2018 PCORI Annual Meeting

Plenary Session
How Much, How Often? What to Do When One Treatment Approach Isn’t Better Than Another

Presenters:
George J. Chang, MD, MS
Katrina Donahue, MD, MPH
Erik Hess, MD, MSc

Moderator:
Aaron E. Carroll, MD, MS

Discussants:
Janet McCauley, MD
Shelley Fuld Nasso, MPP
Michael Thompson

SESSION TRANSCRIPT

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Ladies and gentlemen, at this time we ask that you please take your seats.

Ladies and gentlemen, welcome back to the 2018 PCORI annual meeting plenary session.

To begin our discussion, here is Dr. Joe Selby.

>> Welcome back, everyone.

Hope you had a nice break, got meet some people and have a little refreshment and saw some posters.

I wanted to start just by mentioning something that I didn't mention before which is that we are live Tweeting from here with the hashtag of PCORI 2018. You see it there.

And you can also watch the whole thing on webcast at PCORI.org/live. But you're here in the room so you don't need that information.

So, as I gave you a bit of a preview just before the break, we have found and this is not necessarily something I would have predicted, but there's a lot of things about PCORI that I would never have predicted.

But one of them is that when you get patients and researchers together, some of the questions that people come up with are extraordinarily practical questions.

That question about single fraction radiotherapy is one of the questions that exemplifies this.

And we're going hear about three of those types of questions.

So, patients ask do I, personally, really need that?

Is that the right thing for me?

Or if it is the right thing for me, is this the right dose?

Or if it’s the right dose, is it the right frequency or is it the right duration?

If I've got multiple sclerosis or rheumatoid arthritis and you're telling me that there's this drug that costs 80 or $100,000 a year and a lot of it comes out of my pocket as out of pocket costs, do I need to take those drugs forever?

Maybe.

Or do I need to take them for two years or three years?

Or if I have been totally quiet for the last 12 months, can I take a break?

Those are the kind of practical questions that don't very often, certainly not often enough, get asked and answered.

And we find ourselves funding a lot of them.

Should I take an adult Aspirin or a baby Aspirin if I've had a heart attack or stroke?

And I would like to prevent another one.

Nobody really knows.

Even the guidelines don't degree.

Here's another one.

If I have had treatment for a cancer and now I'm told that I need to have either imaging studies or or blood tests or endoscopies, how often am I supposed to have them?

We're funding four studies that have kind of question.
And again, as I said, I wouldn't have predicted it, but it makes sense when you put patients at the table and in the room asking these questions, is it the right dose, the right duration, the right frequency, is it right for me? You're going to come up with a lot of those questions and we have. And we're going talk about three of these studies today. One of the important aspects of these studies is that they can be very difficult to analyze and to make sure that you've got the right answer. So, to find that there's no difference between a higher dose and a lower dose. Between every year and every two years. Is tricky from an lytic point of view. So, we're going to talk about three examples from three different conditions and three different aspects of care. And I really cannot think of anyone better to moderate to introduce and moderate this panel than Dr. Aaron Carroll. Dr. Carroll is a professor of pediatrics and he's the associate dean for research mentoring at Indiana University. I will say that I knew Aaron when she was just a kid. 20 years ago, I met him and it's so nice to see him all grown up and [Laughter] And making such fabulous contributions these days. But in addition to being a professor, he runs one of the PCORI Learning Health System traineeships at the University of Indiana. But in his spare time, he is a worldrenowned blogger. And he blogs both at the for the "New York Times." His blog is called Upshot. And he also blogs as part of the group that blogs under the title the incidental economist. These are fascinating blogs and they talk about some of these very same questions. And so, I want to say that I'm very grateful for Aaron for taking the time to be with us today. And now it's my introduction my pleasure to welcome Aaron to the stage. And he will introduce the panel. And then we have three discussants from three different walks of life after the panelists. Thanks, Aaron. [Applause] >> Aaron Carroll: I'm going to be very brief because I want to get focused on the panelists and talk about the things we're here to say. It's a pleasure to be here. Thank you, Joe. For also making me blush.
But one of the things that I write about quite a bit and that we do a lot of research in is, you know, we try to take the perspective of I'm besides being a pediatrician and besides being a researcher, I'm a patient.
I have chronic illness.
And it is interesting that I think sometimes we assume talking about treatments that they've all been researched, and people know what's the best thing for you.
How much of it should you get?
A lot of the things that Joe just talked about.
We spend billions of dollars on research every year on the discovery and development of new drugs and treatments and scans in ways of diagnosing and treating illnesses.
But so little that research with the exception of a big part funded by PCORI is focused on what patients and physicians need to talk about.
And other providers as well.
How do these therapies compare with what we're doing?
What are the benefits and harms of screening regimens.
Are they all good?
How much do you need?
When does it tilt?
What's the best thing to do for you?
Compared to the research, it's sometimes the only way to get at those questions.
And to my delight, it's a focus of so much what have you're going to hear about today and the over the next few days.
I'm going to dive in and introduce the panelists, so you can meet them, and they can talk about their fascinating research.
First is from MD Anderson cancer center, the division of surgery, Dr. George Chang.
[ Applause ]
And I'm not I'm gonna let him sit and shake all their hands.
Second from the University of North Carolina, director of research in the department of family medicine, help me welcome Dr. Katrina Donahue.
[ Applause ]
And then finally from the University Alabama, the advice chair for research and emergency medicine, Dr. Erik Hess.
[ Applause ]
So, we're going to begin with Dr. Chang whose study focuses on the critical issue of caring for people after they have had surgery for colorectal cancer.
Dr. Chang.
>> George Chang: Thank you.
That felt a little bit like getting selected during the draft with the music in the background and everything.
[ Laughter ]
Thank you so much for the privilege of being able to speak to all of you today.
I want to first start by thanking PCORI for supporting the kind of work that we're going to be hearing about today.
I want to thank all of you for being here and for pushing forward all of these efforts and working on this research.
Today I'm going to be talking about posttreatment surveillance for survivors from colon and rectal cancer.
These are my disclosures.
Colorectal cancer is extremely common.
The good news is if we can detect it early enough, it can be cured typically with surgery and sometimes with the addition of chemotherapy or radiotherapy.
And if you look on this chart you can see there are almost 2 million survivors of colorectal cancer anticipated in 2026.
The second most common group in men and the third most in women.
For these patients we typically recommend followup or surveillance we call it.
What are the goals?
Why follow them after curative treatment?
Some patients develop reoccurrence.
We want to detect reoccurrence, so we can treat those patients.
But the treatments can have longterm sequella.
Associated toxicity or bowel dysfunction from some of the surgery, et cetera.
We also want to make sure that we don't miss opportunities for ensuring continuity of care, secondary prevention, making sure that our colorectal survivors get their mammograms as an example.
And there's a lot of anxiety with a cancer diagnosis and we're responsible for helping our patients address some of those psychosocial wellbeing issues.
But most of the focus actually in surveillance, at least if we think about guidelines and a lot of the emphasis is placed on testing.
And that's what I would like to talk to you about today.
If we look at testing there are guidelines.
So, clearly there is value in testing for reoccurrence.
There's value in identifying reoccurrence through tests.
There are other ways that reoccurrence can be identified.
But I think if you just look at the international landscape of guidelines, you can see there's tremendous variation from no testing to scanning up to twice a year or certainly annually that we see on the U.S., on the right of the screen and you can see in other parts of the world such as in Europe and the UK somewhere more in the middle.
This reflects the fact that there's insufficient evidence perhaps.
It also reflects the fact that it's difficult to make the decision about what's the right thing to do.
Why is that?
Because there is benefit in treating patients who develop reoccurrence.
So, this is some data from MD Anderson, from our group, where we show if we can identify patients who undergo curative surgery, they do a lot better than those patients that cannot at the time of reoccurrence detection.

Do we need testing to detect reoccurrence to do that?

That is a bit of an unanswered question.

So, that's the benefit.

But what are some of the downsides of all of this testing?

Maybe we should get a lot of tests, so we can identify people that we can operate upon.

But there are many patients in this room who certainly can understand better than us as clinicians the concept of the anxiety that we face every time we're waiting for a CT scan results as an example.

Obviously when the results are reassuring, that's what we want to see.

But during that time, it can be very disruptive to our lives.

We've seen these signs.

Xray in use that is an indicator potentially of the potential harms, the risk for additional cancers to develop.

