SPEAKER 1: Hi. Welcome to CCAT's Grand Rounds. I'd like to welcome Tom Maddox to present today. Tom is a cardiologist at the VA Eastern Colorado Health Care System and associate professor at the University of Colorado. He's a practicing non-invasive cardiologist working with US veterans. His research interests focus on learning health systems designed to leverage real-time clinical data, deliver high quality care to patients with cardiac disease.

And I think what he's going to talk about today is really relevant and important to better understand as we sort of move that forward broadly. So without further ado, I'd like to thank Tom. Thanks so much for coming.

[APPLAUSE]

All right. Well, thank you very much for coming out. It is my first trip to Minnesota. So far, so good. Nice place. So I want to talk to you today-- I realize that we sort of have a diversity of folks here with varying levels of experience in cardiology and clinical medicine, so I'll try and sort of define things as I go. And obviously, if there's something that needs further clarification, just sort of throw something at me or let me know.

But I want to take you through a little bit of the concept of learning health care system, which I suspect most of you are somewhat familiar with, but just sort of how we think about it and then in particular talk about this VA CART program, which is a national clinical quality program for all the cath lives in the VA throughout the country. So as you know, we're a large health care system. We cover eight million veterans, we have 125 medical centers in almost 1,000 clinics scattered around the country.

And within that, we obviously provide the full spectrum of cardiac services. So we've started to think a little bit about how can we both collect and then use that data to ensure that the care we're providing is as good as possible and potentially serves as a foundation for ongoing discovery and evidence generation? So I don't have any disclosures to make here with this talk. And the learning objectives are to define

some of the essential elements of learning health care systems, to understand the elements of this CART program that I'll describe, and then finally how the to interact with one another.

So just as a start-- and I think a lot of people are familiar with this, it's likely why you are here-- is that the health care system doesn't have consistent quality safety and knowledge. We obviously have wonderful innovations and practitioners throughout the country in our health care system, but the application of that in a sort of proportionate, even, equitable fashion is quite a bit lacking. And we do know that evidence is incompletely applied across the country and we know that we have excess heart attacks and mortality and other things because of that.

We know that safety is an issue, it was raised as an issue in the IOM report back in 1999. And we still see that there are potentially avoidable issues still occurring in hospitalized care in the outpatient environment. And then finally, knowledge itself is a problem. So in the cardiology world, as is true in most clinical specialties, we have guidelines and we have sort of codified best knowledge out there, but the actual translation of that to practice, as well as the generation of high quality evidence, is lacking. As of our last guidelines for managing cardiac disease, about half of those only have level C evidence, meaning it was expert opinion only and still wasn't that informed by randomizing controlled trials or even large observational studies.

So even though there are pockets of greatness, including this one here, there is still a lot of work to do to make sure it's great everywhere for everybody. So one thing that we've kind of realized is that mistakes are not because people are lazy or stupid, but it's actually because systems are just sort of designed to let some leakage go out. And we need to start thinking about a systemic level if we want to address the problems. And so here is a graphic.

This is from the IOM report, where it's better care at lower cost. And this kind of lays out the idea of learning health care systems. And as you can see in this cartoon here, if we think about the spectrum of medical knowledge going from the science that we see in our labs and in our clinical trials and then it's transferred into evidence into these recommendations backed by data on the best thing for us to do and then finally the actual point of care delivery, where we're seeing our patients and our clinics in our communities and our hospitals. We see at each point sort of a

bleeding out of various inefficiencies.

So from the science, the insights are poorly managed and poorly translated into our evidence. The evidence is then inconsistently applied at the point of care. And then probably the biggest, I think, revelation of this report is that once we do deliver that care, we actually do a fairly terrible job of collecting that data. We certainly have EMRs, and that's an important first step. But we systematically gathering it in a way where A, we're understanding the quality of the care that we just provided; and B, are we able to inform the care of the next patient or the next group of people that come through the door of where we're providing that care?

And this all ultimately affects, of course, the patient experience. So in order for this to improve, we need to start thinking about a system that can actually be designed to learn from the care that it provides. And so the idea is that you go from sort of the inefficient system that we've described here to more of a system that is sort of an iterative, continuously learning process. And it's basically the idea that we want practice to inform evidence so that evidence can inform practice.

And it's sort of that circular idea that appears to be the best option we have for improving the efficiency and the quality of the that we provide. So as you can see here, the science evidence and care is still here, but now they're organized in a little bit more of this iterative fashion. And then a little hard to see, but this blue circle around it is another equally important part of this, and it's that you have the leadership and the culture and the incentives in place to both collect this data and then use it in an efficient fashion.

