

# Do Cardiology Quality Measures Actually Improve Patient Outcomes?

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Cardiovascular quality measures for inpatient care have undergone a rapid evolution over the past three decades. Isolated efforts at simply measuring quality have developed into national programs dedicated toward the public reporting of hospital performance on a number of quality measures. Most recently, performance on quality measures has become closely tied to hospital and physician payments. With the implementation of the Affordable Care Act (ACA), further changes in how we measure, report, and pay for quality health care will continue in coming years.

At their core, quality measures in cardiovascular care are meant to improve the quality of care delivered to patients, and in doing so, improve patient-relevant outcomes such as mortality, hospital readmission, and patient experience. However, the relationship between quality measures and hard outcomes has been inconsistent, and thus, problematic for policymakers and clinical leaders who aim to use these measures to effectively drive improvements in cardiovascular care. In this review, we examine the evidence behind three major mechanisms of quality improvement: measurement alone, public reporting, and pay-for-performance. In characterizing the successes and failures that have occurred as part of each of these mechanisms, we provide a framework to inform future quality improvement efforts.

## Quality Improvement Through Process-of-Care Measurement

### History of Quality Measurement

The earliest steps toward quality improvement involved simply creating and implementing basic mechanisms for quality

measurement. In the 1950s, the Joint Commission on Accreditation of Healthcare Organizations (formerly JCAHO, now The Joint Commission, TJC) began mandating hospital compliance with a set of “Minimum Standards” of quality (Figure), which were later incorporated into the process of hospital accreditation under the ORYX Initiative of the 1990s.<sup>1,2</sup> As part of ORYX, accredited hospitals were required to regularly provide TJC with a subset of performance data to identify areas in need of improvement.

Cardiovascular care was among the first areas in medicine in which standardized quality measurement was attempted on a national scale. In 1992, the Health Care Financing Administration (HCFA, now the Center for Medicare and Medicaid Services, CMS), began measuring and tracking a series of disease-specific process-of-care measures for Medicare patients under the Health Care Quality Improvement Initiative.<sup>3</sup> The chosen measures were based on evidence-based guidelines at the time for prevention and treatment of multiple conditions, including acute myocardial infarction (AMI), heart failure, and stroke. In concert with early TJC efforts, the program intended to provide hospitals with performance data and nonpunitive highlight areas for improvement.

The Cooperative Cardiovascular Project (CCP) was a program under the Health Care Quality Improvement Initiative that defined and measured adherence to evidence-based practices for AMI care,<sup>4,5</sup> such as the use of thrombolytics or aspirin during hospitalization, and the receipt of beta-blockers and angiotensin-converting enzyme (ACE) inhibitors at discharge. Initial data from this program demonstrated widespread deficiencies in care: among “ideal candidates,” 69% of patients received thrombolytics and 83% received aspirin during hospitalization; at discharge, only 45% of patients received beta-blockers.<sup>4</sup> CMS later launched the National Heart Failure (NHF) project in 1999,<sup>6</sup> which aimed to define and measure adherence to standards for high quality care for heart failure, such as measurement of left ventricular (LV) systolic function, and the use of ACE inhibitors in patients with LV systolic dysfunction. This program similarly found suboptimal and variable performance across hospitals: the range of appropriate evaluation of LV systolic function spanned from 21% to 66%, while adherence to ACE inhibitor therapy for eligible patients spanned from 51% to 93%.<sup>7</sup>

