

## SHAPE Task Force Recommendations for Widespread Screening Generate Controversy

**July 25, 2006** -- The recently issued SHAPE report has stirred up a number of controversies. The SHAPE (Screening for Heart Attack Prevention and Education) Task Force made up of a number of well-known cardiologists and cardiac imaging specialists, among them a Past President of the American College of Cardiology, issued a guideline two weeks ago for noninvasive screening of all men between ages of 45 and 75 and women between ages of 55 and 75 to assess the calcium in their coronary arteries, also called subclinical atherosclerosis, using a Calcium Scoring CT scan, as well as their carotid wall thickness, using ultrasound imaging -- even though they have no symptoms of coronary artery disease.

The report was issued against the background of current guidelines for risk assessment, which mainly follow the Framingham Risk Score that long has been used to rate the level of risk of developing heart disease, based on factors such as cholesterol levels, lifestyle choices (diet and smoking), family history and a range of others. The SHAPE recommendations differ in that they call for the direct observation of arterial disease, as opposed to calculating "risk factors".

These recommendations were characterized in one medical publication as "a bold new report", yet in another they were labeled as "scientifically extremely questionable" and they "should be repudiated". In the public realm, today's Boston Globe ran a feature story questioning the apparent conflict of interest involved by who paid for the publication of the guidelines, which ran as a supplement in the July 17 issue of the *American Journal of Cardiology*. The supplement was funded by Pfizer, manufacturer of Lipitor, a statin drug that the newspaper pointed out might be prescribed much more widely to all the new coronary artery disease patients found by the advocated screening.

Dr. Harvey Hecht, Director of Cardiovascular CT at Lenox Hill Heart and Vascular Institute of New York and one of the members of the SHAPE Task Force, told Angioplasty.Org, "I'm quite pleased by all the controversy it's elicited -- at least it brings it into the public eye." He also called the allegations of conflict-of-interest leveled in the Boston Globe article "absolutely insulting" and described the Task Force's motivation for issuing the report:

"All of us involved in it feel that the current evaluation of risk is woefully inadequate and you can do just about as well, particularly in the intermediate risk population, by flipping a coin.... We know that risk factors do not equate to disease. So it makes much more

sense to look at each patient as an individual and determine whether or not whatever has gone on in his life, *whether or not he has risk factors*, has affected his arteries. It's a very simple concept. If a patient is free of subclinical atherosclerosis, he's at low risk. If he has extensive subclinical atherosclerosis, he's at high risk, and this has been demonstrated in a remarkable number of studies and in thousands of patients."

While many cardiologists felt that the call for increased screening could be helpful, several were circumspect. Dr. Robert Califf of Duke Clinical Research Institute stated to [theheart.org](http://theheart.org):

"...it's not a guideline that's been vetted through any kind of ecumenical group of people who have any official standing to make clinical-practice guidelines...there's enough evidence to have an opinion about this; I don't think there's enough evidence to have a policy about it."

Others, like Dr. Philip Greenland, MD, chairman of the Department of Preventive Medicine at the Feinberg School of Medicine, Northwestern University in Chicago, were more critical, as he stated to [Medscape](http://Medscape):

"...this SHAPE report, from a group that apparently has no oversight or outside input or review, which also offers no framework for its recommendations, and which also provides almost no scientific support for its recommendations, is an apparent effort to subvert the long-standing evidence-based guidelines approaches of the [AHA, ACC, NHLBI]."

Bolstering the direction that the SHAPE task force took was one of the most prestigious cardiologists in the profession, Dr. Valentin Fuster, head of no less than two cardiovascular institutes at New York's Mt. Sinai Hospital and Past President of the American Heart Association. In an accompanying foreword to the guideline, Dr. Fuster stated:

"Despite questions regarding the feasibility and practicality of such an ambitious proposal, the SHAPE Guideline is a worthy and timely effort that goes beyond traditional risk assessment and has the potential to transform the field of preventive cardiology. The driving passion and commitment of the members of the SHAPE Task Force is commendable. It serves as an example to all of us who wish to stop and reverse the epidemic of atherosclerotic cardiovascular disease."

Where the SHAPE guideline differs from traditional practice is in how to identify those at risk. As Dr. Daniel Berman of Cedars-Sinai Medical Center, another Task Force member, told [Angioplasty.Org](http://Angioplasty.Org):

"Half of cardiac events are occurring in patients who have *no symptoms*...and our therapies are really good in preventing heart attacks. We just have to identify the people who need those therapies. There have been several studies now that document that it's not enough to rely on Framingham scoring for this purpose. I would hope that the SHAPE guidelines would be embraced, so that we could use the full potential of the examination to do our best to eradicate heart attacks."