So this is sort of the philosophical underpinnings of the learning health care system. And they've kind of codified in this report sort of the elements you need to have this kind of system put into place. So you can see here there are four general domains. There's science and informatics so that we can best understand what to do and collect evidence to continue to improve upon that base. Patient-clinician partnerships are a big part of it. Incentives to make sure that reimbursement and the other incentives that drive health care are not getting in the way and ideally helping this continuous learning.

And then finally, culture is really important. It is essential not only from a provider

point of view, but from health system leadership. All the allied health services and the patients themselves all have to sort of be oriented to achieving these sort of efficiencies. And you can see here specific needs were outlined-- digital capture of the care experience; real-time access to knowledge; we need engaged, empowered patients to accompany our providers; incentives aligned for value; and have full transparency to all the stakeholders. And then finally, a leadership instilled culture of learning and supportive system competencies.

So I'm not going to talk about all of this today, but instead I'm going to focus on just the first domain, the science and informatics and the digital capture of the care experience. Because this is where the CART program has made a little bit of an inroads and ideally is going to be informative with all the other efforts that Nileigh and others are leading around the country as we're trying to sort of solve this puzzle and improve the overall efficiency and quality of care. So with that sort of background and philosophy of what a learning health care system is, let's translate that to what I do in the world of cardiology, and in particular what we're doing in our cath labs in the VA.

So like I said at the outset, the VA CART program-- and CART stands for clinical assessment reporting and tracking program, which is probably the least informative title I've ever been associated with, but nonetheless, that's the title that was handed to us-- is a national quality program for all the VA cath labs. For those of you unfamiliar with cath labs, this is where we perform a lot of our invasive coronary procedures. Probably the most common procedure in a cath lab is when we take a picture of the coronary arteries using a catheter that we put into the patient.

It goes up to the coronary arteries. We inject dye and then use x-rays to take pictures of the blood flow through those arteries, and there we can see if there are any blockages or any other sources of disease. We also, if we do see a blockage that we think is causing a problem, we can then at the same time through the same process open up that blockage using a balloon and a stent. And this is a very, very common procedure, very effective procedure and in the VA occurs about 50,000 times a year. So a big issue to track and obviously, important to gain insight from, as well as optimize the quality.

And you can see here on the map of the United States sort of the distribution of our

cath labs. The closest one to you guys is in Minnesota and then you can see down to the bottom we have one in Puerto Rico. I keep advocating for a site visit there, not yet, but eventually we'll get down there. So let me give you a little bit of a guideline about what we're going to talk about with CART. So I'm going to give you an overview of how the program is set up and then we'll talk specifically about how we gather our data, how we've designed that gathering of the data, and then how we try to ensure data quality as much as possible.

That's an absolutely essential part of learning health care systems. Then with that sort of background, we'll talk a bit about what we've done, both in our quality and safety areas, to ensure that we're providing the highest quality care and that we're also being safe in what we do because there are risks to these kinds of procedures. And then finally, just as importantly with this data, it's not only important to make sure that the care we provide today is of high quality, but we also want to continue to build on our knowledge. There's a lot of new insights that can happen, and with this kind of data it's a very valuable resource to glean those insights.

So we want to give you a little bit of a sense of how we're using that so that we can generate the new evidence to inform the next generation of care. Obviously, there are limitations in future directions and we'll cover this at the end. So the CART program, clinical quality program. We've actually put some of the stuff that we do into the peer-reviewed literature. This is an article down below cited talking about integrating quality improvement that we published in the *American Journal of Cardiology.*

And what we were initially focused on doing is ensuring that what we are offering is of the highest quality possible to the veterans that we serve. So in order to do this, we needed to be able to capture really granular data and we needed to be able to capture it quickly, almost at the same time that the procedure was happening. And so in order to do that, we decided to build a module inside the VA's EHR that's called CPRS. And then within this, we have some specified fields where the operators are able to right at the end of their procedure put in the various data elements that are relevant about both the patient and the procedure that we performed.

So it comes up as three different screens. The first one is our pre-procedural screen. This is usually filled out by one of our providers as they're interviewing the

patient and getting them ready for the procedure. And here we have up to about 120 different data elements. It's surpass medical history, it's their demographic, it's all those things that go into the reason they would need the procedure, some of the reasons that might make it risky for them or other medical conditions that would affect what we do.

Importantly, we did work with the overall EHR to where stuff is automatically imported. We tried to eliminate some of the system redundancies so that if we already know what their medical history is-- we obviously already know their name and age and that sort of thing-- that it's automatically important and so we're able to save a little bit of time for the clinician as they're doing it. I think the other thing that's really important is that the operator themselves is putting the data in. We have a lot of very large cardiac registries, but most of them require abstractors, usually you know a nurse or another health care professional.

