NEW YORK STATE DEPARTMENT OF HEALTH
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL
HEALTH PLANNING COMMITTEE
November 12, 2025, 1:00PM – 4:00PM
90 CHURCH STREET, 4TH FLOOR,
90 CHURCH STREET, 4TH FLOOR, CONFERENCE ROOMS 4A AND 4B, NYC
TRANSCRIPT

Dr. Rugge Should we get started? I would think. That'd be good. In part because I have a very clear need to be finished by 4:00pm or within a couple of minutes of that. We'll try to rush through all this. Glad to see everybody who's here and we have a couple more apparently presumably coming. I have to start by just saying by my lights, we've really made progress this year. We had such a struggle of identifying a topic and where we could be useful as a committee.

Dr. Rugge I can't move the mic.

Ms. Monroe Maybe it's not on.

Dr. Rugge The mic is on, but it won't move the cord.

Dr. Rugge Is that better?

Dr. Rugge I'd have to talk like this.

Dr. Rugge Oh, look at that. Thank you.

Dr. Rugge Anyway, I think what we have learned is number one an important topic up for serious consideration that we can contribute to. We know that PCI per cutaneous coronary interventions are being an important asset to ambulatory surgical centers and most of the country has these already in operation and New York does not yet. This will take a regulatory process of which we seem to be, I think really are an integral part. Not to deliver a long policy paper, but instead to develop very specific recommendations for consideration by those in the Department of Health who will be drafting those regulations, only to have them return to the council, our council, for consideration and presumably approval. Dr. Heslin all along the way has been helpful in terms of how we provide the guidance and the guardrails we need. Our work has then been proceeded systematically in three different phases. One was learning sessions and information gatherings, so we know what other states are doing across the nation. What is at stake in New York? What legal parameters we have to work within? Phase two, soliciting input from stakeholders and the public. Finally, we come to phase three, which is why we're here today. That is to begin the process of decision making and making recommendations for serious consideration by DOH as one next step. This is our first opportunity, strangely enough to review and approve our committee minutes from July 1. If anybody would care to raise their hand. We can do that.

Dr. Rugge Any anybody available for a secondhand motion?

Dr. Rugge Competition. It's already started.

Dr. Rugge Further considerations?

Dr. Rugge Is there a vote to approve?

Dr. Rugge All in favor?

All Aye.

Dr. Rugge None opposed.

Dr. Rugge Thanks.

Dr. Rugge See where we go next.

Dr. Rugge Something of a brief summary of the information and the data that we all have learned about, read about and depend upon going forward. As I said, nationally, most states in this nation have already been proceeding with PCI. Much of this was prompted by Medicare in the year 2020, authorizing the project and setting financial prices. Six thousand six hundred dollars for ambulatory settings and ten thousand five hundred dollars for inpatient settings. For all the surge in growth, still less than two percent of all PCIs are done in ambulatory settings. We're really at the beginning of a movement rather than being terribly late. We did have the advantage of hearing directly from the authorities in Illinois about their experience, which was to approve PCIs in ASCs in the Fall of 2021, four years ago. Since then, for left heart catheterizations, there have been performed seven hundred and forty-three in the state. And of those, one hundred and forty have been done as PCIs. With fifty being referrals for cabbages, coronary artery bypass grafts.

Dr. Rugge Hey, here he is. He's right over there.

Dr. Rugge There is, as we can all imagine lots of variability in terms of regulatory process. At least three states have no regulatory process. People just started to do it. None of them happen to be in the Northeast. In any case, across all the states and all the settings, the available data indicates the complication rate for PCIs is less than one percent in both the ambulatory settings and in the hospital settings. That is not a distinction that we have to be too concerned about. Data for New York State indicates that eighty-two thousand diagnostic catheterizations were done two years ago in 2023 by ADA hospitals. Fifty-two thousand PCIs were performed in 2024 by seventy-seven of those eighty-eight hospitals. There are no PCIs as I've mentioned in ambulatory settings, except there is a quote resemblance at the Northwell Greenwich Village ED, formerly part of Lenox Hill Hospital opened as a kind of a not freestanding but independent, even independent but only providing emergency department services in 2014. Just in time in July of this year the Cardiac Cath opened for elective cases. This month, I'm not sure which day but this month they're going live with full coverage for STEMIs, true heart attacks. That is being done in an ambulatory setting, although it is regarded and regulated as a hospital setting. There are criteria in the hospital setting for all of us to be aware of that the physicians must be board certified. They must have a volume of a hundred and fifty cases per year with thirty-six being emergency PCIs. We are here to give consideration to public input. Ann Monroe is our leader.

Ms. Monroe Do you want me to speak now?

Dr. Rugge Yeah.

Ms. Monroe Hi, everybody. We had a great public comment session. Those of you who are here, I think experienced a real rich interchange of information from a variety of segments and sectors of interested parties. There were providers. There were health plans. There were advocates. If you haven't had a chance, I would encourage you to at least zip through the recording of the public comment because I think it crossed a variety of perspectives that are important to us in our work today. We don't have any experts in the room. It's just us. Not that we're not good at what we do, but we are not experts in this field. The responsibility is on us to come up with the recommendations that seem to make the most sense from all of the different inputs that we had across the last few meetings. I think the public comment meeting and then the meeting we had with the Cardiac Advisory Committee were both very informative about what we might need to do today. I'll come back when we start facilitating the discussion about what those rules are and how we want to hear from everyone, etcetera. John, I don't know if you want me to turn it over to Gene or do you have more to add on this?

Dr. Rugge No we can do that in a coordinated fashion.

Ms. Monroe Well that's what my request is to you if you want me to turn it back to you or to talk to Gene.

Dr. Rugge Dr. Heslin, it's your turn.

Ms. Monroe Gene's going to talk about the November 3rd Cardiac Advisory Committee meeting.

Dr. Heslin Thank you.

Dr. Heslin Eugene Heslin, Department of Health, been supporting this committee along with Abby and Jacob who is soloing today because everybody else had something else they were doing. A small but mighty group working here today helping to support this. Cardiac Advisory Committee met December 3rd.

Ms. Monroe November 3rd.

Dr. Heslin November 3rd, and they received the same exact slide presentations that Public Health Council received with the same exact people presenting because they needed to be level set as well because they all come from different sex of cardiac. Functionality, some of which are people that are within the state, and some of them are not within the state in terms of their experiential profiles. They had a very thoughtful discussion. They talked about this for a while. They came up with a couple of thoughts, but not specific recommendations yet. This was their introductory meeting to have their introductory discussion, and they're planning to have another meeting towards the end of December where they're going to have more concrete thoughts, and then subsequently they will be submitting to the Department, very similar to what Public Health Council is hopefully going to do, a series of recommendations for the consideration of how to craft the regulation. Things that were important to them were particularly about monitoring quality and safety. Sound familiar? The relationship with hospitals, particularly those that provide thoracic surgery support. They discussed the limited data that's out there and the need for more data. They recognize that they collect no data for diagnostic authorizations because years ago they decided that they were so safe that there was no need to collect data on diagnostic authorizations, and they only collect data on percutaneous cardiac intervention. As we talked in the beginning, there's a difference between a diagnostic

health and percutaneous cardiac intervention. They suggested that they would think about a considered measured approach, particularly around patient selection and backup hospitals for support. They questioned whether this should be a pilot or not, and they still needed to have further definition in their thoughts as to where they might land on that. They did not have a position of support or opposing this because they hadn't had enough information or discussion yet to be able to land in a thought process. They'll make more formalized recommendations to the department. What I expect will happen is the department will take both sets of recommendations for consideration as the department will move forward with this. That was essentially what they had done. What I have to emphasize is they're very, very thoughtful people. There was a concern about hospitals losing business. We'll put that right out on the table. There was equally an acknowledgement that ASCs are something that are moving forward. It's that same familiar discussions that have been around this table for the last seven or eight months with a different group of people. I felt very good about the fact that everybody is sort of thinking in the same way, whether it's our public group or our group of cardiac experts that the state has employed well not employed, utilized for the last two and a half decades as they've thought through the different cardiac issues. I'll stop right there and turn it back over to Dr. Rugge and Ms. Monroe.

Dr. Rugge We're looking at our process to come to consensus and Ann Monroe is going to outline that process that we'll be following today.

Ms. Monroe Thanks, Gene.

Ms. Monroe We're going to do this in two pieces. One is we're going to go around the room and hear from everybody what you've learned, what you don't know yet. If you have a position, you know, that would be the time to kind of begin to put it on the table, although we're going to have a very robust discussion about those positions as we move on. We want all of you to participate and have an opinion. It's very important that when we go forward to the to the council that we have recommendations that may have a minority of report assigned to them. It may not be that we reach consensus on everything, and we want to make sure that both the council and the department get all of that rich discussion, not just what quote one out over the other. It will be, as I said, both pieces of the decision. We want you to consider everything you've learned, everything you've listened to, and kind of where are you at? We're going to tap that for five minutes each, no more than that. If you don't have five minutes, that's fine. We do want to hear from you. We're going to have a facilitated discussion of all of us. Going through those questions that we asked everybody who commented to us to address. We'll go through them kind of with a what are the gatekeeper questions and then what the more refined questions after that are. We'll see where we are at the end of that time. Maybe we will have preliminary recommendations, or maybe we'll have a couple, but the rest is still fuzzy, and we need to finalize that. And just as you know, in December we'll come back for our last meeting. A product of that meeting would be our recommendations with, as I said, a minority report if there was one and the logic behind the recommendation. Don't feel pressured to do it today. One other thing I want to mention. In some groups there's great pressure to come to unanimity. I think that would be a loss for us if that's what we drove to. We need to be able to recognize everybody's comments, place them in the right place in the discussion, and come out of this with a sense that everyone's been listened to, has had their questions answered. One of the last things I want to mention before we start going around the room is one of the weaknesses of this whole meeting system that we've had has been the question about a lack of data. I think that we have to accept that, or we probably will accept that, and put expectations about data in whatever we recommend, but not hold up

our recommendations because there isn't enough data. Because if that's the place we go, we'll never come to a recommendation. It's like that is kind of a how do we build that into the process rather than as a requirement for our recommendation. Does that make sense? Everybody okay with that? I have a little timer here. Are you going to do it, John?

Dr. Rugge I can do that.

Ms. Monroe Okay, fine.

Ms. Monroe I'm going to go around the room and ask people to share.

Ms. Monroe Pardon me?

Dr. Rugge That's my job.

Ms. Monroe I lost my thought now. We'll go around the room. I'm happy to start with whoever wants to talk first or I can point what did they call that, the fickle finger of fate?

Ms. Monroe Thank you.

Ms. Monroe Can you speak more into the mic, please?

Dr. Ortiz I don't have too many issues with doing some type of pilot or initial launch so that we can begin to evaluate data in terms of quality, were there issues? My concern sort of lies again, and Dr. Heslin, I brought this up at the meeting in Albany. I'm still very concerned about expanding services in lieu of the current and more impending nursing shortage. I always wonder like I love that they have the criteria for physicians laid out, but I also want to know the criteria, the staffing ratios, what are the quality indicators for a nurse to work in a setting like that that, especially if it's going to be independent a hospital system, right? I don't think it's criteria like so many years worked, but I think certification should be attached to it also. I'm looking more at it from the day-to-day experience of that if they are going to pull nurses from the hospital system into the ambulatory, who's going to be staffing the hospital? It's this double-edged sword for me.

Dr. Rugge Good.

Dr. Rugge Any other concerns since you didn't do five minutes; gaps in data, anything else besides the staffing and the certification on staffing and support?