And then we also, you know, we have a test that might find something that might not actually be anything but mainly to a biopsy or other invasive procedures which themselves may be at risk for complications.

So, as Aaron had mentioned, there are potential harms of all of this as well.

And this is in addition to the burden to our patients.

So, what we wanted to ask was, does higher surveillance intensity, does doing more improve the detection of reoccurrence?

Because it's the detection of reoccurrence that allows the potentially curative surgery, and does it impact survival?

This was a collaborative effort.

Thanks to PCORI's support.

This is a collaborative effort with the commission on cancer and the national cancer database and the American college of surgeons clinical research program as well as the alliance for clinical oncology network.

What we did is we worked all together, and we have to give a shoutout to the cancer registrars around the country who played an integral role in the study.

We looked at patients treated in the United States with colorectal cancer who had been cured and treated.

We went to the medical records and identified all of these data points.

And what did we do?
We took the factors that we took the characteristics of patients and of their tumors and of the environments in which they were, of the facilities in which they received their followup care.

And using that, among patients who did not have reoccurrence, we created a model to predict how frequently can we anticipate patients to get testing?

So, this is not based on the guidelines. This is based on what's actually happening in the real world today.

And so, based on that predicted number of tests for the patients that were treated in the different facilities approximately, 1100 facilities in the final analysis.

And this covers the so, the National Cancer Database, just as an aside, I'll tell you, covers or collects data on 70% of all incident cancer diagnosis in the United States. This is a very broad representation.

We were able to identify facilities that perform more testing or that perform a higher intensity of testing than we would have anticipated and others that are performing less intensive testing than we would have anticipated based on the models.

And so, then we asked, are we detecting more occurrences sooner and are patients living longer?

All the graphs I'm about to show you, they follow the same. There's CAT scan testing on the left, and blood testing, CEA, carcinogenic antigen it's a blood marker on the right.

And on the top, to give you a sense of low intensity. That's 1.5CT scans in three years.

That's half a test per year.

And high intensity, about three tests in three years.

One CAT scan per year.

That is approximating the U.S. guidelines.

The left approximates UK and EU guidelines as it turns out.

In the orange we see rectal cancer.

In blue we see colon cancer.

And there are actually four curves.

It looks like there are two because high and low intensity are overlapping in their detection of reoccurrence.

That is more frequent testing or being cared for in a facility that tests more frequently than we would have anticipated did not improve the detection of reoccurrence.

And here we can see the same for survival.

Being followed in a facility that does more frequent testing than we anticipated versus less testing.

It did not improve survival.

And that was the same for imaging, the CAT scans or for the blood tests.

And then finally we talked about surgery as being kind of an important component. And I just happen to be a surgeon.
But we can see that there was a very, very small impact. And in fact, this is a very expanded Y axis. It's a negligible impact on the rate of surgery and only in the patients with the highest risk. We might identify a group in which the testing can actually make more sense. But it's a very, very small impact. So, what does all of this tell us? Well, it tells us that the intensification of surveillance really has a negligible impact on question occurrence or survival. We often think of testing as a way to try to address this concern about, you know, do I have recounter cancer? And, yes, that's an important modality for that. And we should perform testing when we suspect are you counter cancer. But it may not be of benefit to do repeated testing at a high frequency. Or perhaps with every visit with a provider. It makes no sense based on this data to do that. It may slightly increase the rate of surgery for reoccurrence, but it, again, is a very, very small impact. And certainly, there's probably no need to image more frequently than once a year. What we saw in our study is in some settings there's even higher levels of frequencies than the mean value or the average testing frequency that I described in the high intensity group. And okay, there were some facilities that performed even less testing and arguably insufficient amount of testing. And there are different patients in different risk categories. Perhaps defined by stage. One of the easiest ways to define our patients risk categories is what stage of cancer do you have? And there are patients at lower risk that may need less testing than what we examined. But I think another really important point of all of this is we emphasize so much the testing. But I started off this discussion talking about some of the other goals of care. And some other goals of followup care. And that has to do with management of treatment associated toxicity, health promotion and helping to manage psychosocial wellbeing. And perhaps we need to not forget that those are also very important components. I think that I think that as a community we generally do a pretty good job of that. But we can very easily get distracted with tests and the discussions around tests. And perhaps this is an opportunity for us to think about how should we refocus some of our efforts so we can optimally provide for the patients. PCORI support developed a decision support tool which we're still working to test.
But that we feel may help patients and their providers actually have the conversations around these issues.
And address some of the important gaps that exist in these conversations in the care of our patients with colorectal cancer.
So, with that, thanks very much for your attention and the opportunity to present our work.
[ Applause ]
>> Aaron Carroll: Thank you, Dr. Chang.
Next will be Dr. Katrina Donahue who I introduced before.
And she's going to discuss her study on whether a common form of self-monitoring for type 2 diabetes is helpful.
Dr. Donahue?
>> Katrina Donohue: Okay.
Good afternoon, everyone.
I'm gonna I'm gonna figure out how to use this remote control.
And also discuss the effect of glucose monitoring on patient and provider outcomes in non-insulintreated diabetes.
In terms of disclosures, our team had developed a glucose messaging and treatment algorithm for the purposes of licensing it.
And it was used in the study.
So, a little context about this study.
Guidelines regarding self-monitoring of blood glucose are inconsistent.
And these are national guidelines in terms of the role of glucose self-monitoring in adult patients with treated type 2 diabetes.
And the recommendations from health care providers also vary widely.
Numerous stakeholders have an interest in this debate.
And as we thought about this question of the role of blood glucose monitoring, we did engage stakeholders, patients and providers and asked these questions. We talked with our health care providers and asked them, do you recommend blood glucose monitoring in patients with type 2 diabetes not on insulin.
We were surprised by the variety.
Some said no, I don't recommend monitoring.
Others say I recommend once or multiple times daily in this group.
With the patients, the responses were diverse in terms of what their health care providers were recommending in terms of blood glucose testing.
We thought we're on to something here.
Self-monitoring of blood glucose, it's been widely practiced in patients with diabetes since the 1980s.
And the benefits have been well established in patients with type 1 diabetes on insulin and type 2 diabetes on insulin.
For folks that have type 2 diabetes not on insulin, the studies have been diverse.
Glycemic and the studies that have shown some benefit, the glycemic benefits have been minimal at best, an A1C of improvement of .2% which is statistical, but of doubtful clinical significance. Some proponents of blood glucose testing note it does improve self-efficacy. Improving the patient's confidence to take care of their diabetes daily activities. But we must remember the potential obstacles which is that blood glucose testing is invasive. It involves pricking your finger daily with a blood glucose test strip, which is costly. And there has been a study showing an increase in depressive symptoms. So, a variety of different outcomes out there. Our stakeholders got together and talked to many different types of stakeholders. And asked them, if you were going decide to look that the question, what outcomes matter to you? And with that we’ve developed the monitor trial. So, in the monitor trial we assessed the impact of three SMBG testing approaches over one year in 450 patients with non-insulin treated diabetes. 15 care practices in North Carolina. We randomized them to, you know, number one, the first group, no blood glucose testing. We told them, congratulations. Throw away your monitor. You don't have to test for the next year. Group two, randomized, gave them a glucometer and said go ahead and test daily. The group three, we gave them a glucometer and programmed it with messaging based on American diabetes association guidelines. Every time they test their blood sugar they get a recommendation or encouragement or instructions just depending on what that rating showed. All groups were instructed to go see their primary care provider for the regular diabetes care. Keep it as pragmatic as possible. Everyone continued to see their primary care provider. And the provider had access for the blood glucose testing groups. They could see it was wirelessly enabled. They could see the trends of the blood glucose. We had an evidence-based one pager based on those readings. But it was up to the patient and the provider in order to make any adjustments. So, we followed these guys for a year. So, the population included, again, primary care patients. These were patients that saw their primary care provider for diabetes care. Not specialists. They were able 30 and over.
Type 2 diabetes. Not on insulin and their A1C was moderately controlled between 6.5 and 9.5. English speaking and not pregnant. Based on our stakeholder input, we had two primary outcomes, glycemic control as measured by A1C and quality of life from baseline to one year, or 52 weeks. We looked at a host of second dare outcomes including diabetes-related quality of life, self care activities. Whether they had treatment satisfaction or improved their communication with their health care providers. We also passively pulled data from the electronic health records so when they were going to see their health care providers, we pulled all of those A1Cs over the year. Adverse effects, hypoglycemia, ED and urgent care visits. So, our population, this is just a quick description, is this patient like me is a good question? Our patients were on average middle aged in their 60s. Obese. Average BMI of 33. And many had established diabetes about 78 years. We did have 10% of our population that were newly diagnosed. But on average this was an established group of patients with diabetes. And over three quarters were reporting they were doing home blood glucose testing before they were randomized into the three arms. So, what did we find? Well, in the I guess in keeping with the theme of this plenary, at the end of one year, we found no significant differences in glycemic control as measured by A1C between arms or overall. We also found no significant differences in quality of life at one year. And as you can tell, baseline A1Cs were about 7.5 for our two testing arms. They went down maybe .1%, but again not statistically significant. We also looked at our second dare outcomes. Hoping we would find something. But, again, we did not find any significant differences mien among the among the arms in terms of their quality of life. Communication with their provider was about the same. Only activity that was different was of the blood glucose testing in testing arms. And most importantly, there were no adverse events that were study related between the arms. So, thinking about this study and the context. This is a study of continuing monitoring rather than initiating monitoring what I mean is this cohort of patients, the group of patients we had in this trial, the majority were established patients with diabetes.
We did have 10% that were newly diagnosed, though. Not all patients, as you can imagine, adhered to the group that they were assigned to. But we actually looked at that as well and found no differences with the highest compliers at the end of one year. These practices were all based in one health care system. Allowing us to pull their data in the southeast. And finally, probably most importantly, these findings don't apply to patients that are on insulin. So, in conclusion, over the course of a year there were no clinically or statistically significant differences in glycemic control or quality of life between patients with non-insulin treated diabetes who performed SMBG testing compared to those who did not. Additionally, the addition of tailored feedback provided through messaging via the glucometer did not provide any advantage over glycemic control. So, in summary, enhanced blood glucose testing, at least in the pragmatic trial real world setting offered no additional benefits. Thank you.

