Dr. Michael Coburn speaking:
Welcome to our panel discussion. Today we will review the findings of two important studies published earlier this year in JAMA: The Journal of the American Medical Association, and we will share our thoughts on how these studies have an impact on patient-centered care. I’m Mike Coburn, professor and department chair for the Scott Department of Urology at Baylor College of Medicine in Houston, Texas. Joining me on this panel by phone are Dr. Ronald Chen, associate professor of radiation oncology at the University of North Carolina School of Medicine in Chapel Hill, North Carolina; Dr. Daniel Barocas, urologic surgeon and oncologist and associate professor of surgery and associate professor of medicine at Vanderbilt University in Nashville, Tennessee; Dr. Frank Domino, professor of family medicine at the University of Massachusetts Medical School in Worcester, Massachusetts; Ralph Conwill, a patient and prostate cancer survivor; and Sarah Daugherty, senior program officer at PCORI Patient Centered Outcomes Research Institute. Also, here with me today are Todd Kielman, who is an instructor in urology at Baylor College of Medicine and a very experienced physician’s assistant working with urologic patients, and Lisa Icard, who is a practicing nurse and nurse manager in the department of urology, also with great experience in working with patients with prostate cancer and many other urologic conditions.

I’d like to draw your attention to the two other presentations in this CME activity. Those presentations by Ron Chen and Dan Barocas go into greater detail about the findings from these important studies.

So, to get us started, I would like Ron Chen, the author of one of the two studies, to give us a brief overview of the study’s findings.

Dr. Ron Chen speaking:
Just to kick us off, I think I would like to put the results from Dan’s study and my study in context of the treatment paradigm for prostate cancer.
It’s important for the listener to know that prostate cancer is grouped into different risk groups: low risk, medium risk, and high risk. And according to the most recent American Urological Association guidelines in 2017, for low-risk prostate cancer, which is the very earliest diagnosis, the preferred recommendation is active surveillance or no treatment. But for patients who have more aggressive prostate cancer—intermediate or high risk—the recommendation is to pursue either surgery or radiation.

These two studies provide patients information about the quality-of-life impact of surgery and radiation compared to active surveillance. Specifically, we looked at four different domains of quality of life, including impact on sexual function, urinary leakage or incontinence, urinary irritation, as well as bowel symptoms. And these two studies looked at modern surgery, mostly robotic surgery, as well as modern radiation, either IMRT intensity-modulated radiation therapy or brachytherapy. As a very quick summary, the studies show relatively favorable quality-of-life outcomes of modern treatment compared to active surveillance. The studies did find that in terms of sexual function, surgery is associated with somewhat worse sexual function compared to active surveillance, as well as worse urinary leakage.
Radiation is associated with more short-term urinary irritation, as well as bowel issues. And I think for patients who have the diagnosis where treatment is indicated these different types of quality-of-life impacts of the different treatment options can help patients think about what treatment they would like to pursue that meets their preferences.

**Dr. Coburn speaking:**
Thank you, Ron. I’d like to now turn to Frank and ask you to comment from your perspective as a primary care physician. How do you view the importance of these studies? And how do they impact on how we work with patients in the process of shared decision-making?

**Dr. Frank Domino speaking:**
Mike, thanks for asking me to comment. I believe both of these studies help me as a primary care provider, someone who sees patients and counsels them on the pros and cons of screening for prostate cancer, how to decide when it looks like a patient does have cancer, and how best to treat it. Both of these papers are helpful in that they evaluate not only the outcomes of the cancer but, more importantly, the adverse events and complications of treatment. It’s my sense that most patients, when you give them the diagnosis of any chronic condition that's life-threatening, they try to find the shortest path to receiving the best benefit. And when you have cancer, especially a solid tumor cancer, patients' first inclination is to “cut it out.” Both of these papers—while commenting on what might happen had you gone aggressively with a radical prostatectomy or taken a slightly more conservative approach with regards to radiation treatment—demonstrate that although there may be some adverse risk associated with any aggressive treatment, it needs to be balanced with what most of us call active surveillance, or closely following patients without implementing a treatment by rechecking their bloodwork, rechecking their physical exam, and rechecking their symptoms on a fairly regular basis. Having this information from these two papers allows me to pull out real numbers to help patients in their decision-making. That being said, most patients have a high level of anxiety with regard to having a cancer and often will side with aggressive treatment because they almost always have an intuition that that’s going to lead to the best outcome.