But they are typically abstracting the data and putting it into a case report form often days or sometimes even weeks after the procedure. And so we're unable to see and wrap relatively rapid fashion what we've been doing. And we find by having the operator do it directly, A, operator has the best knowledge about what has just happened and so he or she is able to give probably the most accurate information, and then B, the timeliness is really important. Once they put that in, we do the case, we take the picture, we're able to understand the kind of anatomy where blockages might occur, what kind of disease we might have, and we're able to put it here.

You can either do it directly or through this anatomic map or just do it through pulldown menus. And then finally, if they go on to need the balloon and stent, or PCI as we call it, we have all the data here. And importantly, the other thing that we collect is all the information about the equipment. So we use a lot of catheters, a lot of stents, a lot of balloons. There's a lot of mechanical equipment there and as you can imagine, not all of it it's going to be perfect all of the time.

And so with FDA and other surveillance programs, we're able to communicate with them and ensure that if we do see something in the field where a certain lot or batch of stents or catheters or whatnot appear to not be doing their job, we're able to identify that very quickly, aggregate it across our system, and then work with our FDA and the other partners to ensure that we're able to provide the safest possible

care. So as of now-- the CART program started in '09 or I guess it started in '05 and we got everybody on board by '09-- so since '09, we've had all 79 cath labs contributing data. And here you can see just a little bit of the numbers of what we've collected now.

So since 2009, we have just over 360,000 coronary procedures. And you can see the split between the angiograms, which is just the x-ray pictures the arteries, and the PCIs, the balloon and stents, there. Over 800 health care providers have interacted with CART. And like I said, it is critical that they with the most accurate and timely knowledge about the patient and the procedure are the ones interacting with the system. And then most importantly, of course, the patients.

We have almost a quarter of a million now in our database. And then you can see the breakdown a little bit about what we've found. So for the PCIs that we perform for an acute coronary syndrome, for a heart attack that is occurring right then, it comprises just over half of our cases. You can see that there's a distribution of coronary disease; three-vessel disease, meaning you have blockages in all three of the major vessels of the heart. You can see that occurs in 12% of our veterans, and then it gradually-- we just listed it here and in decreasing level of severity. And so you can see that we get down to non-obstructive disease and even normal coronaries in 12.1% of our patients.

And then finally, like I said, we're trying to monitor safety so procedural complications are very important. We look at all our complications, that's what the "Other" means, and that's a 5% rate. And these can be anything from very minor just some site bleeding or maybe a little bit of itching from some of the meds or some of that stuff, so some stuff that is not life-threatening. But the subset that has is major adverse events, MAE. We we're happy to see that although they happen, it's only about 30 events a year across our entire system, which translates to 0.06%.

So that certainly gave us our first sort of look and some comfort, but now we're obviously focused on those 0.06% to see if there's any way we can drop that even further. So let's talk a little bit about the design and the quality. So like I said, it's integrated at the point of care; it's integrated into clinical workflow. And what we have found is that for any EHR, whether specific to cardiology or any specialty at all, it is essential that it be assisting providers in the clinical workflow; otherwise, it's

essentially a nonstarter.

It's obviously a very busy job to provide health care, health systems are massively complex things. And if we can't design a system that allows us to collect the data as it's occurring in a reasonably efficient fashion, and ideally it was sort of a zero sum game in terms of clinical workflow, then we largely are dead in the water. And so I think it behooves all of us to think very carefully as we're designing how to collect that data from the care, how can we take into account and use the clinical workflow to help us instead of hurt us?

We also have the CART data is immediately available. So it turns out that as the providers are entering the data, it goes automatically into the EHR. It is also fed into our analytics servers, which are based in Denver. And at the end of the day, they are updated constantly, multiple times a day. So it turns out that if a lab in St. Louis calls us that day and says, this past week I want to understand the outcomes of my diabetic patients who had a PCI, we have that data for them. Obviously, we won't be able to run robust models, only have probably done 15 or 20 cases.

But if they at least want to identify those patients and try and understand the trends of what's happening in their labs, then that's something we can do right away. And that's another critical step, in addition to workflow, to being able to have this almost immediate data feedback. We also found it's really important to standardize our data. So for folks working with big EHRs, this is a huge source of a headache. And I think one thing that we wanted to pay attention to is that a lab in St. Louis or Puerto Rico or Denver or Minneapolis are all saying the same thing when they use a term.

And so to do that, we're fortunate, most specialties do have standardized terms, cardiology certainly does through both the American Heart Association and the American College of Cardiology. So we were very clear about what terms we're going to use. They're accepted across all of the labs. And we provide some sort of training for our new fellows and other users of the system to ensure that they do understand when they are saying a term what they mean. And we have found that to be very critical for data quality.

