The United States is in the midst of a healthcare crisis. With access that is spotty,1 quality that is uneven,2 and care that is often suboptimal, we lag behind other countries in key health metrics such as life expectancy and infant mortality.3 Furthermore, our healthcare costs are approaching an unsustainable 18% of Gross Domestic Product, and we were recently ranked among the least efficient healthcare systems in the world.4

Clearly, new solutions are needed. With the passage of the Affordable Care Act (ACA) in March 2010,5 the United States started down a complex path toward reform of our healthcare delivery system, with the goal of making health care higher in quality and lower in cost. As a result, we have seen an enormous number of rapid and significant changes in health policy. As the provisions of the ACA roll out across the country, patients and healthcare providers alike are trying to keep up with new quality metrics, payment models, organizational changes, and reporting requirements. These interventions although initiated by the ACA, are often mirrored by private payers and represent a fundamental and likely long-lasting change in the way that health care is financed and delivered. Policies can be enacted at the federal or state level and may interact with strategies used by private payers or professional societies; they can target hospitals or hospital systems, clinicians, patients, or payers (Table).

In large part owing to the fact that heart disease and stroke remain the leading causes of morbidity and mortality in the United States and among the highest-cost areas in medicine,6 many new policies specifically target cardiovascular disease for quality and cost interventions. Thus, it is critical for cardiovascular clinicians to understand the policy landscape.

This review is the first piece in a series of articles on the relationship between health policy and cardiovascular medicine. Its objectives are to provide a broad overview of some of the major themes in recent legislation and other current health-care policies as they relate to cardiovascular disease and care, each of which will be discussed in more depth in the pieces that follow in this series. This review also discusses ways in which we as clinical leaders and researchers can and should contribute to the ongoing dialogue on how we can ensure that health policy is rational, data driven, and most important, in the best interest of our patients.

The First Step Toward Accountability: Public Reporting

Public reporting has gained support as an important quality improvement tool. The idea behind public reporting is that making providers’ performance public will incent providers to improve their performance through a “peer pressure” effect and give consumers the opportunity to select providers on the basis of their performance, shifting market share to those providers who provide the highest-quality care.

Federal public reporting efforts at the provider level have been via the Hospital Compare Website. This program is a massive national effort undertaken to publicly report hospital performance on processes and outcomes of care, initially focused on acute myocardial infarction (AMI), heart failure (HF), and pneumonia. Since its launch in 2004, the Hospital Compare Website has served as the main portal through which the public can access information on hospitals’ performance. Although initial reports included only processes of care for the 3 index conditions (such as giving aspirin for patients with an AMI), the program later expanded to include outcomes, initiating reporting of mortality for these conditions in 2008 and readmission rates in 2011.7 Currently, >95% of eligible hospitals participate.

One change that has been accelerated with the passage of the ACA is the number and sophistication of the quality metrics that are collected and reported. The conditions for which reporting is mandated continue to expand; the reports have recently added processes of care for stroke and will include outcomes for stroke in coming years. Furthermore, the claims-based reporting measures are increasingly coupled with registry-based measures that incorporate clinical data, creating a deeper ability to compare hospital performance while appropriately accounting for differences in case mix. For example, the American College of Cardiology teamed with the Hospital Compare program to make readmission rates after percutaneous coronary intervention (PCI), calculated from the CathPCI registry, publicly available via the Hospital Compare site.8

Although much recent action in public reporting has been at the federal level, state-based public reporting began in the early 1990s, when New York State mandated public reporting
of outcomes for coronary artery bypass grafting (CABG) and PCI. Two other states, Pennsylvania and Massachusetts, followed suit in the 2000s, although Pennsylvania has since discontinued its reporting program for PCI. An increasing number of states are working to publicize quality, and sometimes even cost,9 information on state-based Web sites.