**Dr. Coburn speaking:** Okay. Well, thank you, Frank. We very much appreciate your thoughtful analysis. Ralph, would you like to provide the patient’s perspective on how shared decision-making is impacted by the data from these studies?
Ralph Conwill speaking:
Frank, thank you for what you said. That's definitive of how a patient feels. I agree totally that the patient goes out and tries to find the shortest path, but also the desired result based on their preferences, because different patients have different preferences. So as a result, the younger guy with prostate cancer of course is probably going to protect his sexual function more so than someone 75 years old finding out that he has prostate cancer. What you stated to me is dead on. That is exactly what we do—we try to find the shortest path to getting it out sometimes. I think that's the mistake that a lot of patients make. They do things that they don't need to do because they cannot reconcile the fact that they have cancer with the fact that they don't have to have it removed. For most patients, including me and patients whom I've talked to, your first reaction to hearing the doctor say, "You have cancer," is to say, "Get those cancer cells out of me as fast as you can and as far away from me as you possibly can, because I don't want to deal with this again." And so, it leads a lot of patients to make decisions that they don't need to make. I think this is where the USPSTF U.S. Preventive Services Task Force got involved because patients were making the wrong decision based on the information that they had simply because they do not understand the implications of a low-risk or low-medium-risk prostate cancer diagnosis.

Dr. Frank Domino speaking:
Ralph, I appreciate that you brought up a key point there. You mentioned age and possible choices that people make based upon where they are in life and what their future looks like. When I'm helping a patient try to decide how aggressive to be with a treatment, one of the many things that we try to bring into perspective is life expectancy. And so, if you're a healthy 75-year-old, you probably have 15 or 20 years of life expectancy. I like to remind patients that it's not just about dying; it's about living a good quality of life. Sexual function is one issue, so is urinary incontinence, and so is persistent bowel dysfunction. So, I do bring those issues up when I counsel patients. But, I also ask them how they're going to feel, how they can project how they would feel, if they had surgery and let's say they had no complication. Would that change a great deal if they had a complication like less sexual function or an alteration in sexual function? I'd say most people do fine if they have surgery, but a subset will have persistent incontinence and they might need to wear a diaper the rest of their life. Is that something that's important? I also think—and Ralph, you brought this forward—is the risk of death, and I think that's everyone's fear. And while that becomes foremost, these two studies remind us that mortality is an important outcome in most people's minds when they hear the word "cancer." But in a disease like prostate cancer, especially if it's low or intermediate risk, it is the complications that should help them focus their decision. As a primary care provider, I look to my peers in urology to help the patients understand that it's not all about just living and dying, but it's about living a quality of life that they want to live. So, I guess my thoughts would be to hear from both Dan and Ron about how they recommend helping patients clarify in their mind which morbidities they might want to risk and at what cost.
Dr. Daniel Barocas speaking:
Sure. I think, again, a very interesting discussion, and the perspectives are really important. One of the key things to recognize is that our studies have relatively short-term outcomes—2 and 3 years (2 years in the UNC study and 3 years in our study) and the main outcomes are the harms of treatment, the side-effects. Any shared decision-making process should include not just those harms and side-effects but also the potential benefit in terms of controlling the cancer, the patient's perspectives and priorities, and the spouse or partner's priorities and preferences. And so, there are actually many components that go into the decision, and our data helped to inform one of those components. It’s a key component, but it’s only one. I think one of the complexities here is that the data for one of the other key components are not perfectly clear. So, the oncologic benefit of treatment has not been worked out perfectly. The studies that we have are fairly limited in terms of their applicability to the cohort that we see today and the treatments that we use today. And so, it lends a lot of complexity. In addition, there’s a wide range of risk that we see. So, I agree completely, wholeheartedly, 100 percent that most men with low-risk cancer are best served with observation, and not with treatment, because it preserves the quality of life and in that setting, in most cases, the treatment is worse than the disease. The patient should be informed of that long before we have a discussion about their pathology. In other words, at the time of biopsy, or perhaps even at the time that we're drawing blood for a PSA test, the patient needs to understand that most men will have some small amount of microscopic, low-grade prostate cancer at some point in their life and that those are not the ones we’re looking to treat. If we find one, we’re just going to watch it. So that way, they’re not terrified and surprised when you inform them about their pathology report and they don’t rush off to treatment. I think that's actually very important. But, there are higher risk types of cancer where the risk of progression is quite real. In those settings, we do feel like treatment is probably beneficial, and there are some studies that have borne that out. So, I think we have to bear that in mind when we start informing patients. It's not simply that the harms of treatment are bad so we choose surveillance; it’s that the harms of treatment can be significant, but we have to balance them against the risk of progression and the patient's own preferences. One of the interesting things, both in Dr. Chen’s study and in our study, is that a lot of men in the age group in which prostate cancer is diagnosed already have existing erectile dysfunction. So that turns out not to be a priority for up to 40% of men who are diagnosed, and so that’s an interesting component that we figured out here. I do hope and agree that these data can be used constructively to facilitate and inform shared decision-making. My only concern is that since we've only elucidated this one component and that it will be conveyed that treatment has bad side-effects so you shouldn't do treatment. I think that would be a mistake for men with a long life expectancy and higher-risk cancer who may really benefit from treatment and have to accept some risk of side-effects to get that benefit. I guess I'll stop there and hand off to Dr. Chen so that he can have some input as well.