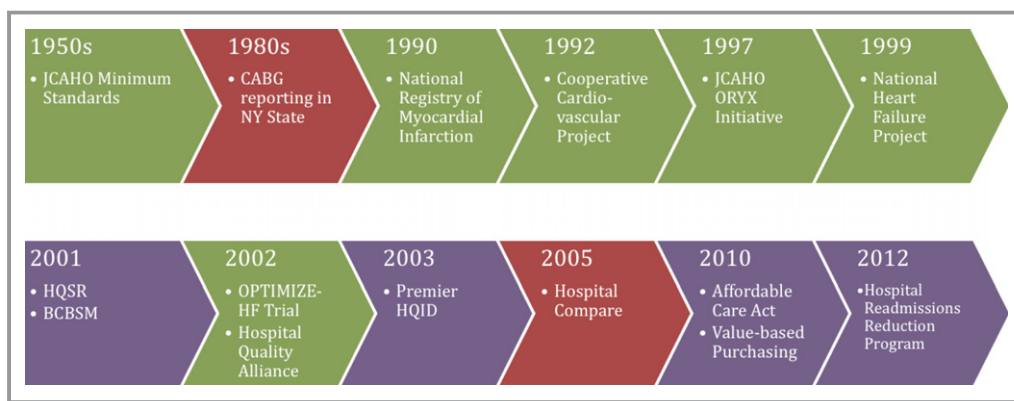
In concert with these federal efforts, the 1980s and 1990s saw the growth of national registries to track, measure, and

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*J Am Heart Assoc.* 2014;3:e000404 doi: 10.1161/JAHA.113.000404.

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**Figure.** Timeline of quality improvement programs in cardiovascular care. Green: quality measurement programs; red: public reporting; purple: pay-for-performance programs. BCBSM indicates Blue Cross Blue Shield of Michigan Participating Hospital Agreement Incentive Program; CABG, coronary artery bypass graft; HQID, hospital quality incentives demonstration; HQSR, Hawaii Medical Service Association Hospital Quality Service and Recognition Pay-for-Performance Program; JCAHO, Joint Commission on Accreditation of Healthcare Organizations; OPTIMIZE-HF, Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients With Heart Failure.

improve quality in cardiovascular care. The Society for Thoracic Surgeons (STS) introduced the STS National Database to track risk-adjusted outcomes in adult cardiac and general thoracic surgery for both internal quality improvement and public reporting purposes, while the National Registry of Myocardial Infarction began to track and measure practice patterns and outcomes for AMI patients. In 1997, the American College of Cardiology developed the National Cardiovascular Data Registry to consolidate clinical data in cardiovascular care. Early registry-based studies confirmed the widespread underuse of thrombolytic therapy, aspirin, and beta-blockers, particularly in elderly patients and patients with delayed AMI presentations.<sup>8</sup> Perhaps more importantly, the registries were the first large-scale efforts to track patient outcomes in addition to process measures, indicating a marked change from the CMS and TJC programs.

Borne out of a public-private nonprofit partnership, the National Quality Forum (NQF) was formed in 1999 to set national standards of healthcare quality. Specifically, the NQF defined quality metrics, organized data collection, and reported standards in accordance with recommendations from the President's Advisory Council.<sup>9</sup> Importantly, the NQF improved public access to quality data while playing a key role in introducing new quality metrics for adoption by CMS, with an eventual emphasis on outcome measures.

Efforts at quality measurement were further bolstered by the public release of the Institute of Medicine's landmark study, *Crossing the Quality Chasm*, in 2001.<sup>10</sup> In response to the pervasive quality gaps described therein, TJC introduced identical quality measures as CMS beginning in 2002 and required over 3000 of its accredited hospitals to submit performance data on at least 2 of 4 condition-specific

measures: AMI, heart failure, pneumonia, and pregnancy-related conditions.<sup>11</sup> In addition to standardizing quality measurement, TJC provided hospitals with quarterly performance reports to motivate improvement. Studies of this quality measurement scheme after 2 years of its implementation showed a 3% to 33% improvement from baseline in the proportion of patients receiving appropriate care for AMI, heart failure, and pneumonia,<sup>11</sup> with the lowest-performing hospitals at baseline showing the greatest improvement.

By the early 2000s, quality measurement in cardiovascular care involved a multilevel framework, with both public and private contributions at the state and national levels. A growing body of evidence confirmed widespread variability in adherence to guideline-based process measures, suggesting that simply defining quality metrics did not necessarily translate into adoption by clinicians. Nevertheless, such frameworks set the stage for understanding whether adherence to process-based care led to improved patient outcomes.

