NEW YORK STATE DEPARTMENT OF HEALTH
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL
HEALTH PLANNING COMMITTEE EDUCATIONAL SESSION
October 22, 2025, 1:00PM – 3:00PM
Zoom
TRANSCRIPT

Dr. Rugge Let's get started. I am John Rugge. I Chair the Planning Committee of PHHPC, the Public Health and Health Planning Council. By way of background, this is the fourth meeting of this committee to consider and then eventually make recommendations by December to the full council, which, when approved, will be conveyed to the Department of Health to assist in the development of a regulatory structure and expectations for PCI, percutaneous cardiac interventions, coronary interventions in the ambulatory care setting. Something new for New York, well, almost new, not for the rest of the nation. Up to now, this committee has spent its time selecting PCI as our priority as a Planning Committee to refresh ourselves regarding regulatory expectations and responsibilities, to assess the state experience and the national experience with PCI, and also to obtain public input at our last meeting. We have an educational session. I tried to reach out to some of the best experts as our educators today.

Dr. Rugge Before going forward with that, Ann Monroe, I believe you've got a mention in a request regarding our last session.

Ms. Monroe Yes. Thank you, John.

Ms. Monroe We those of you who were not able to join us, we had a session a few weeks ago that was public comment. It was open to the public. It was a very rich session with very different perspectives on the issue, but it really gave everyone from providers to consumer groups an opportunity to share their thoughts on where this should go. That video or recording is available to be viewed. I really would encourage people to do that. It's about an hour and fifteen minutes of fascinating discussion. We will send that video out to people so you can watch it in advance, particularly in advance of our next meeting where we're going to wrestle with everything that we've heard and the comments that we've received both then and today. That will come out to you in a packet, and I want to thank those who came to that meeting and those of you who couldn't come to that meeting. The video will be very informative for you.

Dr. Eisenstein Ms. Monroe, could I ask a quick ref referring to the prior meeting, a quick question?

Ms. Monroe Sure.

Dr. Eisenstein Numerous speakers at that meeting said that they had data to share. We asked them to share it with us. I haven't received an email or anything like that. I'm curious if the PHHPC has received that follow-up data from the people who claim to have data supporting whatever their position might have been.

Ms. Monroe I believe that we did receive a little bit of data and that's going to come in a package to you before the next meeting.

Dr. Eisenstein Great. Thank you.

Ms. Monroe Also with kind of a departmental analysis of the validity or usefulness of that data. Some of it is more going to be more useful than others in making decisions.

Dr. Eisenstein I was just following up on the comments.

Dr. Rugge We are set to go.

Dr. Heslin Dr. Rugge.

Dr. Rugge Yes.

Dr. Heslin I'd like to just do a couple of housekeeping things if possible. Unfortunately, I cannot raise my hand because I'm the one driving the slides. Too many things on one computer don't work. I just want to remind council members and staff this is a subject to Open Meetings Law and is being broadcast over the internet. The webcasts are accessed through the Department of Health's website. On-demand webcasts will be posted no later than seven days. There are some ground rules that we need to consider. This is being captured by synchronized captioning. It's important that people do not talk over each other for the captioning to work correctly. One person needs to speak at a time. When you're speaking, please identify yourself as you speak with your first and last name. The first time you speak, and whether you're a council member or DOH staff or other affiliates today. Note that the mics will be picked up no matter what you say. For people in the audience, if you're watching or listening, according to joint Commission on Public Ethics, you need to submit an attendance form. That can go to the www.NYHealth.Gov so that we have that available for you. For those that are presenting today, I'm going to be the one that is driving the slides. I apologize for anything I do that's a foible along the way. Let me know either hand signal or next or some sort of way of being able to push the slides forward for you. Thank you for your considerations.

Dr. Rugge Thank you. I would not have been capable of all that information.

Ms. Monroe If I could just add, if you want to make a comment, please use the hand on the bottom of your screen or write your comment into the chat. I will monitor for John the raised hands and we'll call on you in the order in which we get your indication that you want to speak.

Dr. Rugge And also just as a little advice for our presenters, please pay careful attention to the timeline set out in our agenda. We are starting a little early. Thanks for this introduction going quickly but need to conclude by 3:00pm. Please take a look at the time watch as you as you go.

Dr. Heslin May I add one more thing?

Dr. Rugge Sure.

Dr. Heslin I'll point out that we have clinicians on the phone that are actively practicing. They have patients that are scheduled. We do need to be mindful of their time. And so that in that mindfulness, I'd ask that depending upon how we're moving along, we actually may hold questions as we move through to make sure that we are getting those clinicians back to what they really need to do, which is caring for patients. We do very much appreciate their ability to join us today.

Dr. Rugge We share our understanding of priorities. Yes, indeed. I think with this we can move to our Cardiac Advisory Committee, a feature and a resource for policy development in New York State regarding health care, cardiac care.

Dr. Rugge Dr. Osinaga, would you care to give an overview and perhaps introduce your colleagues on the committee who are here today?

Dr. Osinaga Yep, I sure will.

Dr. Osinaga Thank you very much for having us back here and to present. This is the first time that we have two cardiac advisory committee members speaking to you all. There's others that have joined us on the call, but we have two presenters. My name is Alda Osinaga as you can see from the slide. I'm Department of Health staff. I work in the Department of Health. I'm a Chief Medical Officer and Director of the Clinical Center in our Office of Health Services, Quality and Analytics.

Dr. Osinaga If we go to the next slide, we'll go through what our presentation is. Our presentation has a total of four speakers, including me.

Dr. Osinaga Thanks.

Dr. Osinaga The first presentation will be by Dr. Jacobs, who is the Chair of our Cardiac Advisory Committee. Dr. Jacobs will go over the evidence of what we know so far and what has been learned from prior studies regarding cardiac catharizations, PCIs, and ambulatory surgery centers. I know that this Health Planning Committee has heard about evidence. People have spoken about evidence, but we wanted to go through an actual presentation today of everything that we have so far and that you've heard bits and pieces of. That's our first presentation. Our second presentation is to go over guidance from the Society for Cardiovascular Android and Interventions, otherwise known as SCAI. Again, this is something I think the Health Planning Committee has heard. People have mentioned the SCAI Guidance. This presentation will be given by one of our Cardiac Advisory Committee members, Dr. Naidu, who also is the President of SCAI. He will go through this presentation. And then our last presentation will be some more data that we have to present to you. This will be given by Kimberly Cozzens, who is the Director of our Cardiac Services Program and who has presented in our in our prior visits here to the committee.

Dr. Osinaga With that, we can go to the next slide.

Dr. Osinaga I wanted to start by just giving a little bit of details about the Cardiac Advisory Committee since you will be hearing from them today. And just for people who may not know, the Cardiac Advisory Committee is a body that is in regulations. It's in Title 10 of our New York Codes, Rules, and Regulations. 4529 says that there should be a Cardiac Advisory Committee consisting of physicians and other professionals with expertise in cardiac care. They are to consider any manner related to cardiac services. Our membership currently includes clinicians from in state and out of state. We have perspectives from those who are practicing in state and out of state, and they serve in an advisory role.

Dr. Osinaga We can go to the next slide.

Dr. Osinaga We just wanted to mention that our committee members are also subject to Section 74 of the Public Officers' Law, which is our Code of Ethics Law. We've asked that the members exercise their duties and responsibilities as committee members in the public interests, and that they should not permit their employment to impair their independence in the exercise of their duties as committee members.

Dr. Osinaga With that, we can go to the next slide.

Dr. Osinaga The Cardiac Advisory Committee has been asked to do two things related to cardiac catharizations and ambulatory surgery centers. I just wanted to frame that for you today. The first thing they've been asked is to present to you the Health Planning Committee and an education session, and that's today's section session. We'll discuss what I went over in the agenda slide. And then the other thing is that the committee has also been asked to make recommendations to the state related to patient selection, so case selection program requirements and monitoring, including quality and safety considerations. If the state were to move ahead and put cardiac catharizations, allow cardiac catharizations in ambulatory surgery centers. This is something we will not discuss today. This is something we still haven't concluded.

Dr. Osinaga If we go to the next slide, I wanted to give an update on where we were on this.

Dr. Osinaga We have started these discussions. We have a work group of Cardiac Advisory Committee members who have started these discussions, and they've already met.

Ms. Monroe This is Ann. Peter Berger has said that the slides aren't visible to him. Should they be? The answer to the should they be is yes.

Dr. Berger Oh, it must be me. Okay, so then I'll figure out what I'm doing wrong and keep going. Sorry for the interruption.

Dr. Jacobs Peter, I think you have you have to click on the top where it says Dr. Heslin's slides.

Dr. Berger Thank you, I'll find that.

Ms. Monroe Thank you for asking.

Ms. Monroe All right. Sorry to interrupt you, Alda.

Dr. Osinaga We have met twice with our work group. Our work group is formulating a proposal of recommendations that they will present to the full committee, right? This work group is a subset of our committee members. Our next full committee meeting is coming up. It's on November 3rd. We'll discuss the proposals from the work group at that time. Our hope is that we'll be asking the full committee to finalize the recommendations to the state by the end of this year. Again, this is something that we're doing. We just have not come to the conclusion yet.

Dr. Osinaga We can go to the next slide.