[Applause]

>> Aaron Carroll: Thank you, Dr. Donahue. Our last research presentation before we introduce the rest of our participants and turn to the panel is from Dr. Erik Hess whose study looks at a critical question for people who go to the emergency room with chest pain. Dr. Hess.

>> Erik Hess: Thank you. Today I'll be describing to you an intervention that we developed to help clinicians provide care with their patients and not simply for their patients or on behalf of their patients. I have no complicate of conflicts of interest to disclose. So, Michelle is a 42 year old man who is a husband and father of two children. And one afternoon when he was playing with his children at his home he developed chest pain. Now, he knows that his own father died of a heart attack when he was 50 years of age and so he immediately feels a sense of anxiety rise within him. So much so that he begins to feel a knot begin to develop in his stomach. He calls his wife, Annie, who is at work and describes to Annie what he is experiencing. And together they decide to go to the emergency department to figure out if this is serious or not. Annie cancels here meetings for the rest of the day and calls a friend and gets childcare coverage for the time, so they can be seen in the emergency department. In the meantime, Michelle had driven to the emergency department. He walks right through the front doors and walks up to the registration desk and tells the clerk there, I'm having chest pain in his broken English.
Because he is a French-Canadian and English is not his first language. Within just a few minutes, a woman in a black outfit uniform wheels takes a wheelchair, asks him to sit in the wheelchair and whisks him back to the treatment room. When he's in the treatment room, there are two health care providers to care for him in addition to the nurse transporting him. They immediately help him change into a gown. And one of them puts a piece of plastic with oxygen in it in his nose and another gives him four small tablets, four baby Aspirin to start chewing on. Then a fourth health care provider comes in the room, this is within 5-10 minutes. And Michelle tells me all these people look pretty serious. Four health care providers. Walks up to him and starts putting stickies on his chest and his arms and his legs. And they print out a pink tracing that has some weird squiggling lines on it. A few minutes later, a man in a white coat introduces himself as Dr. Jones. He asks questions and listens to his chest and on his back with a stethoscope. And then after that, Dr. Jones says, Michelle, I would like to take some of this blood that the nurses just drew and send it for testing. And I would like to get an X-ray your chest as well. And then he walks out of the room. Shortly before that, he says, Michelle, I'll be back in an hour and a half. And then in the meantime, Annie shows up. Now, Annie is the English speaker of the two. She's very comfortable and fluent in English. She starts asking, Michelle, what's going on? What did they tell you he describes everything that's happening and doesn't know what tests are being obtained or why? An hour and a half later Dr. Jones comes back, hey, this is what we found. We tested you for heart attack. You don't have any evidence of a heart attack. The pink tracing, that's an electrocardiogram. You are not having a heart attack, but to be 100% sure, we need to do one more blood test. And by the way, I think you're at low risk for this being pre-heart attack or heart attack symptoms. But it's not no risk. So, I would like you to be admitted to the hospital overnight for some more testing. And then the doctor leaves the room. Now Annie and Michel look although each other, our kids are at home. He's like, I don't speak great English. Don't leave me alone in this hospital.
And they’re like, none of our friends are going to survive our kids for 24 hours. So, we have to make it home.
So, Annie gets the nurses attention and asks the nurse to speak with a doctor. So, the Dr. Jones comes back and says, Annie has this question. She says, tell me a little bit more about his risk. What do you mean by low? And the physician looks a little taken aback. And he's like, I can’t tell you exactly what his risk is. I just know that it’s low. But it's not zero. And I would feel like it would be best for Michel to stay overnight. So, the conversation is over, and they start talking again and they decided to leave and go home against medical device and to be seeing a doctor the next day. And the next day he sees a cardiologist and told that everything is fine and that he has nothing to worry about. This is the experience that led to Ann any and Michel joining our study as the patient and caregiver representatives.
What I have described so far is a patient’s experience. One of the things that Michel mentioned that blew my socks off, because no one told me what the risk was, I had to read body language. Beyond that, I can't understand half of the words that everyone was saying. And everyone looked serious, so I thought my risk was 50%. You take the car to the mechanic, and they're going to keep it overnight. Something is wrong with your car. So, what I have described so far is the patient's perspective. Now, I'm going to refocus the conversation to the physician's perspective. I'm an emergency physician.
And every time they work a shift on average I'll care for between 2025 patients. And many times, I'll be caring for four, five, six patients simultaneously. And chest pain is the second most common reason patients come to see me. On any given nine hour shift I'll see 45 chest pain patients. Do the numbers quickly. Over a career, I'm going to see thousands of chest pain patients. And I know that our testing, the literature tells me that we might miss up to 1% of patients with pre-heart attack symptoms. And so, this is why I want to sleep at night and not worry about missing that 1%. And I'm tempted to tell people like Michel I want you to come into the hospital. And I know that it causes unnecessary hospital admissions, tests that don't need to be done. And many of the tests will be false positives. And some of the false positives will lead to unnecessary procedures.
And so, we have two different parties.
Each of which has a different perspective.
And so, our idea was to create an evidence informed conversation that also brings up the preferences of both the patient and the physician.
And Annie and Michel, as well as our emergency department patient advisory council met with our investigative team and a designer and we developed a one page tool that you can bring to the bedside in the emergency department.
And notice that as you are all aware, I'm not a short person.
And you have to get at the patient's level to have this type of conversation.
And it's when you start using this tool, you start using language like, why don't we consider doing this?
Or let's do this rather than walking in, standing at the end of the patient's bed and saying your testing's negative.
I'm a little bit worried.
I recommend you being admitted to the next hospital.
Going on to the next patient, thank you.
A lot of times it's our baseline of how we interact with patients.
Here is our one page tool.
The first section tells Michel that based on the blood testing that we obtained, and a test called a cardiac troponin, and the pink tracing with the electrocardiogram, you are not having a heart attack right now.
We need to do another blood test to be sure.
After that blood test comes back, do we need to pursue further testing.
I can tell you confidently whether or not you're having a heart attack, but I can't tell you whether or not you have pre-heart attack symptoms.
And there's a couple of tests that we can consider based on your individual risk.
First is a stress test.
And much like the test you just had in the emergency department when you had the tape stuck to you and the pink tracing, same thing, but on a treadmill and we'll watch you under stress and see how that changes the electrical activity of your heart.
And the next is an angiogram.
You are on a bed and go through a doughnut type structure.
And we can tell you what the heart anatomy looks like and see if there are any blockages.
Those are the two things we're considering.
But first let's talk about your individual risk, Michel.
I know you're 42.
You're a man.
We have seen your blood tests.
I've asked you characteristics about your chest pain.
And I can tell you based on risk prediction models in the past that out of every hundred people just like you, one will have a heart attack or pre-heart attack in the next 45 days and 99 won’t.