However, despite its widespread acceptance, data are mixed on the efficacy of public reporting.15 Initial evaluations of the Hospital Compare program showed that performance on process of care metrics improved significantly over its first 2 years, and11,12 follow-up studies showed that higher performance on these reported measures was associated with lower risk-adjusted mortality rates.13,14,15 However, a recent study demonstrated that, although mortality rates fell over the first 3 years of the Hospital Compare reporting program, this drop was identical to preexisting trends in mortality before the program.16 A large-scale, randomized trial of public report cards for cardiac conditions at hospitals in Ontario showed no differences in processes of care but noted a significantly lower mortality rate for AMI in the intervention group.17 Finally, in terms of state-based programs, initial reports showed lower mortality in reporting states for CABG18 but more recent work suggested no mortality benefit for PCI.19

There has also been concern that reporting programs may have the unintended consequence of limiting access to care. Studies have shown a lower propensity to undergo PCI for AMI in New York compared with Michigan (a nonreporting state),20 particularly in the setting of cardiogenic shock.21 Additionally, states with mandatory PCI reporting were shown to have lower rates of use of PCI for patients with an AMI; this was associated with higher mortality for patients with ST-segment–elevation myocardial infarction, although overall AMI mortality rates were similar to those in nonreporting states.19 There is some evidence to suggest that public reporting may also influence clinical practice for CABG, particularly for racial and ethnic minorities, although here the data are less consistent.22–25

Physician-level public reporting is much less common than hospital-level reporting. Surgeon-level CABG outcome reporting in New York State is essentially the only large-scale mandatory physician performance reporting system currently in operation. However, the ACA has mandated a degree of transparency on the physician side that is significantly greater than what has taken place before. At the federal level, building on Hospital Compare, Physician Compare is a new mandatory reporting program that will report physician performance on a set of quality metrics. At present, the site is incomplete in its inclusion of physicians and, even for those physicians whose information is present online, contains primarily demographic information such as certification and practice locations, as well as whether or not physicians participate in federal quality improvement programs such as e-prescribing.26 By late 2015, the Centers for Medicare & Medicaid Services plan to include performance on quality metrics for both primary and specialty physicians on this Web site, although the details on how this will be done have not yet been finalized.

**Putting Dollars in Play: Pay for Performance**

Health reform has ushered in a series of changes in payment models that are designed to move from paying for volume to paying for value. One important tool here is pay for performance (P4P), or the practice of providing financial rewards for hospitals or physicians with high levels of measured quality. P4P has been tested in one form or another across many settings, although evidence for its efficacy has been mixed.27

One of the first large-scale federal efforts at P4P was a Centers for Medicare & Medicaid Services demonstration project called the Premier Hospital Quality Incentives Demonstration (HQID). This program enrolled 252 hospitals in the mid-2000s,28 paying bonuses to hospitals with high performance on process metrics for AML, HF, and pneumonia and penalizing those that performed poorly.
On the basis of the HQID experience, the Centers for Medicare & Medicaid Services launched a national mandatory P4P program in fiscal year 2013 called Value-Based Purchasing. Under this program, a portion of payments to hospitals is held back (1% in the first year of the program, 1.25% in the second year, and so on), and hospitals can earn these dollars back via their performance on a set of quality metrics. In the first year of the program, quality was assessed on the basis of processes of care (such as the provision of aspirin for AMI) and patient experience, as measured by the Hospital Consumer Assessment of Health Care Providers and Systems survey. In year 2, the performance of hospitals on mortality rates for AMI, HF, and pneumonia was also taken into account, and in 2015, metrics of efficiency (taking into account costs of care) will be factored in also.

Again, evidence is mixed on the impact of the federal P4P programs thus far. The first published study of the HQID program showed greater improvements in adherence to process measures in participating hospitals compared with non-participating hospitals over the first 2 years of the program. However, another study released in the same year with a broader comparison group showed no significant difference in quality or mortality rates between participating and non-participating hospitals. In the long-term evaluation assessing 5 years of the program, researchers found no difference between HQID and non-HQID hospitals in any of the quality metrics and no difference in mortality rates between the 2 groups.

Initial reports on the Value-Based Purchasing program similarly suggest no significant change in quality metrics and patient experience in the first year of the program, and it has been noted that safety-net hospitals have received, on average, higher penalties and worse financial losses. Value-Based Purchasing is still a very new program, and it will be essential for researchers to track its impact on hospital quality and outcomes in the years to come to determine whether this program ultimately leads to meaningful improvements in care.