Dr. Osinaga This is a list of our work group members who have been discussing this. You will see that our two speakers today, Dr. Jacobs and Dr. Naidu are on this. You can also see that Dr. Berger, who has joined us, is also one of the work group members. I believe that is my last slide.

Dr. Osinaga If we go to the next slide.

Dr. Osinaga It is. So, I'm going to hand it off to Dr. Alice Jacobs. As I said already, Dr. Jacobs is the Chair of our Cardiac Advisory Committee. She's also the Emirist Professor of medicine from Boston University.

Dr. Osinaga With that, I'm going to hand it over to her to begin her presentation.

Dr. Jacobs Thanks very much, Alda.

Dr. Jacobs It's a pleasure to be here and to have the opportunity to review with you what is known about the PCI or percutaneous coronary intervention in ambulatory surgery centers.

Dr. Jacobs Next slide, please.

Dr. Jacobs While the evidence base is not robust, we can review and extrapolate, I hope, from relevant prior clinical studies. So first would be the emergency and elective PCI at hospitals without surgery on site and what we went through years ago thinking through that. What we now know about same diet same day discharge PCI, the safety of that. And then finally, there are two studies of elective PCI in ambulatory surgery centers. In thinking this through, in the early days of PCI, the complication rate requiring emergency bypass surgery when it all started was from 6 to 10%. Over the years, with the advent of new technology, particularly stents, so drug eluding stents and bare metal stents, and then anticoagulation regimens, the need for emergency surgery for a complication during the procedure dramatically decreased. Currently, it's less than 1%. In addition, around that time, there was an increasing performance of primary, what we call primary PCI, and that's PCI for patients having heart attacks. That was increasing in frequency because it was shown that that's the preferred therapy to decrease the size of the heart attack and decrease mortality. The issue was at that time there are about 5,000 acute care hospitals across the country, and only about 1,300 had cath labs, and not all of them had on-site cardiac surgery. The question arose would it make sense now that the emergency rate for needing surgery is so low to perform these procedures in hospitals without on-site surgery? It was first looked at for the emergency PCI, so patients who are having heart attacks, and that made some sense because time is so critical there. The faster you open the artery, the lower the mortality and the better the heart function. It was shown in some randomized trials and smaller studies that you can perform for emergency PCI for these heart attack patients safely in places without onsite surgery. The next question was well, can we extend this to patients who are elective? Can we do that safely? Does it make sense to do that? The thinking was that since the number of patients undergoing the emergency PCI was so small at these sites that if you added the elective PCIs, the volume would increase, and you could probably increase the robustness and the quality of the program. There were two randomized trials.

Dr. Jacobs Next slide, please.

Dr. Jacobs May I have the next slide?

Dr. Jacobs Thank you.

Dr. Jacobs The cardiovascular patient outcomes research team non-primary PCI, the C-PORT Trial. This was trial that was performed between 2006 and 2011 in sixty hospitals across ten states across the country in 18,000 patients. They were randomized three to one. Three to one, three in these hospitals without on-site surgery. There were co-primary endpoints. One was mortality at six weeks, and the other is a term which you'll learn from these slides called MACE, which is major adverse cardiac events. In this study, those events were death, heart attacks, myocardial infarction, and target vessel revascularization, the need for a repeat procedure.

Dr. Jacobs The next slide shows the clinical status of the patients with no on-site surgery compared to on-site surgery. You can see that only the only significant difference was a slightly higher incidence of urgent and emergency procedures in the on-site surgery patients, but everything else was similar. The clinical characteristics and the risk factors were also similar, with the exception that the patients who had no on-site surgery, their procedure in those hospitals had a slightly but significantly higher incidence of prior heart attack.

Dr. Jacobs The next slide shows the outcomes at six weeks and nine months. This is the primary outpoint at outcomes. And for this type of study, when there is an effective therapy, it's not thought to be the best way to do it to compare to placebo. You're comparing the two procedures at the two different types of hospitals. The design, the statistical design is a non-inferiority design. If the p-value is significant, that means it's significant for non-inferiority. You can see that the one primary endpoint, death at six weeks was 0.9% versus 1%, and that had a significant p-value, so that was non-inferior. If you look at the bottom of the slide, the major adverse coronary events at death at six at six weeks, so all combined, also the p-value was significant, so that was non-inferior. The only endpoint that was different was target vessel revascularization, which was higher at the sites without onsite surgery. Hold that thought because you can sort of see a signal here in a trend in subsequent studies.

Dr. Jacobs The next slide shows the events now. These are not the primary endpoints, but the events in six weeks and nine months. Interestingly, there was a higher incidence of coronary artery bypass graft surgery at the sites with on-site surgery. The investigators hypothesized that it was confounded by the fact that patients who didn't undergo the index PCI and then had a bypass surgery, that was considered a target vessel revascularization. We can hypothesize why that was higher at sites with on-site surgery, but easier to do and maybe more complicated. I think we just have to think that through. The only other significant difference was unplanned catheterization and any subsequent revascularization, again, higher at the no on-site surgery hospitals. We need to keep thinking about that.

Dr. Jacobs Next slide, please.

Dr. Jacobs The second trial was one that we performed in Massachusetts. It was called the MASS COMM Trial. This was performed between 2006 and 2011. 3,600 patients also randomized in three to one fashion with threefold at hospitals without on-site surgery. The co-primary endpoints were MACE at thirty days and twelve months. MACE was a combination of death, heart attack, repeat revascularization, so repeat procedures and stroke.

Dr. Jacobs The next slide shows the design of the MASS COMM trial. Patients undergoing just diagnostic coronary angiography at a hospital without on-site surgery was randomized three to one. It was stratified for diabetes, which is a risk. There were ten sites without on-site surgery and seven sites with on-site surgery.

Dr. Jacobs Click again, please.

Dr. Jacobs The exclusion criteria are shown here. These are really similar to all of these studies. We exclude high-risk patients. Patients with a reduced heart function, a left ventricular ejection fraction that was low. High-risk lesions. This is just the list of them. Unprotected left main, that's the artery that the main artery that feeds blood to the heart and other devices. If you have to perform the procedure in a vein graft that a vessel that was already bypassed, and then in a vessel that's serving the only myocardium that's alive. All those patients are excluded, and that's similar to in all of these trials. These are low-risk patients that are selected for these procedures at hospitals without onsite surgery.

Dr. Jacobs The next slide shows the outcomes.

Dr. Jacobs This is MACE at thirty days. This is our safety endpoint, comparing no on-site surgery to on-site surgery. Again, so this is non-inferiority, and you can see that the P-value is significant. 9.5% versus 9.4%, no difference. The components of the thirty-day endpoint, the death, myocardial infarction, repeat procedures, and stroke also no significant difference.

Dr. Jacobs Next slide, please.

Dr. Jacobs This is similar at 12 months. Again, the non-inferior P-value is significant. There was no difference between the two types of hospitals and no difference in any of the components of the endpoint.

Dr. Jacobs Next slide, please.

Dr. Jacobs This trial is from our own New York State Registry by Ed Hannon and several of us who are on the committee worked on this study with him. This was between 2013 and 2015, and 7,600 patients, only 14% of whom were had their procedures performed at hospitals without on-site surgery. Ed did propensity matching of the patients. You can see what the risk adjusted outcomes are. The observed mortality rate and the adjusted odds ratio and looking at in hospital and thirty-day mortality between the two groups, two-year mortality and two-year TLPC is target lesion PCI. That's repeat procedure of the same lesion, same vessel, no significant difference.

Dr. Jacobs Next slide, please.

Dr. Jacobs What do we know? I think summarizing those charts, those studies of no on-site surgery, it seems that outcomes are similar and carefully controlled studies evaluating low risk patients. A little bit of a signal for repeat procedures that we have to think about and watch. Now, what do we know about discharging patients on the same day? That's what this study asked. These are patients in the NCDR registry, which is between 2009 and 2017, there were 1,700 hospitals and over 800,000 patients, 14% of whom had same-day discharge.

Dr. Jacobs Next slide, please.

Dr. Jacobs What they clearly showed was the rise, the temporal trends and the rate of same-day discharge following elective procedures, again, because the procedures with new technology, new anticoagulation regimens, the complication rates had decreased, particularly among patients who now had their procedure performed through the radial artery, the artery in the wrist, rather than the femoral artery, the rotary artery and the groin. You can see that this spike, if you will, increases even more after CMS passed the two-midnight plan, where patients had to be in two midnights to be considered inpatients. Apologize for my laryngitis. What they investigators also showed looking at both groups of patients, despite this rise in same day discharge. Interestingly, both groups of patients had higher risk factors. They were older. They had more comorbid disease. It was a higher risk group.

Dr. Jacobs Next slide, please.

Dr. Jacobs In 2,000 patients that they could link to CMS. This is the Medicare population. You can see the age is a bit older. Mortality was low. It was 0.2% in both groups. This shows the patient characteristics by discharge among patients with thirty-day mortality. These patients who died, these were their characteristics. There were really no difference in these clinical characteristics between the patients that were discharged the same day versus patients that were kept overnight.

