Mis-SHAPEing Public Health Policy

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On June 19, 2009, the Heart Attack Prevention Bill, a bill mandating health insurance coverage of radiographic screening tests to detect asymptomatic atherosclerosis, was passed through the Texas legislature and enacted in September.1 The bill, written by the SHAPE (Screening for Heart Attack Prevention and Education) Task Force and championed by Representative Rene O. Oliveira, was first introduced in 2007, but failed at that time because of a lack of scientific data. However, without further evidence or modification, the bill was recently reintroduced and passed, requiring health insurance companies to cover the costs for either cardiac computed tomography (CT) scan to measure coronary artery calcium score or ultrasound to measure carotid artery intimal thickness every 5 years for all men aged 45 to 75 and women aged 55 to 75, along with persons of any age who have diabetes mellitus or an intermediate Framingham Risk Score.1

The Heart Attack Prevention Bill introduces complex questions about the level of scientific evidence needed to support legislative mandates for medical coverage. Neither screening test has demonstrated clinical efficacy in preventing acute myocardial infarctions nor is supported as a primary prevention strategy by any of the major guideline committees.2 In the absence of validating data, mandating medical coverage for these procedures raises concerns of unwarranted costs or harm to patients and potential for conflicts of interest.

This article (1) considers the rationale for mandating insurance coverage, (2) considers criteria for evaluating the merits of such policies, and (3) applies these criteria to evaluate the rationale and merits of the Heart Attack Prevention bill, including the political, economic, and social forces at play. As health coverage and payment reform efforts gain increasing momentum, it is critical that legislative coverage mandates qualify as effective public health policy.

Rationale for Mandating Insurance Coverage

Currently, most health insurance coverage decisions are at the discretion of insurers, who have the autonomy to decide which medical services, procedures, and treatments to cover. These decisions are variably determined by standard clinical practice, physician review committees, Medicare policies, or employer discretion, and are often held to the standard of demonstrating “proven benefit” or “medical necessity.” However, they have also been criticized for lack of transparency and prioritization of cost over quality.

Legislative mandates requiring insurance coverage of specific health care services have become increasingly common and have the potential to standardize, and perhaps improve, clinical practice.3-4 According to the Council for Affordable Health Insurance, there are now 2133 state mandates.5 For example, for disease prevention, most states mandate coverage of at least one cancer screening test. However, the rationale behind coverage mandates is not often made clear and there is little data to suggest that decisions are based on the prioritization of evidence-based guidelines, gaps in care, or anticipated benefit to the public.5-6 Are state mandates intended to ensure that services with strong evidence reach the entire population? Or are state mandates intended to standardize coverage to ensure provision of services with equivocal evidence supporting their efficacy but which may prevent or treat serious diseases for which there are no effective diagnostic tests or treatments?

For example, mandates legislating equal access to health services may be justified based on their potential to reduce disparities in care. In 2008, legislation was enacted that required insurance coverage for mental health services to be equal to that appropriated for physical health services.7 However, policies intended to increase access may also diffuse unproven strategies, encourage outdated clinical practice, and stymie future research. For example, a bill in Minnesota legislating coverage of high-dose chemotherapy with autologous bone marrow transplant for women with advanced breast cancer was legislated before there was substantive evidence supporting its benefits. When the treatment was later found to be ineffective and to cause premature death, more than 20 000 women (20 times the number of women it had been tested in) had received the harmful treatment.8-9 The rationale for and goals of proposed legislative mandates must be made transparent, including a clear definition of the unmet health problem or need being addressed.

Evaluation of a Health Insurance Coverage Legislative Mandate

In assessing the merits of a health coverage mandate, legislators must carefully consider the available scientific evidence supporting the bill and the impact of translating science into public health policy.10 Solid scientific evidence most often comes from randomized double-blind controlled trials and meta-analyses conducted by objective investigators inde-
dependent of financial conflicts of interest; however, even these findings may be disputed. It is thus critical that legislators consider the opinions and recommendations of national guideline committees and national societies with scientific expertise. In addition, high-quality observational research offers a feasible, inexpensive, and rigorous approach for evaluating public health policies.11

Importantly, in the case of preventive care policies, evidence must support that early detection and subsequent treatment improves outcomes, and for all policies, the proposed care should be tested in the populations it is intended to treat. This may take the form of validation studies, pilot programs, or demonstration projects. For example, before implementing a program nationwide, the Centers for Medicare and Medicaid Services (CMS) initiated seven demonstration projects to examine the clinical effectiveness and potential cost-savings for several highly supported, yet unproven, disease management programs. Preliminary findings were mixed; most did not reduce utilization (or costs) or improve outcomes, challenging CMS to reconsider strategies to effectively improve care and reinforcing the value of pilot testing before investment in broad policy reform.12,13

Effective health coverage mandates must explicitly define the target population. Ideally, the benefits will far outweigh risks, which are minimal, but any potential risks to the population (or subpopulations) need to be clearly described and carefully monitored. Arbitrarily applying one policy to all, no matter how strong the scientific evidence, may not qualify as good medicine or good policy. For example, in 2008, the United States Preventive Task Force updated their recommendations for colonoscopy screening, which originally recommended screening all persons over the age of 50. They added an upper age limit and consideration of comorbid disease in response to new data demonstrating limited benefit, and potential harm, for people 75 years and older and those with comorbid disease.14 State mandates need to reflect the most up-to-date scientific evidence to minimize potential risk to those for whom the evidence does not support receiving the care being mandated for coverage.