And then finally, importantly, CART data is only capturing that data that occurs in the walls of the cath lab. So the patient comes in and we collect their data, we do

the procedure, we collect that data. They leave and then CART itself is done. But obviously, the patient's not done. They have the rest of their care to experience. And so we found it important to be able to take CART and then link it to the broader longitudinal databases that do exist in the VA.

And so with that, we can now link to our pharmacy data and understand what they're prescribed in their appearance patterns; we have a link to their outpatient visits and understand the intensity and type of care that they receive; we link it to lab results that we have throughout our program nationally; and then finally, other hospitalizations, mortality, MI. And we also tried to identify not only the care they would receive in the VA, but then for our patients who are also covered by Medicare to link to CMS data.

There's obviously about a two-year lag for that kind of connection, but nonetheless, it does provide some insight on long-term trends of these patients and the outcomes so that we can start to both understand and then ultimately optimize. So in summary, really, the CART data is organized to generate this. A lot of these design characteristics were part of the initial strategic thinking and then obviously built into the design. And we feel like this is sort of feeding into that learning health care system domain of science and informatics where we think very critically about how do we organize our information that makes clinical sense and ultimately can give us the insights for both quality and new evidence generation.

And you can see the things that we've covered here. So does it actually enhance data quality? We certainly hope so, but we are not only clinicians but scientists and we did try to at least study it. So what we did is we took a look at our data after we had set up CART and gotten in place for about a year. And then we sort of did a retrospective look at how we collected our cath lab data before CART was in existence. And we looked at three different domains. There's obviously a bunch of ways to look at data quality, but we chose three domains in particular that we felt were very important.

One is validity, one is completeness, and one is timeliness. And we were happy to see that all of them made improvements. None of them are perfect, but certainly in the direction we want to be going and things that we think are important to focus on. So we did find that when we compared the CART data elements to the data

elements that were in other parts of the EHR, there was very high agreement and what we would define as validity. We found that if we did say in CART that somebody had had a history of a heart attack, it was true in well over 95% of the cases.

There were some other elements where it was a little bit less valid and we're continuing to work on those, but the overall summary validity, of course, was very high. The other thing was completeness. We often found that prior to CART, clinicians just sort of recorded what came to mind, and obviously different individuals would have different priorities assigned in their mind about what was important to record. And by providing more of a standardized interface, we found that clinicians would just sort of naturally fill them out more completely.

We actually did not require that all the data fields be filled up by each of the clinicians. We felt that it was really important for buy-in and to be able to have good uptake of this program that we weren't compelling physicians and potentially interrupting their workflow anymore than necessary. And we had a big debate about this because a lot of us, myself included, said nope, we have to require it just like you have to fill out everything for your credit card information or something else if you're buying something on Amazon.

And wisely, the people who are ahead of me and a little smarter were like, let's go easy. Let's let them fill out what they will fill out. Over time, we can start to work on that, but the buy-in critical here. And they're very true. So with that, what we found is that the number of data elements-- and this is sort of the ideal data element list that our society puts out about what should be recorded out of a cath lab visit. That was our gold standard.

We found that prior to CART, just looking at the random notes that providers would put in, exactly 63.1% of those data elements were complete. And then after CART, we found that it was 79%. It's not 100%. This is when I would then argue about locking the fields and mandating them. And this is an ongoing tension that I think any data collection method will have, but obviously a significant improvement in the direction we definitely want to go.

We feel like this format can help us do. And then finally, timely. We talked about this a little bit. It turns out that a lot of providers prior to CART were taking quite a while

to put the full cath information into the chart. A lot of times, they would make a small note at the end of the procedure so at least the treating team could know the headline of what was occurring in the lab. But in terms of having all the data not only to be able understand the care for the patient, but the overall trends for the labs, we were seeing that it took up to four days to get just 75% of those reports into the chart.

And now with CART, because in some ways it's sort of built into the workflow and providers have now kind of bought into it and are now using it at the end of their case and are sitting down usually within five to 10 minutes and are done, and it is now recorded in the chart and on the analytics servers and inside all of our surveillance systems so we can look for various trends. We are finding that almost all the charts were done within a single day. So we felt like that was one of our big wins for this design.