And just in case Michel is too anxious for those numbers to make any sense. Show him a picture and help him decide in his own mind which of these characters is he.

The blue ones or the one red one in the bottom right?

We then transparently list the management options that the physicians normally keep in their head.

In the course of normal care, I might come in and recommend one option. But, okay, based on your risk, you can stay overnight for a possible stress test.

You can be seen by a heart doctor within 13 days.

If you feel comfortable with your own primary care physician, you can arrange an appointment with them.

But you can have them as backup and I will provide a followup appointment.

And the last is, this is too much.

Perhaps Annie didn't make it to the emergency department and you want me to take the decision for you.

So, we're all excited.

We developed this tool and it really kind of makes sense based on their experience as well as their ED patient advisory council.

We wanted to know how well does this tool work?

Thanks to PCORI who decided they would fund our study, we did a multi-center randomized trial.

If Michel walked into an emergency department in any of these six states, he could have been enrolled.

California, one in Minnesota, one in Indiana, two in Philadelphia and one in Florida. And it's meant to enroll patients just like Michel.

So, someone whose primary issue is chest pain who is being considered by their clinician for admission or discharge.

But if they have any positive tests that indicate Michel is a high-risk patient, he would not be involved in this study.

And those I listed there.

So, interacting with our patient caregivers and our ED patient advisory council, the issue of how important it is for patients to know why things are happening just kept on coming up.

You can imagine in the situation Michel was in, you don't speak English and people disappear.

In our imaginations, tend to imagine things are a lot worse than what actually happens. So, they wanted to know what's going on and why they're being tested and what the outcomes of each of those tests are.
We also measured how well the physician engages patient in the decision making process.
We asked the patients and the doctors how was this experience?
How acceptable was this decision to you and your practice?
We also followed these patients for 45 days looking to see if there were any missed heart attacks that were sent home.
And compare the rates of hospital admission or stress testing between the intervention and control arms.
We randomized the patients to either the usual care or use of this intervention to facilitate shared decision making.
What did we find?
After maybe six months of writing the grant, a year planning the study, two years of recruiting the patients, sweating, wondering if we're going meet the sample size goal, we finally get the results.
Yes, the patients do know more about their risk.
And what their options are, much more than if they didn't use the tool.
Clinicians engaged patients with the tool two times greater than normal clinical practice.
Changing clinician behavior with just a piece of paper.
We decreased our stress test admission rate 60% over excuse me.
At the emergency department evaluation time and at 30 days we decreased our stress testing rate by 30%, also a significant difference.
Our providers liked the experience and wanted tools for other conditions.
And the patients like Michel decided to go home and they were comfortable with that.
We followed them forward for any missed heart attacks.
There were not any missed heart attacks in either arm of the trial.
So, what's next?
So, of our 898 patients, because this is a low risk group, there were not many patients who had a heart attack or other adverse events.
Prevalence of the adverse events was not high enough to be 100% safe.
We have not tested the tool outside of the context of a tightly run trial.
We want to scale up to implement it in practice and monitor its safety as well as the patient's and clinician's experience with care.
Now I invite you imagine for yourself.
You're at home.
Maybe you're in your car.
Maybe you're here at the meeting and your chest is starting to hurt.
You develop chest pain and you decide to go and be seen in the emergency department.
When you walk through these doors, do you want someone to provide care for you? On your behalf?
Or would you prefer to have care that was done with you?
When you walk through those doors, are you supposed to drop your autonomy at the door?
And just walk in with open arms like if anyone's ever had a surgery, you all know how vulnerable it feels when you're lying there with no clothes on about to be intubated. This is a situation where our patients feel like they're in. And this is the question that I'll live you with. Do you want care that is for you or with you?

Thank you.

[Aplause]

>> Aaron Carroll: All right.

That was great.

Thank you, Dr. Hess.

Now that we've had the opportunity to hear from our three researchers, I want to bring up our three discussants for what is going to be a fascinating and compelling conversation.

We will be taking questions from the audience in a bit after we have had a chance to talk up here.

And also, via Twitter should anybody be listening or if that's how you would like to submit your question. Use the #PCORI2018.

Again, that's #PCORI2018.

Start getting those questions ready and getting them in.

We will get to them soon.

First, from the National coalition for cancer survivorship, their chief executive officer within please help me welcome Shelley Fuld Nasso.

And next from the National alliance of purchaser coalitions, President and chief executive officer, please help me welcome Michael Thompson.

And last, but certainly not least from Blue Shield of North Carolina, their senior manager of effectiveness, Janet McCauley.

[Aplause]

And so, while I'm giving up my seat, I think I'll rove more often.

But the first person I would like to talk to is Shelley.

A lot of these decease, in fact all of these studies wound up saying perhaps less care and screening would be better, less testing would be better. But patients and often patient advocacy groups fight for more. That we're not doing enough.

How does research like this resonate, and obviously you're not speaking for all patients or patient advocacy group. But how does this type of research resonate with you?

>> Shelley Fuld Nasso: I think that patients are very willing to consider doing less if they understand.
We heard from Amy earlier about, you know, how less has been more for per because of her, you know, how it's impacted her life.
But what I love about the tool that Dr. Hess talked about was that it really explains it to the patient.
Why we're not just sending you home and saying you don't need to have these tests. We're explaining to you why and pictorially showing what your risk is. It takes more time to explain why less could be better, but it can. But I think patients are open to that if they really understand it.
And I think, you know, when you talk about patient advocacy groups, I think that, you know, some want more, but I think they really want to be able to make those decisions with their doctor and not have decisions imposed upon them.
And I love what Amy said that, you know, if we're all trying to live our best lives, best life is different for every single person.
So, when you have situations like some of the studies that we heard where there's not a clear answer or there's not necessarily a clear benefit, then having those discussions are so important.
But unfortunately, doctors are rushed. You don't have the time to spend with patients. We don't value the time spent with patients as much as we value procedures and drugs and other interventions.
And that's what's needed to help patients really understand their options and to make those decisions.
And I think they're willing to do less if they understand it better.

>> Aaron Carroll: So, let me pivot to Janet. I think you're representing perhaps payors here. Part of what is being said here makes sense, if we have time to explain to patients, they can make their decisions. But it's at a big level in research. At a policy level. We should do fewer colon colonoscopies and less blood testing. That maybe means payors won't pay for those things.
How do you view this research?

>> Janet McCauley: Of course, lack of evidence really drives lack of information which drives variation in care which drives over and underutilization or misutilization which leads to misappropriation of resources. And certainly, less desirable outcomes. And often less than desirable experiences.
I think we have had three good examples today of what happens when there's not that information and at baseline when there is a lot of variation in care. The payors are interested in all the above. The appropriate use of resource.
Driving to the right outcome in the most efficient way possible and the best possible experience for the patient or our member.
So, the advent of having these tools that have come out of the comparative effectiveness research really leads to a better way of getting to those answers much more quickly.
The payor wants to align the payment.
And in the value role, this is even more important to align the payment to the process of going through this.
Not so much the bright line around the binary decision of this is covered, this is not.
But the process of going through this is just as important.
And looking towards the outcome is the ultimate decider.
>> Aaron Carroll: Does this change the way you might reimburse for the tests or treatments?
Or more of a guideline on the care side?
>> Janet McCauley: It may change as far as directing towards the outcome.
Again, the process being as important as the preconceived choice of one decision or one mode of care or the other.
Ultimately, I think it aligns very well in the value based world where we’re going to be looking more at outcomes and not so much at the bright line of this is covered, that is not.
I don't think the purpose of what is coming out say for Katrina’s trial with the glucose monitoring.
We're more interested in going through that process and having the patient understand the pros and cons and say okay, well, you know, we're not going pay for daily glucose monitoring.
That's not the intent at all.
This is a much better platform for accelerating.
Getting the information that everybody needs to make the right decision.
>> Aaron Carroll: Fantastic.
Michael, for the benefit of the audience which might in the know what the national health care alliance of coalition of health care providers is, perhaps talk about who you are representing?
>> Michael Thompson: We have an organization nor employer coalitions across the country.
From large size companies to midsize companies to municipal municipalities, states, the federal government as well as union type organizations.
>> Aaron Carroll: How does that research resonate with you?
>> Michael Thompson: No matter what the purchaser is, they have two key interests.
The first is they want their employees, their families, to get the care they need.
They don't want to stand in the way of that happening.
And in fact, they want to remove barriers to the extent that it's clear what they should get and get it and they should get reimbursed under their plans.
At the other side wing much like the pairs, they're concerned about the value of the care that's being provided.
And so, we know that there is a significant amount of care that doesn't add incrementally to value.
And so, when we have evidence to support that, it really helps us to educate employees and their families.
But also, to influence the balance of the system to refocus their efforts to care that does make a difference.