### Relationship Between Quality Measurement and Patient Outcomes

Early data on the relationship between measurement and outcomes in cardiovascular care showed inconsistent correlations. One of the first studies to address this, a small, patient-level observational study of stroke care in 3 New Zealand hospitals, showed significant differences in process-of-care scores (as assessed by obtaining a head CT, performing a swallow study prior to feeding, and completing a multidisciplinary care meeting) between non-survivors and survivors at the time of hospital discharge. Yet, paradoxically, of the 3 hospitals studied, the hospital with the poorest process score

demonstrated the best-case, mix-adjusted outcomes of death and functional status at the time of discharge.<sup>12</sup>

The process-outcome relationship for AMI care has also been shown to be significant, though variable in magnitude. A study from the Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes With Early Implementation of the American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines (CRUSADE) trial demonstrated a strong correlation between processes of care and outcomes, with every 10% increase in composite adherence to process measures associated with a 10% decrease in in-hospital mortality.<sup>13</sup> However, a larger hospital-level study of AMI care for Medicare patients showed that while receipt of beta-blockers and aspirin at time of discharge was associated with lower risk-standardized 30-day mortality rates, when taken together, performance on process measures explained only 6% of hospital-level variation in risk-standardized, 30-day mortality rates.<sup>14</sup>

The process-outcome relationship for heart failure has also been shown to be modest. In the Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients With Heart Failure (OPTIMIZE-HF), a patient-level registry designed to promote guideline-based care for heart failure patients, none of the process-of-care measures were found to be associated with lower mortality at 60 or 90 days, and only ACE-inhibitor or angiotensin receptor blocker use at discharge was associated with lower readmission and later post-hospitalization mortality.<sup>15</sup> Ironically, though beta-blocker use at discharge was not established as a process measure for heart failure performance at the time, it was shown to be strongly associated with reduced mortality rates. More recent studies have confirmed this weak overall process-outcome relationship in heart failure care: analyses from the American Heart Association's Get With The Guidelines Program for heart failure (GWTG-HF) demonstrated that more frequent measurement of LV ejection fraction and use of ACE inhibitors or angiotensin receptor blockers in patients with LV dysfunction did not translate into lower 30-day mortality rates, but did result in small, but significant, reductions in 30-day readmission rates.<sup>16</sup>

### Limitations of Quality Measurement in Improving Patient Outcomes

While process measures are intuitively valid as quality metrics, their impact on outcomes remains limited. One possible reason for this modest relationship is simply that some process-of-care measures are not designed to impact short-term mortality. For example, measuring ejection fraction or counseling patients on smoking cessation, while good care practice, are unlikely to have an immediate impact on short-term mortality. Furthermore, as guideline-based

cardiovascular care has become codified, there is little between-hospital variability in adherence to some process-of-care measures, making it difficult to detect associated differences in mortality rates. Finally, risk-adjusted mortality measurements may suffer from residual confounding by clinical complexity or socioeconomic factors, thus limiting the ability to determine the true relationship between process-of-care and mortality. Nonetheless, in spite of their weak relationship with outcomes, process measures continue to be useful quality metrics due to their inherent face validity as well as their independent utility in ensuring the delivery of high-quality, guideline-based care.

## Quality Improvement Through Public Reporting

### History of Public Reporting

As quality measurement took hold in American hospitals, the public release of hospital performance on quality measures emerged as the natural next step in incenting quality improvement. The rationale behind public reporting was twofold: first, making performance data public could provide a powerful incentive for clinicians and leaders to improve; second, it would empower consumers to make choices based on hospital and physician performance.