In terms of potential unintended consequences of P4P policies, investigations of the relationship between P4P and access to care have been more reassuring than those of public reporting. For example, a recent study found no evidence that access to CABG for clinically high-risk patients with AMI was worse in hospitals participating in the Premier HQID P4P program. Similarly, another study found no difference in access to hospitalization or to CABG for racial and ethnic minorities under the Premier program.

Another ongoing P4P program is more precisely a penalty-for-performance program. The Hospital Readmissions Reduction Program, which launched in October 2012, penalizes hospitals with high readmission rates for AMI, HF, and pneumonia. The maximum penalty was capped at 1% in the first year of the program but rose to 2% in 2013 and 3% in 2014. The program expanded to include readmissions after hip or knee replacement surgery in 2014. Under the Hospital Readmissions Reduction Program thus far, roughly two thirds of US hospitals have been assessed a penalty, and large teaching hospitals and safety-net hospitals have been most likely to receive the maximum penalty. Initial reports suggest that readmission rates may be falling in the first years of this program, although partially offset by an increase in observation status stays. Long-term results remain to be seen, as the program is relatively new.

Finally, the ACA also signals a shift toward P4P in physician reimbursement. The Physician Value-Based Payment Modifier is a provider P4P program in which performance is assessed in terms of both quality and costs of care. Those physicians who have better-than-average performance on both metrics will receive a bonus payment of up to 2% of Medicare reimbursement; those with worse-than-average performance (and those who choose not to report) will be penalized up to 1%. The program is currently rolling out to large physician group practices but will include all physicians billing Medicare by 2017. Building on the Physician Quality Reporting System, as discussed above, the Physician Value-Based Payment Modifier will reward physicians for quality metrics that are focused largely on primary care, although many have direct applicability to cardiovascular disease (including process measures such as the use of statin therapy for beneficiaries with coronary artery disease and measuring a lipid profile for beneficiaries with diabetes mellitus or ischemic vascular disease, as well as outcomes measures such as admission for HF). No data are available yet on this new program.

Incenting Efficiency: Bundled Payments

Another payment innovation that has significant implications for cardiovascular medicine is bundled payment. This payment model is currently being tested under the Bundled Payments for Care Improvement demonstration project run by the Centers for Medicare & Medicaid Innovations. Bundling is the payment mechanism by which a single fee is paid to a hospital or provider for an episode of care. For example, a bundle for PCI might include the pre-PCI consultation, the procedure itself, and any follow-up care occurring in the next 30, 60, or 90 days. Although a bundled payment may be higher up front than typical fee-for-service reimbursement, no additional payment is made for additional care, including complications, readmissions, or prolonged post–acute care needs. Thus, the provider has a strong incentive to reduce costs and utilization after the procedure. Indeed, this strategy is seen as a major component of efforts to reduce overuse of high-cost, low-value services. The additional payment in the bundle is expected to be used for innovations such as the development of a program for wound surveillance after CABG or the use of a care coordinator to improve patients’ transitions of care after a complex hospitalization.

Prior evaluations of bundling have generally focused on agreements between private payers and providers such as the successful Geisinger Clinic experience with CABG bundling. However, recent experience with trying to scale up these programs, including the slow and troubled rollout of the Provider Payment Reform for Outcomes, Margins, Evidence, Transparency, Hassle Reduction, Excellence, Understandability, and Sustainability (PROMETHEUS) project and an unsuccessful multi-stakeholder effort at bundling for orthopedic procedures in California, suggests that this strategy faces a number of significant regulatory and
organizational hurdles to its success. Additionally, realizing savings from this model is predicated on the price of the service being set below current pricing and on the ability of the provider to reduce costs and thus protect profitability. Both of these present formidable challenges from an operational standpoint and a policy standpoint. Because the federal Bundled Payments for Care Improvement program is only recently underway, there are no major evaluations available of its participants or efficacy yet, although >4500 groups had signed up for phase 1 (the preparation phase) and almost 130 of its participants or efficacy yet, although >4500 groups had signed up for phase 1 (the preparation phase) and almost 130 had transitioned to phase 2 (the risk-bearing phase) by the end of 2014.