Dr. Ron Chen speaking:
Thanks, Dan. So, in our study—although this is not part of the JAMA paper—we actually asked the more than 1,000 men we surveyed what their priorities are. Overwhelmingly, the number one and number two priorities were cure and quality of life. For many men, actually, quality of life was one and cure was two; for other men, it was vice versa. So, I think these really are two of the most important issues for people who have newly diagnosed prostate cancer. The papers from Dan and our group hit on this quality-of-life issue, which I think is a very important issue for men who are diagnosed with this disease. I think
the important thing about these two papers is that treatment has evolved quite a bit over time. So, the impression patients may have about the quality-of-life impact of surgery and radiation—frankly the impression many physicians have about surgery and radiation—on sexual function or urinary function are probably no longer correct because of how much the treatments have evolved. Robotic surgery is now much less invasive than it was in the prior generation, and radiation is also much less invasive in the sense that it's a lot more targeted and there are fewer organs and much less bowel being irradiated. So, I think these two papers can update information for patients and physicians on the quality-of-life impact modern treatment options may have on prostate cancer.

**Ralph Conwill speaking:**
I think what both doctors just said is so important to the patient, especially if you start this discussion with them before the biopsy about the fact that there are different levels of prostate cancer where you have different choices and different decisions that you can make, and start that conversation then. If you start the conversation at diagnosis, we can't hear you because our minds are focused on, "Am I going to die from this?" That's just where a lot of men's minds go immediately when they hear, "You have cancer," because they've had so many relatives who had a miserable life or a death outcome with cancer. I think that point is so critical, with regard to what Ron said, that we talk about these things in advance—EBRT external beam radiation therapy or RALP robotic-assisted laparoscopic radical prostatectomy. It is important to have at least some of those discussions and a piece of paper—a pamphlet—that you can hand to the patients when they go home. Because when doctors start talking about this cancer business, we get frightened and we can't even remember what was said when we get home. But if you gave us something—a clear statement of, "Here's active surveillance; here's radiation; here are the different forms of surgeries." That is so critical to patients in that early stage, and I do believe having it prior to the diagnosis would make a huge difference in the choices they'll make.