So that's how we do our data, that's how we collect it, that's what it's linked to, and that's how we ensure it has quality. So now this is all just building, so let's do something with it. So we've done a variety of things in quality, safety, and evidence generation. So I want to talk a little bit about the quality and safety initiatives that we have in place, and these are just the beginnings of them. There's obviously a lot more that we're going to be doing, but we're excited with what we've done so far. So

The first was that we were noticing that there was a lot of variation in the radiation that we provide to our patients in the cath lab. So the x-ray machines that we use to take the pictures, we need the same x-ray machines when we're guiding up the balloon, guiding up the stent. We need to try and understand, is the amount of radiation that we're giving-- and sort of the overall principle is you want to give patients as little radiation as needed-- is that principle being respected across our labs? And what we found is there was actually quite a bit of variation across these procedures.

So we took a look at everything that occurred between 2007 and 2010, this was 58 sites. And what you can see here is the median fluoroscopy times, so the median amount of time that the x-ray was on and taking pictures and irradiating the patient. We just wanted to understand what was going on. So we saw that the median times

were six minutes for a diagnostic angiogram, just taking the pictures, which is not that long. If you had had a bypass surgery and so you had bypass grafts that were leading from the aorta to different parts of the heart, there's more vessels to look at, it's a little bit harder to get the right views, so it makes sense that it would take a little bit longer.

And it did, it took about twice as long. The median time was about twice as long to take those kind of pictures. And then if you went on to need a balloon and a stent that takes even a little bit more time to position the catheter correctly, deploy the stent, and make sure that everything is placed properly. And that median time was 16.5. None of these times seemed to seemed outrageous to us, but what was concerning was what you see here with our interquartile ranges.

And you see that we have quite a bit of variation across our different sites. I'm not showing you the site variation, but there were some centers where we call it pedal heavy. And the idea is that when you activate the x-ray in the cath lab, you're standing on a pedal so you don't break scrub. And we find that some people really like to just stay on that pedal for a very long time and potentially expose patients to more radiation than they need.

So this kind of variation is what we're able to see with this data. And now we're in the process of setting up various programs to sort of help the labs, especially those on the longer end, to think through, is this as much as you need; are there processes in place where you can select your cases, minimize the radiation; setting up in-lab alerts when they start to reach some of the higher limits of time for x-rays and those sorts of things. So it's this kind of quality initiatives that we're looking at to make sure that we're doing everything as safely as possible.

Another thing we looked at is we noticed that about one in seven patients left the hospital without the proper antiplatelet therapy that they needed after they had a stent. It's really important to have two types of antiplatelet therapy that you take every day for a year after a stent, and a significant number of people we're not getting that and as a result experiencing higher rates of heart attack and death because of it. So what we did is we had CART link to our pharmacy data. This is a pilot program we're doing in Denver, about to roll out to a few other sites.

But when a drug-eluding stent is implanted-- and drug-eluding stents, in particular, definitely need this antiplatelet therapy to avoid clotting up-- it automatically links to the pharmacy. The pharmacist actually knew at the time the stent was being implanted that this was going on. And then what would happen is-- it depends on how the hospital sets up their discharge protocols, but in Denver the pharmacist actually physically comes to the bedside of the patient before they discharge as part of that process, meds in hand to give it to the patient so there's no opportunity for them to kind of waltz out of the hospital without stopping by the pharmacy or not getting what they need.

We only give them 30 days and they need it for a year. And so what we also do is we have an interactive voice response system. So when it starts to come to the end of that first 30-day period and they haven't called the pharmacy to get their refill or come by the pharmacy to get their refill, this system automatically reaches out to them and says, hey, we notice your supply is about to run out. We want to make sure that you continue to get this. Can we help you refill it, are you having problems, is there something we can do?

A lot of it is just this interactive voice response, but it can quickly link to a live pharmacist to be able to help these patients go through it. So we've just started to set up this process. We've seen some very promising early results and certainly gotten some great feedback from patients about the ease of the process. And we feel like this kind of intelligent use of data to inform our processes and optimize them is one of the potentials of this kind of system.

We also have a safety initiative where we review all those major adverse events that I talked about in the cath lab. We've found that peer review is occurring locally. It was often occurring without the input of other interventional cardiologists, partly because most sites only have one or two. They're typically involved in the event so they really can't review themselves to give you the best impartial review. And as a result, hospitals had to rely on other cardiologists who were not interventionists and sometimes not even cardiologists to try and opine on whether or not the technical procedures of what happened in the cath lab was truly of highest quality and they just really weren't qualified to do so.

And then finally, there's very little sharing across different sites. There may be

something that happens in Minneapolis and a similar process is going on in Denver that could lead to the same event. Minneapolis may have discovered the issue because they had an event and fixed the problem, but Denver has no idea if that's what's going on. And so there was very little coordination going on at that time. So what we tried to do was set up a program that would overcome those problems.