Assuming Responsibility: Accountable Care Organizations

The next, more transformative step beyond simply paying more for better performance or offering bonuses for efficiency is asking hospitals and providers to assume the risk for a broader set of quality measures and a patient’s entire costs of care. This is the principle behind accountable care organizations (ACOs). ACOs are central organizing entities that agree to provide care to a group of Medicare beneficiaries with the goal of hitting quality and cost targets. If quality targets are met, the ACO is eligible to share in savings achieved under the projected annual spend. So far, >360 organizations have signed up for either of Medicare’s 2 ACO programs, Pioneer and the Shared Savings Program, with another 200 or so organizations participating in similar arrangements with private payers.

Many of the quality measures in ACOs are cardiovascular in nature. For example, hospital admission rates for HF, blood pressure assessment and control, lipid assessment and control, and the use of such therapies as aspirin, β-blockers, and angiotensin-converting enzyme inhibitors in appropriate populations are all components of quality scores for organizations in the Medicare ACO programs. Additionally, discussions about spending targets are likely to affect the cardiovascular community. Given that cardiovascular care often requires high-cost services such as imaging and procedures and given the frequency of use of these services nationally, organizations trying to find ways to control spending are likely to look to cardiovascular services. Ideally, although ACOs are a primary care–based organizational structure, decisions about ways in which care could be safely improved while reducing spending could be made in close conjunction with cardiovascular specialists.

Early evidence from the ACO programs suggests improvements in quality but variable success in achieving cost savings. For example, in the Pioneer program, performance on quality metrics improved from an overall score of 70.8% in 2012 to 84.0% in 2013; just under half of the 32 participating organizations were able to generate financial savings. The larger Shared Savings Program group similarly improved performance on 30 of 33 quality measures in 2013 in aggregate, and 54 of the 114 organizations generated shared savings. However, neither of these program evaluations includes a control group, and participation in the programs is voluntary; therefore, the degree to which these results reflect changes above and beyond secular trends and the degree to which they are generalizable remain to be seen. However, a recent evaluation of participants in the Physician Group Practice Demonstration, an ACO precursor, demonstrated no change in the use of discretionary cardiovascular and cerebrovascular imaging under the demonstration compared with local controls, raising concerns about the ability of these programs to adequately incent reductions in high-cost care.

Some have raised concerns about potential unintended consequences of ACOs, although there is little direct evidence, given the newness of this model. Prior investigations from capitation and health maintenance organizations showed little impact (either positive or negative) on patient outcomes, although preventive care was delivered at higher rates in health maintenance organization models. However, many clinicians believed that health maintenance organizations had negative effects on the physician-patient relationship, which bears particular consideration as the ACO programs continue to expand.

External Forces: Drug and Device Policy

Of course, an important component of care that is both high quality and low cost is the tools that we use to treat our patients, often in the form of drugs and medical devices. There is ongoing discussion in both clinical and policy circles about how the US Food and Drug Administration (FDA) can strike the right balance between providing adequate oversight and allowing products to reach the market quickly. The job of the FDA is to protect the public by keeping unsafe drugs and devices off the market, which often requires extensive review of clinical trial data. However, even with such a review, it is not uncommon for drugs or devices to be recalled, pulled from the market, or restricted in use after approval when safety signals are identified. Such was the case with rosiglitazone, for example, as well as the Fidelis and Riata leads for implantable cardioverter-defibrillators. On the other hand, the FDA must attempt to make decisions about approval rapidly and nimblly enough to allow patients access to potentially lifesaving therapies, particularly when few may exist for the disease in question.

Striking this balance is a difficult task but affects both the quality and costs of care for cardiovascular disease. One recent study showed that the quality of clinical trial evidence used by the FDA to make approval decisions varied widely across indications, suggesting that there may be room for more uniform policies to be set to improve this process. Furthermore, the Institute of Medicine has recommended that the FDA track safety across the “life cycle” of a drug so that events that occur in the postapproval period can be tracked and acted on in a timely fashion. However, there has been little prior research on how effective new FDA policies have been in achieving its goals, which is a clear need as these policies move forward.