**Dr. Frank Domino speaking:**
This is Frank. I appreciate that last comment from Ralph, and I'd like to now make it very specific. I'd like help from Ron and Dan. I have a patient who presents to me after receiving his diagnosis, and he is at an intermediate or a high risk with a Gleason score at 7 or above. What are the key things you want me to help my patient understand as he tries to make this decision? In particular: How do I structure the discussion about, "Will I be cured?" Because we know these papers help us understand a bit about quality of life, how do you want me to structure, rather, what kind of messages do you think I should be conveying as patients make this decision? So, I'd be curious about what sort of key points you want me to address, especially with regard to the intermediate- or high-risk patient?
Dr. Ron Chen speaking:
So, I think I'll start. This is Ron here. I'll give you my perspective. I think that the question about intermediate and high risk is really relevant because, as we've discussed already, I think, for most patients with low-risk cancer, active surveillance really is a good option. It's not the only option, but as somebody who's been involved in writing some of the guidelines on prostate cancer for ASCO American Society of Clinical Oncology as well as the AUA American Urological Association I think most of the guidelines do favor active surveillance as a good option for low-risk cancer, because low-risk cancer is slowly growing, and active surveillance is the best way to protect somebody's quality of life. So, for intermediate and high risk, I do think most guidelines for high-risk and intermediate-risk prostate cancer usually favor treatment, unless somebody has a very limited life expectancy. Honestly, if somebody has a very limited life expectancy, they probably shouldn't have had a PSA test to begin with. But if they have a life expectancy and intermediate- or high-risk cancer, most guidelines would favor treatment instead of active surveillance, and most of the treatment options would involve surgery or various forms of radiation. I usually advise patients to have a second opinion and to talk to multiple providers, to hear about surgery directly from a surgeon, and to hear about the various radiation options from radiation oncologists. I think patients should make an informed decision once they've heard about the treatment options and about the pluses and minuses and the side-effects of the different options available to them. I think that even with high-risk cancer there is time to get a multidisciplinary consult or a second opinion before jumping into a treatment. And so, I think multidisciplinary care for patients with cancer is good, and that applies to prostate cancer as well.

Dr. Daniel Barocas speaking:
So, this is Dan. I agree with Ron completely. I was going to say something similar, which is that anytime I've diagnosed somebody with an intermediate- or high-risk cancer who is contemplating treatment, they meet with me and a radiation oncologist. I think it's important to get both perspectives to make a really good decision. In other words, they're going to live with the results of this decision for the rest of their lives—hopefully it'll be a long life—and they have to be comfortable and confident that they've been fully informed before they dive in. So, that's one issue. The other issue is that the discussion with the patient be long and nuanced. There are a lot of components, as I talked about before, in terms of emphasizing harms, explaining the expected benefits, eliciting the patient's preferences, and helping to communicate with them and coalesce all these moving parts into a good decision. Regarding the discussion about expected benefit, what I would value from the primary care provider's perspective is to have a patient coming in who is prepared to recognize that we don't know the best answer. If we knew the best answer, we would do the same thing every single time. We believe there is equipoise between treatments, that surgery and radiation have about the same likelihood of preventing progression; in that light, many men end up deciding based on the convenience of the treatment or the side-effects. Now, that being said, there are nuances and there are patients who we would steer toward one or the other treatment because of their anatomy, because of the severity of their disease and the risk of progression, because the patient does or does not want to layer hormone therapy on top of radiation, because of other medical reasons, and so forth. So, there are nuances to this discussion. I think we should start from the point: "Sir, you have a cancer that probably should be treated. Any treatment we do is going to
have some degree of side-effects. As far as we can tell, the treatments seem to work similarly in terms of their effectiveness." That’s the starting point for the discussion, and then we encourage them to hear out the options and weigh them thoroughly before jumping into a treatment.

**Dr. Frank Domino speaking:**
Now when you say "treatment," do you include in that broad term watchful waiting or active surveillance? Or, are you focusing more on surgery versus radiation?