Public reporting was initiated at the state level prior to its use as a national strategy. In 1989, New York (NY) State began reporting risk-adjusted mortality rates for coronary artery bypass grafting (CABG) surgery by hospital and surgeon. Pennsylvania (PA) followed suit in 1992, reporting CABG outcomes as well as costs of care; Massachusetts (MA) initiated a public reporting program for CABG outcomes in 2002. These states have also initiated programs for public reporting of percutaneous coronary intervention (PCI): New York in 1991, Pennsylvania in 2001, and Massachusetts in 2005.<sup>17</sup>

However, the first large-scale, national endeavor to publicly report hospital quality data began in the early 2000s, when the Hospital Quality Alliance (HQA) was borne out of a collaborative venture between CMS, TJC, and several medical professional organizations. To support the HQA efforts, Congress passed the Medicare Modernization Act of 2003,<sup>18</sup> which tied hospitals' participation in public reporting to annual payment updates, effectively incenting hospitals to report data to CMS on 10 evidence-based process measures for the management of AMI, heart failure, and pneumonia—essentially the same set of metrics that had been collected by TJC and HCFA in earlier years. The first set of HQA data was released in 2004, and for the first time, the American public could access quality data on nearly all U.S. hospitals on a centralized website, Hospital Compare.<sup>19</sup>

## Relationship Between Public Reporting and Patient Outcomes

The first studies to examine public reporting's impact on outcomes were from the state-level CABG reporting programs. Initial results suggested that public reporting in NY led to decreases in CABG mortality over time, which was initially attributed to de-selection of surgeons with high mortality rates and improvements in processes of care in response to reporting.<sup>20–22</sup> However, subsequent work showed comparable decreases in states without public reporting,<sup>23,24</sup> suggesting that these improvements might have been the result of secular trends rather than public reporting, per se. Studies of the PCI public reporting programs have found no overall difference in mortality rates for reporting versus nonreporting states.<sup>17</sup>

In contrast, the first evaluations of the Hospital Compare national public reporting program were positive: though baseline performance on these metrics was variable,<sup>25</sup> studies showed that overall performance on process measures improved significantly over the first 2 years of public reporting.<sup>11</sup> Perhaps even more impressive was the finding that higher performance on these process measures was associated with lower risk-adjusted mortality rates for AMI, heart failure and pneumonia, though the differences were, again, small.<sup>26,27</sup> A follow-up study examining the first 3 years of the program also showed that improvement in performance over time was associated with improved outcomes for AMI: a 10-point increase in performance on process measures was associated with an 0.6% reduction in 30-day mortality rates and an 0.5% reduction in 30-day readmission rates.<sup>28</sup> There were minimal effects for heart failure and pneumonia, however. Nonetheless, this study raised the possibility that public reporting of the same metrics that had been simply measured for many years might be a key innovation in incenting meaningful improvements in patient outcomes.

However, more recent studies of Hospital Compare have painted a less rosy picture, suggesting that the improvements in mortality might be more the result of underlying hospital quality than about the publicly reported measures themselves. For example, a recent study showed that of the 180 hospitals in the top quintile of mortality rates for AMI, fewer than one-third (31%) were in the top quintile of the composite process score, and that together, the HQA process measures explained only 6% of hospital-level variation in 30-day mortality rates.<sup>14</sup> Perhaps most striking is the recent finding that while mortality rates for AMI, HF, and pneumonia improved in the period after the introduction of Hospital Compare, the improvement essentially followed the trends in mortality prior to the program, suggesting that the addition of public reporting did not lead to a more rapid improvement in mortality rates than was occurring under quality measurement alone.<sup>29</sup>

## Limitations of Public Reporting in Improving Patient Outcomes

The major limitation of public reporting is the concern that it may lead physicians to avoid high-risk patients in order to avoid poor outcomes. Studies examining this in the context of CABG surgery have been equivocal: while one study found an increase in the number of patients transferred to the Cleveland Clinic from NY State after the initiation of CABG reporting,<sup>30</sup> another demonstrated that the risk profile of patients receiving CABG in NY State actually worsened after the adoption of public reporting, and NY State residents who received CABG surgery in-state were of higher-risk than those who received surgery out-of-state.<sup>22</sup> Whether this was due in part to greater attention to coding of medical comorbidities as a response to public reporting is unclear.

