



IMAGING

Heart-attack prevention bill, mandating coverage for CAD screening, passes quietly in Texas

JUNE 23, 2009 | Shelley Wood

Austin, TX - Last Friday, while wading through reams of other bills and paperwork awaiting his attention, Texas **Gov Rick Perry** signed off on the controversial **Texas Heart Attack Prevention Bill**, mandating health-benefit plans to provide coverage for certain screening tests for early coronary artery disease [1]. This time around, the **ACC** says it "officially supported" the legislation, whereas the **AHA**, by contrast, has refused to take a formal position on the bill.

As previously reported by [heartwire](#), the bill grew out of the gutsy 2006 **Screening for Heart Attack Prevention and Education** (SHAPE) task force "guidelines," which called for blanket screening of all "at-risk" men and women [2]. After some revisions, a rocky ride in and out of the Texas legislature (it was twice introduced), and most recently a perplexing pairing with bariatric surgery, the bill passed through the Texas House and Senate on June 1 and 3, 2009, respectively. The final wording of Act HB1290 stipulates that health-benefit providers cover the cost of CT coronary-artery-calcium (CAC) scans and carotid ultrasonography in men between the ages of 45 and 76 and women between the ages of 55 and 76, as well as anyone (at any age) who has diabetes or is deemed to be at intermediate risk or higher for developing CAD, as determined by the Framingham risk score. With the governor's blessing, the act is now poised to go into effect September 1, 2009.

According to **Michael (Tony) Gray**, a staffer for the bill's champion, Texas House **Rep Rene Oliveira**, the bill was first amended to exclude select coverage plans, enabling it to pass the House, then amended to include a provision that offers state-sponsored bariatric surgery for morbidly obese state employees under specific circumstances—a tactical procedural amendment intended to help the bariatric-surgery bill pass the Senate. "The heart-scan provisions remain untouched," Gray told **heartwire** in an email. "We consider this to be a big victory, given insurance-company opposition to mandates."

Oliveira introduced his bill his first full day back in office after CABG surgery, a procedure he underwent after a CT scan indicated severe coronary blockages. The bill is based in large part on the SHAPE task-force report, reported by [heartwire](#), published as a Pfizer-sponsored supplement in the *American Journal of Cardiology* [2] and initiated by the Houston-based **Association for Eradication of Heart Attack** (AEHA), founded by **Dr Morteza Naghavi** (American Heart Technologies, Houston, TX). While a number of prominent cardiologists were on the writing group and editorial committee for the SHAPE report, which explicitly billed itself as "a new practice guideline for cardiovascular screening in the asymptomatic at-risk population," neither the ACC nor the AHA—both of which have released their own cardiac imaging guidance documents in the past few years—were involved in the SHAPE recommendations.

Professional societies take a soft stand

Contacted for its formal position on the newly minted legislation, the AHA deferred calls to **Joel Romo**, regional vice president of advocacy for the AHA, who does the AHA's lobbying in Texas. Somewhat cryptically, Romo would say only that the AHA "does not take any position on the legislation."

He continued: "From the AHA's perspective, our science is still demonstrating a limited return on investment, and we encourage patients to visit with their physicians and discuss all the options available to them that are most appropriate for their given situation. . . . AHA prides itself in using science to determine the positions we take on pieces of legislation, and the science just isn't there yet for determining the how or why on mass screening."

At the ACC, a spokesperson told **heartwire** that the Texas ACC chapter "officially supported this piece of legislation, and we are glad to see that it has passed."

Dr Raymond Stainback, a councilor with the Texas ACC chapter, elaborated to **heartwire**: "The feeling is that the language is not unreasonable, and it likely reflects clinical practice 'on the ground' in some settings, in which the patient may be paying 100% out of pocket for such tests already. In some cases, the doctor may feel that an additional piece of concrete imaging screening data would be helpful for encouraging aggressive and sometimes expensive-for-the-patient preventive measures, such as statin therapy, with requisite follow-up over many years. When a dramatic plaque burden is demonstrated, it seems to make sense that doctors and patients may take this more seriously than the theoretical risk. The somewhat-contentious remaining issue is that asymptomatic at-risk patients would presumably already have aggressive prevention measures in place, regardless of these additional imaging studies."

While there are a number of outstanding questions, Stainback conceded, "We all have anecdotal examples of how screening tests inadvertently picked up dramatic disease and may have saved a life. There are some published studies supporting both carotid ultrasound and coronary calcium scoring for supplementing the imperfect current practice guidelines. While questions remain, we are pleased that labs performing the exams must be accredited laboratories so as to address the quality/accuracy issue."

In the past, the refusal of the major cardiology societies to take a stronger stand for or against SHAPE and Oliveira's bill has drawn complaints from both within and beyond the cardiology community. In January 2008, University of Michigan health law and policy professor **Dr Peter Jacobson** wrote an editorial in the *Journal of the American Medical Association* decrying the ACC and AHA for not taking a more vocal stand against the SHAPE report and Oliveira's bill [3]. Contacted by **heartwire** yesterday, Jacobson said that his preference would have been for the governor to veto the bill, but since he hasn't, it will be key for the bill's effects to now be monitored very carefully.

