



Transcript of Dr. Shaw's presentation at the 2nd Vulnerable Patient Symposium held by AEHA on March 6th in conjunction with the Annual Conference of American College of Cardiology 2004 New Orleans, LA



I really thank you all for staying so long. I now I had an eight o'clock meeting this morning and it's a long day for all of us. I can really start to talk -- my name's Leslie Shaw. I'm from Atlanta -- not that far away, short flight over here. And I guess the way that we assess about screening when we start to think about imaging or you start to think about laboratory tests, one of the factors that comes to mind is how can we truly integrate this into medical practice, namely is as you start to discuss about -- can this be a reimbursable test and then we start to talk about the public policies today of screening. What's interesting, if you think about the public policy today of screening, it really brings into mind a lot of the other tests that we screen for -- cancer screening, for example. Now, the value in cancer screening, breast cancer screening, lung cancer screening -- any kind of cancer of cancer screening -- is that early detection leads to improved outcomes -- early detection leads to improved outcomes -- and late detection is associated with very costly and worsening outcomes and therefore, if you have a test, a pretty good test, because many of the screening test like mammography, for example, are not that great screening tools, but if you have a relatively inexpensive test, then if it's applied on a population base level, then it can be what we considered not only clinical

effective but also cost effective. And does that paradigm also set cardiovascular disease, our number one killer? Absolutely. So, we already have a good paradigm in cancer screening. So, applying that kind of rationale to cardiovascular screening, which is going to apply -- I know Allen and I both were involved in the Bethesda Conference, Allen being the Chair of that. I was involved in the area of cost effectiveness.

And so when we start to think where we are in cardiovascular disease, you have to think of our current state of our healthcare system and the economics of cardiovascular disease, the economics of healthcare. About 50% of our healthcare costs for any stage or hospital care. The average yearly health expenditure for an end-stage care is about five fold higher than non end-stage care and this is from CMS -- so this is from a little bit older population, Center for Medicare and Medicaid Services. There's well-established evidence that if we shift care to the outpatient sector, it's going to reduce costs. There are some concerns about driving up the prescription drug costs. If you think about screening a population, although I think prescription drug costs are rising most of that's due to rising costs, not to do with rising utilization -- so, if we think about the potentials from 30,000 foot level, we think about shifting care within our limited resource budget. There's a potential of we could kind of move some of those costs in the in-stage care, move some of those cost in hospital based care, shift down to a screening program, one can see how -- I think the societal burden of this is very easy to envision.

Cost effectiveness comes to mind. The government, all of us make cost effective decisions in our own life, hopefully, and a cost effectiveness is by definition looking at the simple calculation, looking at the differences in cost divided by the life years saved. And this is going to be a problem when it comes to screening because the full gamut, when we talked about what the U.S. Public Health Services define cost per life years saved, we don't always use tests to save lives. We don't always use -- perhaps we also want to avert a heart attack, i.e., the name of the organization and therefore, some of these standards may not apply but the general standard is about \$50,000 per life years saved and we have an advantage -- we can actually get a very low cost item, but it's not

that effective and we can still find some value in it, of course, when it is -- has associated with increased cost and decreased effectiveness, either side, the numerator or the denominator, we can find the item not to be cost effective and of course, the win-win for society is that we save money and we have a better tool and I think that's kind of some of the evidence that we see is unfolding here in the area of screening and of course, generally speaking in medicine, most things are more costly and we have to weigh those balances between of whether or not we think it's worthwhile.

Now, shifting the paradigm to screening is what we would hope is that early detection leads to improved life expectancy, less costly, less invasive care, less hospitalization, shorter length of stay. We know patients who are less complicated have shorter length of stay. Every day in the hospital is around 1500 to \$5,000 a day. We do know that these patients, if we can keep them asymptomatic, they have more productive lives and therefore society is more productive and the question -- some of the key questions is it more productive asymptomatic individual reduce the cost of care in relation to a symptomatic patient. And we know the answer, symptomatic care is very expensive. I have an abstract in a couple of days showing that symptom -- life time symptomatic care is about a million dollars per patient.

