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ASSOCIATION FOR ERADICATION OF HEART ATTACK

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Well, thank you all for staying late. It's a bit of oxymoron to work for the government and talk about cost effectiveness! but we'll give it a shot. What I'm going to talk about is -- in terms of atherosclerosis imaging some concepts of -- what's it's going to take and whose responsibility is it? I'm not going to send you out with a number. This is the cost effectiveness of calcium scanning because as Leslee mentioned there's so many assumptions, and your assumptions are not my assumptions, are not his assumptions and since its very assumption based, the numbers you get have a somewhat air of artificiality about them. Certainly the leverage point is that in terms of calcium screening, the risk of developing coronary disease is certainly increased with calcium is present and the potential thus exists to capture risk as misclassified by heart disease risk factors.

The cost of screening though is subclinical atherosclerosis to identify risks is really poorly understood and so what factors influence the cost effectiveness. I think this is a necessary but rigorous standard for a diagnostic test, which when you think about cost effectiveness from the standpoint of therapy but what we have to do then is

cardiovascular prevention as a continuum. It starts -- as some of these talks tonight -- about screening to detect, but it moves on from there and leads mostly to treatment that adheres to that prevents outcomes and what we're all talking about tonight is right here -- screening for detection -- but where we're all very responsible is on the second line. As another principle, anatomic screening has to be additive to risk factor screening. That is, the comparison has to be between multi-variate model risks such as with the Framingham Risk Score, versus that plus some anatomic tests -- in this instance, we'll talk about EBCT. And I think as Leslee mentioned, its weakness is that it talks only about mortality and adjusting for quality, but it is what society asks for and that is quality of life years saved.

So, what are the model in considerations? What do we have to be cognizant of if we're going to think about using any test -- the tests that you're interested in in a cost effective way. First of all, it begins what the population in its applied. What's the risk of that population as Leslee mentioned, cost effective is in a lower cost rate and will not be as high -- as in a higher risk population. The second is the aspects of the test itself. What the incremental value that test for risk prediction and what's the actual financial cost -- it's actual cost? And then there's the concept of induced testing and internal findings -- induced testing, tests that follow on the consequence of the first test; fourthly, what additional medications are used and what's their cost and what's their efficacy? Lastly, is the concept of utility and utility is a really important concept when we think of quality adjusted life year saved -- utility is if you've got arthritis what's the value of everyday compared to someone for you -- compared if you didn't have arthritis? Think about that for a minute. The burden of a diagnosis on a daily basis is measurable and in fact, a Beverdam Study -- measured this in a screening population and asked people what's life like to you with your diagnosis. Various diagnoses that were prevalent in the population and in fact, for most symptomatic diagnoses, it was below 90%, less than 90% is good as if they didn't have the diagnosis and you can kind of time trade off methods. Even aor an asymptomatic diagnosis like hypertension, where it engenders medication, visits and so forth. Quality of life is degraded and so as we label people with

subclinical diagnosis, we've got to think about the effect on the utility of life and quite frankly, you don't know -- no one has ever studied the utility of a year of life with subclinical atherosclerosis diagnosis. It's something we don't know of, for hypertension, though, it's 94% -- a 6% decremental in quality of life and we'll come back to that.

And so if you think about these variables and you sequentially model them, this is a model that Pallamani and our group put together and basically, you start with screening and you either do it risk factor screening alone or you add an anatomic test and this is showed one sequence of nodes to what gets to be a very complicated sequential model, but you identify people as what their risks is, what the incremental risk shift is, there might be some induced testing, some medications might ensue. There might be incidentall findings from the scan. You've got a model on the effectiveness of the medicines and so forth. And what you wind up with is a number -- that number is based very highly on some assumption and variables that you input. In a model I'm going to ascribe to you that's in press, we made a variety of assumptions. First, is that there would be increased identification using EBCT of individuals at risk and that shift would be to approximately four-fold increase; that is, there'd be an incremental four-fold increase in risk in identification of at risk individuals using calcium scanning. And that it would occur at modest cost, around $400 per patient. This is we took cost and model cost in the perspective of the pair, not society. This is the common way to do it, who will be paying for the tests and then look at induced costs. Assuming as a base case that medicines would cost on average $300 a year and there would be some incidnetal findings that would engender costs. In at risk individuals -- someone who was identified as being a greater risk on the basis of the anatomical than by the risk factor screening, we proposed there's be some modest increase in subsequent cardiovascular testing induced testing, stress testing, in about a third of those individuals perhaps, that there'd be substantial increase in preventive therapies like we would all hope-- perhaps in 10% in the people not at risk to object upwards of three-quarters of the population would be treated appropriately with risk reducing medications and that there'd only be a mild decrement in utility down to about 98% -- now, remember hypertension is 94%. So, we

felt those were fairly stable assumptions to take as a base case. Other assumptions include life expectancy. When you diagnose, someone at age 40, anything you do is going to last for life expectancy or you hope it's going to have an effective across life expectancy. This is the problem screening early in life is that the cost model through life, but someone at risk, someone who's at risk, an increased risk might as a population have a slight decrement in population's longevity of approximately 5 years over a low risk population and that's the efficacy of primary extension would be about a 30% relative risk reduction for mortality and then again, there is a four-fold independent increase risk associated with coronary calcium. Those are the base case assumptions, keeping in mind they are a starting point. Using these assumptions in a lower risk population around $90,000 for quality adjusted life year saved, going from screening to treatment and this is a modestly expensive by conventional standards. And the caveot here is many assumptions are made and it applies to a certain population, but I'm going to talk about and I think it's important and I want you take home though sensitivity analysis and I think this is particularly informative.