Dr. Jacobs If you look at the next slide, interestingly, it's similar. This is the characteristics by discharge status among patients with thirty-day rehospitalization. There's some significant p-values there but shows that the same-day discharge patients actually were sort of lower risk. They had less prior congestive heart failure, less peripheral vascular disease, a better ejection traction, so better heart function, more radial access, no surprise. What they showed was that over time, the mortality, despite the fact that same-day discharge was going, was increasing didn't really increase, but the rate of rehospitalization decreased over time, and that decreased faster in the same-day discharge group. It seems like, and again, carefully selected patients, same-day discharge has been shown so far to be safe. I think the thing that really has helped that is the radial artery access site. These two studies, the next two studies are the two studies in PCI and ambulatory surgery centers. This was presented by Dr. Dangus to you in July. I know you are aware of this, so I will just briefly go through it because it's one of the two studies we have.

Dr. Jacobs Next slide, please.

Dr. Jacobs This is the patient selection that was taken from the advisement of the Society of Cardiac Android and Interventions, which is referenced there. The patients evaluated for ambulatory surgery cite PCI by an experienced operator and then they go through the checklist. Do they have adequate social support? If no, you have to be deferred to a PCI hospital. High risk clinical features, yes, you go to the PCI hospital. If the anatomy is not known, you get your diagnostic angiography. If it is and it's complex or high risk, you go back to the PCI hospital. That's if all those things are no, no, no, no, you proceed to ACS PCI.

Dr. Jacobs The next slide shows their methods. I think you've seen this. They had 100% sample of the Medicare carrier. What they decided to do is they this was between 2018 and 2022, and they decided to exclude patients before 2020 when the CP codes were not

reimbursed. That's when Medicare decided that they would reimburse PCI and ACS hospitals. The patients were divided, and they looked at these thirty-day outcomes.

Dr. Jacobs Next slide, please.

Dr. Jacobs These are the clinical characteristics. Again, these are standardized mean differences, and that means if the value was over 10, then that's significant. The patient population was a bit different. There was prior MI within one year was lower in the ambulatory surgery center patients. The peripheral vascular disease was actually higher. Prior inpatient visits was one year was lower. The performance of atherectomy in these other more advanced procedures was lower, as you would expect in the ambulatory surgery center.

Dr. Jacobs Next slide, please.

Dr. Jacobs Interestingly, the thirty day, these are the absolute event rates are actually slightly lower or not higher in the ambulatory surgery center, with the exception of repeat procedures. Again, that repeat procedure issue was significantly higher in the ambulatory surgery center.

Dr. Jacobs If you look at the next slide, now these are the adjusted rates. You can see that all cause admission and myocardial infarction, so heart attacks were significantly higher in the outpatient center than in the ambulatory surgery center. But again, repeat PCI at the bottom significantly higher in the ambulatory surgery center. There's a signal there that we need to think through.

Dr. Jacobs The next slide shows the other study that's been published on elective percutaneous intervention in these centers. This was performed between 2007 and 2016. This was from commercial insurance claims and Medicare supplements. The primary outcome was at thirty days again, a combination of heart attacks, bleeding, and hospital readmissions. Here's their flow diagram. You can just concentrate on the right side because that's where the outpatients are. You can see the exclusions that are listed. When you get down to 163,000 outpatients, they excluded again because you we do this on low-risk patients, so patients with an MI or an acute coronary syndrome within ninety days, or if they had perennibas surgery on the same day, they got down to 96,000 outpatients, and then they propensity matched the 849 who had their procedures performed in ambulatory surgery centers.

Dr. Jacobs Next slide shows their outcomes.

Dr. Jacobs I'm sorry, the next slide shows the balance of outpatient and ambulatory surgery center patients before and after propensity matching. Again, if it's higher than 0.1, there's a significant difference. Once they propensity match the patients, they're all less than 10%. You can see by age, you know, comorbidities of prior stroke, COPD is pulmonary disease, hypertension, diabetes, heart failure, all of these things, kidney disease, vascular disease all match. These are the same type. It's close as you can get to the same patients.

Dr. Jacobs The next slide shows their outcomes.

Dr. Jacobs This is at thirty days. You can see that the P-value is only significant for bleeding complications. This is bleeding complications, its vascular complications, it's

hematomas, it's bleeding at the access site. That was the only signal that they saw that was significantly higher in the ambulatory surgery center. They didn't have mortality.

Dr. Jacobs In the next slide, just where how do we put this all together? What are the evidence gaps? Well, you can see that we don't have prospective randomized trials. We don't have much in long-term outcomes beyond thirty days. We also need patient reported outcomes in Medicare, vulnerable populations with all payers. That's something that will be of interest.

Dr. Jacobs My final slide shows what else do we need to know? We will be, as you heard, making recommendations on behalf of our whole committee, the Cardiac Advisory Committee on Patient Selection Criteria and Program Requirements. I think we have to be careful and really think things through. While I suspect we all agree that mortality is the most important endpoint, mortality is very low in elective PCI. It's very hard to show a difference between sites unless you have a massive, massive study. What we have to be concerned about is the optimal treatment strategy being that's recommended by our guidelines. Are patients receiving that? What about the heart team when there are no surgeons? We have to really think through, particularly since we don't have long-term outcomes. That's much harder to evaluate. So more to come on that. Thanks very much.

Dr. Rugge Thank you very much, Dr. Jacobs. This is a great review, and I very much appreciated how you went through it, going through the historic, even the ones that you did, which were amazing studies that moved us forward in the way we've functioned and also the more recent stuff. I think your clarifying comments at the end are very telling and are appreciated.

Dr. Rugge In terms of the committee, are there any clarifying questions, Dr. Lawrence or Dr. Eisenstein?

Dr. Eisenstein Sure.

Dr. Eisenstein Thanks, Dr. Heslin.

Dr. Eisenstein Thank you, Dr. Jacobs.

Dr. Eisenstein I'm Dr. Larry Eisenstein, member of the council. I really appreciate that presentation. There was a lot, and I look forward to having more time to really look at it. You know, as committee members working on regulation, of course, we want to make sure we're doing what's in the best interest of the people of New York State, our residents. You started your presentation by making an interesting comment, which you kind of clarified at the end, which is the evidence is not robust. You presented interesting evidence. That kind of matches what we've heard at the hearing, the last meeting, where we heard both sides of this discussion. I had asked a very similar question to Dr. Osinaga at a prior meeting about do we have significant evidence? Dr. Osinaga gave similar answer to you that I don't remember the exact wording, but it was similar. Correct me if I'm wrong on that, Dr. Osinaga. I think it was similar. I guess my question is, I'm trying to come to grips with how to help this committee move forward. It sounds like cautious optimism. I don't want to put words in your mouth, but that's kind of how it sounds. Even in cardiology, as I've stated before, cardiology has been based on some of the biggest clinical trials of all time. My question for you is does it make sense for us to take a cautious, studious approach as we move forward rather than just something grand and big? Is something like a study period or something similar makes sense for this?

Dr. Naidu Do you guys' mind if you go through the presentation before we have discussion? It's going to be the same topics, I think.

Dr. Heslin Yeah, I think that Dr. Naidu has a patient. We want to make sure he gets through before we get to the discussion. I do want to remind people that the questions that are allowed in education sessions are clarifications of the presentation, not the opinions of the people that are presenting. This is education. This is not an open meeting in terms of wide discussion topics.

Dr. Eisenstein My apology.

Dr. Heslin No, no, that's fine. I wasn't clear in the beginning. I put it in the chat, but I do want to make sure because otherwise we'd all be in person sitting in a room and that would be more difficult to do. This is really education. We can take all those questions, and we can get answers to them as we're going through. Thoughtful questions are good. We're going to have our session on November 12th to be able to discuss all these things and then get answers to them as well. I do very much appreciate Dr. Jacobs.

Dr. Heslin We're going to turn it over to Dr. Naidu now, and I'll try to do a better job with the slides this time. I do apologize.

Dr. Rugge A quick comment for you, Larry, and all of us to write down these discussion points that we should be sure to talk through at our next meeting. And also, just to say I'm certainly impressed that rather than dealing with hundreds or thousands of people and comparing outcomes. It's hundreds of thousands. We're certainly well along our way in terms of doing reliable studies for reliable information that we all need.

Dr. Rugge With that, I guess we're moving on to Dr. Naidu.

Dr. Naidu Thank you.

Dr. Naidu It's a pleasure to be here presenting and educating about this topic that SCAI has been involved in for some time. I think we knew this was coming, and certainly in 2020, we provided guidance on this, and we're in the process of updating this. about every five years or so we have an update. Writing committee is already engaged to try to look at this topic again. There may be some additional information documents in the coming year.

Dr. Naidu Next slide.

Dr. Naidu This is the writing committee that did this in 2020, right during COVID.

Dr. Naidu Next slide.

Dr. Naidu The overall opinion of SCAI was that performance of PCI in the ambulatory setting was overall acceptable. The complication rate for PCI seems to be extremely low in the current era. We do know that, and therefore the performance of PCI in ASCs does seem to be reasonable. We acknowledge the potential benefits of cost reduction and increased patient satisfaction. As you already heard here today, there's potential unanticipated cost increases and other issues that could come into play, such as, for example, the repeat PCI that you heard. We have to dig into why that may happen. Sometimes it could be things like if you're in an ambulatory center, there might be more

incentivization to do more PCI than if you're in a hospital with other guidance. Some of the things that you see in the trials you may not see in the real world setting where there's less oversight and all these other avenues of creep in terms of why people may want to do a procedure and whether it's less oversight. That's why a lot of the discussion entails a lot of oversight, quality assurance and who's watching these centers to make sure that they're approaching patients in the same way that you approach them in the hospital setting with more oversight and surgeons involved as well.