>> Aaron Carroll: So, I'm going to turn to the studies for a second.
So, how do you I want to know how do you get to these questions.
Did you talk to patients or involve patients in the work before it got started?
Because some of these clearly, we do colonoscopies, they help in monitoring for cancer, blood glucose testing because it works.
How do you decide to say maybe less is better?
How did you get there?

>> Michael Thompson: Well, you know, we saw that there was so much variation in practice and there was so much variation even in the guidelines.
And so, we actually worked together with survivors and patients and we worked with other clinicians.
You know, it's a very complicated interchange of factors that leads to the decision for a test.
It may seem quite simple, but actually it has a lot to do with the individual patient's experience at the time, their level of anxiety.
What the physician's workload might be.
Sometimes it's easier to order a test than to have a 15minute discussion and a test can be reimbursed while a 15minute discussion might not be.
I think these are all very complicated issues.
So, we thought that, you know, this was an opportunity for us to try to generate some evidence around this around this area because we have as providers we have patients coming asking for more tests.
As providers we also don't want to miss anything.
And so, we're, you know, we feel obligated to get more tests.
And so, we wanted to help that decision making.

>> I was really glad you talked about anxiety.
I loved that slide.
And I think that's really important.
And I looked at the decision tool that you're developing and asked the questions about, you know, how much of a hassle is it to have these tests?
How important is it to you to know that your cancer has reoccurred?
What would you do if you found out?
I thought those were really good questions to ask.
Because I think, you know, we have to understand like while scanxiety is big, so is fear of reoccurrence.
You have to look at the risks and balances for that individual.
Are they going to be more concerned about the additional anxiety of having the scan or the fear of reoccurrence if they don't have the scan?
And also looking at the hassle factor is really huge.
Because if you're talking about having to take off from work.
Colonoscopies, not an easy, you know, in and out procedure.
And also, people travel.
Specially to go to a place like MD Anderson.
That could be four hours away.
I know patient who is travel long distances to go there.
Patients have to figure out how this all fits in their life.
And that's why I think having to be able to have those discussions about all of these aspects to help make an informed decision is really important.
But like you said, that's not that is a 15minute conversation, at least.
And it's not always reimbursed as well as just going ahead and ordering the test.
>> Well, I think one of the things that we observed, and I think this is a point that shouldn't be missed, is that patients rearrange a lot of their activities around these tests.
And I think the simple question of, can we get this test if we get a test in January, can we get the next test in December, so I can get it within this year's deductible?
Kind of gives us an indication of the financial impact as well.
And so, one of the challenges we've learned about is actually it relates to this concept of fear of reoccurrence.
Because a patient often with very low risk for reoccurrence will think that they're going to reoccur next year.
And so, providing that education and that's one of the things we try to do with this tool is to provide this education on what is reoccurrence, what's your risk and things like that.
>> Aaron Carroll: I'm going push on the pair for a second.
You're describing a fantastic example of why is the system this way?
Trying to squeeze it into one year, we have come up with out of the blue a system where the deductibles change once a year app why?
Is there a better way to do this that would more accurately represent the way that different chronic illnesses perhaps or different conditions require care?
>> True.
That's the traditional before the design is based on yearly benefit period and this sort of thing.
That's why this whole process of having these evidence informed discussions is really what should be driving it.
That should be really Driving the decision making rather than drawing a hard line around you can get this many scans at that frequency and more you can't do. Or, you know, not to put the hard lines around it, but actually to have the discussion based on evidence and not assumptions and fear.

Because we, you know, when we don't have the information, you kind of lapse into assumptions and fear.

And I would think that a lot of patients may be very relieved to know that maybe I don't need this scan with this period of time.

Taking that factoring that information in this could actually lead to a much more flexible benefit design.

I can't pull out of my pocket today.

But, you know, when you look at making these sort of informed decisions and basing it on that interaction, that really could actually lead to a better way of providing coverage and more flexible benefit design.

>> Aaron Carroll: So, I want to ask a question about yours, it doesn't appear that the blood glucose doesn't work. How did we start to begin with?

Why not do it?

>> Katrina Donohue: That's a good question.

I think when the technology evolved in the '80s we know, and the evidence is there that the blood glucose testing should be done for patients with type 1 diabetes and patients with type 2 diabetes on insulin.

And maybe expanded from there.

But I don't think we really knew what's the evidence for that.

That's that was a good question that when you asked whether well, how did we come up with this question?

I have a personal interest in diabetes.

But I was sitting around with my endocrinology colleagues and talking about the role of blood glucose testing.

That was one area, hey, there is not much evidence in that area.

We have to look at it closely.

>> Aaron Carroll: And, so, it's interesting you bring this up because it's an interest of mine as well.

It's very, very hard to get the health care system to change when new Ed comes up.

It's even harder to get the health care system to stop doing things when new evidence comes up.

Dead option is incredibly difficult.

Do you feel this was perhaps not a tool that helped patients make better decisions, but help doctors change their behavior as well in a sense?
Some of this is, how do we get from the provide we are side for us to adopt this information as well.
And then accurately deliver that to patients.
It's not entirely on patients too, but certainly we're part of the discussion as well.
Do you think that it's also focused on the provide centers?

>> Yes.
That's a really good point.
Because when we're developing a tool that shows to the doctor at the same time what this individual patient's risk is as well as the patient, the doctor has an opportunity to calibrate their own internal sense of risk which is based on often years of experience and hundreds of cases.
And it's honestly, we're human beings too.
We do have a visceral fear.
And, so in emergency medicine, we better not miss the emergency.
It's almost like a this psychological effect.
It's not that common.
But pain in the back, aortic dissection until proven otherwise.
That might be one in a thousand, but to us, it's every patient.
It gives a better understanding of what this individual patient's risk might be.
The other thing that strikes me that Janet brought up earlier about reimbursing based on process, I think that's brilliant.
Because if you motivate physicians to engage in a process, you're changing behavior.
And the mindset up until this point has been where exactly is this threshold?
Cut off.
I like her idea of thinking about process.
That can bring patients and physicians together.

>> Aaron Carroll: Mike, what role do they are?
<< This is the essence of value based reimbursement.
Reimbursing for the outcome, not so much on what step is doing and each additional step and adding and adding and adding.
The old adage of the fee for service reimbursement.
We believe that, you know, it matter house we pay providers.
But what we would like is to base this on the outcome, let the decision be made informed between the patient and the provider and let them go down that pathway to the best outcome without the plan saying

>> Aaron Carroll: How do we do that?
This is the fascinating part.
So much of when we discuss how do we reform the health care system, it's tinkering with purchasing what already exists.
How do we get to changing?
To these kind of novel ways?
Again, I think it does matter how we pay providers does matter. Incorporating more of an outcome based reimbursement compared to paying more for doing more should make the first step.
But we need this evidence to generate information to have these informed discussions. Because that's been a missing piece for a long time.

>> Aaron Carroll: I want to ask Michael, how do purchasers come into this?
>> Michael Thompson: Yeah, you can think about this as two different interactions, right?
One relates to how they engage with their employees. How they how their benefit plans are set up.
And we talked about the issue of the financial barriers for people getting care that they believe they need, or their doctor has suggested.
And in fact, we know certainly in low wage workers how things get reimbursed actually affects the compliance or adherence to what the doctor says.
We need to be concerned about those benefit programs from that standpoint.
We also will want to incorporate support as appropriate through other sources to help make sure that our employees are informed on what their choices are, what is out there?
But I do think that the other side of this is part of what you're talking about in terms of value based reimbursement.
You know, we have a system that is based on fee for service.
It invariably ends up being a yes/no type approach.
And I think when we kind of move away from a fee for service, a bundled payment or episode based reimbursement we do empower that patient/doctor relationship to make those value based decisions more effectively.
But we can inform them, I think, with studies like this that, you know, if everybody's on the same page that we're really solving for the outcome on a true value basis.
I think we'll see people get better aligned more quickly.