Despite improvements in cardiovascular mortality, Allen's Bethesda Conference really noted that there was a substantial detection gap and we know that if we eliminated this disease and associated conditions, we could actually gain around three years of life for every patient and the goal would be one component of cost effectiveness is to look at the upfront test costs. This is taken straight out of the Bethesda Conference and the goal would be defined in relatively inexpensive yet accurate tests -- that's by definition of screening tests and so anything kind of -- and these are not what you would charge -- this is how much it cost to produce one test -- that's the valued or that's the cost to society. So, we see some of these tools which have been discussed and some comparative tools, EBT in there -- is a very , not a very expensive test and this has been reported in about three or four different papers, CRP is very inexpensive when you

consider a lot of other tests that we can provide. So, we do have available inexpensive tests.

One of the big challenges that we have is we don't have a lot of cost data, so we need to know how much data is induced downstream, why it's by the procedure so it's not just the up part costs but the induced cost and in many cases, the induced are substantially greater than the initial costs. I've seen upwards of 10 to 100 fold induced costs. Here we have an example from Tracy Callister's data out of Nashville looking at around a 19 fold induced cost in an intermediate Framingham Risk Population with calcium screening. So, relatively modest. But we need to more clearly define these induced cost in diverse populations.

And we also need to know not only procedural costs with the induced medication cost, we can see -- it's interesting. I always kind of think, just kind of anecdotally, that the medication cost would be substantial and every type of analysis I've looked at is what we see when we added medication costs are around 7, 12, 14, 15% when you add on purely treating for calcium alone, not what they're currently receiving or any changes to therapy. Looking at statin therapy, for example, and this is how we do that -- it's also one of the most costly drugs that we can give in cardiovascular medicine, in a prevention setting. This would add about 12% of the total costs of care. So, a very modest improvement, at least in terms of my experience in doing some of these analysis. And therefore, we can actually calculate total costs, the number of events that we could actually look at -- now, remember I said that the U.S. Public Health Service looks at cost per life years saved -- I particularly like to look at the cost to identify major adverse events and we can see in a low risk population of Framingham Risk score, under the 6%, about \$73,000 to identify cardiac death or myocardial infarction, but in intermediate risk patient population, you can see actually a more favorable economic profile of about \$37,000 per life you save. I can put it in a Stringent model. One of the challenges of putting it in a Stringent model of cost per life years saved is that I have to extrapolate to life years -- mostly taking some of the 50s, that would require me to afford

to extrapolate almost 30 years into their life. For me to do extrapolations, I can do it mathematically but it may or may not be relevant to somebody who's truly 70 years old. But there are these principles of high risk cost effectiveness models which have had a lot of experience in the literature. They would state that the overall clinical effectiveness of a therapy and the clinical effectiveness of a procedure is increased in higher risk populations. We can use that principle. In other words, the risk reduction is greater in this intermediate risk group than it is in a low risk group. Clinical effectiveness and cost effectiveness do parallel one another for those of you clinicians. So, if we focus on this intermediate risk group, we can actually see if you will get cost per life years saved, you can get values as well in excess of \$50,000 per life years saved. Interestingly, and this was amazing to me. I just purely did this as a mathematical exercise, extrapolating this right at about a 1% risk, or right at that intermediate risk, Framingham Risk, 1% risk per year of cardiac death infarction, we went below the \$50,000 per life years saved. So, this kind of is very supportive and integrated with the public literature and I think that shows that this intermediate risk category can not only be clinically effective but cost effective.

I think this is where we stop -- Allen's going to talk about some of his experience in cost effectiveness, but one of the challenges and we don't have a lot of data in these areas, there are key leverage points in determining cost effectiveness. We have to have a moderately priced test -- we have to minimize the induced cost, we have to have effective tests to stratify. It's helpful to have very long-term outcome data so that we don't have to extrapolate well into the decades beyond that and of course, one of the challenges is we have to have a test comparer -- if we compared a no testing, all of you would agree but left untreated the cost for symptomatic care is substantial and delayed and it could be a decreased societal productivity, could be substantial in patients presenting, obviously, with sudden cardiac death, early retirement perhaps for those patients -- the lost productivity of those with non fatal infarction. These are substantial burdens to society -- versus the Framingham risk score I know Allen's going to talk about that and of course, but these are the real keys when we talk about introducing

national screening. We need to know better than we're doing nothing at all or versus the Framingham Risk and of course, some of the key questions would be which test, but that's the secondary question, second question about which one. And that's my last slide. I'll turn it over to Allen. (applause)