So now we have this automated surveillance system where we event is immediately flagged in Denver and then it's sent out to our national program director. And then we have the chair of a major adverse event review committee that rotates every year, but it's currently one of our interventionists in Gainesville, Florida. They review the event right then and determine whether it needs to be reviewed. And then we activate a committee of the interventional cardiologists throughout the VA around the country.

And they are able to remotely review the data in part, the longitudinal data throughout the DAHR, and then they often set up conversations with the operator on the local side to really dig into the root cause of what potentially happened. Was it just bad luck, were there quality issues that we need to address, what can possibly happen? Committee convenes, we actually just had our call this morning. We meet once a month to discuss the cases.

Only about 20% of them, 10% of them really, have some quality issues. And for those that we identify, we work with the site to improve them and then importantly, we disseminate that knowledge to all 79 labs so that each lab has the opportunity to review their processes, make sure that they're not inadvertently exposing themselves to similar events. So as you can see, as of January of this year, over the last four years or so, we've had 131 major adverse events. You can see the spread here. The majority are deaths, but there's also strokes and emergent bypass surgery.

About 83% were level 1 in. The parlance of peer review in the VA, level 1 means no quality issue was identified, most providers would have done exactly what that team did. And it's just the fact that these are sick patients, these are procedures that although overall safe do have some risks, and it's the nature of the game. But we did see that these other 22 or so level 2 or level 3 events, there were opportunities to tweak our process to potentially reduce the exposure to these events down the

road. And there are some examples down below.

So certainly some early success and we're continuing to build this out. So that's a little bit of sort of our active programs using data generated from CART. Let's talk a little bit about what our research side of the shop is doing. We have roughly 60 research projects going on at any one time and we've now started to get that robust enough that we're starting to get things into the peer-reviewed literature and starting to move the field forward in terms of new knowledge. And there's a variety of questions we can ask with this kind of data. We can ask health delivery questions, we can ask epidemiologic questions, we can ask very specific questions about cardiac disease.

And I'll give you some examples here. So I'm going to give you a little bit of background about PCI. When we started PCI in the '90s, at that time we were just learning the process. And as a result, in about 5% of cases, you could actually injure the vessel enough to where you needed to immediately go to the OR and get an emergency bypass surgery. As we got better, as the equipment got better, as we started using stents, this rate started to plummet and now it's well less than 1% where that happens.

At the same time, we recognized that if you're having a heart attack, early and quick access to a lab that can do a PCI is one of the most lifesaving things we can do. And so there was a real need to try and get as many PCI labs out to our veterans-- about half of them live in rural locations-- and get them as close as possible to this technique in the setting of if they have a heart attack they would need it. The issue is that if you're going to build a center in sort of remote Montana or somewhere far away, it's a lot easier to just build a lab and not also build ORs and cardiac surgery programs.

It's less expensive, less personnel. But the issue is we didn't know if it was safe yet, and that's actually been a big debate both outside of the VA and inside the VA. And what we realized is it's probably safe, but it's really important that we don't assume, that we actually measure. And so because we had CART in place, the VA felt comfortable in 2005 to expand their policy to allow some cath labs to operate and be able to be PCI without on-site CT surgery. But what we wanted to do is make sure that the assumption underlying that policy was actually true, and so this is what we

did.

In that time period of our study, we had 59 labs that were doing PCIs. 19 of those did not have on-site CT surgery. And so what we wanted to do was compare the that 19 that didn't have backup surgery to the 40 that did and see if there was any difference in patient safety because obviously, if there was a signal, we'd want to revisit that policy. And the nice thing is that we didn't see any difference in our outcome. We saw that the procedural rates were low and similar costs both types of labs and then our long-term outcomes, both in terms of heart attack and mortality, were the same.

So we felt it was really important to be able to verify that, and I think it does speak to some of the things that this data can help us see. We also see ways to use this data to understand some of our referral policies. So there's been a bit of a debate in cardiology about what amount of normal coronaries should you see coming through your cath lab. So when you think about it, if you're being very restrictive about the people who come to your cath lab and get a picture because you're concerned about heart disease, then you would expect the number of patients who have heart disease to be quite high.

Because you've put that barrier up, it's a restrictive barrier. On the other hand, if you're not being restrictive and so you're just being very motivated by the fact that you actually generate some reimbursement every time you do an angiogram, you might say, you're otherwise healthy but let's just take a picture anyway. You would expect that rate of normal coronaries to be much higher. And we actually had a national study, not of VA centers, looking at the rate of normal coronaries, and it was 39%.