**Dr. Daniel Barocas speaking:**
I think, as Ron pointed out, most men with a long life expectancy who are diagnosed with a high-risk cancer, or many men with an intermediate-risk cancer, should consider treatment rather than an observation pathway. And again, that’s a nuanced discussion where you can calculate the risk of progression for a particular patient and arm them with that information to make a decision about whether they want to watch it or treat it. I include active surveillance as an option and promote it actively for men with low-risk cancer, very favorable intermediate-risk cancer, or a shorter life expectancy. Somebody whose anatomy or medical history precludes safe treatment and in whom that treatment might carry extra risk, I also would emphasize more the surveillance pathway.

**Dr. Michael Coburn speaking:**
All right. At this point, I’d like to turn to our colleagues Todd and Lisa. Todd, as I mentioned earlier, is a very experienced urologic physician’s assistant, and Lisa a nurse manager in our urology clinic. How do both of you view the results of the studies? What importance do they have for you and the manner in which you interact with patients and the whole patient-centered care model?

**Todd Kielman speaking:**
Thank you very much, doctor. So, I found the study to be very enlightening in regard to the options that were available. Having read through it, I know that when patients come in to see us, and we end up doing a PSA prostate-specific antigen test, that typically that it’s going to be a patient education appointment anyway. So, we’re going to be educating them a lot about what’s going on, what the test results may mean, and what their options are going to be afterwards. These two papers have really opened up and illuminated what all of those options are and what some of their effects could be. So, they have given the primary care provider more tools in their belt to use during that appointment.

Source: Contemporary Treatment Options for Prostate Cancer, PCORI.org
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Lisa Ikard speaking:
To add to what Todd has said, I think these papers were very informative. From a nurse’s perspective, we have a very special relationship with the patient. Oftentimes, patients will call when they’re making their appointments with their urologists and they’ve had a diagnosis of prostate cancer. Immediately, they have questions and concerns. So, I think by taking the information learned we can help to educate the patients that they do have options available to them and educate them about those options. We can share our experience with other patients who have had the same diagnosis and how they fared with their course of treatment.

Dr. Michael Colburn speaking:
Well, Lisa and Todd, thank you so much for your input. We certainly are very supportive of the key role that our advanced practice providers and nurses in the clinic play in counseling patients. And we appreciate your interest and your comments about the importance of these studies. Todd, do you have any comments or questions for the previous panelists?

Todd Kielman speaking:
I do. Actually, one concern that I had while reading through the studies and the papers is that they talked a lot about doing active surveillance, which I know is a more common treatment these days. However, in the primary care setting, it seems like it’s going to be a difficult discussion to have with patients when you’re telling them they have cancer or they’re coming back to you with a diagnosis of cancer and you’re basically telling them, “We want to put you on active surveillance.” In their minds, we are doing nothing. Do we have any suggestions about how we broach that subject and move forward with it?

Dr. Daniel Barcos speaking:
I can help with that one. This is Dan. I think it’s important to consider not just the harms of treatment, but also the risk of progression of the cancer. And as Dr. Chen explained at the beginning of this segment for low-risk cancer, active surveillance is really an appropriate choice because the risk of progression is very low. And, we know that active surveillance is the best way to preserve quality of life. In fact, if you look back a little way here, I think what was really hampering our ability to do the best for our patients in the past was the instinct to treat everybody who was diagnosed with prostate cancer rather than being judicious about thinking who’s likely to progress and who is not. So, I think the discussion is quite nuanced, and the treating doctors, urologists, and radiation oncologists, as well as the primary care providers, can help the patients understand that there are trade-offs being made here—that when you have low-risk disease and you go for treatment, you’re taking on quite a bit of risk of side-effects without much evidence of benefit. On the other side of that coin, if you have high-risk disease or
intermediate-risk disease, there’s more of a trade-off between potential benefit in terms of stemming progression of disease versus potential risk in terms of taking on side-effects. I think in the past we were treating everybody who came along—this was the problem when the U.S. Preventive Services Task Force gave prostate cancer screening a “D” recommendation in 2012. What they were reacting to, in large part, was this overtreatment of men with low-risk disease, subjecting them to the side-effects of treatment without likelihood of benefit. What changed the minds of those on the U.S. Preventive Services Task Force when they came out with their recent recommendation change to a grade “C”—one of the things they enumerated — was demonstrating that we are now doing better at separating diagnosis from treatment and being more judicious about observing men who have low-risk cancer. And, so, the University of Michigan has published a paper about the State of Michigan showing that up to 50% of men with low-risk cancer are now undergoing initial observation; we see the same trend nationwide as well. So, I think those conversations are really important. And from my point of view, from the point of view of a urologic oncologist at a tertiary care center, it’s much easier to counsel a patient about active surveillance if they’ve heard of it before. If they’ve only heard of it after a diagnosis of cancer, it’s actually hard to talk them out of treatment. But if they’ve heard in the setting of PSA testing or in the setting of biopsy that we often find cancer that we don’t need to treat, then it’s very helpful in counselling the patients and helping them to understand that some cases of prostate cancer are relatively innocuous and, at least, initially can be observed, and only if they progress would we intervene.