Dr. Ortiz No, I think with all the materials that have been presented and discussed, you know, I think that the medical parts, the medical something should lie with medicine. I think if a hospital system or a group of physicians have the expertise and the resources and the staffing, I think they should we should support their independent decision making in creating the ambulatory care system. However, I do think there should be clear indicators of processes where we were about to intervene early. I'd rather fail small and fail fast with this. That somehow when they expand to the certificate of need, that we have a better gate to evaluate is it working for that system or is it not?

Dr. Rugge Do you feel that we need more information, or you need more knowledge to be able to come to a preliminary recommendation?

Dr. Ortiz No, I'm fine with that. I think we should rely on the health system to give us the information so that we can make a decision if they are ready to have ambulatory care. I also want to be able if we do approve it... What is it our job of how much information do we need and at what times to show that that the launch of it is actually as smooth as they proposed it was going to be?

Dr. Rugge Very good start.

Dr. Rugge Do we have someone going next?

Ms. Farrell I was looking for the data point and I'm not finding it, but some of the data that was presented by the New York State Department of Health. I can't remember her name, Gene, where they actually analyze procedures all across the state. What struck me was that for patient eligibility out of all of these procedures happening all across the state, what I recall was that basically f only 5,000 of those procedures met the eligibility criteria as defined by medical experts. I can't remember what that data point is. I'm looking at Gene. I don't know if you recall it. I remember asking a question. I said, well, then could we determine the zip codes of those patients who met the eligibility criteria? My bias is toward patient access. As I've been learning and listening, I always think that a more low-cost procedure is better for the system could be better for the patients. When I realized that only 5,000 out of a very significant number of cases being done all across the state really met the eligibility criteria for PCI, I thought it's really not a lot of eligible procedures. I would want to know exactly... Where do those procedures cluster? If we were authorizing PCI in ambulatory settings, I would want to make sure that there was significant density in those locations so that the business model that supports those ambulatory surgery centers indeed could be met, could be appropriate. Does that make sense?

Dr. Rugge Let me just see if I have it right. What you're looking for when something got to coming in for a CON, you're looking for what the needs criteria would be for that particular area and some sort of metric on how to think about that. That's what you're saying?

Ms. Farrell Yes, yes. Obviously, cardiac care is where all the money is. We all know that. There's definitely churning in the sector. I wish I could point to a study, but there's certainly enough legal cases out there to make you realize that very often procedures are done that are completely unnecessary. I appreciated this particular data point around patient eligibility. My concern is that if there was an over capacity of facilities that were allowed to do this, indeed there would be excess cases, unnecessary cases being done. I do care a lot about that patient eligibility criteria.

Dr. Rugge It seems that that pertains more to diagnostic catheterizations as a start rather than to PCI. I think it would be very difficult for a physician to come up or a cardiologist to come up with an excuse. There's no real blockage but I'm doing this anyway because I get the extra fee.

Ms. Farrell We know that that's what happens with stents. There's legal cases, not necessarily in the state of New York where physicians have been sued for placing unnecessary stents all in the desire just to churn and increase revenues.

Dr. Rugge Again, not to go ahead of ourselves, which suggests the need for quality reviews.

Ms. Farrell Correct.

Dr. Rugge Are you prepared for your Harvey?

Mr. Lawrence I think Lindsay's comment for me, I look at first access. Normally screening, you sort of screen people into care and in this instance when you look at the decision tree, the first thing is that you're looking at the level of support that the person has. In this instance, if you don't have the support, you get screened out of this PCI in an ACS setting. The question then for me is... Is that really going to expand access for an underserved population? Whether this is simply going to result in again, more care for populations that are at a higher income and really neglect and really not move the needle at all on access in low-income areas. In addition to that, I guess on top of that is sort of this... You know, the question if this is a really where the margin is in terms of making money in a hospital and institutions, then usually in in institutions you sort of have a cross subsidy. You have some big winners that subsidize some losers, or those that have a pretty thin margin. What does that mean for the overall system? We are sort of jiggling with a part of the system but a part of the system that has the potential for generating a bunch of revenue for institutions that have been historically doing it. What happens when we open the gate and say, all right, private sector not for profit. You have more of these procedures marching out of the hospital and into a private sector model which again, I think there was a reference to nursing staffing. I'm also there's a reference to professional staffing in terms of physicians because I would assume if you marched it into another setting that is going to be much more profitable. There is a lower cost setting within an ACS, but in the hospital you're also carrying a bunch of overhead I assume that again underwriting some other things that are maybe not as profitable. That's another concern. What's the impact on the overall health system? We make this change and then three or four or five years later it's going great, but what happens to hospitals, especially the safety net hospitals? Question for me in terms of profit, nonprofit. In theory, a nonprofit institutions sort of reinvest back into the system. Profit making systems. I buy a yacht with the bottom line. I don't necessarily rein invest in the public health system if there's a profit at the end of the day. This goes back to I think a question an issue that Lindsay raised here, just looking at the Harvard study and I guess it was Mount Sinai. No. Beth Israel. When you look at repeat PCIs, it appears that repeat PCIs twice as many happening in an ASC setting than a hospital. Why does that happen? When I say twice as many, I see here that it's four-point seven percent. This is under thirty-day absolute event rates following PCIs in ACS settings and ten percent for ASC's. That's a concern because if again it's one of those things where if it's not regulated and you get it's being abused, then again that's going to drive up the cost and not really provide the type of care or the quality of care that's needed. I know it was a little all over the place. I guess access, cost to the system, impact on the system, impact not only financially but in terms of the overall costs. We're shifting the cost from one out of the potential revenues from one system into another and so what happens? If that's going to happen then there it should be some sort of a transition period and also maybe some cross subsidy coming back into the system. There are a number of solutions to potentially offset the impact.

Dr. Rugge Who's next?

Dr. Rugge Didn't we skip a couple of people?

Dr. Rugge Go ahead, Marcus.

Dr. Friedrich I remember when we all started the discussion and when Dr Heslin and the department came to this committee and asked for help in deciding that. One of the phrases that Dr. Heslin used was that some of the health systems approached the

Department of Health and asked for this measure in a way to free up the operating room for more acute cases because there's a shortage of operating room space in the hospitals. Going back to what Ms. Farrell said earlier, the 5,000 is about 10% of the total volume. I think that almost all the speakers made that very clear that they would feel most comfortable with the patients that are the lowest risk of all the patients, and that there has to be strict enforcement of the risk criteria. I feel that this is exactly the point to free up OR space by moving the lowest risk patient for these procedures out of the hospital. I feel that a lot of hospitals might be in areas where there is a lot of an access around them, but if there is an independent ASC, that they could be in areas where maybe they of afford more access to these procedures in settings that are not as obvious as where big hospital systems are. I'm pretty strong deciding.

Ms. Monroe What do you mean settings are not as obvious?

Dr. Friedrich Like for example, we all know the big population centers; Manhattan, Long Island and so forth, but I feel in other areas more in the suburbs where the hospital systems are not that this could offer patients like a way to get these procedures forward. I feel also that the doctors should decide where they feel more comfortable doing these lower risk procedures and where they have a higher turnaround time, where they are not getting bumped because of other procedures in the hospital and so forth. I also have a strong feeling about having this as a demonstration project. One thing that was very important to be, and most people know that I work for the Department of Health, that there is such a lag in the data, and the Department of Health had data from 2023. We are in 2025. I feel any demonstration project, and for us waiting on the data from the demonstration product will be four, five years before we decide on the demonstration project. Being a realist about the workload at the Department of Health, this can very easily this demonstration project could overwhelm the workforce at the department and presenting it back to us. That is one. I also feel going back to what my colleague here, Mr. Lawrence said about the Illinois example, John, what you described, and also the example what I read about in California. It is not opening the gate. I feel that the physicians and the ASCs, they were again using the lowest risk patients. I was very underwhelmed with the numbers, like out of all the PCIs or diagnostic tasks that were done in Illinois or in California, how very few procedures were done in the ambulatory surgical setting. I feel this is an area that is still probably growing. I assume that there will be a big growth going forward. I like to have a strong conviction that this can be done in a safe manner in hopefully areas that are currently not having big hospital systems or big population centers where we will see more access to these and so forth. Those were some of my thoughts.

Dr. Rugge Dr. Eisenstein, I think you're next.

Dr. Eisenstein Thank you.

Dr. Eisenstein I probably won't use five minutes, but if I'm down to one, can you give me a finger, Dr. Rugge?

Dr. Rugge I will.

Dr. Eisenstein I thought I knew what I was going to say and then I heard the introductory remarks of Dr. Rugge and Ann, and I actually had an issue with both of them. I'll start there. Dr. Rugge, you mentioned... Actually, I'm going to start with Ann's because Ann said we acknowledge that there's an issue, a shortage of data, and if we wait for that, we'll never get anywhere. Is everybody okay with that? My answer honestly is no, that's not how

we practice medicine. As a licensed physician, we always practice evidence-based medicine or participate in creating the evidence. I'm willing to be supportive of creating the evidence here in the form of a demonstration project and studying the data. While I love Dr. Friedrich, my friend here, I respectfully totally disagree. I think it's our responsibility to put the time in to study the data and come out with the numbers. Our own Dr. Osinaga, I asked her, "Do we have significant safety data?" She acknowledged no. Dr. Jacobs from the CAC who presented to us, her first words were, Quote, "The evidence is not robust." You heard numerous other doctors, including our Northwell presenter talk about the lack of evidence. Medicine in the United States is practiced as evidence-based medicine. If we don't have the evidence to do it, no, I'm not comfortable creating rules about what's okay. The doctor from Albany said something very interesting. He said, I probably think it's okay, but I don't have the evidence to support that. I actually thought that was a very thoughtful comment because that kind of makes a lot of sense, and I'm willing to be supportive of gathering that evidence and a few years from now looking at it and saying, We in New York have proven this is safe. There isn't that the data or evidence to support it safe, as we've heard testimony from. As far as doctors being able to set their own criteria, we heard how many successful, brilliant interventional cardiologists completely disagree with each other. We're going to leave it up to them to determine which patients should be eligible or not. How do you enforce the criteria? Once the horse is out of the barn, the horse is out of the barn. Correct me if I'm wrong, Dr. Heslin, but according to New York State data, when they categorize whether patients should have received catheterizations or not, over a third of them fall into the category in all of New York State catheter PCIs of it was the doctor's discretion. There's no way that we can monitor and none of us are interventional cardiologists, a doctor's discretion. To me, I think we have to set boundaries and let the professionals do their thing. I don't think we can monitor them. We don't even speak their language as interventional cardiologist. Just like as an infectious disease doctor, most people don't understand the antibiotic language that I would speak. I don't proclaim to speak interventional cardiology. To your comments, Dr. Rugge, you said something. You said what we heard is the complication rate is not different between inpatient and outpatient settings. I acknowledge that. My concern is not the complication rate. My concern is the ability to respond to the complications when they happen. That's where the safety concern is. We talked about convenience. Go into people's homes and do it in their bedrooms. That's more convenient than anything. We heard really impressive testimony from Dr. Singh out of Northwell that in their standalone ER, when they do this, they retrofitted two ambulances to intensive care level ambulances to deal with the rare complication. They said, this is a quote from his testimony one out of ninety-three of his low-risk procedures had a vessel rupture. One out of ninety-three. That's one percent-ish sounds very low. When you spread that across tens of thousands of cases, it's not that low. Thankfully, they have the facility there with those ambulances to handle the complication. One of the doctors, admittedly from my system, said, Dr. Schlafmans, who's done among the most procedures of anybody you know around, said, look, as good as I am, once in a while there's a complication, and I need to be in a place where we could handle the complication. That's my concern. My concern is the safety for the few. Let's assume all the interventional cardiologists are competent. No matter how good they are, there's going to be complications. It happens with every doctor and every procedure. Northwell was thoughtful about how they handled this. One comment I heard that I thought was really shocking in the testimony was somebody said why do we care about one anecdotal report? Because if that anecdotal report is me or my Father or my family member, it matters that there's a way to make sure that that complication is treated. For me, it still goes back to being a safety issue and creating the data. My feeling is I think we have the responsibility to take the time to do the due diligence to create a program that is a demonstration project that is closely monitored, that the guidance is led by the

professionals. Dr. Heslin talked about the CAC. They're not ready to give us guidance yet. They know it better than we do. That should be enough for us to say, let's be very thoughtful and careful and move forward, because I do agree with moving forward, but in a manner that we could all do our responsibility as planning council members, protecting our public. I'm sure I'm out of time. One last thing. The nursing shortage is a major problem. The fact is nurses who do cardiac catheter, even diagnostic that's a whole separate training. It's a whole different set of hours. Very often, if we do it in an ambulatory surgical center for low-risk patients, it's going to be 9:00am to 5:00pm Monday to Friday. Good luck filling the hospitals for the most vulnerable with nurses if they can find other jobs that are a whole lot more pleasant.