>> Aaron Carroll: So, I'm a health services researcher, and at a population level when I hear your studies.
I say you have shown this doesn't make a difference.
We at a policy or guideline level should come out and say we should not be doing it every year for colonoscopy; every other year is fine.
The blood glucose, we don't need to do that.
Your study is perhaps on more of how we use that information.
But clearly on a patient level, that discussion is completely different.
But what about me?
And I'm not even in a bad sense.
But how does this apply to me?
How do you know I won't be the one that gets the reoccurrence of cancer?
How do you know I won't be the one whose blood sugar gets really high?
Therefore, how can this apply to me?
And I'm curious how you would answer that question.
>> Well, that's a good question.
I think when you're looking at a study, at a population level, one thing one question you want to ask yourself, well, who is the population that was studied?
And is this population like me?
Would I fit in here?
Do I have an A1C like this?
And maybe and also talk with my doctor.
Talk to my health provider and we can sit down and look at this.
And if we both agree on the results of these studies, maybe I save myself a hundred needle sticks per day.
Not per day.
Per year.
Hundreds of needle sticks per year.
But, yeah.
I think it's individual.
An individual discussion with the doc.
And also, with diabetes and with many different illnesses, there are so many things that one needs to do to take care of their illness.
And there are so many things of high value.
So, thinking about deadopting things that maybe of lower value may come into that conversation as well.
>> Why is an excellent question.
And that's the real challenge.
Because when you're facing a patient right in front of you, having that discussion is it can be very, very difficult.
And every patient is different.
And I think it's really important for us to recognize that.
I think it's I think it's important to not take this kind of data in isolation as an example.
CT scans are not the only way reoccurrences are detected.
In fact, a lot of the reoccurrences are detected based on a clinical suspicion that leads to CT scan.
That's a different kind of a CT scan than an asymptomatic situation.
So, I think we have to be really careful that we don't overgeneralize some of these findings and that we actually have these individual discussions with our patients so that they know to report, you know, instead of just thinking well, you know, I'm going to get my scan and however many months or what have you.
I don't feel right.
This is not right.
I should talk to my doctor and see what's going on.
And then instead of simply being convinced that that's a reoccurrence, give that opportunity for that discussion.
There are complimentary studies, I would say, whether it's a CT scan or blood test or the visit.
Those are all kind of equally important.
And it may be that we should have more visits in some situations and fewer tests in other situations.
It may make more sense, you know, continue with the tests.

>> Aaron Carroll: I'm not asking you to speak for all patients, clearly.
But do you feel they ask this to trickle down or do they look too much at the guideline level?
>> I think, you know, I'm not sure.
But cancer patients, especially when they kind of make this transition, you know, they often tell us that they feel like, you know, that they've had this intensity of treatment where they've got this team that's helping them.
And then they're just sort of left alone.
And the Institute of Medicine report from a number of years ago called cancer survivors lost in transition.
While we've made improvements, they still feel that way a lot of the time.
Part of it is really coming up with a plan of what do we do going forward?
How to get the life back.
Some like the term the new normal.
Not everybody likes that term.
We have advocated for cancer care planning at diagnosis and that transition to survivorship to map out a plan that might take into account not just, you know, the colonoscopies or CT scans or CTAs, but all the things they need to be doing to maintain their health and health promotion going forward in survivorship, so they feel like they have control over what do I do now?
Especially now that I don't have the intensity and the treatment of support that I was going through in the throes of the heavy treatment.
>> And clearly the information, Erik, clearly that tool is amazing.
It's great.
And I love the fact that the information was given in many ways.
Some do better with numbers or pictures.
But do we need one of those for everything?
Or is this the kind of tool we can help train doctors in how to respond better to patients to present information in general?
This is great for chest pain and the emergency room and people at low risk.
We have needs.
What do we expect people to do?

>> Yes.
In terms of making the next step, there are movements to develop decision aids around 'mull.
Risk scores and developing a model to explain risks in a more generalizable way.
I haven't seen it implemented in a way that is fully realized yet.
But I think perhaps that's a way forward.
And training physicians how do you communicate numbers to your patients or risk to your patients?
Right now, that if you filmed four different physicians in our emergency department, they would all be different.

>> Aaron Carroll: sure.
>> I know decision aids are important and they can be important.
With cancer, we know there are so many different types of cancer and so many rare cancers and the science is move so good quickly.
I don't feel like there's any way that decision aids keep up with cancer.
And the same is true in other conditions as the science is changing.
I think there are areas where it's useful, but it's never going to cover every condition, so we have to have the skills of the shared decision making.
Both for the patient and physician side.
I love caring with you or for you.
I think that's so great.
We have to look at how do we make sure that both sides are prepared to have these conversations.
Decision aids can be helpful, but they're never going to solve all of our problems.

>> Just building on that.
Probably the last 15 years, we have focused on consumerism.
Putting the consumer in control.
Giving them information and whatnot.
There's been some positives that have come out, but also learnings that this stuff is complicated.
And the idea that you can just turn the keys to the car over and they're going to know thousand navigate this when there's so many moving parts and it's so complex.
So, I think what we are finding and in fact what we have seen more successful have been advocacy type programs that give somebody the help in the process who does have some level of education and some tools.
And you can't just expect the patient, the consumer, to navigate by themselves.
Certainly, the doctor can while they're in front of them.
But they're not in front of them as often as probably they're going to need the support.
And the patients there's always the possibility the patient is going to say what would you do if you were me? You can't answer that question unless you know about that person as a person and not just the numbers or the diagnosis. Learning about what matters to that parent is going to be making those recommendations.

Aaron Carroll: Absolutely. Go ahead.

If I could just elaborate on that point because I think it is so absolutely true. Even as we have created the support tool, implementing it in practice is to challenge because, you know, how do we make it fit the workflow and things like that? But what we learn from things like these is there are certain things we should be looking for to hear from our patients about. I think what you said was so great about we should be doing some degree of shared decision making all the time. And in fact, one of the ways that evidence like this can be used and how we used it, it's provided us an opportunity to provide reassurance to both the provider and the patient and actually engage in some of these discussions. Do you want to get more testing done or not? If you have someone with a lot of comorbidities. We may find out, get tests. What do you do with the information? Maybe just have a chat to see how you're doing. And it's allowed us to think about doing that and still be reassured about it.

Aaron Carroll: I want to make sure that we start bringing in audience questions. And I can't see, necessarily. They're all going to appear on screen. I'm going to start with some on the screen. If there are specific audience questions. I have a question over by the doors. You can't see me.

Aaron Carroll: Okay, great.

Kim with the Center for workforce health and performance. And wonderful panel. Great discussion. Thanks for all of your great work.
So, I was really intrigued with a commonality in the three intervention studies that were done that you're really looking at discretionary is the wrong word. But why looking at something similar. In the case of the scanning, it was non-symptomatic surveillance scanning. The case of the diabetes, it was noninsulin dependence. And in the case of the chest pain in the ER, it was low risk. If they were high risk, nay would have been admitted to the inpatient. Now, they could have still decided not to be. So, I'm wondering, in terms of the discussion around where income comes in, socioeconomic status, do we need to have a conversation around whether we need to have an explicitly tiered system where non-discretionary or where the evidence is strong. Where a clinician might decide in a high-risk chest pain case that they should be admitted and a non-surveillance scanning test or an insulin dependent diabetes situation. Those folks may be ought not have to be concerned about whether they can afford the monitoring device or the scan or whatever based on income. If the evidence is strong and if they're 99 out of a hundred on the risk diagram, not one out of a hundred. So, I would love to hear thinking about that from the panel and particularly the folks who represent the payors and the providers.

>> Aaron Carroll: We'll start with Janet, go ahead.

>> Janet McCauley: So, is it sounds like you're referring to a higher risk population. Again, you know, as far as coverage for something like that, I mean, those are probably the things that we have more traditionally covered than not. It would be good to know, though, how does this work when the patient is high risk and it's their say an example, you know, in the emergency department. And you want to proceed with the, you know, with this sort of this sort of testing. I don't think that the payment necessarily for a high risk patient would be probably questioned. I think the

>> Sorry, just a little clarity and then I won't interject.