Dr. Naidu Go back again.

Dr. Naidu We emphasize that standards for care, including available emergency equipment and QA should mirror the hospital's setting because even though these are low risk, the same types of catastrophic complications can happen. You do need to get these patients to the next setting. You do need appropriate types of care for that, appropriate equipment and rehearsals for that. We did recommend restricting procedures to relatively healthy patients and avoiding complex lesions that you heard a little bit about already.

Dr. Naidu Next slide.

Dr. Naidu We also updated this document in 2023. This is a complementary document on continuous intervention without on-site surgical backup. We continue to emphasize at this time that the same standards should be in the ASC setting as in the hospital setting for a quality standpoint, but there was more emphasis also placed on physician judgment and case selection because this seems to be the most important part. All the data that Dr. Jacobs showed is heavily case-selected patients. That's why oftentimes the incidence of complications is actually lower than might be expected because clinician judgment on who's going to be low risk and who's going to have low complications is actually quite good. That's a big part of the puzzle here.

Dr. Naidu Next slide.

Dr. Naidu You already went through this. I'm not going to go into it in too much detail, although we will go over some of these tables. In general, this is how you kind of weed in the patients that would be appropriate for the ASC. She already went through this, but social support is a big one. Does the patient have rides home? Is there an ability to check their access site to make sure there's no bleeding? Are there complications? Are they taking their medications? These are all things that we can more or less assure in the hospital setting by educating them the next morning or later in the day with a lot of nurses who have a lot of experience but may not be as prevalent in the ASC setting. Then do they have clinical features, anatomic features, and finally lesion features? Some of these you may not know until you do the elective angiography, but then you have to be able to take the patient off the table and decide that the patient is too high risk to do in that setting. These are all things that have to play into safe performance of PCI in the ASA.

Dr. Naidu Next slide.

Dr. Naidu I'm going to go through some of these. This is the ambulatory surgical centered PCI performance checklist. These are pre-scheduling assessments. This is the social support, access to follow-up care and case selection. Do they have transportation after the procedure? Some of these patients get an anesthesia, sedation, so they need to be accompanied back home and probably shouldn't be that far away from the center. Do they have adequate social support at home, adequate caregiver at home the evening of

discharge to make sure that that person can handle any bleeding complications, make sure the patient's taking their medications, which is very important to maintain patency of the stents or no problems with the stents. Patient resides or stays in close proximity, so within thirty minutes to a hospital capable of providing emergency care for complications that could occur after discharge. No unfavorable patient clinical features or PCI indications, no known complex high-risk anatomy, and patient fully understands plans for PCI and same-day discharge, that what this really means is that we are extending a lot of the care and a lot of responsibility to the patient themselves. If you're going to do it in ASC and they're going to go home that day, those patients really are taking over a lot of the responsibility to make sure that the rest of the PCI goes well.

Dr. Naidu Next slide.

Dr. Naidu These are patient conditions warranting PCI deferment to the hospital setting. We know from lots of retrospective data that there are clinical features that have a higher risk of STEM closing up or complications or bleeding risks or renal failure, all these things that can happen after PCI. Anybody with heart failure, more advanced heart failure, any recent stroke or mini stroke in the last eight weeks, anybody with heart failure or congen or a decreased heart function of less than 30%, anybody with chronic kidney disease, low blood count to begin with because they can't then tolerate any more bleeding if that's the case. Anybody who's on blood thinners because they bleed more commonly. Anybody who has more of an acute syndrome, we're talking about elective PCI. Anybody who you might think it's actually more of an urgent PCI, and this can be a little bit of a sliding scale because people who have chest pain over the last couple of days or a couple of weeks... Is that really elective or is that acute? There's some clinical judgment there about whether the patient may have an acute syndrome because acute syndromes tend to have more clot and tend to have more recurrence of events even after the PCI. That's important clinical decision. Anybody with lung disease or pulmonary hypertension, people with bad lungs or on oxygen therapy. Any anatomy of unprotected left main or three vessel coronary disease, cardiac or non-cardiac signs or clinical instability, so that can be arrhythmia, atrophibrillation, or any type of heart failure or swelling. Significant peripheral disease, because this increases the risk of bleeding or problems with the leg, where you may need to have emergent surgery to fix a leg that has a complication from the PCR, even the radial pulses as well. Severe valve disease in aortic stenosis, that might that is obviously a type of heart failure. Contrast allergy, which would be very hard to treat in an outpatient setting, and certainly anticipated or unclear contrast allergy would be one. Operator judgment on any other condition that they might think makes the patient higher risk.

Dr. Naidu Next slide.

Dr. Naidu These are lesion characteristics, and I know this is harder for people who don't do this for a living, but there are things in the arteries themselves that make PCI harder. In fact, there's a whole class of interventions called high-risk interventions. We call it CHIP or CTOs. These are interventions that not all interventionalists do. Some lesions are much more challenging than others. The more challenging they are, the more chance there is for clot developing in the arteries or complications such as a tear in the artery or perforation, which is a hole in the artery that can cause bleeding around the heart that could be a medical emergency. One is when there's a fork in the road in the arteries, such as what we call a bifurcation lesion, where both with now a larger territory of muscles involved, and you oftentimes have to use two stents, multiple different wires, and so it's more complicated procedure with a higher chance of something going wrong. Severe lesion

calcification. So, most arteries are healthy and flexible, but if they're very calcified, they kind of move like bone, which is that they don't really move very well. It's harder to put stents and wires and all these other things down the arteries. Those are much higher risk factors and require other types of things, like as you heard, like atherectomy or laser or other types of lithotripsy. Angulated segments or excessive proximal tortuosity, so harder to get to those lesions, and if it's harder to get to, there's more complications. Bypass graft lesions. People who've had coronary bypass, so these are veins from the legs that are transported to the heart. These graphs tend to be more complicated and more risk of thrombous forming or what we call no reflow, where after you put a stent in, all of a sudden that whole territory of muscle has trouble with clots. These can be much higher risk patients that should not be done in the ASC setting. Chronic total occlusions, these are where you have a complete blockage and that area of muscles getting some blood flow from other arteries. As you can imagine, that means there's more in jeopardy. Other vessel characteristics that we might feel would make it hard for the stem to get down there, clots in the arteries, unprotected left main. This is the main artery, which basically means that you're jeopardizing too much of the muscle to try to do a PCI there in an ambulatory setting. Because if anything went wrong there, typically those patients would arrest or have a major heart flare or require intubation. That should not be done in the ASC. Last remaining conduit, that's a term for when, for example, most of your bypasses are gone or there's just one artery left that's feeding the entire muscle, that would mean that the PCI is being done in one critical location that jeopardizes the whole heart. That shouldn't be done there as well. Any situation where you might have to use a balloon pump or something called an impelled device, these types of devices that help the heartbeat or push blood forward out of the heart. Anytime you're thinking about that you might need some kind of support for the heart... Certainly, that's too risky of a patient.

Dr. Naidu Next slide.

Dr. Naidu In terms of facilities, this is also important too, that the cath lab is designed in accordance with the industry standards. There are guidelines for this, and SCAI has these, and ACC has these as well, and New York State, of course, does as well. Staff should have appropriate training and credentialing. These are probably not fresh graduates of tech and nursing and ICUs and whatnot, but people who have significant experience that they can transport to the ASC and then transfer protocols. On the right here, we have the key features that an ASC program has to think about pre-procedurally, procedurally and post-procedurally. You guys can read through this at your leisure. Some of the big things are in the procedure, ability to look at the films and make a decision with the surgical colleagues from your home institution or the associate institution about whether the patient should get a PCI or not. We've lived through the situation where if... You know, although everybody tries to be as ethical as possible... When the patients on the table no patient wants surgery oftentimes. There's a slippery slope of the international cardiologist trying to do what they can at that situation, even if it might be better to send the patient to surgery. And so, especially when surgery is not on site, and we dealt with this at hospitals without surgery on site, we worry about inappropriate PCI or excessive PCI in the patient that might otherwise get a benefit, a long-term quality of life and quantity of life benefit from surgery. These are the types of things that have to be addressed in the ASC setting.

Dr. Naidu Next slide.

Dr. Naidu Another thing that came out of the more recent guidance was this issue of operator standards and experience. Interventional cardiologist is a substantial experience that we define as experienced or very experienced here on the right. In general, we don't

recommend that people with less than three years of experience are in ASC settings and people with limited exposure atherectomy and limited STEMI and shock experience, because if anything does go wrong, you need people kind of that's old hat for, as opposed to people trying to invent that wheel at the point of care when they're in a fresh out in a situation that doesn't have all the resources of surgery at their beck and call. Those people should be avoiding ASCs at that time. Other people who we recommend would be an annual PCI volume of fifty PCI. These are more experienced people, three or ten years or longer out in their career and have significant experience at a hospital center with surgeons on site. They know kind of what patients should go for surgery and what patients can stay for the ASC. I'm more experienced, not just technically but also cognitively about the indications and contraindications to PCI.