Dr. Rugge Just one question and that is don't physicians in the inpatient setting also make the decisions about who gets the catheterization and who gets the PCI, just as they would in an outpatient setting. Is there a distinction there?

Dr. Eisenstein I think the distinction for me is if they regardless of what decision they make in the inpatient setting, they have the resources to deal with any complication. That's what when you brought up the complications, I don't disagree that that if they're good interventionalists, whether wherever they do it, their rates are going to be the same, but the ability to respond when they have a problem is what concerns me.

Dr. Rugge Now we move to the left-hand side of the table, at least my left hand.

Mr. Robinson Thank you for arranging this discussion. I think it's great and Dr. Eisenstein, I think you hit the nail on the head. I guess I was going to start with issues around data as well. In fact, one of the recommendations that needs to come out of this group, I think is the immediate start of data collection around Caths just generally done on a statewide basis, so we build a database. We have some sound foundation on which to make strategic decisions. The second issue I have I've kind of not been able to understand is...is there an access issue? I'm not really clear that we've demonstrated that there is an access issue. To Mr. Lawrence's point, I think that in fact the urban centers and people do have access to them are easily accessible to the people in New York City, especially. The CONs that we've approved recently for freestanding PCI centers in hospitals around the state, particularly in rural areas and out in the suburban areas is creating even more access. They're institutionally based and linked to existing cardiac thoracic programs with appropriate backup.

Dr. Rugge Just to say as yet we've never approved a CON for PCIs in the settings.

Mr. Robinson My general view here and I think I'm pretty much aligned with Larry's comments. I'm not sure we're solving a problem by undertaking this. In the event that we feel like we at least want to explore this, in part because we've seen this happen in other parts of the country, I would be much more inclined to go with a demonstration project, and have that demonstration project limited to affiliated facilities to programs that have existing cardiac thoracic programs and all of the backup and all of the data collection and all of the quality programs that are essential to that. Sorry for my voice. I would also suggest that initially that we limit these programs to not for profit entities. I just think we need to take the financial incentives out of the picture as we look at issues of quality first before we decide that we want to extend this kind of program to the for-profit sector. I'm sorry for my lack of voice.

Dr. Soffel I would like to pick up on something that Harvey mentioned. Having to do with health equity, and I feel that anything that we decide we have to keep our health equity lens in place. If this is a situation where social supports are required to do to allow people to safely receive care in an ambulatory setting, we are working in fact against expanding health equity. We are saying that people without social supports are therefore not eligible for this more accessible service. It seems to me that that's contrary to the state of New York commitment to expanding health equity in all aspects of the work that we do. Secondly, I have an ongoing concern about the ability, especially if there's differences in ownership, the ability select patients based on either profitability or more likely better outcomes. I worry that if we allow competing models of care run into a cherry-picking problem that we have not been able to solve in any other setting in the healthcare world. I don't know how you think through in this particular setting the extent to which a provider could pick the more lucrative cases or pick the cases where they're guaranteed that they're more likely to have a good outcome. Therefore, their quality numbers will look better. It is an ongoing concern of mine that we should keep in mind. I wanted to also cite one of the speakers at the last meeting, which I missed but I did a crash course this morning. The guy from SCAI, who talked about ethical considerations, and he went through a whole rundown about remuneration not being based on referrals and physician co-ownership. I think that that list of ethical considerations that he articulated should be fundamental to our recommendations moving forward because I think that they are very thoughtful and address a number of concerns whenever we start to talk about allowing profitability into the more profitability into the healthcare setting. Ethical considerations have to be grappled with upfront. My last comment is I don't know how your, if you allow for profits operating side by side with not for profits, how you allow the not-for-profits to continue to be mission-driven when they are competing with somebody who is being profit-driven. How do you assure that the pressures of a for-profit system, which are to maximize profits for shareholders are not drummed over into the not-for-profit setting because even if you are a mission-driven facility, if you are competing across with a guy across the street who's doing things differently, then it starts, we have seen this in all in all kinds of settings, it starts to change the not-for-profit behavior as well. My instincts are, and that's not only true in this particular question of PCI and ambulatory surgery settings is to say I would really think that we are much better served by limiting services to the public or the not-for-profit sectors and keeping the for-profit sectors out.

Dr. Rugge Dr. Lim.

Dr. Lim I don't think I'm going to say anything vastly different than most folks. I agree with what most people have said. I think the points I would iterate is that I think it is important and there is tremendous value. I think some of the questions that we have can only by be answered if we do a demonstration project or a pilot. There's inherent value in that, as Dr. Eisenstein said, so I think that would be very important. Whatever pilot or project is done, I think we just need to be very clear and focused about what are the concrete goals of that. I think number one has to be the safety. Is this safe to be done? Where is it safe to be done? A lot of people brought up the access issue. That was something that I think in both meetings that I attended, I had asked people who are coming from other states. Did this expand access to Medicaid populations? The answer was either I don't know or maybe. We have to check. It goes back to, and I don't want to say that everyone who's on Medicaid doesn't have social supports. That is not correct. Again, going back to what Harvey said, that if one of the basic clinical criteria is you need to have social supports that by default will weed out a large portion or make that unavailable. One of the, I think the CAC members when I asked him that question. I thought he put it well. He said, it may improve convenience, but it may not improve access. Convenience is not unimportant, but

I think we should just need to be clear-eyed if we do this that improving access may not be one of the major outcomes. At the same time, if we were to do a demonstration project, could we consider, for example, for those people who would not be able to benefit from this because they don't have the social supports. Is there something we can weave into that? Could we provide funding for a whole for short-term home health for Medicaid recipients or other people who would be otherwise ineligible for that? I mean, that's the value of a demonstration project. That's point one. I think the second piece is that I fully agree with the need for within a pilot setting, it does need to be limited to hospital-affiliated programs, and it goes back to the safety issues. I had asked, I think, Dr. Dupree in Greater New York about what are the current accreditation standards. I just want to point out again that there are accreditation standards for ASCs, but hospitals that run inpatient, ambulatory, and even run ASCs, they still have their own hospital-based, very rigorous safety standards. I don't think that gets emphasized enough and how rigorous and the level of oversight and the monitoring and the checking is required. I think for that reason, for that main reason, I think that's why first and foremost a pilot should be limited to the hospital affiliated. It's not just that has a hospital relationship. It's not just a referral relationship. It has to be part of this hospital safety and quality oversight structure.

Dr. Torres I wrote my thoughts down. I have here a demonstration in a controlled setting with an oversight by a specialized hospital. My reflective thoughts, you know, as I was thinking about this. How do we capture data that also reflects cultural considerations that also includes the aging sector? You know, several comments were made regarding the support systems. I'm a little biased because I happen to represent the aging population. For the most part they're struggling with not having enough support systems in the community. That's in an urban s setting. Imagine in a suburban or rural setting.

Dr. Torres Aging.

Ms. Monroe Thank you.

Dr. Torres This is the youngest moment we'll ever have in our lives.

All (Laughing)

Ms. Monroe Clearly, I can't hear.

Dr. Torres Where would funding come from to execute this process of data points? How does the Medicaid target population, the low-income threshold and procedures being met come together? Are we excluding a certain population because of their Medicaid status? That's something that I was thinking about. How does the Medicaid target rates and procedures being met? In other words, are we also meeting and Mr. Lawrence echoes this at a lot of the meetings, where is the commitment to meeting charitable care even in such procedures? But the other piece I have here is the talking points, capacity, access gaps, projected volume, safety, what data points speak to the align speaks to the alignment with community need and how is the community truly defined and identified? When we say community, who are those members? I think that if we were to analyze that a little better, we will come up with a more of a customized type of approach to meet the challenging needs that may be a little bit more magnified in certain populations than others.

Mr. Thomas Anyway, I'm going to weave in a couple of comments and its sort of integrate a lot of comments here. But starting with to me the whole conversation about need, not consumer, not patient need, system need. I think Peter said it. Is there’s a demonstrable

need for more capacity? I think Gene at the first meetings talked about the overutilization of hospital-based cath labs today. Because cath labs are being used for far more procedures than simply cardiac procedures at this stage. They're challenging the existing capacity, which is part of the reason we're having this conversation. I think it would be helpful to get to the bottom of that data. I'm not sure that's true or not. That's a first question. Second is access and patient access. Does this change it? Not sure. On balance, I've been around surgery centers quite a long time. There is a constantly evolving mission in some cases for using surgery centers in a creative and more in some respects people would think unexpected way. Whether it's full total joint replacement in surgery centers, significant urological procedures in surgery centers. I'm in favor of an evolutionary process to allow this with some caveats. We've seen it. I've lived it myself and watched. I know cardiac care is a lot different than orthopedic care. Who would have in the world thought a full a complete knee or a complete hip would be done at a surgery center fifteen years ago? Who twenty years ago would have thought that a hospital that does not have an open-heart surgery program would be running a cath lab? We have sat here at this council for the last fifteen to twenty years and allowed that. Not only that, under the most recent rules that we adopted, encourage it. You've got hospitals in the middle of nowhere without a heart surgeon running cath labs. We have data about that. We understand whether it's dangerous, but that's a fact. I think that is intended to address access, intended to address need in that community. It's apparently working because none of them have been stopped. You might assume here that if we were to allow this, a similar thing would happen. That once the rules are built things can be done properly. Maybe it's a door to balloon. Somebody one in a hundred cases goes bad. I'll pick on our part of the world. Ithaca, New York. That's a twenty-five-to-thirty-minute helicopter ride. You're not doing that by car. They've been running a cath lab there for decades. I think that given that experience, we can probably assume that with the proper guardrails that this kind of procedures can be done in an ambulatory setting. Which brings me to my last point, and we've sort of touched on it, which is should be this be done in a demonstration project? Yes, I believe it should. I also believe that it there's three different types of locations we're talking about here. We're talking about hospital extension clinics. Northwell. Listen to what they said. That the Northwell model is a lot different than the other end of the spectrum. I would say they're about as hospital based as you can be while still being ambulatory than a freestanding ambulatory surgery center owned by the big for-profits. They took their best nurses and built two high-end transport vehicles to take people from that site to their open-heart surgery program. Fantastic. That's a great way to start. You've got hospital sponsored freestanding centers. I ran those. I've got a lot of knowledge about that. They're still not for profit, still mission based, but not constructed legally and regulatorily in the same way as the Northwell, which is truly a HOPD. Then you've got the other end. You've got the for-profit freestanding centers owned by private interests. At this point, I just don't think that we have enough knowledge or experience to support allowing that third category of entity to do to participate in this demonstration. They don't have the integrated relationship with an open-heart program, transportation systems. Yes, they have backup hospitals because they have to run a surgery center, but that's not what we're talking about here. Candidly, I'm not talking about orthopedics. Unless the doctors tell me otherwise, very rarely does a patient die on the table in an orthopedic procedure. Happens, but me really rarely. Heart program is that's different. We're talking about stuff that can go really bad really fast. To wrap it up, my reaction is that if it's needed, can be generated but should be generated in the existing hospital-based extension clinic probably or freestanding not for profit hospital-based centers that have some history of obviously big heart programs would be great because they understand what can go bad. Northwell was the most illuminating conversation we had for me because they really put their toe in the water lightly. The other end of the spectrum is diving in. I'm not in favor of that. I'm in favor

of a demonstration. I'll wrap up, John. We can do the data collection, that we can define access, define the populations we want to meet, and but doing it within the existing framework of hospitals and health and cardiac centers that understand this business.