One of the biggest reasons for bankruptcy in the country is excess medical costs for people who can't afford their care. I'm talking about what actually happens in the system and just trying to understand where does this fit in terms of the evidence and what plans and payors are paying for and what the plan designs right now. Maybe we need 100% coverage for people who are diabetic and actually need the insulin.
I'm asking how we can factor in the cost to care and make sure people are getting access to care that is needed. And I understand that the panel is looking at perhaps discretionary care. I just would like some thinking on that.

>> Aaron Carroll: Michael?

>> Michael Thompson: Yeah, first of all, it is the right question. You're asking the right question. The issue that we have today in the plans that we're reimbursing typically you are employers have largely moved towards high deductible plans. And the average American can't afford those high deductibles. And so, to your point, if we have the discretionary care, which I think we have some examples that might be in the category of discretionary care. There's a lot of care that's not discretionary. Yet still there's these financial barriers to individuals to get that care. And so, you're I think what we believe needs to happen is we need to move towards what we call value based design which essentially would reimburse more comprehensively for that care that is essential, that isn't discretionary and be more selective. Some of that may not come out exactly one of the challenges you have when you do that is defining that. And developing broad designs that you can communicate and make sense to do that. But directionally I think that's absolutely true. One of the changes that we are hoping for and advocates for in the employer community more broadly are changes to the health savings account regulations around what a high deductible plan is under health savings account. Because under that the ability to manage your chronic disease, for example, would be allowable on more of a first dollar basis. And those are some of the changes that I don't think the cost sharing is going to go away entirely. But I think we need to be more sensitive. And particularly for the lower socioeconomic population because we have created barriers to care in some of the ways we have designed the plans historically. I think it's a great question.

>> With value based design, you need to make sure that the copays for patients are, you know, if you've got something that's evidence based and that they definitely should be having, you had a lower copay for that versus something that maybe isn't as evidence based or isn't as needed and then they should pay more. I think that's one of the ways that it works.
Because we do know that even, you know, that even small copays can be prohibitive for people.
And they don't continue with treatments that could be lifesaving because of a $50 copay.
Those maybe shouldn't have a copay.
And maybe something that's less discretionary.
Although I don't love that word for what we're talking about here.

>> Aaron Carroll: I want to move on to the next question, but as a country we use copays in the United States almost like a club instead of a scalpel.
One size fits all, that's erg.
That's how it goes.
One part of the question is being asked, in other countries, there are sets of diagnosis or conditions where copays are waived.
They're supposed to make you think twice about looking for care.
I'll spend your money more than my money.
We want people to go for necessary care, not unnecessary care.
If they have chronic condition and this is necessary care.
No copay.
We do a little bit of that with respect to planning with the affordable care act.
But we don't make these distinctions perhaps we should?
>> This is, you know, value based benefit design.
And, for example, in some of our plans we have a deductible copayment waiver for certain diabetic displays.
I think with this kind of comparative research coming out, we'll be able to do more of that.
We'll be able to do more of this type of tailoring from the patient side.
Steering their you know, we talk about provider reimbursement.
But this is the patient side.
Modifying their behavior in a way that incentivizes getting the right care and makes it easy.
Please do what you can do to make the care of the diabetics make it easy for them to take care of themselves.
I totally believe that.
But what is exciting about this type of evidence and these point of care decisions is we're generating information, you know, that can make this much more granular.
Maybe it's not just diabetic supplies.
Maybe it's other chronic conditions that we can actually offset that based on the evidence that comes out.

>> Aaron Carroll: Great.
I want to take a question.
Oh, sorry.

>> Thank you.

>> Aaron Carroll: Absolutely.
>> We're back here.
You can't see us.
I'm Janice, a patient partner.
And I have been involved with health research and health system improvement for about six years.
And I have seen the impacts that choose some of the choosing wisely initiative projects have really made a difference in our health system.
And so, it's very hard, though, to disseminate that information to other patients unless it's really culturally responsive and appropriate.
And one good thing I just want to mention, the more we're able to share about this type of research, the more patients will be able to be self activated and will start looking up themselves and validated in the evidence based, you know, articles rather than, you know, Yelp and whatever.
Wikipedia.
Thank you.
And I just wanted to know what people thought about choosing wisely and if it's implemented in your systems.

>> Aaron Carroll: Anyone want to field that?
>> Sure.

>> Aaron Carroll: Kathleen and then Michael.

>> Katrina Donohue: Katrina.

>> Aaron Carroll: I'm sorry.

>> Katrina Donohue: I'm called Kathleen sometimes as well.
So, my choosing wisely I think is widely respected because it's a usually it's a non-specialty oriented group that's looking at these guidelines and deciding or looking at the evidence and deciding where is the evidence for these things?
So, I think I think in our it is a certainly well respected.
We have choosing wisely.
And in the case of diabetes, that does not support blood glucose testing in a noninsulin if patients with non-insulin treated diabetes.
We have the American Academy of Family Physicians and the internal medicine supporting choosing wisely.
And we have the diabetes association supporting self monitoring of blood glucose. And the American diabetes educators. We fully support the choosing wisely campaign. But we have to be mindful, there are still various. I wish we could all sit down and look at the evidence together. But

>> Aaron Carroll: Did you want to respond, Michael?

>> Michael Thompson: I want to say, we're very happy with the choosing wisely program. We disseminate with the ABM Foundation. It's in some ways low hang fruit. This is the top five things by specialty that are over utilized or whatever. It's not quite the same thing as compared to the research which is actually helping expand our knowledge of what works and what doesn't. And, again, it's not all about overuse, it's about underuse too. And I think some of the examples that have been raised is where people don't get the care they should be getting. And I don't think we're biased one way or the other. I think where we want to be is to help people get the care they need and let's do less of or at least create a shared decision-making process around the care that is not adding a heck of a lot of value.

>> Aaron Carroll: I want to take a question from Twitter. Dead option is incredibly difficult. How might we better help doctors change procedures or what they do based on evidence. To the panel. Anyone have thoughts? I'm going to have to choose. George, he's leaning forward. [ Laughter ]

>> George Chang: This is a tough one. I think first of all we need high quality evidence. That's Paramount. Because I think a lot of the a lot of times yeah, skepticism about the evidence will certainly affect behavior. And we need to be able to disseminate that high quality evidence. But I think we have to go back even further to where we train our providers, our physicians.
Where we actually train our medical students and our residents to really be more evidence based in their clinical practice. And that, I think, is the only way we're going really be able to get to the point where we have a health care system where we prioritize evidence based care above all other factors. And then finally, I would say that obviously there are a lot of incentives for physicians to practice in ways that might not necessarily be consistent with evidence. And that probably is more of a reflection of our health care system than it is of anything else. And so, I think that's a major factor that would need to be considered in this equation. >> You know, a lot of these studies lend themselves to actually looking at the data and finding out where is this occurring and how is it occurring? And that data can be brought down right to the provider level in a community. And so, I think the ability to actually engage providers within a community. I know health plans do that. Coalitions do that. And say here is the evidence. Here's what's happening. How do we rationalize this together? And I think that's a change process. But it happens over time.

>> Aaron Carroll: So, I'm also going to put Janet on the spot here again. But if we stop paying for some of this stuff, would people stop doing it? Do payors have a role to play?

>> Janet McCauley: If we stop paying for it, there might be a situation where a small number of patients would benefit. And really the point about medical education. The ability to generate and assimilate this type of data is just generations beyond what it was 10, 20 years ago for certain. Whereas we were trained to sort of go down this model of, you know, making the decision based off initially just experience of the experts. And then, you know, statistical chances of this and that. Now we've really are able to generate much more specific information to drive these decisions at a much granular level. It would be exciting to be if I could go back to medical school and be a medical student now to see how you're trained to make clinical decisions at the point of care which really didn't even exist years ago. From the payor perspective, applying blunt hammers usually is not the answer. There's too many inclusions and exclusion.
And if it's a miss, it can be a real problem.

>> Aaron Carroll: Next question.

>> Yeah, I just want to comment on the chronic diseases and health insurance plans and there are copays that are being waived for all diabetic supplies and needs from the insulin to the metformin. How you have to stick yourself and the needles and all that. And also, another chronic disease is hypertension. Any copay for any prescriptive medicines. But you have to be in a program. And I'm an employed person. I work for the State of Virginia. And they provide it. But everybody doesn't know about it because you have to get in a program where you see your physician at least once a year and have certain tests done. So, there are certain things out there to do that. And then there's those people that are on the lower economic status. There's Medicaid that takes care of all those supplies. So, I just want to confirm that and reaffirm that things are being done positively and for quite some time now.