Racial and ethnic minorities are another group that may be perceived to be at higher risk of poor outcomes, and thus may be at risk of decreased access to surgical care under public reporting. Two studies have examined this issue using CABG data from the NY experience, one of which found that disparities between black and white patients in rates of CABG increased in NY State after the adoption of public reporting<sup>31</sup>; the other demonstrated that non-whites in NY State were more likely to be treated by surgeons with high mortality rates after the adoption of reporting.<sup>32</sup>

A study looking at differences in case mix and outcomes for PCI in NY found a significantly lower propensity to undergo PCI in NY than in Michigan (a nonreporting state) for AMI,<sup>33</sup> and an analysis of a registry of patients with cardiogenic shock demonstrated that NY patients in shock were less than half as likely as non-NY patients in shock to undergo PCI.<sup>34</sup> Beyond the NY experience alone, a recent national study demonstrated that the 3 states with mandatory public reporting of PCI outcomes (NY, PA, and MA) had significantly lower rates of use of this procedure for patients with an AMI. This was associated with higher mortality for patients with ST-elevation myocardial infarction, though overall mortality rates in the AMI population were unaffected.<sup>17</sup>

Some of this reduction in use likely is due to reporting-induced risk aversion among physicians; a survey of interventional cardiologists in NY State found that 89% of respondents felt that reporting had influenced their decision on whether to intervene in critically ill patients, although this study did not include data on actual practices.<sup>35</sup> Another study examining hospitals' response to identification as an "outlier" for mortality rates after PCI in Massachusetts showed that the risk profile of PCI patients at outlier institutions was significantly lower after public identification as an outlier, suggesting that risk aversion increased among PCI operators at outlier institutions as a result.<sup>36</sup>



In summary, the experience with public reporting demonstrates little evidence that reporting is associated with improvement on either process-of-care or patient outcomes for cardiovascular disease, above and beyond quality measurement alone, and demonstrates that avoidance of high-risk patients is a real consequence of these programs. Thus, it remains unclear whether the net effect of public reporting is positive or negative. Indeed, the absence of randomized trials of public reporting and the existing observational data limits our ability to conclusively assess its net effect on patient outcomes, and the expectation of conclusive evidence may be unwarranted at this stage. As such, future rigorous trials are required in order to fully exclude the possible small-to-moderate benefits of public reporting. There are certainly many benefits to public reporting that may not be captured in process-of-care or outcome measurement, such as increased transparency and improved trust from patients and other consumers. In this context, it is unlikely that public reporting will cease any time soon. In fact, the Hospital Compare program has expanded to include measures of patient satisfaction, surgical quality, and nursing home ratings, among others.<sup>19</sup> However, whether these benefits will be worth the potential unintended consequences remains to be seen.

## Quality Improvement Through Pay-for-Performance

### History of Pay-for-Performance

Paying for performance (P4P) is the newest quality improvement effort that has been used on a national scale for cardiovascular care. Certainly, P4P has strong face validity in that when the appropriate financial incentives are in place, there is likely to be a strong stimulus to improve on the part of both clinicians and hospital administrators. Furthermore, as cost control became a major concern for policymakers, P4P gained traction as a strategy for maximizing quality while prioritizing cost effectiveness.

As was the case in public reporting, state-level experiments predated federal ones. Large-scale examples of P4P include the Hawaii Medical Service Association Hospital Quality Service and Recognition P4P Program (HQSR),<sup>37</sup> and the Blue Cross Blue Shield of Michigan (BCBSM) Participating Hospital Agreement Incentive Program,<sup>38</sup> both of which were launched in 2001. Similar to many prior quality programs, both programs used process-of-care measures for AMI, heart failure, and pneumonia in assessing quality. While both programs offered bonus financial incentives, neither included a financial penalty for poor performance. Only the Hawaii Medical Service Association program included outcome measures as part of their quality assessment. Both programs emphasized absolute performance over improvements from baseline.