Dr. Rugge Turning to our Vice Chair.

Ms. Monroe A lot of what's been said I certainly agree with. I just want to clarify with you, Larry. I was not suggesting that data isn't important. I was saying what I don't want is us to not be able to make recommendations today because there's not enough data. Getting the data is a big piece of what this ought to be about. Just a couple thoughts that have been raised but maybe resonated more with me. I first thought when it said affiliated with a hospital that it could mean a lot of things. It could mean referrals, or it can mean owned by the hospital. To me that's a place that we should start is that hospitals own this clinic so that there's no question about where the financial incentives flow. With a referral system the incentives can be all over the place. If the hospital owns the clinic, so then I thought, well, if that's the case... How do we get safety hospitals and other hospitals that are not in the financial position of Northwell and others to have the resources to set up such an owned but separate ASC? I think whatever we do, we have to really think about does something come with a pilot, which I happen to agree with as well. Allows or permits or even incentivizes some organizations that otherwise would not go into this area and would just instead see their resources being fettered away through some other system. Is there a way to do that? I think the issue of equity of access. I remember the comment that was made by the woman who came from the advocacy center and said my people don't have to look at this very often. What we think is important is how do you communicate this with people that they're not going to where they used to go for service, but they're going to some storefront somewhere for this kind of care. That goes back to the issue of patient selection of support for the patient. What does that mean that they have to be supported? How does this pilot or whatever we do address that right from the beginning so that we don't end up with a skewed patient population that has ignored everybody who lives by themselves or everybody who lives more than twenty minutes away? I mean, if we're really going to do this, let's test it with real life experiences and make it work through that? That was an important piece for me. The last piece, I think for me this idea that we haven't talked about here, I don't think is what some of the hospitals said they wanted to do this because they need their operating rooms for other stuff. Am I saying that correctly? Maybe it wasn't operating rooms, but they need to free their cath lab up for other more complicated, perhaps even exotic kinds of treatments. That's their incentive. That's kind of where I see based on everything else that we talked about. Patient selection, I think is going to be important if this doesn't fall into what we have all seen happen with other initiatives like that, where they become located in high income areas, they have high incentives to treat the m the highest insured, the folks with the most supports. I don't think we'll learn what we want to learn out of this by narrowing it to such a degree. That's kind of where I sit.

Mr. Robinson I think maybe we'll get to this a little bit later, but I think to get to your point, when you think about a demonstration project, it probably almost needs to be a grant program. A funded program in which the criteria for applying include such things as patient access, patient support.

Ms. Monroe System affordability.

Mr. Robinson All of the things that we would want to test for to make sure that this program does address the equity issues, the access issues, as well as the quality issues

that we are concerned about. I think the only way to do that is to actually lay out a set of criteria that we want to have met and then allow folks to apply for it and to have it funded. Because you're right, this the setup of this program is going to be costly. I don't think any program that gets into the to a demonstration is going to expect that that program is at least in the early stages is going to be even covering costs.

Ms. Monroe John.

Dr. Rugge My turn.

Dr. Rugge You know, as one starting point, I think this is one more example and kind of an extreme example of how many services have left the inpatient setting to go to the ambulatory setting. Who could have imagined twenty years ago or even five years ago that now we'd be doing knee replacements in ambulatory settings, and they go home the same day? We need to take into account all these advancing technologies. The goals need to be several. One is does this improve access? How do we define access in terms of are we talking about poverty levels? Are we talking about geographic inhibition impositions? We need to address those. Another is safety. We need to be sure that we have a way of tracking that and assuring it.

(Beeping)

Dr. Rugge That's not mine. That's for Ann. That was for Ann, not me. Sorry.

All (Laughing)

Dr. Rugge Quality needs to be comparable in both settings because that's what healthcare is all about. And then not least is the cost and financial considerations. That is the current mode is lower costs, lower prices for ambulatory settings and inpatient settings. We need to be taking careful track of that because if we're really destroying the ability of a hospital from using the monies that come from cardiac caths to provide other essential services, treating cellulitis, for example, which is not procedure based but simply medical based. We need to figure that in. I think eventually it could mean raising some hospital prices as they procedures out of the hospital to ensure so we assure that hospitals remain viable. Very complicated to do. Not everything we're going to be able to do in the next two hours. Those are key. Another mention I have that came up to me along the way when we're talking about payer mix and all the rest is we have created expectations of ambulatory surgeries for having a payer mix. How many Medicaid people do you have? We've never enforced that. This could be an opportunity to become more detailed and more stringent and more careful about how we're defining access.

Mr. Thomas John, you just reminded me of one other point that you just made is that I think there's some healthy skepticism around ambulatory surgeries centers, which I think there should be, especially when you look at the percent of Medicaid populations served. It's very low, and even in hospital based. That has to be on front and center. If it's a grant program, as Peter suggests, or otherwise, if access for the underserved population is what we're talking about. I'll be kind and say spotty record in that space. We're going to need the demonstration will have to be designed to allow for that to change. I think the data that come in and we've approved surgery centers all the time show that they tend to do exactly what Ann suggested, which serve the highest insurance, most affluent, and really don't change for the rest. Thank you for mentioning that, John.

Ms. Monroe There's a suburb outside of Buffalo that couldn't fit another ASC within their borders if they tried.

All (Laughing)

Dr. Eisenstein I think defining access may be the single most important thing that we do here. I think we all understand that we're going to need to look at data and quality is going to have to be part of this. One of the comments that we heard during the testimony, somebody said they were describing how they couldn't get their patient the PCI they needed. They said, their insurance companies at a fight with their hospital. I have no idea where to send them. I said, that's not my definition of access. The other thing about access is that's going to be difficult for us that I think we need to be cognizant of is New York State law is one law for very varying geography, very varying population density, number of providers varies dramatically. I think that we have the challenge of trying to make a one size fits all program. That's why I think a demonstration in a place that we have data, I don't know what supportive data we have or not, that shows where there truly is an access issue based on whatever definition we come up with is what makes most sense, rather than try and push one size fits all onto the entire state where there's certainly variation in the services that are available and provided. I mean, just on Long Island, you go two miles it's very different what services you can access. I think you'd be amazed how dramatically things change. My point being just that the definition of access has been brought up and certainly in serving the most vulnerable' s. If we don't get that right, we've missed from the beginning.

Dr. Rugge Do you have another comment to wrap up, Lindsay?

Ms. Farrell I feel that we cannot leave cost out of the equation. Again, I'm thinking about it in a number of contexts. Trying to provide health coverage for your employees in the State of New York has become increasingly difficult for a whole host of reasons. If you as a patient need a procedure, you know, very often you get the bill and you're in shock. You get the bill from the hospital, you get the bill from the ambulatory surgery centers. Indeed, there are differences, but the cost of health care today in the United States and the variation in costs by geography, I just feel so strongly that needs to be something that we are thinking about in this group. Access, I believe is a function of cost. The higher it goes, the more people we price out of the system. I don't know exactly how to do that as a consideration in this group, but I think it is absolutely essential that we consider that part of the equation.

Dr. Rugge This was a very helpful and expansive conversation.

Ms. Monroe Excuse me, now I can't talk, Peter.

Ms. Monroe I'd just like to ask a question and maybe all the data we got from all the places just overruled my thinking. Do we know whether or not people who need a diagnostic or an interventional don't get it? We don't know, first of all if there is an access issue. Secondly, if there is an access issue for those procedures, what does that look like demographically and culturally, et cetera? I don't think we heard that. Did we?

Dr. Eisenstein That's what I was referring to before when I said there's geographic variation. That's exactly what I meant. There are places where I don't know if people are waiting for a caths. There's certainly places where they're not waiting at all. Who are they? That's what I was alluding to before.

Ms. Monroe Mr. Lawrence, you raised this issue. Do you have any sense of that?

Mr. Lawrence I don't have any data to support my suspicion, but I think what I was addressing is that if we are going to take on a new initiative if we should be looking at how we improve access. If we're going to have ASCs that's going to be that will be able to provide PCIs, then do we bring those to underserved more vulnerable communities? Do they go to the suburbs where there are already of tons of ASCs and so because then we're basically maintaining a status quo.

Ms. Monroe Reinforcing.

Mr. Lawrence I suspect, and I don't have the data, but I do know that mortality rates are higher in underserved communities for heart disease. I don't know if there's correlation or causation, but that exists.

Dr. Rugge This can be difficult to measure because some people and maybe I think more for the impoverished people, reluctance to proceed with this kind of procedure than if one is very comfortable in terms of wealth and support.

Ms. Farrell The nursing home presentation that we had last week or whenever that was fascinating. The Attorney General's Office who brought all of the legal cases regarding fraudulent activity by certain owners. I thought it was really very interesting. I'm quite sure there is malpractice data around cardiac procedures that might be relevant. Gene's shaking his head. Again, I'm the mother of a healthcare attorney. I am certainly aware of malpractice in terms of over utilization of services to drive profits. If there was a source of that information, I think we would do well to have it.

Dr. Rugge Next and most important session by some definitions anyway is a series of questions. Everybody's seen. Six questions.

Mr. Lawrence After all of the discussion I'm sitting here asking...I guess I think with Mr. Robinson. What's the goal? What is the problem we are attempting to solve? Maybe if we could just have someone articulate that for me, it would help because what is it that we're attempting to achieve by this in one or two sentences.

Ms. Monroe A woman from I think the hospital association asked the question that she wondered if we were not a solution in search of a problem. I don't know. The problem, depending upon who you talk to is mainly a cost problem and claim to be an access problem, but without real understanding of access. If you believe the hospitals who spoke here about needing to free up their cath labs to do different things, that these procedures are safe enough to send to the community, and then they could do more, as I said complicated things. Those seem to be the drivers of this, not our drivers, but the drivers of the department that asked us to look at this.

Mr. Lawrence When I look again I go back to the Harvid and Beth Israel information and most of the PCI the ASCs are in the South, in the West where there's a less developed health systems. Much of that I would assume is out of necessity. I'm asking. I'm not asserting that I know. I'm just asking. I'm trying to understand the motivation. That's all.

