PCORI Webinar Series: Considering the Full Range of Outcomes in PCORI Research – Patients, Caregivers and Consumers

Event Date and Time:

Monday, October 5, 2020 - 02:30 pm to 04:00 pm ET

Opening and Welcome

[00:00-06:20]

- **Adam Bloom-Paicopolos, Public Policy & Government Relations Associate, PCORI:** Good afternoon everyone and welcome to today's webinar, Considering the Full Range of Outcomes in PCORI Research: Patients, Caregivers, and Consumers. Before we get started, I'd like to go over a few items so you know how to participate in today's event. We've taken a screenshot of an example attendee interface. You should see something that looks like this on your own computer in the upper right corner. You're listening using your computer's speaker system by default. If you would prefer to join over the phone, just select telephone in the audio panel and the dial-in information will be displayed. Today, you will have the opportunity to submit text questions to today's presenters by typing your questions into the control panel. You may send in your questions at any time during the presentation. We will collect these and our moderator for today's event will address as many as possible in the allotted time during the Q and A section at the end of the webinar. Please note that this webinar is being recorded and all submitted questions will be saved as part of PCORI’s Public Comment Collection on our Proposed Principles for the Consideration of the Full Range of Outcomes Data. The recording of the webinar and a transcription will be posted after this event on PCORI’s website. Additionally, you can access the proposed principles and provide comments at the following locations that you see on your screen. Here's the agenda for this afternoon's webinar. If you have any technical difficulties during the webinar, please contact our AV team at AVsupport@PCORI.org. I would now like to turn it over to PCORI's Executive Director, Dr. Nakela Cook.
- **Dr. Nakela Cook, Executive Director, PCORI**: Thank you so much, Adam, and welcome all of you to the first of two webinars as part of PCORI’s series on the Consideration of the Full Range of Outcomes in PCORI Research. I am Nakela Cook, Executive Director of the Patient Centered Outcomes Research Institute. I am so excited to kick off today's discussion on a topic that I know is deeply important to you and will be central to PCORI's work over the next 10 years. That is how we will approach our new provision to take into account cost burden and economic impact data as part of our funded research. Congress reauthorization of PCORI's funding for another 10 years gave us all a remarkable opportunity to continue to fund research that matters to you and that will help advance a patient centered, efficient, and effective health care system. The reauthorizing language ensures that our work will be even more relevant and useful to our stakeholders by allowing the consideration of the full range of clinical and patient centered outcomes that meet the needs of patients, clinicians, purchasers, and policymakers. This includes, as appropriate, capturing the potential burdens and economic impacts of various health care services, along with the relative health outcomes and clinical effectiveness measures our work is captured to date. As always, we embrace our role as the nation's premiere funder of

comparative clinical effectiveness research and patient centered outcomes research with a deep commitment to multi-stakeholder input. Today is one of many activities we will undertake to understand the diverse perspectives on these issues, all of which we desire to hear, as we strive to take a balanced approach forward. We understand that many of these perspectives may be differing, but yet very important to us as we consider our approach. As is true for all the work PCORI does, we began with engagement. We want to hear from you as our partners and key stakeholders in our work and at this initial step of our implementation efforts, your input and expertise will guide PCORI as we implement this provision and develop guidance for future applicants of PCORI research. We're taking a broad and deliberate approach to implementing this new authority. We'll consider principles to guide our research, updates to our methodology standards, and discussions about how PCORI can contribute to conversations about health care cost and value. As part of this approach, last month PCORI's Board of Governors approved the release of a set of principles for the Consideration of the Full Range of Outcomes for Public Comment. These proposed principles are a high level framework for implementing and describing PCORI's interpretation of this new legislative provision. Following the incorporation of the input from sessions such as these, as well as public comment, they will serve as the basis for PCORI as we develop our guidance for future applicants.

- For today's discussion, we're going to focus on those principles, hearing from an excellent panel of representatives from the patient, caregiver, consumer, and disability communities, on what cost burden and economic cost data to capture, opportunities and challenges on how relevant data may be captured, and when it is appropriate to capture such data. This will not be the only opportunity to hear from the public and our stakeholders on this topic. We hope that you provide your feedback during the open public comment period on the proposed principles, and we're excited to hear from this panel, but also from all of you. As we move forward with our implementation efforts, we will ensure that, in all the work we do, we remain true to our overarching mandate to generate clinical evidence that will help patients, clinicians, purchasers, and policymakers in making informed health decisions. Thank you again for taking the time to engage with us on this important topic today and thank you to our moderator and panelists for lending their time and their expertise to this discussion. And with that, I'll turn it over to Andrew Hu, our Director of Public Policy and Government Relations at PCORI.