The first nationwide foray into hospital-level P4P began in 2003 when 421 hospitals were invited by CMS to participate in the Premier Hospital Quality Incentives Demonstration (HQID), with 252 hospitals ultimately joining the program and providing data for analysis.<sup>39</sup> HQID offered payment bonuses to hospitals based on their performance on a set of disease-specific process measures, which were very similar to measures established by the HQA for AMI, CHF, and pneumonia. Hospitals in the highest deciles of performance qualified for a financial bonus while those with the poorest performance were susceptible to a financial penalty.

### Relationship Between Pay-for-Performance and Patient Outcomes

Studies of the Hawaii P4P program found modest benefit: after 4 years of the HQSR, there were significant decreases in risk-adjusted complication rates and lengths-of-stay for surgical and obstetric procedures, as well as improvements in patient satisfaction with emergency department care as measured by individual hospital surveys.<sup>37</sup> The BCBSM P4P program was associated with improvements in processes of care from 2000 to 2003, with more patients receiving aspirin after AMI (87% to 95%), beta-blocker after AMI (81% to 93%), and ACE inhibitors for heart failure (70% to 80%); but again, outcomes were not assessed.<sup>38</sup>

Studies of the HQID program showed greater improvements in adherence to guideline-based process measures over a 2-year period in Premier hospitals as compared with hospitals without these incentives, though this study did not evaluate patient outcomes.<sup>40</sup> However, another study released in the same year, with a broader comparison group, showed no significant difference in a composite measure of the 6 CMS-rewarded processes between HQID versus non-HQID hospitals, and no evidence to suggest that improvements in mortality were greater at HQID hospitals.<sup>41</sup> Even more problematic was a report examining performance on process measures and patient outcomes at the 5-year mark of the program, which demonstrated no difference between HQID and non-HQID hospitals on any of the metrics and no difference in mortality rates between the 2 groups.<sup>42</sup>

Overall, the available evidence on large-scale hospital pay-for-performance programs for cardiovascular disease suggests that these programs have led to only very modest, if any, improvement in either processes or outcomes of care beyond that achieved with quality measurement or public reporting. However, the success of pay-for-performance as a quality-improvement mechanism most likely lies in the details, such as the size of the incentive, baseline performance levels, and a hospital's inherent ability to improve and respond adequately to such incentives.<sup>43</sup> It is feasible that alternative designs to pay-for-performance programs, for example

including larger incentives, targeting incentives at particularly high-impact measures, and considering both group and individual performance evaluation, may yield better results.<sup>44</sup>

## New National Quality Improvement Efforts

While many of the quality improvement and public reporting efforts described above continue, there are a number of new quality-improvement efforts for cardiovascular disease emerging at the national level, most notably Value-Based Purchasing (VBP) and the Hospital Readmissions Reduction Program (HRRP).

### Value-Based Purchasing

The VBP program is a national P4P program that represents an attempt to fundamentally shift Medicare from a passive payer of services into active purchaser of quality health care. Based largely on the same quality metrics and payment incentives as the Premier HQID, VBP starts with a 1% “holdback” of Medicare payments, and hospitals can earn bonuses  $\leq 1\%$  based on a complex formula rewarding performance, improvement, and consistency on processes of care and patient experience; mortality rates and efficiency metrics will be phased in during future iterations of the program.<sup>45</sup>