"What are the costs of this? And when I say costs, I mean all of the externalities, the extra [tests], the costs of the screening itself, and the potential therapies that emerge from false positives. A second form of costs is whether this legislation, with a very specific statement of what screening procedures should be used, actually forecloses alternatives. It seems to me that this has the potential for short-circuiting alternatives that could be more effective than CT and ultrasonography for measuring plaque in arteries."

A separate issue is whether it will have an impact on how physicians treat patients and whether that is appropriate, Jacobson said. "We know that those who are associated with the SHAPE guidelines will of course recommend the treatment—what will other cardiologists and primary-care physicians do?"

Shaping up for some surprises

Contacted by **heartwire**, **Dr Amit Khera** (University of Texas Southwestern Medical Center, Dallas) confirmed there are still no comprehensive, adequately powered studies showing that these screening tests lead to better outcomes. In a phone interview, Khera said he has major concerns about how physicians will use these tests, particularly primary-care physicians. "I gave a talk last week to primary-care doctors, and there were probably 250 people in the room, and when I asked how many people had ordered a calcium scan, just one person raised a hand. . . . Most people don't even know what to do with the Framingham risk score, so they're going to follow an algorithm that they don't know how to follow to order a test result that they don't know what to do with."

Calling the bill an "important step toward expanding awareness for heart-disease screening and advancing the potential use of atherosclerosis imaging," Khera nevertheless cautioned that a more detailed analysis of who constitutes the appropriate target group should have taken place prior to legislating expanded coverage to "a large proportion" of Texans. "It's one thing if this were an orphan disease with just a few people, where you need to do the best you can. But we are talking about screening a really broad population."

Jacobson, likewise, pointed out that a SHAPE press release [\[4\]](#) explicitly states that screening for calcium and IMT thickness will "prevent more than 4300 deaths from CVD each year in Texas," a statement that, he notes, has no solid basis in scientific research.

"I've never pretended to be a cardiologist, but it seems to me that there is no scientific support for this, and I doubt that there is any more professional consensus. Not good, in my view. It sets a very dangerous precedent that has potentially beneficial consequences but potentially adverse consequences both financially and for individual treatments and outcomes. . . . It's understandable why legislators think that mandating these kinds of guidelines will improve health, but it's not based on science."

Legislators need to have the discipline to "stay out" until professional societies reach some consensus, Jacobson said. "My real concern is that you end up with state legislators driving this kind of practice and worse, encouraging fragmentation in specialties and having all sorts of competing guidelines where there are potential conflicts of interest and lots of money at stake. The conclusion that this is driven by financial considerations rather than science is inescapable, and that's bad public policy."

But **Dr Daniel Berman** (Cedars-Sinai Medical Center, Los Angeles, CA), a member of the SHAPE task force, insisted to **heartwire** that the evidence supporting CAC screening, in particular, is too "compelling" to ignore.

"It's correct that there is no direct randomized-trial information indicating that screening saves lives, but the same is true for the Framingham risk score, which is widely used throughout the US, and for other scores in use throughout the world."

CAC scanning, he says, "provides more information about cardiac death than any other form of testing that we have. . . . At this point, it wouldn't be ethical, or at least it would be difficult and costly, and take a very long time to get a randomized controlled trial done."

He also pointed out that in several Western states, CAC scanning is already covered by **Medicare**. Moreover, a recent AHA/ACC statement "actually supports the use of CAC scanning in intermediate-risk patients, although they don't talk about mandating its availability."

Berman concluded: "I think actually the pendulum has finally turned and people are finally beginning to recognize the mounting consistent evidence and it's time to make the test available. This is a landmark decision for people who couldn't afford to pay for this important test on their own."

Also contacted by **heartwire**, Naghavi, who testified on behalf of the bill, says SHAPE has been misunderstood. "Although on the surface SHAPE appears as a revolutionary change and a giant leap in the old-fashioned primary-prevention field, if you dig deeper it simply is an evolutionary response to our increasing understanding of atherosclerosis coronary artery disease and our increasing ability in identifying those with subclinical coronary and carotid atherosclerosis, the abilities we didn't have when the **Framingham Heart Study** was launched and came up with the concept of 'risk factors.' "

The new Texas legislation is merely "an effort to fill the gap between our knowledge and practice of primary prevention," Naghavi added. "Our job is far from done."

Others are also hailing the bill's passage. **Dr Alan Taylor** (Washington Hospital Center, DC), called it "a major piece of legislation for prevention "and "a huge step forward."

JJ Garza, another staffer in Oliveira's office, had no additional comments about the bill's quiet passage last week, other than to confirm that Perry had signed the bill on June 19, 2009. "He signed hundreds of bills without any real comment, and this is one of them," Garza told **heartwire**.