guidelines for CPR and ECC. Thus, there is a clear need to develop and implement appropriate measures of quality in this patient population. Furthermore, the current systems for publicly reporting the outcomes for postarrest patients undergoing PCI inadvertently put clinicians in a difficult situation. Given the comparatively high mortality in these patients compared with non-CA patients, if an individual operator chooses to follow the 2010 AHA Guidelines for CPR and ECC and takes a disproportionate number of these patients to the catheterization laboratory on presentation, which is what is seen in CRCs, he or she will likely be faced with having higher

personal and institutional mortality and the subsequent penalties that are associated with this reporting. Although it might be tempting for clinicians to ignore a Class I AHA recommendation to protect their publicly reported reputation, such a response would be ethically inappropriate. Correcting the system avoids having clinicians struggle with this issue and promises to enhance care.

Finally, if all appropriate CA patients are not receiving early catheterization and intervention when indicated, then our perception of the outcomes and the ability to perform adequate risk adjustment on this population will be incomplete and likely not representative of the truth when the entire gamut of postarrest patients is considered. If only patients who are awake after ROSC or hemodynamically stable with exceptionally good outcome prediction are offered advanced therapies, then the data that evolve from these reporting systems will falsely represent the outcomes when generalized to the entire postarrest population.

Recommendation

CA may occur outside of a hospital, in a hospital, or in a catheterization laboratory during a revascularization procedure. The outcome of these CAs is affected dramatically by factors such as the location of the arrest, performance of immediate high-quality CPR, the presenting rhythm, rapid defibrillation, total ischemic time, and the extent of systemic reperfusion injury. It is nearly impossible to perform adequate risk adjustment for the single variable "CA" given the diversity of this population. Therefore, CA patients should not be considered as a single category in a publicly reported outcomes database. All registry-reported outcomes of PCI after OHCA either aggregate the various components in the Chain of Survival rather than reflecting the quality of emergency PCI independently or do not address the confounder of CA at all. The accurate prediction of outcomes of PCI after OHCA in an effort to measure quality of PCI is difficult, if not impossible, and has the unintended consequence of hampering improvement in systems of care and the optimal use of reperfusion for patients who have had an OHCA. There are 3 potential approaches to the dilemma posed by the current inclusion of OHCA in STEMI-PCI quality reporting:

1. Quality-tracking organizations could simply exclude OHCA cases from individual operator and institutional STEMI-PCI mortality reporting by categorizing these cases as compassionate use of an appropriate treatment in exceptionally high-risk patients. This approach is suboptimal, because it would not permit evaluation of the quality of STEMI-PCI services and would waste the opportunity to collect data and pursue quality-improvement initiatives. OHCA cases could be included in quality reporting if appropriate risk adjustment could be made. The problem is that current risk-adjustment models are not adequate, as noted, and given the diversity of the CA population, they are not likely to ever be adequate.
2. OHCA cases could be included in quality reporting if appropriate risk adjustment could be made. However, as noted and given the diversity of the CA population, risk adjustment models are not likely to ever be adequate.

We believe that categorizing OHCA STEMI-PCI cases separately from other STEMI-PCI cases represents the most appropriate solution, because the inclusion of OHCA patients in the public reporting of PCI outcomes does not accurately reflect quality. Therefore:

3. Our recommendation is that OHCA cases should be tracked but not publicly reported or used for overall PCI performance ranking, which would allow accountability for their management but would not penalize high-volume CRCs for following the 2010 AHA Guidelines for CPR and ECC. Until an adequate risk adjustment model is created to account for the numerous out-of-hospital and in-hospital variables that impact survival more than the performance of PCI, we believe that categorizing OHCA STEMI-PCI cases separately from other STEMI-PCI cases and not including them in public reporting represents the most appropriate solution at this time.