Bringing Policy to the Patient: Value-Based Insurance Design

Another important set of policies are those that begin to bring policy not only to the provider but also to the patient.
**Value-Based Insurance Design (VBID)** is a policy mechanism that uses financial incentives in the form of cost sharing to promote patient choices that are aligned with high quality and low costs.63 For example, a VBID plan might allow preventive care such as statin therapy or smoking cessation counseling or other services felt to be high value with no cost sharing, while setting high copays or coinsurance for services felt to be low value. This is a strategy explicitly mentioned in the ACA; in fact, the ACA provision that preventive care must be fully covered is a type of VBID in and of itself. Currently, VBID is being used in state insurance programs62 and in employer-based plans; it is also used in many health systems internationally.65 The application of this strategy has relevance to cardiovascular care at both ends of the spectrum.64 Many experiments in VBID have examined providing free access to expensive cardiovascular medications such as statins and antiplatelet therapies after AMI or CABG,65,66 whereas others have advocated flexible pricing schemes that reflect the differential value in high-cost services such as cardiovascular imaging and PCI.

Unlike the prior policies that were discussed, VBID is focused largely on changing patient behavior. The data thus far suggest that this policy strategy may be successful in doing so, at least to a degree, but that cost savings may not necessarily follow. For example, a trial of the elimination of copays for medications after AMI demonstrated no change in first major vascular events or revascularization, a small reduction in major vascular events, and no overall cost savings.66 A recent systematic review evaluated 13 VBID programs and found that they, on average, increased adherence to medical therapies.67 However, this will be an important policy to track as it gains traction in both public and private programs nationwide.

**How Policy and Legal Efforts Can Work Together: Improving Patient Safety**

With the publication of To Err Is Human: Building a Safer Health System, the Institute of Medicine’s landmark report on patient safety,68 the problem of medical error and adverse events took on a new level of visibility in medicine. For many years, medical liability had been seen as the primary mechanism by which patient safety would be protected, which represented a view of medical errors limited to mistakes made by individuals. Patient safety was thus ensured through the legal system via a complex and variable state-based set of malpractice regulations. However, there is increasing recognition that errors and adverse events are often systems problems rather than individual problems, and thus, a host of new legal and policy approaches to improving safety have emerged that attempt to incent system improvement.

Patient safety is monitored at the state level, with mandatory reporting of adverse events in many states and at the federal level, through surveillance programs including that at the Centers for Disease Control and Prevention.69 Two of the major recent federal policies aimed at improving patient safety are Medicare’s policy of nonpayment for preventable complications and the Hospital Acquired Conditions Reduction Program. Nonpayment for preventable complications began in 2008 and targeted central line–associated bloodstream infections and catheter-associated urinary tract infections. Initial evidence suggested that the rate of these adverse events declined over the first 3 years of the policy but that the decline was similar in nontargeted complications such as ventilator-associated pneumonia.70

In late 2014, the Hospital Acquired Conditions Reduction Program, initially targeting central line–associated bloodstream infections and catheter-associated urinary tract infections along with a set of claims-based metrics such as the development of pressure ulcers, iatrogenic pneumothorax, and postoperative thrombosis, went into effect. This program penalizes hospitals in the highest quartile of adverse events, up to 1% of payments.71 Because the program is brand new, no empirical data are available yet on its impact; however, nationwide data suggest an improvement in patient safety in recent years for Medicare patients, particularly for those admitted with AMI and HF.72

Although the number of medical malpractice claims in the United States has been falling steadily over the past decade,73 medical liability remains important in ensuring that cases of true negligence are appropriately detected and addressed. Approaches to reform include traditional strategies like pretrial screening panels and caps on damages, as well as emerging strategies such as communication-and-resolution programs and safe harbor policies. These have been implemented at both the state and hospital levels, and some strategies have demonstrated success. For example, the communication-and-resolution program implemented at the University of Michigan was associated with a 36% drop in claims and 59% drop in dollars spent on patient compensation.74 Ultimately, patient safety will best be served if the medical and legal communities work together to improve legal policies around medical error and malpractice and to incent systems-level solutions to common adverse events.