Dr. Heslin I'll add just a couple of comments because I'm said I would be quiet today cause it's not my arena to speak here. But issue was brought to the department by

physicians and a couple of hospitals. That's what generated this. I'm not going to say which hospitals. The hospitals that spoke at our public comment period were among the group that did bring it forward. The issue is that as the population is aging, more and more cath labs are spending time doing ablations, which is a complicated procedure that takes longer time than diagnostic and PCI caths. They're running into a problem where they don't have enough catheter lab space to be able to do those procedures which is becoming the standard of care for atrial fibrillation. Years ago, the standard of care for atrial fibrillation was you controlled the rate, you put them on blood thinners, God bless, good luck, you go home. The biggest risk was stroke. The standard of care is starting to become ablation. Ten to fifteen percent of anybody over seventy-five is in atrial fibrillation. It is a common thing that happens to the aging population and takes much longer to deal with in the cath labs. The ask was, could these lower end procedures? We talk about PCI, which they rated that ten percent could be done, five of the fifty thousand could be done. Even Dr. Nadu acknowledged that in the diagnostic world it could be much larger than that because and that's eighty-nine thousand. If you remove ten percent of those and five percent of these, you're taking out some of these lower end procedures. It allows for these more complicated procedures to be done in these lower end settings. That was the impetus behind how we started to take a look at this. Why is it happening in the South and other places? Frankly, they're not regulated. And so, in the more regulated states, they're wrestling with developing the regulations. Michigan has a regulation, but it took them a year to be able to put that together. Illinois has a regulation. There most of the states that are currently doing this type of procedure, and there are about sixty centers around the country are doing it in non-regulated states. Why is the data showing that they're actually doing as well? Patient selection is a bar part of it. We talk about the readmission rate and having it done you brought that up. Well, that's been true for hospitals without surgery for a decade in New York State. We've never studied it. It simply was just there. It was acknowledged. It was God bless. Good luck again. It has existed in those hospitals that do cardiac catheterization without surgery the entire time. It's never been not there. It's not a new signal. It's just a signal that's being recognized because this is a new area that's being looked at. We have to think about that as well. In terms of, you know, access, again defined in many different ways. The questions I ask are we going to build a different standard of care for this as compared to the rest of the ASC world? Are we going to look not just at access for Medicaid, but what about the people that that's the people that have commercial insurance. It's six percent or so of the money that gets collected by every institution, sort of like a tax, that we spread around for disproportionate share and to safety net hospitals and to support organizations. Those are the people that have these huge, huge deductibles and copayments. We never talk about those people here. They are the ones that are paying. They're the ones that actually don't go for care because they don't have the ability to pay their bill. But that group of people we need to think about because that's a group of people that doesn't have their costs covered. It's a choice between eating their meal or having their catheterization. Does a lower cost facility possibly make it easier for them to achieve an access to care that the Medicaid patient doesn't have to worry about? There's a lot of nuances to the system that have to be thought about when you talk about access and finance, because we take from all those people, and we give it to the safety nets. HECRA, that's how HECRA is funded. That's how we do all these wondrous things that we do supporting places. Does it need to be a demonstration or not? That's for people to decide. I think that You walk before you run, right? You crawl before you walk. What we have to do is we have to decide are we going to build standards of care that make something possible to be able to be evaluated and to go forward? Are we going to build something that is so hard to do that nobody simply does it? Because the industry is going to need that catheterization space to be able to take care of the aging population. Right now, New York State has one in about five people that are over the age of sixty-five.

It's going to be one in four In the next five years. In many of our communities, particularly Upstate, which has less access because there's simply less hospitals and less areas to do this. Some counties it's already 70% of the population is over the age of 65. 40% of the population is routinely over the age of 65. This is going to be something that continues to come forward, and we simply have to figure out. Are we going to wait for it to occur and then have to get there? Are we going to build something sensible that gives us the ability to think it through for when it it's arriving? Because it's really already here. I'll stop there. I hope I answered your question.

Mr. Lawrence I think I'm crystal clear now. Did the hospital systems indicate a preference for whether there should be done through in a hospital setting with I guess ASC or would they be open as well to sort of a profit model

Dr. Heslin They were agnostic on that point and that was probably because nobody asked. I think that the bigger issue isn't so much that issue. I think the bigger issue is the ability to provision for what's coming. The forward-thinking hospitals at least are thinking that way. One of the things I'll mention is we talked about for profit, not for profit, incentivization. All physicians are incentivized. They get what's called productivity bonuses. When you do more of these things, you get more money. That's true in hospitals as well as any other site. As we start to think through what we regulate and what we stop, how far do we go? Do we have that in the mix for hospitals that exist now? Because if you're doing twenty of these a day, is that too many? Do we have a too many list for ASCs? Again, it's a very complicated issue that you have to think through because, as my friend Jim Tallon once said, we have a socialistic view of what we should have. Unfortunately, we have a capitalistic reimbursement system that we have to deal with. I'll stop there.

Dr. Rugge Item for us is to actually develop our recommendations. To do that, Ann is going to be posing each of the six questions. I'm going to be scribbling some of the remarks and some of the conclusions we come to. I think I was chosen to do that because my handwriting is so bad. You won't know why you won't know what it is. There'll be lots of uncertainty.

Ms. Monroe I am going to suggest that we come back at quarter to three but just take a break so that you can stretch your legs and do whatever.

Ms. Monroe I'm fine with a five-minute break, but my guess is people will be back.

Ms. Monroe Six/seven.

Dr. Rugge Seven minutes.

Dr. Rugge Because I think we need at least ten minutes for each of these questions and then a little time to summarize and make next plans. Thank you. Yeah.

Ms. Monroe Well, we're going to talk about these questions, but we're not necessarily going to go boom, boom, boom, because I think they will blend and feed into one another. The first one I think is pretty self-explanatory, at least the first part. Should the ambulatory surgical center program initially be a demonstration project? We heard a lot of comments about that. Could I just see a show of hands about who would think it should be a pilot/demonstration program? We're not talking about what it looks like now, but should we start with that? If you don't agree, I'd like to hear what your perspective is.

Ms. Monroe We can put all the definitions we want on it, but that's if we say no to a demonstration then we're laying it all out.

Ms. Monroe I know Marcus, you want to speak to that.

Ms. Monroe We're going to hear from the people who oppose the idea of a demonstration project.

Ms. Monroe We'll start with you, Marcus.

Ms. Monroe No, I think you did not raise your hand, and Peter did not raise his hand. Well let's start with you, Marcus, and then we'll go across the table. What would you see from supporting it as a demonstration?

Dr. Friedrich I don't see the value in a demonstration product. Not supporting a demonstration product in my playbook does not mean collecting safety data. I want to collect safety data. I want to collect outcome data. I want the same data requirements, but I feel again that this is a question too high to ask from my colleagues in the Department of Health who to put the burden on them to not only oversee the demonstration project, but also to come back to us in two, three years with data and then make a decision on should we continue this or not. I feel this is in a way kicking the can down the road without understanding that we are still in the driving process, even if we say no to a demonstration project and allow with tight guidelines, with data requirement, to go and just approve it versus having a demonstration project.

Dr. Soffel I would also like to add to Marcus's because I think that I think I'm going to fall on that side. There are so many variables. You can't possibly have them all be incorporated in a demonstration project because you would need to have a hundred sites to test all the variables that we are actually sort of interested in that we've been talking about in terms of the other things. I don't think you would get an answer that's any clearer if we waited, if we said, okay, we'll allow ten sites to do this for three years and then we'll come back and take another look. We won't have learned enough in that time period and with that limited number of sites to be able to informative.

Dr. Soffel I think that we need to fairly proscriptive in the requirements that we put, be it around data collection, be it around ownership requirements, be it around staffing requirements, be it around expertise required, and have the department have a very clear sense that we are revisiting this question and if in three years we are finding that these there's a group of folks who are poor performers and there's another group that are doing just fine and so let's look at the poor performers and figure out and do something about that. I think that there are ways to learn what we want to learn, and a demonstration project would not give us enough new information to in better inform a decision in three years.

Mr. Robinson I think that while it's not exactly the same, I see this like almost like a clinical trial. I would say that to get to your point, Dr. Friedrich, I think the way that we should structure it is the Health Department ought to contract with a clinical trial coordination centered like entity to actually undertake this demonstration project so the burden for that doesn't fall on the DOH staff and that that center is the one that is responsible for reporting back to the department with the outcome. I see it as being like a multi-center trial. I think that's almost the gold standard for how you to intake data and

evaluate it. I really believe that's the right way to go about it. Secondly, and I'll say this maybe it's not as political, but it allows us to slow walk the adoption of this thing a little bit more, which I think is in our patients' interests. I think it's also in the interests of the institutions that could be even financially hurt by a rapid transition to adoption of this. I think it gives us time to evolve into where we're going to go, and the clinical trial will help to clarify the direction a little bit more. That's kind of how I would envision this going.

Dr. Soffel The number of sites.

Mr. Robinson I don't think we have the answers sitting around this table.

Dr. Soffel We don't.

Mr. Robinson It seems to me that you'd need enough so that you have geographic and the distribution, we have payer mix distribution, we have socioeconomic urban, rural, suburban. There's got to be enough critical mass so the data actually informative.

Dr. Soffel My concern is to get to the point where we have critical mass.

Mr. Robinson I think you can do it with five to ten sites.

Dr. Eisenstein I think that the concern about time is the reality. I mean, medications that save people's lives take twenty years to come to market because we have a procedure and a process here to show safety and efficacy. I think that as Mr. Robinson said, this is not a formal clinical trial, but it's a similar concept as far as gaining the safety data and impact. It's not only safety that's impact on the system and our patients. Does it really change access to care? Is it really reaching the people that we need? The fact is you can't just snap your fingers and have data appear which has been acknowledged by virtually everybody that we don't have. It's our responsibility to have that data in order to make sure what we do is protective of the residents that we're supposed to be serving.

Dr. Soffel I don't disagree with that. My concern is that having ten sites over three years doesn't give us the data that we need.

Dr. Soffel Ten sites and three years of additional data is just not going to be enough to better inform a bigger decision.

Dr. Eisenstein If I can respond, whether that's true or not, it doesn't change our standard of making sure what we're doing is safe and appropriate. We're talking about thousands of people across the state. I don't know that it doesn't. I think that if we have enough sites and one of the things that made the most sense to me, I've heard on the whole conversation since this started was Dr. Heslin's discussion of the need to be doing other things. Well, maybe there are places where this is much more in need and the patient volume is much higher. We haven't discussed those numbers yet. I think what would make sense is targeting this to where there are populations and in medicine you don't rush trials just to get an answer. You take the time you need to get it right and I think that's our responsibility.

Ms. Monroe I'm concerned that we may fall into a semantic trap if we call it. Because what you're describing to me is also like a demonstration project. It's either have some structured project that people have to apply to be part of or have to sign up to collect the

data and all of that, or we just throw the doors wide open and let anybody in who decides they want to be in. As soon as you limit that, to me it's a kind of demonstration project.

Mr. Robinson I think the other piece of this is that... You know, I think everyone around the table, I hope I'm not misstating this but seems to agree that whether or not it's here now, we need to start collecting the data. We need to start to capture the information that will be useful either to help incorporate that into a demonstration project or a trial, or if we're going to leap all the way to saying let's let this happen, then having a mechanism for monitoring quality and oversight on an ongoing basis. I think that to me got has got to be the fundamental recommendation coming out of our group is start collecting data.

Dr. Torres I just have a question. Where would the funding for that come from?

Ms. Monroe I think if the department is going to go ahead with it they have to identify where the money's going to come from.

Dr. Heslin Just a couple of things. We do collect data already on PCI. That has been going on for decades. There is data that exists. We have never collected data on diagnostics, not in fifteen years, because there was a trial at the very beginning when cath was first being done, and that went away. It's never been collected since then. Building a whole new diagnostic system is extraordinarily expensive. What I think the department could do is we can certainly piggyback the PCI data and have comparative data between the two systems. I don't think is that hard to do, especially if it starts off as hospital affiliated because those pipes already exist and then you have the two comparators. If it's not hospital affiliated and it's freestanding completely, what Mr. Thomas said, the third avenue that's a requirement that could be put in place as a requirement. One of the things I want to remind everybody is while regulations exist, CON authority for establishment is your responsibility. You could literally say no to a site. It doesn't exist. They can argue it, they can fight it, they can do all these things, but you have the ability to say, no, we have enough in this geography, or we don't have enough in this geography. You have CON authority. You have the ability to put contingencies in place with that authority. You are the ultimate arbiter, whether it's a demonstration or you know, free-for-all out there to decide who gets to go and who doesn't get to go. That is a responsibility you have. Having clearly defined rules, regardless of demonstration or pilot or whatever, however you guys decide and think about, you still have the authority to decide yay or nay based upon what you see, and to the point that was made about having the appropriate data, patient selection, staff selection, site selection, demographics and things like that. That is your ultimate control. The one thing I will say helps the department is in writing regulation if you say it's going to be a demonstration, the criteria about how you move out of demonstration is extremely important. It's part of law, regulation is law. If you limit in the law, in regulation that it's only going to be within this site, then we have to go back and change that regulation, which takes a year to two years as you've seen in other processes. Our preference would be is however you decide, having the ability to start with whatever X is and then be able to when appropriate based upon all the things, data, patient selection, otherwise, be able to move to Y makes it easier for the system to be able to function. Just as a thought.