Disclosures

Writing Group Disclosures

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Mary Ann Peberdy	Virginia Commonwealth University	None	None	None	None	None	None	None
Clifton W. Callaway	UPMC-Health System; University of Pittsburgh	All awards to my institution (University of Pittsburgh)†; U01 HL077871 (Principal Investigator, 40% effort) NHLBI 2004–2015 Pittsburgh Resuscitation Network (money paid to University of Pittsburgh)†; K12 HL109068 (Yealy/ Callaway Co-PI, 20% effort) NHLBI 2011–2016 Pittsburgh Career Development Program in Emergency Medicine Research (money paid to University of Pittsburgh)†; United First Responders LLC (Callaway PI, 10% effort) DoD 2011–2013 Remote Bio-medical Detector (money paid to University of Pittsburgh)†	Medivance, Inc: laboratory equipment in 2009*	Society for Critical Care Medicine*; Sudden Cardiac Arrest Association*; Take Heart Austin, Austin, TX*; St. Mary's Hospital, Seoul, South Korea*	None	Apple Computer, Inc†	None	2000 US Patent #6,438,419, CW Callaway and LD Sherman, "Method and apparatus employing a scaling exponent for selectively defibrillating a patient." Licensed to Medtronic ERS, Inc until March 2012 (now terminated). I received royalties prior to March 2012.†
J. Michael DiMaio	UT Southwestern Medical Center	None	None	None	None	None	None	None
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T. Bruce Ferguson, Jr	East Carolina University	None	None	None	None	None	None	None

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Duane S. Pinto	Harvard Medical Faculty Physicians, Cardiologist	None	None	Harvard Medical School*; PRIMED*; Terumo *	Provided analysis for a malpractice provider (CRICO) defending physicians in a case of mesenteric ischemia*; provided analysis for a malpractice provider (CRICO) defending physicians in a case of limb ischemia related to closure device*	None	ROX Medical*; Medtronic: advisory board*; Medicines Company*	None

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Jeremy Sugarman	Johns Hopkins University, Professor of Bioethics and Medicine	NIH†	None	I am generally invited to give multiple talks each year at different institutions on a variety of topics related to bioethics. These talks tend to be sponsored by the institutions.†	Query and Harrow, case unrelated to current writing assignment†	None	Genentech Strategic Council†; Merck KGaA Bioethics Advisory Panel†; neither is related to the current writing project.	None
Demetris Yannopoulos	University of Minnesota, Interventional Cardiologist	None	None	None	None	None	None	None

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (1) the person receives $10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (2) the person owns 5% or more of the voting stock or share of the entity, or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

Reviewer Disclosures

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*Modest.

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Circulation

American Heart Association

Impact of Percutaneous Coronary Intervention Performance Reporting on Cardiac Resuscitation Centers: A Scientific Statement From the American Heart Association

Mary Ann Peberdy, Michael W. Donnino, Clifton W. Callaway, J. Michael DiMaio, Romergryko G. Geocadin, Chris A. Ghaemmaghami, Alice K. Jacobs, Karl B. Kern, Jerrold H. Levy, Mark S. Link, Venu Menon, Joseph P. Ornato, Duane S. Pinto, Jeremy Sugarman, Demetris Yannopoulos and T. Bruce Ferguson, Jr
on behalf of the American Heart Association Emergency Cardiovascular Care Committee and the Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation

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Movie Legend

Movie 1. Echocardiographic 4 chamber view : Dilated RV with mild contractile dysfunction seen. Best viewed with Windows Media Player.

Movie 2. Parasternal short axis view at mid cavity level: Normal size and contractility of the LV and dilated RV is shown. Best viewed with Windows Media Player.

Movie 3. Cine MRI demonstrating normal LV and dilated dysfunctional RV. Best viewed with Windows Media Player.

Movie 4. Right coronary angiogram Left anterior oblique(LAO) view demonstrating proximal total occlusion. Best viewed with Windows Media Player.

Movie 5. Right anterior oblique(RAO)view of right coronary angiogram. Proximal total occlusion. Best viewed with Windows Media Player.

Movie 6. PCI and Stent deployment to proximal RCA. Best viewed with Windows Media Player.

Movie 7. Post balloon angioplasty and stenting showing an open vessel which is small in caliber, supplying essentially only the right ventricular branches. Best viewed with Windows Media Player.

Movie 8. Final result after deployment of stent in proximal RCA. RCA is open and essentially supplies only RV branches. Best viewed with Windows Media Player.

Movie 9. LAO and **Movie 10** RAO views of left coronary angiogram: Dominant left coronary artery without significant disease seen. Best viewed with Windows Media Player.

Movie 11. Left ventriculogram showing normal LV function and no RWMA. Best viewed with Windows Media Player.

Movie 12. Follow up Cine MRI : Improvement in RV function and marked disappearance of RWMA seen. Best viewed with Windows Media Player.