Effective health coverage mandates should also consider the associated costs of the mandate for insurers, individuals, the health system, and all vested parties. Although the economic costs of mandates may initially be covered by insurers, these costs are likely to be passed on to patients as either copayments or higher baseline insurance premiums or to be offset by eliminating coverage of other procedures or treatments.5 Ultimately, the entire health system is burdened by increased insurer costs. On the other hand, the rising demand for the mandated health service may have enormous economic benefits for individuals and companies who provide the service. It is therefore critical that the economic costs and benefits of the policy are outlined and that key stakeholders with potential financial conflicts of interest maintain, at a minimum, transparency and ideally remain outside of the health policy decision-making process.

Rationale and Merits of the Heart Attack Prevention Bill

The rationale for the Heart Attack Prevention bill is not clear. Although cardiovascular events occur in patients with minimal or no risk factors, the assumption that early detection and subsequent treatment of asymptomatic disease will result in fewer cardiovascular events has not been established.2,15 Importantly, it is also unclear whether the lack of widespread use of these tests is a reflection of poor access, perhaps because of cost and limited insurance coverage, or because data are insufficient to support the tests as effective screening tools.

There are few merits to support this bill as an effective public health policy. National guideline committees have yet to endorse the recommendations of SHAPE, as strong scientific evidence is not available. Moreover, proven and effective alternative screening tests for coronary artery disease are already widely available. The targeted population outlined in the Heart Attack Prevention Bill is large, and its impact will be costly. If rigorously followed, all men aged 45 to 75, women aged 55 to 75, and persons with diabetes mellitus or an intermediate Framingham Risk Score will be screened using either CT scan or ultrasound carotid artery intimal thickness to detect asymptomatic heart disease. We can expect this legislation will increase the diffusion of these unproven clinical strategies; the associated individual- and population-level benefits and harms will need to be closely monitored. Ultimately, given the legislation’s unclear rationale and limited merits, it is important to consider the political, economic, and social forces that might have influenced its enactment.

Political Forces

Legislators and physicians who advocated for the bill are vested in reducing the burden of heart disease and improving patient health. The SHAPE Task Force has received considerable support from leading cardiologists and other physicians throughout the country, most of whom presumably have laudable public health intentions. In addition, Representative Oliveira (who sponsored the bill) credits the cardiac CT scan with saving his own life; he underwent coronary artery bypass surgery after his screening examination revealed coronary calcifications. In turn, he is likely advocating for his constituents, trying to ensure their access to new, innovative, and potentially life-saving technology.

Economic Forces

Many economic interests are well served by this bill, but seemingly not patients’. The proprietors of the cardiac CT scan and carotid ultrasound technology, cardiologists, imaging centers, hospitals, and medical device companies will invariably benefit financially as more and more patients undergo these diagnostic tests and subsequent therapeutic interventions, once they are covered by insurance companies. Pharmaceutical companies also stand to profit from the increased use of antilipidemic and other therapies resulting from greater numbers of people diagnosed with atherosclerosis. Of note, the manufacturer of the most commonly prescribed antilipidemic medication supported the development of the “guidelines” on which the Heart Attack Bill was based, guidelines that were not peer-reviewed.16 Finally, although the bill requires insurers to cover a minimum of $200 of the $1000 cost for each screening test, how that cost will be
distributed throughout the health system has not been determined and is likely to be passed along to patients as higher premiums.

Social Forces
In an effort to gain public support, the SHAPE Task Force developed a public service announcement depicting a young apparently-healthy woman who suddenly dies at the wheel of her car from a massive heart attack. The advertisement implies that her heart attack could have been prevented had she been screened for coronary artery disease. Such propaganda engenders unwarranted concern for an unlikely event and misleads the public into believing that these diagnostic tests are able to effectively screen for and prevent heart attacks. Personal anecdotes are powerful social messages and, likely have also influenced the success of this legislation. In addition, legislative support of these unproven clinical strategies further feeds into healthcare’s “more is always better” mentality. However, even screening tests may result in more harm than good.

Conclusions
The Heart Attack Prevention Bill defies the basic tenets of current national health care reform approaches. That is, to invest in cost-effective high-quality care by researching best clinical practices (ie, via comparative effectiveness research) and to establish sustainable expansion of health coverage to promote equity. Instead, it sets an unscrupulous precedent for the passage of future health coverage mandates and has reduced exciting and promising technological advancements into premature laws that are at best ignored but difficult to overturn and at worst ineffective, harmful, and costly. The efforts of SHAPE and the passage of this bill exemplifies the strength of a few vested interests and undermines the necessary foundation of public health mandates, based on sound scientific evidence, defined risks and benefits for a targeted population, and consideration of the financial health of the system at large.

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