We don't know what the answer is, it's not zero and it's not a 100%. But there's probably a best balance where you're being appropriately restrictive, but not so restrictive that you're actually missing people with a disease. So 39% is where sort of the private practice community is. They do have some incentives out there that may cause them to refer a little bit more readily and not just solely in the interest of the best cut point for seeing if disease exists. The VA is a salaried integrated health care system. We feel like those incentives are not as strong among our providers and we wanted to see if that bore out in the rate of normal coronaries.

And you can see that the overall rate of 21% is obviously quite a bit lower than what we saw out in the community, and so it did make us think that maybe some of these incentives are in play and it allows us to ask these kind of questions. We also see, as you see in the figure, we have a lot of site variation. So you saw some sites had a 5% normal rate. And you could argue that maybe they're being a little too restrictive and we should revisit their process for referral. At the other extreme, we saw that some people were getting as close as 50% and they, in turn, may be being a little bit too liberal.

So it just, again, gives us a heads up display of what's going on. There may be nothing wrong going on and these are different centers, they have different prevalence of disease in their communities. There may be absolutely nothing wrong, but to have this data and to be able to start to see what's going on and then ask questions and get insights into that really is sort of how learning health care systems are designed to work and we're hoping that we continue to gain insight here.

We also took a look-- just some other examples of studies we've done. Women in the VA used to be oil and water, there were no women in the vet in the military so there were no women in our veterans' system. But obviously, as the amount of women in the military has increased and then they've transitioned out of the military into their veteran status, we've seen more and more come through. Especially with the more recent conflicts in Iraq and Afghanistan we're seeing more young women. We've actually had to start thinking about OB services and other things that the VA had never really thought about before.

But in terms of cardiac disease, we're seeing more women come through our cath labs. It's only 3.7%, but with our denominator that's over 3,000 women. And so we just wanted to kind of understand what was their presentation like, what was their disease like, what was their care like? Were they getting similar care as what we provide our men? Women sometimes present a little bit differently with heart disease. Are we taking that into account and doing right by them?

So we were able to take a look at some of those demographics. And sort of the headline takeaway was we found that they tended to be younger than men who

came to the cath lab; they tended to have more obesity, depression, and PTSD; and we are starting to explore some of those, the intersection of some of the mental illnesses and manifestations of cardiac disease. But the good thing was that the long-term outcomes for the women who had confirmed disease was similar to their male counterparts. So we were comfortable that the system we're providing is doing right by both genders.

We also take a look when new technologies come on board. So for a long time, the only way that we were able to put a catheter in a patient's body was to go through the femoral artery at the groin. But in the last several years, we've realized that we can actually go through the radial artery. It's a smaller vessel, has a less bleeding, easier to recover from. You don't have to lie down to let it heal up, you can just have a band and sort of sit up and feel a little bit more normal while you're recovering. So there's a lot of advantages to it and it led to less bleeding long-term.

And so we wanted to understand what was going on in the VA with this kind of technique. And you can see that back in '07, it was at about 2% and really it's taken off in the last couple of years as we've seen evidence of its benefit and our younger operators started getting trained in the technique. And we've also seen that it's been accompanied by a decrease in bleeding rates, a decrease in transfusion rates. So we're able to see that the uptake is good, start to think about learning curves, and then obviously we want to make sure that we're reaping the benefits from whatever technology we adopt.

We can also take a look at larger epidemiologic questions. So one thing that we wanted to look at is we're usually very focused on the very large blockages, those are the ones that are most amenable to this balloon and stent type of technology. But we also know that there are patients who come through that may not have blockages so severe that they need a balloon or a stent, but they don't have normal coronaries. And what they appear to have is developing disease, and we call this non-obstructive disease. It's blockage of roughly 50%, rather than 90%.

But up until this point, we had not had the data for us to take a look at those patients with relatively mild disease and their long-term outcomes. And at this point, our guidelines were largely silent about these kind of patients. They largely would deal with them as they would somebody who had normal coronaries. And certainly,

those of us in this field don't feel like those or similar patients, likely have different risks. But up until this point, we were blind to that information. And so with the data through CART and the LINKS data to long-term outcomes, we were actually able to see that as the amount of blockage goes up in your heart, so does your risk of heart attack and death.

Not surprising when you think about the biology, but we hadn't verified that. And that's obviously an important thing to do if we think about strategies to help prevent events in these patients. And so now with this knowledge that in our non-obstructive patients here-- as you can see, the non-obstructive CAD-- with the increasing risk here after adjustment, anywhere from a two to a 4.5 times higher risk of heart attack and death. Now we can start to say, these patients have defined risk. Let's think a little bit about that pharmacotherapies and other things we can do to help reduce that risk.