While the long-term benefits of VBP in terms of improving hospital quality remain to be seen, it is of concern that the Premier HQID program on which VBP is based has led to little improvement beyond secular trends. Moreover, the fairly small amount of payment that will be at risk for hospitals<sup>46</sup> suggests that there should be at least some degree of skepticism about its likely impact on quality, and in turn, on patient outcomes. Other concerns have been raised about whether the VBP penalties will be too punitive for hospitals that disproportionately care for poor patients. A recent simulation of the VBP program suggested that despite overall improvement nationally on quality metrics, hospitals in disadvantaged areas would continue to have lower performance levels in comparison to hospitals in better-resourced areas, leading to significantly higher financial penalties.<sup>47</sup> Other studies have shown that safety-net hospitals are more likely to be penalized under VBP, particularly on measures of patient experience.<sup>48</sup> Nevertheless, these prior studies have been modeling exercises, and can only serve as predictive models of the future of VBP. It is possible that the majority of hospitals will be able to respond constructively to the financial incentives created in the ACA.

### The Hospital Readmissions Reduction Program

The HRRP is a program that reduces Medicare payments to hospitals with higher-than-expected readmission rates for

AMI, heart failure, and pneumonia.<sup>49</sup> The intent of the program is to place increasing attention on good discharge practices, encourage enhanced communication with outpatient providers, and reduce fragmentation of care. Initial reports from the year leading up to the implementation of the HRRP suggest slight drops in readmission rates nationally,<sup>50</sup> which is an encouraging early signal for the potential success of this program.

However, there are concerns about the HRRP as well. For instance, while readmission rates have a high degree of face validity, prior studies have shown that only approximately 27% of readmissions are “preventable.”<sup>51</sup> Further, there is little relationship between typical measures of hospital quality and readmission rates.<sup>52–54</sup> Another potential concern with the HRRP is the inverse relationship that has been demonstrated between mortality and readmission rates for HF in particular, though the mechanism underlying this relationship is poorly understood.<sup>55,56</sup> Finally, readmissions may be influenced by patient socioeconomic complexity, as well as by community resources,<sup>57,58</sup> which are not adjusted for in the CMS penalty scheme. Perhaps reflective of these issues, early research on the impact of the HRRP demonstrates that large hospitals, teaching hospitals, and safety-net hospitals are currently receiving the highest penalties.<sup>59</sup> Whether or not this will have a significant negative downstream impact on these hospitals is not yet known.

## Methodological Issues in Cardiology Quality Measures

### Defining Metrics

Although process measures remain minimally correlated with outcomes and may represent clinical concepts that are somewhat inaccessible to patients,<sup>60</sup> they do have independent value as a marker of a hospital’s ability to provide widely accepted, guideline-based clinical care. To this end, the ACC/AHA Task Force on Performance Measures released a report in 2005 outlining attributes of optimal performance measures, including interpretability, actionability, clear numerator and denominator calculation, and feasibility.<sup>61</sup> As the number and complexity of quality metrics proliferate, adhering to these recommendations will be increasingly important.

### Using Appropriate Analytics to Test Quality Measures’ Impact

The earliest studies on quality measurement programs were limited by the absence of a comparison group and lack of adjustment for secular trends toward improvement, thus

creating the illusion of success when in reality the improvements seen were simply reflective of larger national trends in care. This is particularly important for cardiovascular care, where such trends have resulted in falling mortality rates for AMI and minimal variability in process adherence across U.S. hospitals. Future studies of quality metrics should include a comparison group whenever possible, be sufficiently powered in sample size to overcome the issues of variability and adequately tease apart the low signal-to-noise relationship between process and outcomes, and account for secular trends.

Another analytic issue is determining the appropriate level at which to conduct studies of quality improvement. Analyses at the patient level allow a more granular study, but are difficult to conduct due to issues of privacy and limitations in data collection; hospital-level analyses allow for ease of measurement but are constrained by the loss of specific information at larger study units and the inability to fully control for confounders. Indeed, some have argued that the absence of a strong, consistent relationship between process and outcome measures may be the result of ecological fallacy in falsely generalizing hospital-level analyses to the patient level.<sup>62</sup> Given such tension, future studies should employ hierarchical analyses when feasible to allow for the adequate examination of patient, hospital, and health system factors in achieving quality.