To a great extent, the SHAPE report was issued out of frustration by physicians who see images on a day-by-day basis, images of patients who already have or who are at significant risk for developing blockages in their coronary arteries, but who have experienced no symptoms and who have scored low on the Framingham risk assessment. These cardiologists and radiologists know that new imaging technologies have been developed and they are anxious to affect the way patients are diagnosed -- in their view, more accurately, by using these new tools.

The national organizations, such as the American College of Cardiology (ACC), American Heart Association (AHA), etc. historically have authored professional guidelines -- these tend to be relatively conservative, making sure recommendations are not only safe, but efficacious, and proven through a number of studies and clinical trials. Reportedly the ACC/AHA are working on new guidelines for imaging technologies, to be issued in the fall. One of the criticisms of the SHAPE report is that it isn't "evidence-based", that it hasn't been shown whether the advocated Coronary Calcium Score screening will affect patient outcomes and save lives. Dr. Hecht counters:

"There is no data provided in the purely scientific way that these critics would like that shows that echocardiography affects the outcome in congestive heart failure or in any disease, that stress testing affects the outcome in coronary disease, that cardiac catheterization and stenting affects the outcome in any situation other than in acute coronary syndrome, that electrocardiography affects outcomes. These are basic tools which tell us about anatomy, physiology, perfusion, the electrical issues dealing with the heart. Nobody has ever done a study that demonstrates that any one of those basic techniques that we use every day affects outcome. So why are we asking for a study showing that a tool that demonstrates subclinical atherosclerosis...affects outcome? We're asking for evidence-based medicine in *this* arena, but we've not asked for it in other arenas that cost an infinitely greater amount of money and that are basically entirely unregulated.

Besides which, such a study would be absolutely unethical because there are so much data saying that patients with high calcium scores have very high risk that it would be unethical not to use the data obtained on that scan which identifies a high risk patient and not to treat him aggressively. You could not randomize him to a study based upon his Framingham risk score alone when you know that, despite his Framingham risk score, he's at very high risk.

A final concern was expressed to Medscape by former AHA President Dr. Robert O. Bonow over the increased radiation from multidetector CT scanners, reportedly higher than that from standard angiography, and that this would make it difficult to recommend as a screening tool. The Boston Globe article also accompanied its critical report with a very hi-tech 3-D 64 slice CT scan. However, nowhere does the SHAPE guideline mention the use of multislice CT angiography, a relatively new imaging technology that gives striking 3-D pictures, and requires a higher radiation dose, as well as injection of an iodine-based contrast dye. The SHAPE report refers instead to Coronary Calcium Assessment, a much simpler CT exam that, as Drs. Berman and Hecht pointed out, uses much less radiation, almost ten times less than a standard nuclear stress test, which is

done all the time for risk assessment.

As for the Globe's concern about Pfizer paying for the supplement (the drug firm also gives financial support to the SHAPE organization's website, along with a number of other sponsors) the question arises that if corporate support were not leveraged, how would information like this be publicized? It's true that the AHA/ACC guidelines are not specifically "sponsored" by any company, but those and many other professional organizations enjoy a not insignificant amount of financial support from medical device and pharmaceutical companies -- usually these corporate grants are listed on their web sites, and a visit to the exhibition halls of any of the national meetings reveals a very significant corporate presence. These organizations also have strict rules of disclosure for speakers and presentations, aware that when financial ties are hidden there is room for undue influence. Likewise, in the case of the SHAPE report, the financial support was clearly indicated.

One attribute of Calcium CT scans much publicized by the AHEA (the organization headed by Dr. Morteza Naghavi that issued the SHAPE report) is the image itself. It is assumed that a patient who sees a picture of coronary calcium in their arteries will change direction, alter their lifestyle, diet, etc. and comply with prescribed medications. However, it is a long-standing tenet of behavioral science that "Information Does Not Change Behavior". And many cardiologists say that it is very difficult to get patients, who have already been identified as being at high risk for heart attack, to do what they need to reduce their risk factors (how many patients get an angioplasty or stent and continue to smoke?). There are not nearly enough rehabilitation or risk reduction programs readily available to patients -- and they question if finding more at risk patients will change this?

There are many questions to be answered, and part of the SHAPE task force's purpose seems to be to shake things up. In the words of Dr. Prediman K. Shah, head of cardiology at Cedars-Sinai in Los Angeles and leader of the SHAPE Task Force Editorial Committee:

"With the publication of the SHAPE guideline, we hope to build a new momentum in cardiology that inspires physicians to use modern technologies for the prevention of heart attack, rather than using expensive technologies only to treat heart attack, which is too late and results in too little benefit to the patient."