Dr. Naidu Next.

Dr. Naidu The assurance standards are PCI and ASC should be performed with the same expectations for quality as in the hospital. The quality program must be in place to evaluate procedure appropriateness at the time, technical performance and assurance of quality of care.

Dr. Naidu Next slide.

Dr. Naidu Participation in a registry, obviously it's a New York registry that's specifically designed or modified for the ASC setting will be necessary for ongoing quality assurance, and data should be used to monitor PCI operator institutional volumes, outcomes, and procedural appropriateness. I would highlight the last part, which is are they doing oftentimes the least appropriate procedures are the least risk. It's oftentimes buried in it that the outcomes are so good, but it's still maybe highly inappropriate. These are the things that we want to make sure are not happening as we try to improve access.

Dr. Naidu Next slide.

Dr. Naidu Just one slide on ethical considerations. I alluded to them in in one regard in terms of doing the appropriate patients and the slippery slope of repeat PCI and whatnot in an ASC setting versus in the hospital setting. Obviously, these other considerations are there in terms of financial, which is remuneration and desire to do more in the ASC or getting pressure on that. I think these are some of the concerns that I think as a society we were concerned about as you do ASC. One of it is the quality, but two is a slippery slope that you may not realize until later. We do need to watch for these types of things.

Dr. Naidu Next slide.

Dr. Naidu The current position is supportive of laws that allow the performance of PCI in the ASC, but that the expectations for quality are the same as the hospital setting, safety equipment, utilization of adjunctive technologies such as intracoronary imaging and physiology should not be less. Quality assurance program tied to the referent hospital. I think there should be some oversight to make sure in auditing of these prones to make sure that that they're doing the appropriate patients and they're not doing excessive PCI as opposed to surgery, or they're doing PCI that would not be considered appropriate in a hospital setting, and or maybe not indicated in a hospital setting. Low-risk procedures that otherwise could be treated medically, for example. Patient selection is important. Encourage the avoidance of high-risk patients' procedures in the ASC, emphasizing position judgment.

Dr. Naidu Next slide. I think that's the last slide I had.

Dr. Naidu I think overall, you know, SCAI is very supportive. We trust our members to make the proper decisions, but the system can have inadvertent consequences, and that's what we want to make sure are addressed as this is rolled out.

Dr. Heslin Thank you, Dr. Nadu.

Dr. Rugge We'll hesitate on questions until the final presentation.

Dr. Heslin I was going to pause for a second because I know Dr. Naidu has a time limit to be out of here to treat a patient at a sharp stop. I was wondering. There's one question I think for Dr. Naidu in the chat from Ms. Monroe asking if there you distinguish between diagnostic catheterization and PCI.

Dr. Naidu Yeah, so in the document it was about PCI, but I know that this committee, of course, is engaged in the discussion of diagnostic overall. I think diagnostic the bar is lower, of course, in that for some of these things, if they have clinical instability, you know, all of those aspects probably should not be done PCI, but you can do the diagnostic cat still. I think if they're instability, obviously you can't. Anything else, I think this approves diagnostic angiography. If those other characteristics come up, it informs a discussion about PCI, those patients would move to the to a hospital setting for the PCI.

Dr. Heslin Thank you.

Dr. Heslin Dr. Lim has a clarifying question.

Dr. Lim I do.

Dr. Lim Thank you, Dr. Naidu.

Dr. Lim This was brought up in the hearing a few weeks ago where many people stated that this was important to expand it out to ASCs for access. I was struck by both in your presentation and in Dr. Jacob's presentation that in as part of the selection criteria, like the first one is adequate supports at home. My concern is that not all, but many people who have Medicaid or some of the Medicaid expansion plans may not have those kinds of supports. They're automatically not eligible. Are you familiar with any data in other states were expanding to ASCs actually did have an impact on expanding access to Medicaid? If you happen to know, because I asked the same question at the earlier hearing.

Dr. Naidu Alice, do you know?

Dr. Jacobs There are where a couple of studies that showed that there was a higher proportion of patients, you know, the social determinants of health, that they had lower social determinants of health. On the studies that I presented, I think also their in... It's interesting in the hospitals without surgery on site, there was a lower prevalence of white patients. I think this maybe expands access to patients, the Medicaid type patients. There's that suggestion. I think that's an interesting question. The social vulnerability index, I think that was in the Dangus paper that showed that that was higher in the ambient surgical centers.

Dr. Lim I'll read that.

Dr. Jacobs Yeah, so I think that's an important question. Thank you.

Dr. Naidu I do think that so it probably does improve access to a certain extent, but you're probably also right that it also improves access to people who probably could have just gone to the hospital too. It's not such a big inconvenience to them because they are they're commercial, they're also they have support and it's just more of an inconvenience rather than access. I think that is something to look at, which is how much of this is improving access and how much of this is improving inconvenience, especially in a state like New York, right?

Dr. Heslin A question for Dr. Nadu. Is SCAI going to have recommendations about diagnostic catheterization as well as PCI in this next version as part of their write-up?

Dr. Naidu Yeah, I think we will have to make that distinguishing factor on what's good for diagnostic versus PCI, because I think it wasn't something that we thought about previously as we were focusing on PCI.

Ms. Monroe Dr. Berger has a question.

Dr. Berger Harry, I have a question for you. You reviewed, if I caught it correctly, the requirement that patients be able transferred to a receiving hospital in one hour. Is that what it said? One hour?

Dr. Naidu Correct.

Dr. Berger Has SCAI, or do you personally think it optimal to go beyond that and talk about the time to which it would take a patient to get in a cath lab or an operating room? Because as everybody listening should be aware, some hospitals are good, some are medium, and some are awful about the time by which they receive an emergency, and they are ready to operate or perform a cath procedure on that patient. Optimally, we wouldn't be talking about time to the front door, we would be talking to about time to treatment in a cath lab or operating room. Your thoughts?

Dr. Naidu I think you're absolutely right. It's similar to time from chest pain to PCI and these types of things. Oftentimes, it is the transfer time that you can operationalize from a system standpoint. And then the onus is on the hospitals to strengthen up and tighten up their quote unquote door to balloon time or door to the OR time at that point.

Dr. Heslin I'd like to point out that hospitals without surgery have that same obstacle as hospitals as this potential. I do want to recognize Mr. Lawrence, who has his hand up.

Mr. Lawrence Thank you.

Mr. Lawrence Harvey Lawrence, member of the council. I just want to get back to the, I guess the question that Dr. Lim raised in terms of access. As I was sitting, I was and again the whole issue of needing support to access the ambulatory surgery. Then that presents a problem, I guess, in terms of low-income people and people that don't have those support. But also, my question is what the impact on the overall system in terms of the cost is and also in staffing. I would assume that this is a procedure that's available in an ASC, that at some point it becomes a pretty lucrative practice as for group practices and

for physicians to form those practices, and that at some level they will move from institutions or institutions will have their own set of physicians that are working for them. This will impact on some of the safety net hospitals in terms of staffing and also impact on the potential cost of delivering.

Dr. Heslin If you do have a clarifying question about the educational session, then please ask it. If it's going to be a long discussion, then that's not appropriate for this session. It needs to be in the open session that would be on November 12th.

Mr. Lawrence I could respond simply by w has there been any modeling on the impact, the potential impact of this change in terms of staffing or cost to the overall delivery system?

Dr. Naidu As far as I know, no, but these discussions have happened, which is that if you do shun some of the PCI to an ambitious center, how does that impact the hospital? We've thought about all those things. It hasn't been as far as I'm concerned, a systematic discussion of the cost of that and how it impacts those hospitals.

Dr. Heslin One final question before you leave. This also goes to Dr. Jacobs. When the quality comparison is done between inpatient settings and ambulatory settings, does that on the inpatient side exclude those very high-risk patients who would have higher rates of complications? Is it comparing both populations?

Dr. Naidu Alice, do you have that as from your presentation?

Dr. Jacobs The high-risk patients in all of those studies are excluded at the moment. It was that your question?

Dr. Naidu Apples to apples.

Ms. Monroe There is a question that Jeffrey Gold had asked a clarifying question.

Mr. Gold No, I just in your summary slide you didn't reference the experience level of the professional and supporting staff. I think that's a very important consideration. I'm just wondering if you'd be willing to consider adding that to your summary slide.

Dr. Naidu Yes, yes. Absolutely. I think I alluded to the experience of the staff that has to be there, and they should not be introductory staff.

Mr. Gold Yeah, sorry, you did.

Dr. Naidu Absolutely. That's a very important point.

Dr. Heslin We have less than twenty minutes for the next presentation, so it might be best to go to that and then use whatever time is available for further questions.

Ms. Cozzens Thank you.

Ms. Cozzens My name is Kimberly Cozzens. I'm the Director of the Cardiac Services Program. I have spoken to this group a couple of times in the past. Thank you for inviting us back. I'm going to share a little bit about a view of the New York State PCI registry data that we have looked at.

Ms. Cozzens Next slide, please.