>> Aaron Carroll: Question?

>> We have a question.

>> Aaron Carroll: Go ahead.

>> Good afternoon. My name is Beverly Rogers, a patient advocate and a family caregiver advocate. And we're talking about informed decision for the patient. We're talking about all the right things and getting the patient to the right doctor, to the right prescription. My question for the panel, whoever dares to answer, how do we get all of this filtered down into HMOs and managed care where the decisions are not mapped out that easily?

>> Aaron Carroll: Anyone want to field that?

>> I think, again, it's a great question. Again, I think that we're an evolving system. We've gone through a different periods, if you recall back at the end of the last century, we had a lot of backlash around managed care that really changed a lot of things very quickly.
In some ways I think we took a righthand turn at that point and started moving towards what I would call consumerism. Part of that was higher cost sharing, let the consumer do more and take more special responsibility.
And I actually think we're at another inflection point. There's a little bit of backlash on that too. That what we need to do is figure out how to get it right. How to fine tune this in a way that is evidence based, that is supported by the right incentives, the right programs that lead to the outcomes, to your point. And, you know, I don't think we'll ever be done on this, but I do think sometimes some of what we have done has has not been all good. Some of it has caused harm and we need to be constantly in a course correcting modality to get the designs and the support programs right. And to realign with providers and partner with providers to make it better too.
>> And I think some of what has led to this not being mapped out at the level of health care plans is not having the information to map it out to that level of detail. And that leads to these sort of high level, again, these blunt hammer decisions that are all or none that tend to include and exclude. A lot of that is just the science at the time and just not even having that level of detail. And making the assumption that if it's more expensive, it's never going to be as good. Well, there's sometimes things there are more expensive that are better. Sometimes there are things that are more expensive that aren't as good. We can't talk about cost, PCORI can't look at cost, technically. But that is a next avenue for payors is really to look at where the incremental value is and to factor in that cost factor. As far as HMOs and mapping down to that level of coverage or administration, I think the lack of information has led to a lot of policies that have just been too blunt.

>> Aaron Carroll: I think if we can keep questions succinct and quick, we can probably get to a few more.
Let's try.
>> Hi.
Kathy, patient ambassador with the University of Buffalo, department of family medicine. It was mentioned about doing less with more knowledge and everything. But what I find, as a patient and a lot of the people I work with, there's a culture especially with doctors they use big words. Alphabet soup. And it's like, when you're talking to a patient, you almost have to kind of go back to that, okay, I understand it. But does the person I'm does my patient understand that?
So, you have to kind of. I don't want to use the term "Dumb it down," but that's pretty much what you have to do.

>> Well, if you can't communicate with a patient, where are you left?
So, I wholeheartedly agree with that.
You need to be able to communicate your thoughts, so each partner understand what is you're saying.

>> Yeah, I would like to echo that point as well and give an example.
One of our collaborators is an oncologist who is taking care of the mother of another oncologist.
And in fact, you know, prides himself on having a very detailed discussion.
As we all many of us do.
And at the dinner table when that patient went home to talk to her daughter who is one of this one of my collaborator's partners, with the message that she described as what her doctor had told her was completely opposite to what he thought he was deliver.
And he thought he was delivering really well.
It was a really important lesson for us.
We have to think about ways of communicating very effectively.
Perhaps use a lot more things that we give to patients on paper, things they can take home.
Different ways of providing information.
As much as the tools have utilized different ways of showing the data.

>> And

>> Go ahead.

>> Okay, thanks.
We haven't talked that much about care of delivery.
And I think patients know an awful lot.
But in care delivery, using this type of information and evidence tends to be more team based.
and I think that there's a lot to be said for a team care coordination where there's different types of practitioners delivering similar messages and tapping into different concerns rather than the doctor knows all and do what I say and don't ask any questions.
Team based care, I think, fits very well with the type of information that comes from PCORI work.

>> Aaron Carroll: Shelley?

>> Shelley Fuld Nasso: And I think checking in with patients on their understanding.
You can say all of this, but then they don't necessarily hear what you think that in your example shows that exactly.
So, if you check in with them, I think that helps.
One of the things that I love, one of your collaborators, Victor Montori talks about the work of being a patient.
And I think some of what you all of you are looking at or getting at that term in terms of the hassle of the test.
Sticking your finger every day, that is work and cost.
This isn't just about the decision of whether or not to do a test, it's about the whole work of being a patient.
Especially when you're diagnosed with a serious illness that's a longterm illness.
And I think I love your point about team based care.
There are other members of the team sometimes who can do a better job of dealing with some of the other aspects of the care coordination and even reinforcing the discussions to, you know, maybe maximize the physician only has a small amount of time.
But the social worker or nurse or somebody else helped reinforce those messages and check in for the understanding and help with understanding all of the aspects of that patient's life that are going to be affect whether they're going to be able to follow through on the treatment that was even discussed.
In fact, whether they can even do the treatment that you're talking about because of the this work of being a patient and being a caregiver to a patient.

>> Aaron Carroll: And I want to be respectful of time.
But one more question and then
>> Yeah
>> Aaron Carroll: Go ahead, I'm just going to keep looking out.
>> Okay.
Thank you.
My name is David.
I'm the founder of medical collaboration network.
It's a national care coordination and telemedicine network which connects providers as well as patients.
I came today, and I want to ask the panel, I would love to hear also from the audience.
As you may know, 85% of all the total health care costs goes to chronic disease patients.
And these chronic disease patients stems from lifestyle.
Or change in lifestyle.
What I'm trying to hear today if anyone has any suggestions how to incentivize the system instead of dealing with diseases or to manage disease, is to manage health.
In other words, to focus on prevention which really will solve most of the problems.
I would say according to some studies, 80%.
So, before we are trying to talk about this or these testing, how to prevent diabetes, wouldn't that be better?  
[ Applause ]
>> I certainly agree.
And in the case of diabetes, there are many high value things one could do to improve one's course in the illness or revert their illness in terms of diet and physical activity. Or even medication adherence.  
So, I think at least for this study it really makes you rethink, what's of value? And a lot of it is behavior. In that instance. But how do incentivize, I don't know. That would be that would be great. If we could incentivize that.
>> You know, I'll just throw out, you know, 85% of employers have wellness programs. And we haven't improved the health of our population. And so, when we talk about evidence, comparative effectiveness, we need to be thinking broadly about what works. And I step back, and I look at what worked with tobacco. Which is a major, major success story I think for the country. Bringing the tobacco use rate from 60% to 16%. And if you look at what caused it to occur, it wasn't one thing. You know, was it the tax on cigarettes in was it taking the ads off TV? Eliminating smoking in the work place? You can go through. There was 20 things that occurred to make some of these things happen. I think when we think about health, we have to open our minds to bigger think than just educating people on diet and exercise. But I agree with you. Get moving upstream makes sense. And, again, managing chronic disease is critical, but we can still go even higher in terms of the system in terms of managing health. I agree with you. >> And another caveat of that, we have captured wellness within the medical care system. And wellness is more fundamentally based within the community, talking about social determinants of health or food deserts. And any lifestyle fact theirs go on in the community that never contact with the traditional medical care delivery system. That might be one reason they're adopting the wellness programs. They're under the same umbrella of medical care and that's where some of the opportunity may lie to frame that differently.
>> I hope you'll join me in thanking our panel today.
Dr. Erik Hess.
[ Applause ]
Dr. Katrina Donahue.
Dr. George Chang.
Shelley Fuld Nasso, Michael Thompson and Janet McCauley.
Thank you very much.
[ Applause ]
>> Well, call me a geek, but that was just a phenomenal discussion.
A very patient centered discussion.
Very much about what PCORI was established to do, I believe.
And clearly about what PCORI is doing.
So, I want to thank the moderator, Aaron.
I want to thank the three investigators for the wonderful studies and the three discussants that really added this sauce to make this discuss so relevant.
And I would suggest that maybe we thank them once more and then go to the reception and keep talking about these same things.
This is really what it's all about.
And as somebody said, it's not it is complicated, but it is very interesting and talking about it and coming to understand it better can make care for everybody.
We heard clinicians get stress and angst about this as well as patients do.
So, let's go to the reception and the posters are still open.
So, look forward to talking to you all there this evening.
[ Applause ]