Dr. Soffel Understood, but Gene, the challenge that I have struggled with around CON for the three years that I've now been on PHHPC is how hard it is for us to articulate how to define need. As I've been listening to this conversation over the last six months about PCI, no one has been able to clearly identify how you define the need for PCI and therefore whether we have sufficient services or we don't have enough capacity. We just don't have any way of evaluating that. To say that we have the CON tool in our toolbox is true, but if

we have no criteria of need against which to weigh that it's not a very helpful tool in my mind.

Dr. Heslin Right, so that's where I was going with pilot or demonstration to be able to get to having that data to be able to have that type of discussion. Once you hit that data's point where the line having it move out of demonstration into something that is more permanent gives us if we do that all in one regulatorily. It makes it much easier to function, but you have to have the lines.

Mr. Robinson Dr. Heslin, you were very helpful in responding to Mr. Lawrence around what was the sort of trigger to get us going on this conversation around these. You cited the need for at least some select group of hospitals who are struggling with facility capacity and wanted to find an outlet and a way to sort of transition to offload some services so that they could use their core facilities. Is another approach to this solving this problem to respond to those specific needs and say to those programs let's do something that is similar to what we do with ambulatory surgery centers with sort of a limited life CON that we that we approve for the two or three institutions that may come to mind where they've outlined what they want to accomplish. We require that it be hospital sponsored and affiliated so that it's not creating any new entities. We require as part of that that they start to put together the data collection that's going to be needed in order for us to evaluate how things go. Essentially, we're solving the problem without boiling the ocean.

Dr. Heslin You're not solving the problem because those are the two or three that have approached, not the count the rest of the universe that will say you didn't give us the opportunity to do this. Second, essentially what you've done is you've described a limited demonstration project in that area. One of the things we don't know, and the data was very apparent when I looked at it, there are sections of the state that do way more catheterization as a percentage of their population, not even by age, because it's not the oldest section of our state and our most sick population. There are sections of the state that are significantly underrepresented in that. Nobody's been able to answer for me are they doing too many?

Ms. Monroe That was the earlier question of do we know people who need it and don't get it?

Dr. Heslin Are their other parts of the state that aren't getting enough because there isn't access with all these other issues? We don't know that answer because the system isn't powered to determine that question. The system is powered to receive the information of who got it, not who needed it. That's a failure of the system, and that I don't think is going to change, because there's no way to gather that.

Dr. Heslin We're attempting to develop a program that will probably just in the way the conversation is going will start off as projects that will then grow into a larger program. What we're looking for as the department is we're looking for if it starts here how do we get to here? Because having to go back and revisit this every year to write new regulations is an impossibility. It just doesn't exist in the world.

Dr. Torres What is the characterizing of the PCI expansion?

Ms. Monroe Say that again.

Dr. Heslin There's nothing that says that it has to start off as PCI. We talk about PCI, but as you may recall, in New York State, when we first started doing hospitals did not have thoracic surgery, they started off doing diagnostic tests for a half a decade before they started to allow PCIs to occur in that market space. In that world we walked in the safest area, which nobody even studies because it's so safe to the less safe area. We didn't even require them to have ambulances on site. They just basically called the ambulance when something bad happens. All we did was say, you could do it as long as you had trained clinicians, appropriate lab site, appropriate staff, and you partnered with a thoracic institution essentially, hospitals without surgical backup started doing diagnostic tests after I think you started them in 2010, in 2016 or 2017 started doing PCIs.

Ms. Monroe I think before we go too deep into that and I'll come back to you, Lindsay. Whatever we call it, PB&J. I don't care what we call it. We are saying, I believe that we need to start well-defined group that isn't anybody who walks in the door. Is that an accurate statement? Marcus, does that get to what you were talking about? You want it open to whomever wants to apply.

Dr. Friedrich Whoever comes in front of us, and we approve it or not approve it, but I feel Mr. Robinson, like what you said triggered something in me that how do you make the selection criteria for the few? Are certain geographic areas again preferred than to others? Why not say everybody can apply who fits these criteria and we make the decision in the CON process either to grant it or not grant it?

Ms. Monroe Lindsay.

Dr. Friedrich I feel much better about that because I feel like to develop the criteria for the selected few for the club of the have and not the club of the have nots, I feel is just unfair to everybody else.

Ms. Farrell Couldn't you use some public health data regarding the burden of disease with respect to I don't know cardiovascular disease. That's something that is tracked to be able to identify the geographic variation that you noted, Gene. You said some parts of the state are doing a lot more than other parts of the state. Couldn't you neutralize for that using some proxy data, for example, that's reasonable?

Dr. Heslin That would be hard to do, but I'll think about it more.

Ms. Farrell I'm sensitive to the geography issue, right? Because that's the Dartmouth Atlas, right? Why is so much activity happening in New Jersey as opposed to Iowa, for example?

Dr. Heslin Some of it is burden of disease, some of it frankly is burden of aging to be quite honest.

Ms. Farrell Then use both as proxies so that you could better target like where you would want to put this demonstration project.

Dr. Heslin It's interesting because when you talk burden of disease... I would postulate. As to Harvey's point, we know that certain minority populations have way more diabetes, which is a huge driver of cardiovascular disease. They live in a geographic area of the state, which actually is the youngest part of the state, and you're talking burden of disease on aging, it's in a different part of the state. When you start looking at burden of disease,

geographic variation and start accounting for these confounding variables, you end up everywhere.

Ms. Monroe Did you have something, Dr. Ortiz?

Ms. Monroe Can you use a mic, please?

Dr. Ortiz I'm just thinking about if we want a saturation of data from a select few of sites, we're going to have to give them very clear timetables from which we would want data. Who's going to evaluate the data? I'm not sure what the workforce is within the departments. What's going to be the indicators of meets criteria, exceeds criteria, significantly exceeds criteria? Because whatever regulation we make, we're going to want it so that we have a meet criteria that really is going to be exceeding criteria. I keep thinking is it six months of data collection for the next two years and at some point we decide, or the department decides maybe a year and a half, we have a saturation of data that is meaningful and could give us clear indication of what we could articulate as a site that is an exemplar of how we want other sites to be. You know, because we keep talking about how we are going to evaluate the CONs, but we haven't talked about what's the mechanisms by which we're going to use to look at it. I keep thinking when we have a request for proposals for anything. There's criteria that that tells you... Should I even apply? I think that's where I am. I am struggling with the access. Because I also am sensitive to the fact there will be agencies who say, Well, you wrote it so much that no one in this part of the state could apply. What type of data? We're already going to be skewing the data because we're creating the indicators that are going to tell them what they have to meet, and we're basically going to tell them if we don't see this, this isn't going to happen. We're almost creating the answers that we want answers to.

Dr. Eisenstein To kind of piggyback on Dr. Ortiz's thought, it almost sounds like to do this right we're going to need to have people who are trained at designing data collection and analyzing it. It kind of sounds that it makes sense to me that this should be done. This is the first time I've had this thought through academic centers who know maybe this doesn't need to be an IRB formal protocol, it doesn't need to be formal research, but say they certainly have the people and ability to design the data collection to make sure if it's going to be a year and a half or two and a half or five years. To me, it takes a little longer to get enough patience to be statistically significant, but maybe I'm wrong. That's a guess. I think that we have to make sure that there are neutral people without an interest on either side of it except the interest of providing the answer to the questions that we have and collecting, stratifying, analyzing the data appropriately. Basically, having a real epidemiology program guide us on the way is what's based on what Dr. Ortiz said makes sense to me.

Ms. Monroe Harvey.

Mr. Lawrence I'm thinking that essentially what we develop is a program and then we develop a model that overlays that sits on top of the entire state. It would be by region, sub regions, and then we could have the data that is consistent with what we want to see in terms of access in each of these areas. It doesn't have to be one issue at all. It could be subbing parting.

Dr. Heslin Can I ask a clarifying question of Dr. Eisenstein?

Dr. Heslin In terms of academic medical centers doing this... Does the academic medical center have to own the program, or could they be an independent evaluator of the program as part of the ASC model? Instead of having this limited to academic centers as part of the start of the program, each one of these has to have its own independent evaluator that would evaluate the criteria.

Dr. Eisenstein I should have been clearer. I was actually suggesting nonclinical academic oversight. In other words, more important to have a public health or epidemiology program design the data and kind of be our eyes and ears to make sure that the data's legitimate and that the patient selection has been done appropriately and correctly, and they can do the geography and all of that.

Dr. Heslin That's what I was saying. We'd have a set of criteria and this independent evaluator as part of having one of these things would then each of these new centers, if you will have to have this independent evaluator produce the data to be able to bring back.

Dr. Eisenstein Yeah, and then ideally they'd come here and present to us in a few years.

Dr. Heslin I'm just thinking through how I write a regulation around that.

Ms. Monroe I also wonder if you need to have a separate individual evaluator for every part every group that's participating or whether you want a kind of overarching evaluator that can begin to compare and contrast.

Mr. Lawrence I guess what I'm suggesting is that we do that evaluation, and we build a model in advance. The second leg of that is then to have someone monitor whatever we created. Before you even issue the regulation, you have the done that modeling and you know that you want to have four or five ASCs in this area, ten in this area doing these procedures, and then you work with the academic institutions to make a monitor.

Dr. Heslin Difficult to build the model that way because frankly, the data doesn't exist to be able to design that. That's where on your null hypothesis of building a model ahead of time to then populate it given the data that currently exists.

Mr. Lawrence The conditions that we're looking to address in the various communities around the state based on what data that that's available and it's an assumption. You're looking for the academic institutions to monitor and test that those assumptions.

Dr. Heslin That would probably be something you put in guidance as opposed to regulation because regulation is force of law, which we then do enforcement against. Guidance is how we say this is what needs to happen, and these are the ways we do it. Think about us as we have statute, this is the enacting law.

Ms. Monroe I think we don't need to go into quite so much detail right now.

Ms. Monroe John, did you have something?

Dr. Rugge Yes, I think this discussion reveals how complex even this question is. Are we going to have a demonstration project as is a mode of going forward? The only positive conclusion I can reach is we'll need to schedule at least four meetings before December 3rd to go to the other questions. How in the world are we going to get there is my concern.

Ms. Monroe I appreciate your asking that question. I think we need just a little more clarity on what various people are talking about and then I think we can get to process.

Dr. Eisenstein Could I ask a question that hasn't been asked yet? I don't know, Gene, how you feel about this, but with everything else we do at the PHHPC, ultimately the State Health Department makes a recommendation to us. I know the point of this was for us to provide the information, but I do think at some point it's important for us to know what the State Health Department thinks too, because we're spending a lot of time and if we don't know and we're going in a totally different direction, then we've lost a lot of time. Are we... Maybe not today or...Is that something we're able to get? What are you guys thinking in general? I don't want us to diverge here and then we have a real problem.