Legislative History and Context

[06:20-15:01]

- **Andrew Hu, Director for Public Policy, PCORI:** Thank you, Dr. Cook, for the introduction and for the opening remarks. Good afternoon, everybody. I'm Andrew Hu, the Director of Public Policy and Government Relations here at PCORI. I wanted to echo Dr. Cook and thank everyone for joining us today and look forward to the discussion.
- Before getting into the discussion, it's always helpful to know what's included in our reauthorizing that was enacted by Congress at the end of last year. It is a new authority from PCORI to capture, as appropriate, the full range of outcomes data in the course of our research studies. The new provision expands the range of outcomes that PCORI has already been collecting to now include the cost burden and economic impact related to the utilization of health care services and more patient centric perspectives on cost and burden, as well. This includes medical out of pocket costs, health plan benefit design, non-medical cost to patients

and families, including caregiver burdens, effects on future cost of care, workplace productivity and absenteeism, and costs associated to health care utilization.

- This final policy took a lot of deliberation and input from the broader stakeholder community. When discussing reauthorization last year, Congress heard from a wide range of stakeholders on this topic. Understandably, the topic of addressing cost and value continues to be a sensitive subject amongst the broader health care community, as it had been during debate during the authorization 10 years ago. To make sure there was a balance between those who had advocated PCORI be allowed to conduct cost effectiveness analysis research and those who argued PCORI's focus should remain purely clinical, Congress compromised on a new mandate for PCORI to consider a broader range of outcomes to now include costs and economic impacts, but maintain prior prohibitions on cost effectiveness and the establishment of the quality adjusted life year threshold.
- This webinar and our public comment period on those principles is just one part of a broader implementation plan. Given the complexity of this topic, PCORI is proposing to take a very deliberate and transparent approach to implementation and we've broken it down to three separate pillars. Pillar 1 is meant to serve two separate but related goals. The first is the establishment of the high level principles, which will inform the public how PCORI is interpreting this new provision. Those proposed principles were approved by our board and is now open for public comment. The second is based off the principles and the input we received on them on how PCORI will develop guidance for future applicants and how they can operationalize this new mandate into their research proposals. We're hoping to finalize these principles and develop guidance for applicants by February or March of next year. Pillar 2 is focused more on establishing and updating methodology standards to further inform how PCORI-funded studies should capture relevant data. PCORI's methodology committee will play a leading role in this effort and we expect this to be a transparent process, as well. This do expect this be a little bit longer in terms of the timeframe, but will ultimately result in an update to PCORI's methodology standards. In pillar 3, the focus is on PCORI's role in discussions and how this information can and should be used. We expect that this will be an ongoing discussion as it relates to broader policy and clinical decisions. These three pillars definitely do not have to happen sequentially and we are already working through each one to identify opportunities for PCORI to play an impactful role. But for the webinar series and the discussion today, we are focusing on pillar 1 and getting input from the broader stakeholder community on this new authority and the proposed principles themselves.
- As noted, we're currently focusing on pillar 1 and here's where we are in that process. This includes the release of the proposed principles which PCORI's board did at our last meeting on September 14th. That opened up a 60 day public comment period on those principles. As you can see, we're now squarely in the seeking public input stage of this process. That public comment period will close on November 13th. Additionally, discussion and input collected from today and tomorrow's webinars will also be incorporated into the public comment record. Based off the input we receive through the public comment period and through discussions like this one, PCORI plans to have a final set of principles approved by PCORI's Board of Governors either in February or March of next year. We expect guidance to be developed for applicants to be ready for the spring 2021 funding cycle.
- Now getting to the principles. This slide is meant to highlight what they are, why we need them, and how we expect them to be used. In terms of "what," these principles are the high level framework to describe PCORI's interpretation of this new mandate. In terms of "why" we

develop them, we felt it was important for PCORI to provide the public and future applicants with an understanding of PCORI's interpretation of the law and the mandate. Lastly, how they'll be used. As noted, we expect these principles to serve as a point of reference for PCORI as the basis for developing future guidance to potential applicants and for updating PCORI's methodology standards. The proposed principles themselves should not be considered the actual standards or methods for research.

- Getting to the principles themselves, included below are the four principles that PCORI has submitted and is posted in our proposed document. The full document itself is available on the PCORI website, along with the form where you can submit your public comments, if you haven't. On the left-hand column, you'll note that principals 1 and 2 focus on identifying the relevant cost burden, economic impact, outcomes, and measures. Principle 1 notes that the PCORI funded research may consider the full range of outcomes important to patients and their caregivers. This includes the cost burdens and economic impacts. Principal 2 directs researchers to consider the outcomes important to respective stakeholders when those outcomes have a near-term or long-term impact on patients. Principle 3 describes the certain criteria regarding the collection and consideration of the data. It notes in particular that the collection of data on the burdens and economic impacts of treatment options must be appropriate and relevant to the study. Below that, Principle 4 opens up a discussion about the possible consideration of certain economic analysis. We acknowledge that beyond the collection of data, PCORI may support the conduct of certain types of economic analysis as part of a funded study to enhance the relevance and value of the information to health care decision makers. As I mentioned, all four principles and the full document itself is available on our website and available for public comment at the moment.
- Here are the references and resources for you. If you like, the links will take you to the proposed principles themselves as well as that public comment form. With that, I'll turn it over to our moderator, Susan Dentzer, who is a Senior Policy Fellow at the Duke-Margolis Center for Health Policy to begin the discussion. Susan, the floor is yours.