We've also done some work in the testosterone world. Those of you who've been paying attention even to the lay press, you've probably heard a lot about this. And it's the fact that the testosterone replacement industry was quite large. Pretty much, if you came in and you were a guy and you said you felt you were a little sleepy, then you got testosterone. But biologically, we were concerned because we know that it does promote some side effects that are potentially deleterious to health. So what we wanted to do was take a look at our veterans and understand what happened to them if they were on testosterone replacement.

And what you can see here on the chart is that we have a propensity matched time varying covariate. We adjusted it for when you were actually being exposed to the testosterone. So if you had no exposure at the time you were not exposed, you were contributing to events on the red line. If you were on testosterone, you were on the blue dotted line. And we saw that over time, over the course of our follow-up, that patients on testosterone therapy had an adjusted 30% higher risk of heart attack and death.

And we saw this play out in a couple of other non-VA data sets, and the totality of that evidence may the FDA put a black box warning on replacement for men who did not have low testosterone and they're currently undergoing trials now to see if the signal truly holds up. But I think it's of these kinds of signals from the field that

CART and other systems like that can help provide. We also take a look at some of the operative risks among our post-PCI patients. So we know in that year following your stent going in surgery is especially risky, partly because you have to come off those antiplatelet meds, also because we think the stress of surgery can promote from thrombosis in the coronary arteries.

And so what we did is over on this figure A, we took a look at the risks over time. So this is just time between when the stent was placed and when the patient had surgery. And as you can see, we just separated it here by different kinds of stents. But the general trend was true for both, that for the first six months or so after surgery was where your risks were exceptionally high. And then they dropped fairly dramatically and stabilized six months and beyond. And so it gave us a sense that as much as we can to delay surgery in that six months following a stent, regardless of the kind of stent type you had, is probably the best policy to minimize your risks during that surgery.

At the same time, we had some previous suggestion that you needed to wait an entire year. And the data here suggested that we might be able to shorten the time window just a little bit. And so if somebody was waiting with a lot of pain for a hip replacement, for example, they may not have to wait the entire year, but it might be OK to go with six months and then it's an acceptable cardiac risk to go through the surgery. So that's just sort of a flavoring of some of the projects we have going on across different parts of health care delivery, associations between different risk factors and their outcomes, and just sort of all the questions that can kind of come when you have a large set of cardiac patients and the long-term data that informs their care and outcomes.

So what future directions do we have? So obviously, we have still plenty of work to do in data quality. I will get my way, we will start to lock some of those fields and improve the data quality. But we need to think about doing that in a thoughtful way that doesn't accidentally get in the way of clinical workflow. Clinical decision support is something we're going to start doing. There are risks to what we do in the cath lab, we've talked to some of them.

Another one is the dye that we use can sometimes be toxic to the kidneys. And so we have a lot of sort of understanding about the types of patients that have higher

risk for this and we want to make sure that our providers, even before we start the procedure, have a heads-up display of that risk and potential ways to prevent that. And so we're working with the workflow to kind of think about as they're populating the patient information from CART, can we then have sort of a generated user interface that says, hey, this patient is a high risk for this risk to their kidneys, here's some potential interventions and start to see if we can move the rate down from its current 5% level.

Patient reported outcomes are important. We want to start involving the patient and telling us what their symptoms are, rather than us just interpreting it, and that's obviously rife with a lot of bias and mistaken information. So we're starting to work with patients with symptom questionnaires and other things where the data is directly imported into CART to where we understand directly from them the impact the disease is having on them and then ideally, we can measure it again after we've done our intervention to see if we've actually had the impact we believe we're causing.

We also want to start capturing other cardiac procedures. I've told you mainly about the coronary procedures, but in our cath labs, we do a lot more. We do the electrical procedure should we put in pacemakers and defibrillators, we do balloon and stent procedures in the legs and the carotid arteries, and we actually-- as you probably know-- are starting to do valve replacement using these catheter-based technologies. So all of these are ongoing in VA labs, and what we're doing now is building up the CART system to be able to capture the relevant data fields and be able to use the data to gain similar insights to those procedures as we have for our coronary procedures.

This obviously can to be adapted to a lot of different other specialties, primarily procedural is the most easy way to go first. And so working with our surgical colleagues, working with our GI and pulmonary colleagues who tend to do various procedures thinking with them about ways where they can put this kind of data collection and insight into their workflows is something that we're doing. And then finally, obviously, we're VA-based right now, but we feel like these concepts can spread to a variety of both health systems and EHRs.

And we're working with colleagues sort around the country about ways that they

can use what they have in place to adapt it and, again, allow for sort of that real-time insight that comes from learning health care system design, data collection, and use. So that's what we've talked about, all in the rear view mirror for you now. And I appreciate your time and attention and I'm happy to take any questions.

[APPLAUSE]