Dr. Heslin Good, good question. The department wanted this group as representative of the public, because it's cross-sectional, to provide a series of recommendations for consideration on how we write the regulation. We may not take every one of your recommendations as we craft. We're also asking the Cardiac Advisory Committee, whom are the experts in patient selection, and they got the president of SCAI and all this other stuff to essentially do the same thing. We're going to take the recommendations for consideration, which is why this is such an important thing, rather than a yay-nay vote, but the discussion. Take and look at what the public said in public comment because everybody staked out a position. Try to craft a regulation that meets as many needs as possible to be able to put a program forward. On any one of these points, it maybe we just can't do it, but then we have to have a reason why we can't do it. We're going to go in this direction, but there's a reason why behind that. Once we build that regulation, why we went through that whole discussion about how we get through SAP and stuff, it will then go out for official real public comment. We hope to have had by this process three things occur. Number one, we only have to go out to public comment maybe once as opposed to twice because we've gotten it down the first time. We've gotten it right. Number two, we end up with a program that is viable because of a lot of input, as opposed to doing it behind closed doors and then waiting to get input. Don't like that process. Number three, most importantly we got a whole bunch of Public Health Council members that have become educated in a new and different topic that when it does come up will know the right questions to ask, to Denise's point, and we'll understand where we don't know what we don't know. That will make the whole CON process more valuable because you'll at least have had thought about this in a critical way. Those were the three things and the goals that we had. Does that answer your question?

Dr. Friedrich Towards moving on, I think like when I look at the questions that it is not each questions in a vacuum, but maybe the first three questions could be answered somewhat together because we are already talking about academic medical centers. Every academic medical center is hospital affiliated and probably a multi-specialty which is already in place because most academic centers already have ambulatory surgical centers that are multi-specialty, that is probably the most likely way. I wonder instead of going one by one and spending half an hour on each of them, is there a way maybe to take tackle the first three questions together? I'm just asking as a suggestion.

Ms. Monroe I think that's fine. I think that there is a fundamental question about whether we want to ask certain kinds of organizations to imply. We set those criteria. Not we in this room, but the department sets those criteria. We want you to apply if you do X number of these things, or if you serve a high Medicaid and uninsured population, or whatever those criteria might be, or whether we want to say we are interested in whoever comes forward and will try to make a program out of all of you. That's how I think the question is. If we

can't answer that one, I think it's going to be, I don't like going down the order either. I think if we can't ask... Does the department articulate what kinds of groups should be applying? Does the larger provider community determine who applies? There's disagreement there's disagreement. We have to kind of move forward with an idea in our head about what we're looking for.

Dr. Soffel Ann, I think that there is a pretty clear idea. I have not heard anybody say we should open the floodgates and let anybody who wants to apply come in and join the party.

Ms. Monroe No, I don't believe that's what Marcus is saying.

Dr. Friedrich I feel that we should be again careful about the definition of demonstration project because I feel that that is the opposite of opening the floodgate. I think it should be a fair process where everybody and maybe let's talk about every academic center can apply not be part of the demonstration but be part of opening an ASC where this procedure would be allowed. I'm in between. I cannot say yes or no to exactly what you were saying. Is that opening the floodgates? I don't think so because the floodgates would be to allow every freestanding, every commercial entity that comes into New York to apply to open. That's certainly not what I want as well.

Ms. Monroe We start with N, a number of them. The department in the regulation defines that number. Is the number determined by whoever comes forward?

Mr. Robinson You ought to set some criteria.

Mr. Thomas In terms of definition, I mean, at least what I was speaking about earlier, and I'm sorry I missed this twenty minutes is taking the most sophisticated groups of cardiac programs. However, you cut that, is volume, it whatever. It doesn't have to necessarily be in an AMC setting, in an academic medical center setting, although most are, not all are. Really defining the people who are eligible to apply for the demonstration project as being the people who made the cut on biome and history, I think. That means that they have already had decades of open-heart programs. They've had they sponsor freestanding hospital cath labs, they do training programs, whatever it is, and most will be AMCs as Marcus suggests, but not all. Do the cut that way so that you don't have Hugh Hospital in the middle of nowhere, which happens to have a cath lab affiliated with New York Presbyterian. I shouldn't be doing a demonstration project for this. You see what I mean? I think you got to cut it in a different way.

Ms. Monroe I think that fits with what Harvey was saying.

Ms. Monroe I don't know where we are right now.

Dr. Heslin Rather than fighting and gnashing over demonstration or no demonstration, maybe the committee might want to think about what are the important things that you want to see because that largely can determine the rest of this, right? What I've heard is we're particularly concerned about patient selection. We're particularly concerned about safety. Safety came up in every discussion. Is it safe? Is it safe? Are we safe? Is it going to be safe? If we start to think about safety as a way to define this program then that can get too potent potentially demonstration, size, geography, all these other things can flow out of that way of thinking. It's the opposite way of thinking about it as opposed to saying twenty or ten or fifteen. Define it against the things we want to know. We want to know safety, patient selection. We want to know staffing. We want to know physician. Those are the

things we want to know. We want to compare it to three things. I do everything in three. Sometimes, I put A, B, and C underneath if I can't get through three. Number one, we want to compare it to our hospitals with thoracic surgery, because they're our most complicated patients. Number two, we want to compare it to our hospitals without thoracic surgery, because they're doing the less complicated ones now, theoretically. And then number three, we want to compare it to the others that are out there in the rest of society to see how we stand up against them. In our quality safety data, and if we design it around that. How long does it take to get the safety data rather than sites or this or that or all the other things? It may have to be, it starts off in the hospital world.

Ms. Monroe Sophisticated.

Dr. Heslin Because it is the safety data that gets us there. We expand as we have proven that safety is not a site issue. Safety is based upon staffing, equipment. Patient selection. Our big argument is... Is it sight safe right now? If the answer is yes, then those other things are more important.

Dr. Heslin Dr. Lim had her hand up. I'm sorry.

Dr. Lim I was going to say thank you for bringing that up. I think the main question is what are the questions that we want any pilot to answer? I think we have to go really back to basics. We're introducing kind of a service into within a level of care. When we're doing something new like that, it really has to be really simplistic. How do providers even operationalize this, right? Do we really need two ambulance bays? Do we need five ambulance bays? What are the equipment's? What are all those protocols? I don't think they set that up within like a couple of weeks. That took months and months of refinement. I don't think a pilot needs to be five, ten years long. I think an inherent value of having whatever we call it is to answer the question of how do we safely operationalize this care within an ambulatory surgical setting? Hospitals have some familiarity with that because some do it in an HOPD, some may not do it at all, right? There's going to be different groups of hospitals. We don't want to exclude hospitals who've never done it before. Maybe they need more help, and they can learn from this. I think just getting really simple. Thank you, Gene.

Mr. Robinson I think that you maybe want to think about walk before you run, right? I would suggest that actually we establish criteria for institutions that can apply for providing this kind of service initially to institutions that have done this before, that are more that provide comprehensive services, that have quality programs, that have teaching programs, whatever it might be. Once we've seen the outcome of that, we may be able to allow other institutions with maybe less qualifications to step in. I think we got to be careful that we don't open the door too wide in the beginning because you can't pull back once you once you've got this started. Walk before you run kind of may be the right approach here.

Dr. Eisenstein If I can add to that, just I was going to say something very similar, but you know, Gene, you kind of summarized some questions that we all have. We don't know what the impact is going to be on access once we can define access. Is it safe was a question I've asked fifteen times. Is it equitable? Are we going to be reaching everybody who needs catheterization versus just people with certain insurance opportunities? As you listen to the conversation more and more, this is going to come down to research design. Since the purpose here, as you said is to kind of get our thoughts and ideas, to me we're kind of homing in now, as you just described on the certain questions that we're trying to answer. I just want to be very clear about something. When Dr. Ortiz, I think we're on the

same page when we brought up doing this from an academic center. We clarified. I think that people what I meant with an academic center is I meant that epidemiologists who know how to do research design are doing this. Not the places that have university cardiology operations. In fact, if we really want to be fair about it, it's probably better to have public health and epidemiology programs that are not affiliated with cardiology programs to give an unbiased accounting. I think since we now have homed in on the questions, the best way to do this would be to bring it to the experts, put it out to the various public health and epidemiology programs and say, this is what we're trying to answer. How should we design this? How do we go about it? I definitely think we have to be careful about unintended consequences. If we start too big, as Mr. Robinson said, once you open the barn door, the animals are out. You can't get them back in. We don't know what some of the consequences are going to be as it relates to staffing and outcomes, et cetera. That's the point of being methodical and sometimes unfortunately slow in doing biomedical research is safety first. I don't know, I like the idea of turning it. It doesn't have to be formal IRB approved. I'm not suggesting that that will take forever and will never happen. I think there needs to be the way we design the data and evaluation of this is either going to give us the answers we need or it's not. I think we need experts in that field to guide us.

Dr. Rugge Perhaps pilot is a better word. The idea is to a multi-center trial. Inclusive of hospital centers with deep experience and competence with PCIs.

Dr. Rugge I didn't think I could bring it off the table.

Dr. Rugge The geographic distribution this to do and to study. Ensure that we have all payer participation, good payer distribution. That patients are carefully selected as people who will be benefiting from this. We look to assess the impact of this kind of outreach. What does it mean? Are we serving more people more appropriately? Are we just doing it safely all over? Can it be done because is it's not so safe? I doubt that. Initial project is comparing PCI data carefully between inpatient settings and new ambulatory settings. That's an ongoing assessment that we need to have. That this is all about whether it's a CON or considered a trial, I think that's more likely. Limited a lifespan and we need to define the timeline in advance. Is it three years? Is it five years? Is it twenty-five years? Again, starting with a well-defined group, whether one at a time, having a group that starts together so we can do cross comparisons for these trials. Have an independent evaluator who is well qualified to do the assessment and is not biased by virtue of one connection to another through employment.

Dr. Rugge That's another thing. That's question number four, but so I have it not addressed it, but I think that is understandable. There are there any objections to that to have any new pilot be not for profit.

Mr. Lawrence We're making it hospital sort of institution base. Hijacked a talent from a hospital and set up something with an ASC that has all of the necessary components, all of the people with experience, and a facility that is on par. Is that something that wouldn't work?

Dr. Rugge I think the presumption is we're starting with hospitals already in place and every hospital in New York State is not for profit. That's just an understood criteria.

Ms. Monroe Would affiliate mean owned by the hospital?

Mr. Lawrence It could be a partnership, I guess.

Mr. Lawrence I'm not familiar with the hospital world, so I'm just asking. You'll probably need grants to get this up and running. In the current fiscal environment, I'm not certain that you're going to have a bunch of grants coming in to take on innovative new initiatives. The question is there some tolerance for maybe a hospital led partnership with you know a sort of a buyout potential ten years or five years into the future.

Dr. Rugge I think we're talking about being certainly hospital affiliated, and the hospital involved needs to decide am I the owner or am I a partner?

Mr. Robinson If this is just an effort to create another ambulatory surgery extension clinic focused exclusively on this particular discipline institutions are likely to consider doing that as long as they can determine financial feasibility going forward. Where I think the support is needed to go to need to come in is actually with the data collection and with the evaluation of the performance. That may be where significant additional costs are going to be accrued that need to be considered as part of as sort of a blended grant program for a limited period of time to do data collection and that kind of thing, but the operational expenses are sort of baked into the business model for the organization.

Dr. Heslin I just want to make a couple of clarifying points. Dr. Rugge is right. Every hospital in New York State is not for profit. They can also own for profit captives underneath them. You don't have to have the ASC could actually be a for-profit ASC under a not-for-profit hospital, and that does exist in the world.

Mr. Thomas We're talking about a really tiny exception to the general rule.

Dr. Heslin No, it is a tiny exception, but I just want to be very clear that our laws do provision the allowance of for profit under hospitals.

Mr. Thomas That's true, but stepping back a second, if we're going to define those eligible to participate in this as the geographically dispersed, urban, suburban, whatever Heart programs, at least today, by definition, those are not for profit programs in the State of New York.