Ms. Cozzens As we've discussed before, the PCIRS, or the Percutaneous Coronary Interventions Reporting System is a clinical registry for PCIs performed in New York State. It is closely audited for risk factor accuracy and completeness. We are also able to match this New York State database to other New York State data, including the statistics to have information about out-of-hospital mortality. We can match it to SPARCS, which is the administrative discharge database to look for readmissions. This is also the data that are used for our public reports of outcomes. What we've been doing is applying the SCAI guidance that Dr. Naidu just presented to our PCIRS data to try to estimate what this PCI and ambulatory surgery center cohort of patients might look like based on our data. I can share some of that with you.

Ms. Cozzens Next slide, please.

Ms. Cozzens These estimations are based on the CAC preliminary recommendations that they've been developing, which follow very closely to that SCAI guideline. Some things to keep in mind is there are some criteria that are in the SCAI documents that we've just heard about that are not available in PCIRS at this time. An example of that is severe contrast allergy. We can't say anything about patients with that particular risk factor because it's not in our data. There are also some criteria where we have to sort of approximate the SCAI qualifications based on what is in our registry data. An example of that is in SCAI, there's references to stroke or transient ischemic attack within the past eight weeks. In our registry, we just have any history of. It's an approximation. Obviously, as these recommendations are finalized, the numbers may change a little bit.

Ms. Cozzens Next slide, please.

Ms. Cozzens What we see here is we are using our 2022 PCI discharges. We're using those two guidance documents that Dr. Naidu described to say how many patients might there be eligible for PCI and acute ambulatory and ambulatory surgery centers. The first group of patients that we remove, we start out with 48,647 patients. We remove a bunch of patients that are not suitable for planned PCI or have signs of cardiac instability. Those are things like patients that have had a cardiac arrest or they're in cardiogenic shock, they have an arrhythmia, a heart rhythm problem of an acute nature. The second group that we remove are patients with acute coronary syndrome. That would be patients that have an MI with a heart attack within the past seven days before the procedure, or they have unstable angina. That's angina or chest pain related to ischemia that's new or getting worse in the past two days and it's or past two weeks. It's really limiting. It happens with ordinary physical activity, walking a block or two or going up a flight of stairs. These are the patients that really wouldn't meet those first two main criteria. You can see when those are taken out of the full set of PCI patients, we're down to almost 15,000 cases left in that bottom right-hand corner.

Ms. Cozzens Next slide, please.

Ms. Cozzens At the end, after all of these criteria have been applied, there were 5,033 patients that meet this rough approximation of eligibility for PCI in an ambulatory surgery center.

Ms. Cozzens Next slide, please.

Ms. Cozzens We looked at outcomes for these 5,000 or so patients. You can see that it's a pretty low risk population relative to all PCIs that are performed. Among these 5,000 patients, there were no in-hospital mortalities. There were five thirty-day mortalities. When we think of a combined endpoint of in-hospital or thirty-day mortality, that was .10. Those are patients that don't have a heart attack or shock but have some of those other conditions that we've eliminated from this population. The in-hospital thirty-day mortality rate was 0.80. Quite a bit higher. When we think about every PCI that's done in New York State, the in-hospital thirty-day mortality rate is 1.33. You can see this is a very selected group of patients when we apply all of these criteria. Readmission 2.64%. Some of those being readmitted for PCI, some of readmitted for cabbage. We looked at discharge to an acute care facility. In this population that we're talking about, because this is all patients, obviously, that have had PCI in a hospital that would be transferred to another hospital. That was three patients. Low rate of needing to be transferred to some higher level of care.

Ms. Cozzens Next slide, please.

Ms. Cozzens These include a number of different kinds of complications that we collect separately but have been grouped together under this any major event category. That was only .54% of patients had any in-hospital major event. Again, if we compare that to all of the non-emergency PCIs, what was reported was 1.66% of a major event. For every PCI that was done, it was just under 2% at a major event. You can see also we looked specifically, we broke out the bleeding at the PCI access site at another kind of event or complication at the access site, also quite rare. Emergency cardiac surgery or PCI, only two instances of that out of these 5,000 patients, which obviously that is in the hospital setting there would be resources available for that, although patients receiving PCI at a hospital with no surgery on site that could require a transfer to have cardiac surgery. These would be events that we would be of great interest in an ambulatory surgery center.

Ms. Cozzens Next slide, please.

Ms. Cozzens One other thing that we were asked to take a look at is that the question of what outcomes are like at centers with and without onsite cardiac surgery. Dr. Jacobs presented an excellent overview of data about outcomes at these sites, and some of that actually was generated from the New York State data. We have not done another full study on that, but we were asked to look at recent data. One of the things that we did is we looked at our most recent reporting cycle. Again, this 2022 data. We said is having your PCI or being treated for your heart attack in a center that has PCI but no cardiac surgery on site a risk factor for higher death or readmission. We saw that for mortality, having your PCI or being treated for your heart attack was not a risk factor for mortality. Patients who received PCI at a hospital without cardiac surgery on site were statistically more likely to be readmitted within thirty days than patients that were otherwise the same in terms of their significant risk factors.

Ms. Cozzens Next slide, please.

Ms. Cozzens We can see a little bit more detail about those readmissions here. We can see about 20% of 22% of patients had their PCIs at hospitals without cardiac surgery on site. 77 almost 78% were at sites with cardiac surgery. The observed readmission rate is 7.9 at hospitals without surgery on site compared to 7.34 with surgery on site. You can see we've broken down, we know a little bit about what the reason for that readmission. If they

were readmitted for a PCI or a cabbage, we know that because we're able to track that within our registries of both PCI and cardiac surgery. Cabbage being the cardiac surgery, coronary artery bypass graft surgery. There are also most of the readmissions. About 6% of patients were readmitted for some reason that was not PCI or cardiac surgery. Although, the rate of reasons other than PCI and cardiac surgery are relatively similar, 5.99 versus 5.83 between hospitals without and with cardiac surgery on site. The expected readmission rate was a little bit lower at centers without surgery on site. You can see here we have the risk-adjusted readmission rates for those two sites.

Ms. Cozzens Next slide, please.

Ms. Cozzens Just as a caveat, this is not a full-scale study of complete outcomes. There's a number of statistical analyzes that have not been done. A bit of a quick look at the numbers, as well as important markers of quality, such as in hospital complications, procedural success, and need for repeat procedures were not closely assessed. I believe that is next slide brings us to the end. Yes, thank you.

Dr. Heslin Questions will be limited to five minutes, so make them brief so we don't have to exclude anybody.

Ms. Monroe All right. Lindsay Farrell is asking if the patient's zip code of the five thousand patients identified as low risk. Is the zip code known? Where these patients live?

Ms. Cozzens Yes, we do have zip code for those patients.

Ms. Monroe Did you find a difference?

Ms. Cozzens We have not looked at that at this time.

Ms. Monroe I think that's it.

Dr. Heslin Marcus Friedrich has his hand up.

Dr. Friedrich The Cardiac Advisory Group have worked extensively on these social determinants of health with that social index. Have you looked into the difference in those groups, those who got PCI with cardiac surgery on site versus not on site? If there is a difference in the determinant index?

Ms. Cozzens It is not something that we have looked at.

Dr. Ferdinand I have a question for Kim. Bearing in mind that two members of the committee asked questions about whether access would be improved, perhaps the department has some experience that might shed a little light on that. So, Kim, when the department embarked on expanding access for PCI in the hospitals without surgery on site, was there any change in profile of those patients, specifically as it relates to perhaps insurance, Medicaid versus non-Medicaid or other markers that might indicate improved access for underserved populations? That data might provide a little insight as to whether or not ASC expansion might improve access for underserved populations.

Ms. Cozzens I don't believe that the specific question about access, I don't know that we have published data on that. Obviously, we do have the historical data, so that could be

something that the department might want us to take a look as in terms of a model from past experience.

Dr. Heslin My suggestion is that we can take that back and we can possibly bring it up at the public session when we go into discussion on November 12th, which is a couple of days away from now. But trying to stay to schedule here is going to take me a moment to flip my screen. I apologize. I'm going to stop sharing for a moment.

Ms. Monroe Well, in the meantime, I missed Howard Berliner who had a question a while ago. I'm wondering, Howard, if you can fill this gap with your question.

Dr. Berliner Yeah.

Dr. Berliner My question is in one of the first studies that we were shown, there were patients who were in the ambulatory or the non-fully equipped hospital setting who were having problems. I am assuming that those patients were then transferred elsewhere. In those cases, where did the statistics go? Did they stay with you know with the ambulatory or non-equipped hospital or did they their statistics move to the to the full hospital?

Dr. Jacobs I think that questions for me. I think it would be with the ambulatory, but I have to look at that and get back to you.

Dr. Berliner Thank you.

Dr. Jacobs I will do so.

Dr. Heslin There's two minutes to spare.

Ms. Monroe Well there's one more question we didn't address. Lindsay asked about what a about a definition of the heart team that Dr. Jacobs mentioned. Who is the heart team?

Dr. Jacobs The heart team are the cardiologists and the coronary surgeons, the cardiac surgeons. It's critically important when you have a patient with complex disease or clinical factors that those two groups discuss the optimal therapy. You can imagine that that would be limited at an ambulatory surgery center without cardiothoracic surgeons on site. Some of the requirements are that you have access, I don't know, either by Zoom or some way that we can actually speak to surgeons when the patients on the table to help plan the optimal procedure according to guideline recommendations. A very important concept and something we don't want to forget if these surgery centers start to expand.