Dr. Michael Coburn speaking:
Well, thank you for your comments. I now ask Dr. Ronald Chen and also Ralph Conwill, our patient and prostate cancer survivor, if they would like to make any comments on the topic as well.

Ralph Conwill speaking:
Well, I would. Regarding what Todd said earlier about the patient having trouble reconciling the fact that the doctor says, “You have cancer” with active surveillance, that is such an emotional time for the patient in understanding the fact that prostate cancer cells are not like all the other horrific cancers that you’ve heard of and maybe watched relatives die from. You have to understand what’s going on with your case specifically. You’re not dealing with all the other cancers in the world. You’re dealing with prostate cancer. You have the ability to monitor this thing, and you have the ability to know where you stand and not lose sleep at night by testing routinely and making sure that your progression is not moving toward being more aggressive. That is a difficult thing for patients to understand. And at the moment of diagnosis, when patients are talking to the nurses and the physician assistants, they don’t know what to ask. They don’t want to appear ignorant. At the same time, they don’t know how to ask the questions. They don’t know what’s important at that point. They don’t understand what’s going on. And, so, it would be that period of time that is so critical to the people who
are true candidates for active surveillance. I’ve known many patients who made decisions they didn’t need to make because they did not understand what they were hearing.

**Dr. Ron Chen speaking:**
This is Ron here. I do think that the medical culture has changed, and we recognize that low-risk prostate cancer is often a slow-growing disease and that active surveillance is an appropriate option. In my experience, here at the University of North Carolina UNC, when we see a low-risk patient in clinic and explain that it’s a slowly progressing disease, that it’s an early diagnosis and favorable prognosis, and that active surveillance is a safe option, I think many patients actually feel relieved understanding that they don’t have to immediately go through treatment and have the potential quality-of-life impacts from surgery or radiation. And, in fact, the majority of patients we see here at UNC with low-risk cancer, after a discussion with their doctor, will choose active surveillance. I think this also is a trend that’s seen around the country. If this is the case, then primary care providers can help in the discussion and in helping patients make the decision. On the flip side of this, I think it’s also really important that patients who have a more aggressive diagnosis understand that active surveillance is probably not the best option for them. And in this particular discussion that we’re having with primary care providers—a collaboration as well—helping patients who have the more aggressive diagnosis understand that they are actually needing treatment and thinking about surveillance is not appropriate can really help patients make the appropriate choice.

**Dr. Michael Coburn speaking:**
Well, I now would like to turn to Sarah Daugherty from PCORI, the Patient Centered Outcomes Research Institute. Many of our listeners may not be that familiar with the work that PCORI does in the area of shared decision-making. Sarah is here to provide some background and give us a sense of how PCORI pursues its mission, selects research projects, and addresses its efforts in research and dissemination of information. Sarah, please tell us anything you’d like to inform our listeners about.