Dr. Heslin Correct.

Mr. Thomas There's a bigger question about private equity in New York, but we're not going to be dealing with that today into hospital ownership. I think what we were talking about is creating a universe of programs that are eligible to do this. Most of them probably already run multi-specialty surgery centers, either as hospital outpatient departments or as freestanding centers that are not for profit in their systems and use that universe of programs as being the end, and those are eligible to apply. To me at least, those are the programs that are best able to assess data, to do the comparable with the hospitals that they back up that are freestanding cath labs now. You know, you laid it out, Gene, those are the three data sit points that we want to follow. I think that's what I heard.

Dr. Heslin The other thing to just to split, hospital owned doesn't always have to be a hundred percent owned. It has to be hospital ownership control, which is at least fifty one percent ownership control in a thing. There are many ways to split this. It doesn't have to always be a hundred or zero as you're thinking this through. If you're moving down that hospital lane, and it sounds like people are, you could potentially have a hospital that owns

fifty one percent and it be owned forty nine percent by all the docs. Who knows? There's many different ways to slice this. Hospitals have entered into many arrangements that ASCs are not fully owned by themselves. They are exactly for you what you're saying, Harvey, which is the other portion can bring capital to the table to help to be able to finance these things. The people have figured out how to get around the financing question in many different ways.

Dr. Eisenstein Well, as we're talking about hospital systems, I don't the conversation just evolved. I don't think we should forget about all the letters and testimony that we received as a PHHPC from the various hospital systems. They write letters, we should pay attention to them. There's a reason they do it. We heard all different opinions, but we heard Greater New York, who represents a lot of hospitals, but I'm sure not all come here and be very eloquent in their position. The reason I bring that up is the hospitals, I'm not sure they're not already biased in this discussion because they've already taken a position. I know where my system stands. Northwell had different slight perspective. They have a program that they put incredible amount of effort into building in New York City. Albany had a very thought Albany Med. I don't know them. They had a very thoughtful letter of suggestions and hesitancy, but not a complete no. You know, people wrote us a lot of letters. I think that's important to recognize that now we're talking about hospital systems as if they're all going to want in and they all should. They already have an opinion on this, most of them. They've told us what it is. I'm not sure if we open it up to hospital systems, the ones who want it are going to run to try and make it work. The ones that don't are going to run to try and make it not work. I just want a fair and honest data set and process.

Dr. Heslin I'll also point out that you got a letter from all the health plans that basically wanted it to be a full wide-open system. There are diametrically differing opinions why this is such a great topic to discuss and actually wrestle with is because it's taking into account just everything that has to do with our healthcare ecosystem. It's so much it this is why it's fun.

Mr. Robinson I think they're with especially when the health plans get involved, remember this whole issue of site of care and Medicare that's actually being debated at the federal level right now is going to have an enormous effect on health systems and disadvantage hospitals enormously. Health plans in some ways have the same incentive, which is essentially to pay less for the same service, which is not necessarily a bad motive, but I'm just pointing out that that's we ought to recognize why people are making the recommendations they're making.

Dr. Heslin In all directions.

Dr. Heslin If you hit site neutral across the board, right, site neutral which was talked about by CSS at the public comment period. If you hit site neutral, there may be a huge incentive for hospitals to be doing this in the HOPD or the outpatient world because they're losing a huge markup fee for a site and they may all of a sudden economically have to think about it differently or the opposite way, which is they have to have the whole world just to make it survive.

Mr. Robinson They bring more things physically inside because I think that the obviously the whole issue of site of care and the differential in costs, at least hospitals would argue is driven by the amount of standby costs that hospitals have to have in place, no matter what, which these ambulatory sites do not have to have.

Ms. Monroe If the hospital owned the ambulatory site, the revenue that came from that site would not necessarily be siphoned off from the hospital as a whole. It would still be part of their revenue.

Mr. Robinson Revenue, but obviously it'd be revenue at a lower level.

Ms. Monroe I want to go back to Harvey's point because I think in listening to this, our goal is that at some point in time PCI, diagnostic and PCI will be available in the safest, most cost-effective places that provide the greatest access to the population. We're not going to get their step one. We've got too much we have to figure out the data to evaluate them by, we have to see where it works, where it doesn't work. To me... If our goal is the larger picture, we get there through some sequential steps. Do those again, like what do we say, you have to walk before you can run, and that we have enough of a variety in that pool that we start with that we can learn about different sites and different places. The goal is to have it be wherever it can best be provided for the public.

Mr. Lawrence I think that's a great goal. But atrophy sometimes creep into that where the first round, second round, and then people get comfortable learning.

Ms. Monroe That's why you kind of have to---

Mr. Lawrence How do you write the statute in such a way that it captures and reflects what Ann has just articulated?

Ms. Monroe The department's going to have to write that regulation.

Dr. Heslin As I said, all recommendations will come in, and the beauty of a good regulation is everybody's going to hate it, but we're all going to figure out how to make it work because at the end of the day, what we're going to end up having to do is figure out how to care for people in New York State in a safe way. What we're really debating right now is the whole health ecosystem, finance, all sorts of things. At the core of this discussion is really safety. Dr. Lim said it. If we keep it relatively simple and we focus on safety, what you end up with is... Is the site safe? Because all other things are extraneous to the discussion. We started off where it was only done in thoracic surgery hospitals. That was the only safe site back in 2001. We went to hospitals that don't have that, and we decided that they were safe for diagnostics. They were safe for PCI. We changed sites. If we can get that answer out of the demonstration everything else just becomes part of a different, bigger discussion of the economics of medicine, all this other stuff that we can wrestle with and we do with every single application that comes in. The core issue is... Is it safe? Is the site safe? Because that's the only real thing we're deciding here. Everything else is part of that bigger discussion. If we focus on that narrow thing, that's a regulation that can be crafted.

Dr. Friedrich I love what you said, but then based on that, all seventy-seven hospital sites where they're currently doing PCI are all safe sites, correct? Ambulatory surgical centers should match at least from the safety profile both sides.

Dr. Heslin That may be...the decision may be that's where the match is. You have to also remember that all those sites have to be within a certain distance, whether it's flying by helicopter or not, to a thoracic site. There are rules in place in regulation that ensure that those sites met a certain criteria in order to be able to practice medicine that way. It may be that we have to start off with. I'm just going to say it because it may not be where it

ends up. It's got to be a hospital based ambulatory surgery center because the only thing you're changing there where the physicians and where the nurses are doing it, whether they're doing it in the hospital site or the ambulatory surgery site. You now have eliminated all other variables out of that discussion. Your only variable that's left is the site. That's the variable we're trying to be able to find. Is the site safe to be able to do these procedures? If it is, then you can expand it out from there, right? Because at that point in time, it's no longer about the economics or who gets seen or all these other confounding variables that we could discuss forever. Is the site safe?

Ms. Farrell Safe is relative and dependent upon a number of factors. We have more confidence in the hospital center, right, that those factors will be met for all hosts of reasons. How do we assure that there's consistency and definition?

Dr. Heslin That becomes criteria and that's why you have to have the comparator, and you eliminate other variables. Because if you eliminate variables, you end up with an ability to get to a decision.

Ms. Monroe I worry that if all we're looking at is the site safe... Is that we will go to the safe sites. We won't experiment with underserved communities. We won't experiment with more rural areas. We will build on where the sites today in the system are safe. I worry a bit about if that's our only criteria, why wouldn't we just go with where a hospital today has an ASC, and we just let it go with that?

Mr. Thomas I agree that that is a fear, but if you look at the history, that hasn't been the case. Gene's talking about the migration from heart surgery programs to non-heart surgery program cath labs. That evolved. That's twenty years ago. That is very diverse in terms of dispersion across the state. I think that can be addressed. I think the suggestion is that you capture the programs that have successfully done this wherever located, hopefully some very urban, some Long Island, some where we are, et cetera. Because I think if you were to look, if Gene were to put a map up of all of the non-surgery, open heart surgery program hospitals that operate cath labs for cardiac care today. It's pretty diverse, especially because of the new rules that we adopted. That was an evolutionary process, but the beginning was the site safe? It evolved from there. I would suggest it probably wasn't as detailed a conversation as we're having today when that happened. I would almost guarantee it was not. We're evolving. We're going to do this. Let's go. We're doing the state a great service by having a discussion.

Dr. Heslin I'm not saying we limit it. What I'm saying is that if you gather data you then can have discussion and then it expands, which is why it becomes that pilot with data and discussion and then it grows from there. It's never going to end there. If you have to pick a starting point... You pick a starting point.

Ms. Farrell I keep thinking about the nursing home example, right? I thought that the legal presentation was really interesting, right? Because you know the claim was that, oh, there were four shortages, and yet there was data that demonstrated that indeed in this particular zip code that had multiple nursing homes, one nursing home was able to have sufficient staff, whereas another was not. The staffing expectations, I think are really important on this one.

Dr. Heslin Safety is defined in many different ways. Patient outcome is the most important thing. Complication rates are very important. All the other things that are to find safety is

where the devil in the details are that's when you write that type of regulation then goes through all the public comment and everything else that goes into the build.

Ms. Monroe We're going to have to put time on this.

Dr. Rugge We have three minutes.

Ms. Monroe John, do you want to talk about next step?

Dr. Rugge Good question. One question is how do we do a summary of what this discussion was all about?

Dr. Rugge Is that better?

Dr. Rugge The question is how can we prepare a summary of this discussion and what it leads to by way of recommendations? A question is... Do Eugene and your staff, Abby, feel comfortable using this and the outlines we've given to do an outline for a presentation at our December meeting?

Dr. Heslin The answer is we set the schedule, there is no choice. What's going to happen is we're going to as quickly as we can put together the minutes of the meeting, which was a free flowing and excellent discussion. We're going to circulate those proposed minutes, which we're hoping that the committee will then put in the appropriate edits and from those appropriate edits from those proposed minutes, it may actually be just the transcript of the meeting, just send that around and everybody can edit their thoughts. At the end of the day get those out not just the day before, but we have to get those minutes out pretty quickly. From that we should be able to craft series of concepts that become the regulations, right? Safety, site, how you define safety, selection? How you move from initial phase walking to or crawling to walking? What's the criteria where you move from one to the next to running? Is there an evolution path that is defined? Is it something that just happens organically over time? Those are the type of things that become the more nuanced pieces. I think we can get to that place for next meeting to get a series of recommendations that this committee could then work their way through for presentation to Public Health Council December 4th.

Dr. Rugge As one more observation, I think in discussing number one out of six we really addressed all of this. This is an encompassing discussion because your idea of starting with a demonstration topic first I think was very helpful. This framed everything for us.

Ms. Monroe It opened up a lot of things.

Ms. Monroe Just a reminder, and we're not formally required, but we have committed to the council that we will have at the December 4th meeting the preliminary recommendations from this group. As great as our discussions are, we will also have more task focus at the December 3rd meeting. Hopefully, we can come to a set of recommendations, even if it's two or three that lead us into where we need to go.

Dr. Heslin Just be aware, it's going to take a little while to write this regulation because we're going to get the Cardiac Advisory Committee recommendations as well. Having a directional start gives the ability to craft. We may not get it all done, it may be in two tranches, it may be an A tranche and a B tranche by the time it all comes forward. Cause

that's an innovative process. Once we take it inside and we start writing, that we have to do.

Ms. Monroe On behalf of John and I, thank you for hanging in there today. It was a good discussion, and as a couple people have said, we don't have discussions like this through the PHHPC process and that maybe what we could do when we have a different topic is we could tackle that again. Thank you. Thank you, John.

Ms. Monroe Will it be dark out there already?

Ms. Farrell Yes, probably.

Ms. Monroe Oh no.