Dr. Rugge I have to say I think all this information is very helpful as we look to design some regulatory adjustments. Very good.

Dr. Rugge Coming up next. We have a presentation by the one provider in New York that is conducting PCIs that even though they are operating within side current regulatory structures are being performed not in a full-service hospital, but in a village setting, that being Greenwich Village. There happens to be Lenox Hills Hospital. We are welcoming as two presenters, Dr. Varendil Singh and Cynthia Khan, both senior officials at Northwell Health, who have initiated this operation in Greenwich Village.

Dr. Singh Thank you very much for the invitation. I want to thank Dr. Jacobs and the other presenters. I thought they were excellent presentations. As I was watching them, I was

saying it's kind of like a bench to bedside because many of the things that the studies had recommended we do when we rolled out our center, we used a lot of these evidence-based recommendations. Thank you for that.

Dr. Singh I'll begin with my first slide.

Dr. Singh My first slide is the history of Greenwich Village Hospital. This is the agenda.

Dr. Singh We could just go to the next one, which is the history of Greenwich Village Hospital.

Dr. Singh Next slide.

Dr. Singh Northwell Greenwich Village Hospital. This is the history by dates. I'll start with 2000 2010, which is when St. Vincent's Hospital closed. As a practicing cardiologist and interventional cardiologist in New York City for the last twenty-five years, I can tell you that that hospital should not have closed. That hospital was a beacon for the downtown community. It was a real medical beacon for the underserved, especially in the Chinatown community. When that hospital closed, that community, especially the underserved and the underinsured lost their medical beacon. We've tried to fill that gap in 2014 with the opening of Lenox Hill Greenwich Village. It's the same facility we now just call Northwell Greenwich Village Hospital. That is an emergency, a freestanding ED. It was the first of its kind within our health system and probably in New York State. In 2017, we expanded that facility to include ambulatory surgery ORs. In 2019, some changes were made in the PCI regulate regulations, which allowed us to bring back what we've always wanted to bring back to that community, which is really essential cardiac care, and that is door to balloon time, what Dr. Jacobs was talking about with primary PCI. From 2019 to 2025, we did a lot of planning, a lot of thinking, a lot of investment. We opened our cath lab, which is a freestanding cath lab at the end of July. We renamed it Northwell Greenwich Village Hospital. You'll hear me call it GBH. We are a full-service facility. I'll explain to you when we will go full service because we kind of wanted to do a crawl walk-run model. I think it'll be very helpful for this committee to understand in the crawling phase of this. It's exactly what an ambulatory surgery population would look like.

Dr. Singh Next slide.

Dr. Singh What was our rationale for this PCI center?

Dr. Singh You go back to the previous slide.

Dr. Singh Our rationale for this PCI center was to give that community that it's that had lost its medical beacon, the downtown community, access to advanced cardiac care. That was really time is muscle. In cardiology, time is muscle. When you're starting to have a heart attack, the faster it's open, the more muscle you save, the better your outcomes are going to be. We know that we need to do that within ninety minutes. Obviously, it's logical if you come into our freestanding emergency room and there's no cath lab and you're having a heart attack. There's a whole process to get you to a facility. That's time, versus having a cath lab right upstairs and moving you right up. We had almost ten years of accepting heart attack patients. We realized that from the hours of 7:00am to 7:00pm, we were having a hard time making door to balloon time, transferring them out. We made an agreement with Beth Israel to be able to transfer from the Lennox Hill Ranch Village Emergency Room to Beth Israel for their cath lab so we could meet door to balloon time.

As Providence would have it, Mount Sinai Beth Israel closed when we actually opened up. We did not plan that. You could not plan that. That is the word providence. For that community, when they closed, we were able to open up.

Dr. Singh Next slide.

Dr. Singh Can you go to the next slide?

Dr. Singh When we were thinking about our planning this from 2019 to 2025, our strategy has always been in any cath lab we open with Northwell to use the extension model, not a freestanding cath lab model. Those of us that have been in New York State for a long time remember St. John's Riverside, we remember New Rochelle Hospital. These were freestanding cath labs that did not do very well. What we try and do is open up a facility as an extension. Brench Village Hospital is an extension of the Lennox Hill Hospital, which is an extension of Northwell. That's very, very important because what that does locally, regionally, and system-wide is ensure best outcomes. If you look at our operators locally, they are experienced and very experienced. In fact, one of the national clinical masters is the director of the lab and the Chief of Cardiology there. Our nurses, which I thought was a very good point somebody made, right? It's not just the physician team, but it's the nursing team, the ACP team. These are all of our nurses that trained and worked at Lenox Hill Hospital and are very experienced in all the entire spectrum of care of cardiac disease. Those were the people that were moved downtown. On a regional level, because it's an extension, we all of our QAQI is done on a regional level with all of our hospitals that live within our regions. We do a monthly Zoom to review QAQI. On a system level, every cath lab has to attend the PCI task force, which I think is probably the most beneficial thing in our integration because we are truly an integrated health system. They meet the only requirement is you got to check your ego at the door. You basically learn from each other, and you roll out new technologies and you make QA QI protocol decisions. That was our entire strategy here. When I think about this, how did this really lead to really good outcomes? That's what we were thinking. I was thinking like, you know, we've got acute outcome, less than ninety minutes, door to balloon time. That happens in the cath lab. But then there's this period right after the procedure to about seventy-two hours where the patient's really at risk, right? They're still at risk, thus the value of ICUs and CCUs over the last thirty to forty years in the US. That requires a transfer protocol and a transfer process, which is extremely important. You'll hear me talk about this and how important that was in our planning, both for our elective cases and our urgent cases. Because even in the elective cases, complications can happen. They become suddenly acute cases. The last thing before I leave this slide is there's another period of time, not just ninety minutes, not just post-procedure to seventy-two hours, but over decades that determine outcome. We spent a lot of time building an outpatient program that includes every subspecialty of cardiology. These patients, from the time they come into us, we take care of them acutely. If they need to be monitored in the post procedure period, they'll go to the Lenox Hill Hospital. But then afterwards, they come back to a community program that has everything from heart failure to cardiogenetics to general cardiology, all to deliver the best outcome for their life.

Dr. Singh Next slide.

Dr. Singh What are we? What do we have? What don't we have? I like to look at Northwell Greenwich Village Hospital as a modified acute care hospital. We're not a full acute care hospital because what we don't have is an ICU. We have no ICU. We have anesthesia, but we have anesthesia only during the daytime coverage. What do we do actually? We have

all of the things I told you that come with an integration. We have our team members, both our nurses, ACPs, and physicians there. We have two cath labs that both function as coronary cath labs and one cath lab that functions as both coronary and PCI. So, two labs, one that does just those coronaries, one that does coronaries and electrophysiology. We have a general cardiology consult service for that building because we have an eight-bedded inpatient unit, and of course, we have a cardiac CT. It is not a full acute care hospital. It is a modified acute care hospital.

Dr. Singh Next slide.

Dr. Singh The selection criteria for a modified acute care hospital is very, very important. This goes back to what Dr. Jacobs had presented. If you look at the inclusion criteria for all of our elective cases. They are right from all the evidence, right? What we considered low risk patients, right? Low injection fractions are excluded people, meaning people with weak heart are excluded. People who have left main disease. The heart's like a tree, right? You've got a trunk, you've got branches, the trunk is the left main. If the trunk dies, the tree dies. We don't do complex, that high level of complexity at our outpatient site. Lesion supplying single remaining vessels, chronic total occlusions, those 100% blockages, or patients we think that may need support with some new advanced technologies. Again, higher risk patients. Same thing with devices. There's certain devices that are associated with higher out complication rates, including tears in the artery and holes, the perforations and the dissections. Those cases, you may get the diagnostic done at Northwell Greenwich Village Hospital, but you will not get the PCI done. When it comes to acutes, we will take all comers. We are in an over the last two months, we did a crawl walk run. We have only done low-risk elective cases. We have done a few low-risk ACS cases defined by a low grace score. Everybody else is going up to Lenox Hill Hospital. We did that because we wanted our staff and our team to get used to this new model of care of delivery, kind of work out the kinks. And on November 11th, we're going to go fully live for all ACSs, all STEMIs. We will continue to have an elective PCI program, which I think is the value of my presentation for this ASC, because those are the patients that you're going to be looking at to approve in the ASC.

Dr. Singh Next slide.

Dr. Singh The transfer protocol is very, very important. It, you know, being a part of a health system, we were able to very we have our own centralized transfer system. It's robust. It's incredible. But even with what we have, we had to go to them and say, listen, this is not an acute care hospital like Huntington Hospital or Northern Westchester Hospital. Those hospitals have an ICU. If there's an hour wait or two hour wait, there's some place for that patient to be stabilized. This does not have all of that. We were able to create with our centralized transfer center a separate, unique pathway for transfer. We've transferred four patients. I'll show you that. All four patients, the ambulance has been there before the procedure was completed, and that is our goal. Not one hour. It has to be there before the procedure is complete because our ambulance serves as our ICU on wheels.

Dr. Singh Next slide.

Dr. Singh I'll give you our last two months. This is the overall volume. I think the next slide is probably a more robust slide.

Dr. Singh You can go to the next slide.