**How Policy and Clinical Efforts Can Work Together: Reducing Overuse**

There are, as outlined above, a large and growing number of policy interventions designed to improve quality and to reduce costs of care. However, policymakers will be most successful in achieving these goals with the full engagement of the clinical community. One particularly salient example of this dual approach, combining policy with clinical intervention to achieve quality and cost goals, is the ongoing effort to reduce the overuse of ineffective or nonindicated technologies and services. Some policies that were previously described in this review may limit overuse through financial incentives, including the efficiency payments in Value-Based Purchasing, bundled payment programs, and spending targets in ACOs. However, equally important efforts are taking place through the development and implementation of appropriateness criteria (or appropriate use criteria) for procedures and testing,75 as well as through the Choosing Wisely campaign.76

Appropriateness criteria are a set of algorithms based on evidence and expert consensus that evaluate scenarios for use of a
particular procedure or test (eg, coronary angiography). These allow classification of the use of a procedure as “usually appropriate” (as in the case of PCI for AMI), “sometimes appropriate” (as in the case of PCI for stable angina in a patient on good medical therapy), or “rarely appropriate” (as in the case of PCI in an asymptomatic patient without objective evidence of ischemia). The introduction of these criteria in cardiology is relatively recent; thus, their efficacy in changing patterns of use in positive ways is as yet unproven, but they represent a significant step forward from within the profession at developing a clinical set of guidelines to improve quality by reducing overuse.

Concurrent with the rising use of appropriateness criteria, the American Board of Internal Medicine developed its Choosing Wisely campaign. This effort aims to “promote conversations between providers and patients by helping patients choose care that is: supported by evidence, not duplicative, free from harm, and truly necessary.” More than 60 subspecialty boards have added their input to the Choosing Wisely efforts, including the American College of Cardiology, the American Society of Nuclear Cardiology, the Heart Rhythm Society, the Society for Cardiovascular Angiography and Interventions, the Society of Cardiovascular Magnetic Resonography, and the Society for Vascular Medicine.

Thus, the reduction of overuse in medicine, and in cardiovascular medicine in particular, is an example of a way in which both policymakers and clinical leaders can work toward a common goal using the tools at their disposal. Evaluations of the impact of these efforts on both the overuse and underuse of cardiovascular procedures and tests will be critical as these efforts mature.

Ways In Which the Cardiovascular Research Community Can Be Involved

The current era of health policy will directly affect the cardiovascular community in many ways. Although the studies mentioned above serve as important examples of how empirical research can help evaluate and inform health policy, many current state and federal health policies are too new to have been fully evaluated either in terms of their efficacy or in terms of their unintended consequences. This is a need that must be filled and one to which cardiovascular experts can meaningfully contribute.

First, the cardiovascular research community has the opportunity and the responsibility to bring our methodological skills to bear on these messy, tricky, and complex problems. We need to continue to develop new ways to deal with large datasets, and become more sophisticated in how we use them to assess risk and outcomes. This is an area in which the cardiovascular community has led in the past, and one in which we can continue to lead as data become increasingly complex. Moving towards learning healthcare systems, for example, may allow us to harness the power of data at the point of care to improve patient care and clinical outcomes and reduce costs.

Second, we can lead the way in innovating around methods of delivering care. This is another area in which cardiovascular medicine has been at the forefront, for example by redesigning care delivery to reduce door-to-balloon time for AMI, regionalizing care for stroke, and creating outpatient infusion facilities to prevent hospitalizations for HF patients with volume overload. We will all benefit if we can recognize the insights generated by hospitals and providers who are engaged in delivery system and technological innovation, and rigorously evaluate them to determine which provide value under new payment models and could be scaled nationwide.

Conclusions

Many changes are taking place in health policy that have direct relevance to cardiovascular medicine. These policies will fundamentally alter the way in which we provide care to patients and the way in which we are reimbursed for this care. It is critical to evaluate these new policies to determine which are more successful at incentivizing better quality at lower costs while remaining mindful of potential unintended consequences. As a research and clinical community, we have a great deal to offer to help ensure that the needs of our patients are kept central in these discussions and that our ultimate goal remains improving the quality and outcomes of cardiovascular care delivered in this country.

Disclosures

None.

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