Finally, the methods used to assess outcomes themselves are important to consider. In the absence of randomized controlled trials, it is difficult to ensure equal distribution of confounders in comparison groups. Current models, which often rely on administrative data, may have inadequate ability to account for differences in patient population and case mix that may impact hospital performance, and possibly augment the temptation for risk-averse behavior among physicians and hospital leaders.<sup>63</sup>

### Accounting for “Gaming”

As the pressure to comply with quality measures mounts, there is growing incentive for physicians and hospitals to “game” the system to make their performance appear better. There are a growing number of “exclusions” from quality metrics<sup>64</sup> as well as data suggesting that hospitals may game the system by reclassifying patients into or out of publicly reported diagnoses.<sup>65</sup> Upcoding, in which hospitals code a higher number of diagnoses to make patients appear “sicker” and, therefore, risk-adjusted outcomes appear better, also occurs.<sup>66,67</sup> One strategy to combat gaming may be the move to broader outcome metrics, such as all-cause mortality or all-cause readmission rates, though these metrics have their own limitations and do not fully deal with issues of upcoding.

### Involvement of Industry in Quality Improvement

Finally, it is worth noting that several national efforts at quality measurement, including OPTIMIZE, CRUSADE, and the National Registry of Myocardial Infarction mentioned previously, as well as the Acute Decompensated Heart Failure National Registry (ADHERE), were industry-sponsored efforts at quality improvement. This is worth particular consideration when quality improvement is measured by the uptake of sponsored products. For example, OPTIMIZE and the Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting (IMPROVE-HF) trials put in place specific strategies to increase the use of beta-blockers and implantable cardioverter defibrillators produced by their respective pharmaceutical sponsors, prior to the inclusion of these strategies in formal ACC/AHA guidelines.

Multiple prior studies have shown industry-sponsored studies to be more likely to publish results favorable to the sponsor than non-industry-sponsored studies,<sup>68</sup> and that the “industry bias” is, indeed, independent of an otherwise expected “risk of bias.”<sup>69</sup> While the quality of trial methods in industry-sponsored studies have been shown to be at least as good as, if not better, than non-industry-sponsored efforts,<sup>68</sup> recent studies have shown that knowledge of industry sponsorship negatively influences physicians’ perceptions of study quality and lowers the propensity to change clinical behaviors based on trial findings, regardless of a study’s true methodologic rigor.<sup>70</sup> Such implications may be important when identifying strategies for promoting changes in clinical behavior related to quality improvement.

### Conclusions

Quality metrics for cardiovascular disease are here to stay, though their utility in improving patient outcomes remains unclear. Measuring quality does seem to improve quality for processes of care, but unless these process measures are closely linked to patient-relevant outcomes, such as mortality, hospital readmission, or patient experience, they may not have maximal impact. Public reporting of quality metrics thus far has not been shown to have positive impacts on outcomes, and though reporting may have value in improving transparency and promoting patient trust in the health care system, future programs should be designed with unintended consequences of risk aversion in patient selection in mind. Finally, pay-for-performance continues to have tremendous face validity as a quality improvement approach, in spite of its somewhat limited success on a national scale thus far. Future attempts at pay-for-performance may benefit from creating incentives that are large enough to influence provider behavior, measuring performance in a minimally complex and clinically relevant manner, and focusing on high-impact

metrics like mortality. However, these too are likely subject to unintended consequences in terms of patient selection.

Quality measurement in cardiovascular care remains an active area for innovation and continued evaluation. More than ever before, the study of the impact of quality improvement efforts on patient outcomes will be crucial to improve cardiovascular health in the coming years.

## Sources of Funding

Dr Joynt was supported by NIH grant 1K23HL109177-01 from the National Heart, Lung, and Blood Institute. The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; or preparation, review, or approval of the manuscript.

## Disclosures

None.

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**Key Words:** cardiovascular outcomes • health policy and outcomes research • hospital performance • pay for performance • quality