Dr. Singh We've done about 163 patients as of last week. You can see our average age is 69. Sixty-seven percent were males. It's low risk patients. It's 96% outpatients. Again, these are stable elective patients. We are not doing acute coronary syndrome. We are not doing STEMI, not until full November 11th. You can see the indications and the imaging. The access site, as Dr. Jacobs pointed out, right radial, the radial access site, the risk really allowed us to do outpatient cardiac catheterization. It decreases bleeding, it is better for the patients, patient preference, and it allows for better disposition. Really, the driver for that is bleeding. You can see our procedural breakdown between diagnostic cath and right heart catheter and interventions. I do want to take a moment to talk about intravascular imaging and FFR. Dr. Jacobs had, or I think Dr. Naidu had pointed out the percentage nationally, the percentage nationally for intravascular ultrasound OCT and FFR is at best about 20%. I think in the studies that you showed, even in the current ASCs, they do about half of what a hospital-based outpatient lab would do. This is really important because if you want best outcomes, both acutely for putting in your stent as well as longer-term clinical outcomes for less re-stenosis and less thrombosis, you have to make the investment in time and in expense to do the imaging. I think hospital systems are committed to that best outcome. If you look at my team, I mean, they're I was embarrassed. We don't at Lennox Hill, where I do my cases don't have 100% imaging. We're at about 75 to 80 percent. They're doing a hundred percent imaging for all of their PCIs, either with IVIS or OCT. The FFR utilization is about 54%, which is obviously the gold standard for determining whether a lesion has hemodynamic significance or not.

Dr. Singh Next slide.

Dr. Singh This is my last slide. Just one comment about the last the previous slide.

Dr. Singh If you look back at that slide, maybe we can go back.

Dr. Singh I do want to make one point here on this. Even though we're doing low-risk patients, if you look on the right, our MACE has been zero, but if you look, even in the low-risk patient population, we had one perforation, right? You better have the ability to transfer these patients because a low-risk elective case can become an acute case very, very quickly. We've had six transfer’s total. Some of those were for open heart surgery, bypass surgery. We do have an electronic communication and video with our bypass surgeons. Again, we are an extension of the Lennox Hill lab, and a hard team approach was made that after diagnostic, the best thing for this patient was to get evaluated for bypass surgery, and the patient was then transferred up for bypass surgery.

Dr. Singh Next slide.

Dr. Singh This is my concluding slide. I believe that the integration of within a health system for an ambulatory surgery center is crucial because of the extension strategy. It allows for quality oversight. It allows for the team members from the physicians to the nurses. It allows for transfer and backup, really the absolute best outcomes because we are only focused about clinical outcomes.

Dr. Rugge Thank you for quite the model for us to investigate. Let's hold the questions, Dr. Eisenstein, until we have the final presentation and then we'll get to you first.

Dr. Heslin I think that was the final presentation.

Dr. Rugge I thought Cynthia Khan was having more.

Ms. Khan I'm here to answer any non-clinical questions he can't answer.

Dr. Rugge Okay, sorry. Sorry.

Dr. Rugge Back to you, Larry Eiselstein.

Dr. Eisenstein Thank you.

Dr. Eisenstein That was a great presentation. Clarifying question. Can you clarify for us the ICU ambulance versus what a standard ambulance would be? Would you be comfortable doing what you do with just a standard ambulance that might be found anywhere across New York State?

Dr. Singh Very directly the ambulances that can support impella and balloon pumps, patients who get percutaneous support either with an impella device or a balloon pump, that's what I call an ICU on wheels. We are also looking at certain mobile technologies that will allow our ICU doctors to manage and observe the patients in the ambulance as they're coming up so that there's no loss of vision from the patient from the cath lab all the way to the ICU.

Dr. Rugge Let me just ask a question. That's what you're doing to go from one place to the other. That doesn't happen right now with hospitals that don't have surgery that we have throughout New York State. You're essentially saying that you're maintaining a higher standard of care in your current setting than what those hospitals have. Is that correct?

Dr. Singh I think they have an ICU. We don't have an ICU. I had to make sure my ambulances had been ICUs on wheel until they got to an ICU. That's the difference.

Dr. Rugge Thank you. We talked about that yesterday too. Thank you.

Ms. Monroe Dr. Lim has her hand up.

Dr. Lim Thank you.

Dr. Lim You know, you mentioned and emphasized the importance of quality oversight. I wonder if, particularly for the members of the council who may not be as familiar to the depth and the rigor of the hospital based quality assurance and performance improvement requirements under the Joint Commission, CMS, could you provide some examples of, you know, sort of everyday examples that may be both unique to cardiology or just unique to hospitals that you think is important to be aware of? I think sometimes we take that for granted, the depth of the requirements.

Dr. Singh Super important, right? Great question because you have to invest in this. You have to have a team. We must have hundreds of people that are hired just to look at quality, not just put into the ACC or the databases or the NCDR databases, but or the state databases, but to really help and look out at performance improvement projects. We all have a performance improvement project where we have a clinical goal every year. We call it the BICG, whether it was decreased bleeding or lower renal trauma, whatever they are, whatever they decide, we have defined product defined projects over the year. Every week we have a cath lab conference and everybody has to come in and cases are

presented as a QA, QI. If we do have a bad outcome, we'll have an M&M. if it's a really bad outcome, we will do a root cause analysis. I mean, the depths of what we have for quality it's really deep.

Dr. Lim there's also things like ongoing professional competency evaluations, right? All these kinds of things that we talked about competencies before. Thank you.

Ms. Monroe I have one. I can't find the hand on my machine. I'll do this. The earlier presenter talked about the importance of having skilled and experienced staff at such a facility or such a cath lab, or you didn't mention that, but I'm wondering the staffing in your quasi hospital for cardiac. Do you have the most experienced staff from the hospital over here? How have you looked at that?

Dr. Singh I alluded to that. It's an extension. Our doctors are from Lenox Hill Hospital. Nurses, all of our nurses that met that man the Northwell Greenwich Village Hospital lab came from Lenoxville Hospital. Some of them have worked with us for twenty or thirty years. And in fact, our senior nurses are the ones that moved down to Greenwich Village Hospital, and our junior nurses or less experienced nurses stayed at Lenox Hill.

Ms. Monroe I have just one more, if I could. We talked about by having them in ASCs, you could expand access. How does that fit with what we heard from I believe it was Dr. Jacobs, about how the responsibility on the patient is much greater when you discharge them during the day, during the same day. They have to really understand what's happening. I'm wondering if that's a different view of access and might in fact make it less accessible for certain groups of patients who either for language differences or for ability to manage their own care, make a daytime discharge make them less likely to be successful in a daytime discharge.

Dr. Singh Yeah, it happens right now at Lenox Hill Hospital. The first thing that we ask a patient is what is your social support? Who's going to take you home? Who can we talk to after the procedure to educate them? Who can we call tomorrow? If they don't have that, we tell them that they will be admitted overnight.

Ms. Monroe Access may not in fact be expanded but be limited in some way. That's not a conclusion or a clarifying comment. It's just an opinion I have. That's it for me. I don't have any more questions.

Dr. Rugge We are ahead of schedule. Everybody can use this time productively, we hope. Special thanks to you, Ann, for helping, certainly for Jean Heslin in arranging this, all the committee members, continuing our educational process, and this has been notable. Beware for our presenters, we may come back to you with other questions as we go along. Hopefully, have the best possible suggestions to make based on all this information.

Ms. Monroe Just one comment before our next meeting in November, we will have these presentations that people have made for us to refer to, as well as the video that you may or may not have seen from the earlier session and from this one, all for you to digest and think about and bring to our strategy session in November. Look for a packet of stuff. Thank you.

Dr. Heslin Finally, Total Webcasting did this. This will be available online in about seven days' time, as will be the slide deck. We will have that available for public consumption over the next short period of time as we typically do. I do want to reinforce the point that

Ms. Monroe made, which is that we have an upcoming session on November 12th, I believe. That's where we are going to be compiling thoughts about what's happened. That is an open public meeting that is in person for all the committee members to remind them it is in person. In December, we'll be finalizing the discussion to have recommendations made to the full Public Health Council on the recommendations that would be submitted to the Department of Health and how they will consider crafting the regulations involving ambulatory surgery centers. We've got a short next couple of weeks and then a short next couple of weeks after that for two more meetings, holiday season planning.

Ms. Monroe If I could just ask the Cardiac Advisory Committee, if I followed your presentation, Dr. Osinaga in early November, you're going to have kind of a preliminary set of recommendations. Is that accurate?

Dr. Osinaga We have the work group, the smaller subgroup of the Cardiac Advisory Committee will be presenting to the fuller committee their proposed recommendations and there will be a discussion on November 3rd. We'll see what comes out of November 3rd, but we're hoping that the full committee will finalize the recommendations by at least the end of the year, if it's not able to be done at the November 3rd meeting.

Ms. Monroe Well, if there's anything that maybe I'm speaking out of turn here, but if there's anything from the November 3rd meeting that would be helpful to us as we begin to craft our recommendations, I think the committee would really like to be able to have access to that.

Dr. Osinaga We'll keep that in mind.

Dr. Rugge Thank you very much.

Dr. Rugge With that, we will adjourn unless there's an objection.

Ms. Monroe Thank you, everyone.

Dr. Heslin Thank you.