**Sarah Daugherty speaking:**
The Patient-Centered Outcomes Research Institute, also known as PCORI, is an independent nonprofit, nongovernmental organization in Washington, D.C. PCORI was authorized by Congress in 2010 to fund comparative effectiveness research. So, comparative effectiveness research, or CER, the type of research that we’ve actually been talking about today with our panelists, focuses on head-to-head comparisons of benefits and harms of commonly used medical interventions or strategies in order to be able to determine which approach works best for particular individuals. PCORI’s mission is to help people make informed healthcare decisions by producing and promoting high-quality evidence that comes from research guided by patients, caregivers, and the broader healthcare community. This patient-centered research, which is what we call this type CER research, is really a hallmark of PCORI, where patients and other key stakeholders are partnering with
researchers throughout the research study. I can comment briefly on the second part of your question, which was how we select various studies and perhaps why even in the case of the two studies that we’ve talked about today, they were good candidates for our research funding. So, from what I’ve heard from the discussion, there are three aspects that I think have been touched on, and I just want to highlight those parts of these two studies that are also commonly shared among other studies that we fund. The first is that Ralph Conwell, who has joined us today as a patient partner on one of these studies, is a part of the research team. So, as I mentioned this is one of the hallmarks that is required as part of PCORI funding—to include patient partners and other key stakeholders on the research team. And, as you can see, he not only contributed to the design and the conduct of the research study but is actively involved in the dissemination of the results. So, at PCORI, we really do encourage this type of partnership because we believe that it will ensure that the research questions being asked are more meaningful and the results are more useful for informing healthcare decisions. A second aspect that I wanted to highlight that I think is important is that we really do encourage our investigators to consider a full range of outcomes that matter to patients and the people who care for them. So, patients not only care about clinical outcomes—in the case of prostate cancer, recurrence and metastasis—they also care about treatment toxicities and quality of life. I think that’s why these two studies are so important and part of the reason why we’re talking about them today. Because these studies did emphasize the evaluation of the sexual, the urinary, and the bowel outcomes, as well as quality of life, they were able to capture that full range of outcomes. And, as one of our other panelists commented, when you have complete evidence you’re able to consider the trade-offs that need to be made, to consider the harms and the benefits of the various options, and to then allow this evidence to align with the individual patient’s preferences and goals. The third aspect that I think is common to these two studies, but is also common for other studies that we fund, is that they were able to capture a real-world setting with a broad range of individuals who were a part of the study. So, as our panelists mentioned, these two studies were evaluating modern or up-to-date treatments that were used in everyday healthcare settings and also were more inclusive than traditional trials. So, these two studies were more racially and clinically diverse and their results are more generalizable to a broader range of patients. I do think your comment about shared decision-making is really critical, and I think that’s something that PCORI emphasizes. These two prostate cancer studies really highlight the importance of shared decision-making, of trying to determine what is best for the patient when considering their unique status, preferences, and goals. We know that you’re only able to make the right decision if you have good information that can inform your decision, I think that these studies, along with the other relevant literature on prostate cancer treatment, will really help men and their clinician consider the full range of outcomes that matter to men with prostate cancer so they can select the best option for their care.

Dr. Michael Coburn speaking:
I think it’s very helpful for our listeners to understand the important work of PCORI and how studies like this can be brought to the public’s attention and to the attention of a wide range of providers to try to improve our ability to truly provide shared decision-making in our practices. I appreciate your comments, and we’re very appreciative of PCORI’s involvement and support of this type of effort and this type of educational program.

Well, this has been a very important and widely ranging discussion. I hope that the result is that we have more information about the harms of prostate cancer treatment and the complex decision-making that goes into selecting treatment and also a stronger sense of the advantages and disadvantages of the different treatment approaches that are available, and that with this new
information and with the important perspectives that we’ve heard today that the whole process of shared decision-making involving the full range of providers and patients will be enhanced and supported. I think that the usefulness of these studies in real-world decision-making really is very relevant. We greatly appreciate the comments of all of the panelists to help us understand these complex issues better. So, again, thank you to the panelists. We hope that providers of all types and also even patients may find this dialogue of support and value. So, thank you for your participation. Thank you to our colleagues from PCORI. It’s been a pleasure to have you all with us. Thank you.