What's the range across these assumptions that changes occur? And so you develop graphs like this, which shows the marginal cost effectiveness for a range of values of a variable and so what you see here in this green lines shows he combined anatomic risk factor screening cost effectiveness across a range of values is that if you have a four fold increased risk for calcium scanning, which adheres that basic assumption that about $90,000 for quality adjusted life year saved, you've got a moderately expensive test; however, this number is in question. We don't really know the exact incremental value of scanning over risk factor screening. If it's only twofold, and I think some (inaudible) said it might be just twofold, then we're upwards between 140 and $190,000 for quality of adjusted life year saved, not cost effective. If it's very powerful even five fold, the cost effectiveness or it's getting more and more favorable. So, one critical assumption is how good is this test? What's the push? And the push matters. It's not just fighting over whose test is better, it's not making -- trying to get papers published. It

really determines the cost effectiveness, how much value incremental value are there? How many additional people are identified?

The next thing to consider is medication cost. If we assume in the base stage, $300 per year where the base case is $90,000, the quality adjusted life year saved, but if annual cost of additional medication require is only $100, we're back at a very -- we're at a cost effectiveness range, keeping all of the assumptions frozen. So, doing nothing except getting the drugs that cost less and that is an important -- importantly affects quality of adjust life years saved, cost effectiveness. On the contrary, this makes the drug $600 a year, put 'em on Plavix instead of aspirin, okay. And suddenly, you've got $150,000 for quality adjusted life year saved, nothing else has changed that has the same effectiveness and so on and so forth. The drugs a little more expensive, 'cause this goes across many, many, many years of life.

Another one. Utility. This is a stunner. Remember utility is how valuable that year of life after the diagnosis. It's not how accurate the test. It's what's it do to the person's quality of life. This is our base case, 98%, $90,000 for quality adjusted life year saved. Once you go below 98%, in fact, the cost effectiveness is dominated by utility. That is that at a -- with more than a 2% detriment in quality of life, you can show that a million dollars for quality of adjusted life you save, because life just isn't worth living anymore. Now, that's a gross exaggeration, but you can see that we don't know -- have any idea what that number is and if hypertensive 94%, we better figure out what this number is before we go making any arguments about quality of life you save.

Incidental Findings. We don't really talk about it much -- a little secret. How common are these in our incidental findings we get? If they range anywhere from 2% to 32%, you can see right about 20% there's an inflection that if more than one in five people have an incidental scan finding that engenders induced costs, we've got a problem. Some populations -- older populations -- populations from the middle sectors of the country, a lot of pulmonary nodules with lot of extra testing, in fact, have very high rates of cost

effectiveness -- of incidental findings. You have to be mindful of incidental findings amd the induced costs from those. And lastly, it's the mortality reduction on medication. The test is only going to make us treat people and the treating has to be effective, otherwise there's no easy chance of cost effectiveness and we assume the 30% relative risk reduction for mortality -- beneath that -- again, it's dominated. And so if we don't have effective therapy, if anything less than a 30% relative risk reduction in terms of mortality for a therapy, in fact, no screening tests can be cost effective.

So, this is a tornado diagram showing you the different -- important variables and it's across a range of their values with the range of cost effectiveness observed and it's an easy way to sort of portray the sensitivity of different variables on cost effectiveness within a model. What you see here is efficacy of primary prevention ranging from 50% relative risk reductions; 10% relative risk reduction; the utility of medicine with a subclinical diagnosis ranging from .99 to .95; the predicted value of the test five fold increase, twofold increase; incidental scan findings; cost of medicines from $100 to $600 and the cost of EBCT ranging from three to $800. Basically, what matters most is these three things here. The predictive value of the test really isn't that -- doesn't have that strong an influence. Incidental scan findings are not that strong. The cost of medicines are important, not that strong, nor is the cost of the actual test. You can give the test away. It's what happens outside of the test and if we don't have effective therapy and if we degrade quality of life too much, it's off and on.

So, what our analyses show was that within a younger screening cohort at low absolute risks, with some fairly stable base case assumptions, it would be about $90,000 for quality adjusted life year saved to screen with calcium screening but the marginal cost is dependent on a variety of things. One is the independent incremental predictive power for calcium scanning over Framingham. There's got to be at least over four-fold, at least over twofold or we're not going to get anything out of it. And then another case, we have to have utilities have to be over .98 -- this is not well defined, this should be defined. The efficacy of these readings has to be strong and they have to be low cost.

So, health systems, insurers, and society need to understand the cost of the new technologies screening for coronary disease. And what I'm going to leave you with is a thought that cost effectiveness is going to be a partnership between imaging modalities that are accurate and independent. That's what most of spend our time thinking, but it goes way beyond that. It goes to providers. If providers don't know how to use the test and don't treat people to targets -- our efforts will be lost. If patients don't adhere to our therapies, all for none. Health systems have to allow access to test and therapy and industry has a big part of this. They have to not only develop effective therapies and make them inexpensive enough, otherwise, again, our attempts to have cost effective screening tests are going to be lost. So, I put to your attention, I hope I've left you with some thoughts on cost effectiveness you didn't walk in with. You begin to think, oh, this scan costs $300 or $800, so I think it's a lot more than that, isn't it? Thank you very much. (applause)