Panel Discussion

[15:01-1:26:37]

- **Susan Dentzer, Senior Policy Fellow, Duke-Margolis Center for Health Policy:** Thank you very much Andrew. And thanks earlier also to Dr. Cook for her opening comments. It's a delight to be moderating this panel. As both Andrew and Dr. Cook said, the whole point of this panel is to help in the process of guiding PCORI in implementing this new authority under the law. Therefore, our panel is going to explore why it's important to capture cost data from patients and caregivers perspectives. What are the opportunities for doing that, as well as some of the challenges in doing so? What are the relevant data points that should be collected? How might these vary across different types of patients and caregivers? How should the data be collected, and how should it be used, and if all of that is done to the best degree possible, what does success for PCORI, and frankly for all of us, look like? If we are able to incorporate this very important cost data from patients and caregivers, caregivers, perspective, into whatever else PCORI goes on to do in terms of findings and recommendations to improve health and health care. We have a terrific panel lined up to have this discussion. They all live their lives very close to patients and caregivers and therefore are just supremely well-disposed to provide feedback to PCORI on this new endeavor. So, let me introduce them now.

- With us is Gwen Darien, who's the Executive Vice President for Patient Advocacy and Engagement at the National Patient Advocate Foundation, where she leads programs that connect the foundation's patient service programs to the foundation's initiatives while aiming to improve, access to affordable, impartial, quality, health care. It's great to have you with us.
- We're also very happy to be joined by Eric Gascho, who's the Vice President of Policy and Government Affairs at the National Health Council. That's a role he has served in since 2009. In that role, he helps to advance policy positions on Capitol Hill within the executive branch of the administration by advocating for developing policies that aim to improve the lives of people with chronic diseases and disabilities. Eric, welcome to you as well.
- We're very happy to be joined by Leah McCormick Howard, who is the Chief Operating Officer of the National Psoriasis Foundation. Before that, she was the head of the Foundation’s Government Relations and Advocacy Department for five years. In her former position, as well as now, she's very keenly aware of the needs of those with psoriasis and their loved ones, and will be able to shed light from that group's perspective on this whole discussion about costs and patients and caregivers experiences.
- Leigh Purvis is also with us. It's great to see you as well. Leigh is the Director of Health Care Costs and Access at the Public Policy Institute at the American Association of Retired Persons, as it was formerly called, now just known as AARP. In that position, Leigh leads the policy analysis and research teams on health care issues relevant to individuals over the age of 50. She also presides over the Institute's endeavors on prescription drug and mental health issues, which we will be asking her a bit about. She is co-author of the Institute's annual RX Price Watch Reports, which tracks price trends for prescription drugs utilized by America’s older adult population. Leigh, welcome to you, as well.
- Finally, we're very happy to welcome Rylin Rogers, who's Director of Public Policy at the Association of University Centers on Disabilities, where she specializes in federal policy and legislative issues that affect the population with developmental disabilities and their families. Topics of her expertise includes special education, regulations, public and private health care financing, family and professional partnerships. She really provides a unique perspective on the impact of policy and systems issues on consumers and patients, as well as their families. So again, welcome to all of you, and thank you for joining us in this very important discussion.
- We're going to start with the question of the “why” here. Why is it important to capture costs and economic impacts from a patient perspective and from caregiver's perspective? We know that a lot of information about costs and other economic measures is already being used in the health care system to inform a wide array of decisions about patient care and outcomes. So how do we think that having more of this and better measures of cost and economic impact on patients and caregivers can improve decision making? Why go there in the first place? I'm going to ask Eric to start us off and the others will be obviously warmly invited to join in as well. Eric, why don't you start us off on that question?

[20:37]

- **Eric Gascho:** Sure, thank you, Susan. I'm not sure if we have any congressional staff on this webinar, but to those of you who had a hand in this new language for PCORI, thank you as well. I think this is a really transformative new provision that PCORI has been tasked to and has done a great job of getting started despite all of the environmental factors swirling around us kicking us off, so I think it will be really transformative for patients and family caregivers. I think it's imperative that PCORI has a role here, as we're seeing rising costs across the board, both with pharmaceutical interventions, as well as other interventions, that we really have more data for both patients and patient advocates and want to talk about the impact this has on both. From the patient perspective, as we see costs rising and inequities within our society increasing, now one of the biggest indicators of health is your income. It's imperative that patients and families have information about what the tradeoffs might be when choosing between interventions. They may have high out of pocket costs, but may have less downstream impacts on things, such as productivity. Having more understanding of how different interventions may play into that is going to be crucial moving forward. Similarly, if you look at it from a patient advocate perspective, costs are considered by a lot of stakeholders who have a hand in what patients have access to, from manufacturers to health care providers, insurers, both public and private, value assessors. They are all using disparate data. There's gaps in that data and all done with varying levels of patient input. I know Leah can speak about this more than anyone I know about the amount of effort and time that the patient community is putting into providing the patient perspective to all of those various stakeholders. And it can be a burden on patient advocates to have to do it at every step of the process. We're very pleased to see that many of the value assessors now have opportunities for patients to provide input into the benefits of pharmaceutical interventions, as well as what the financial impacts might be. It's a lot of work to do it. One of the things that we saw as we headed into the PCORI reauthorization is that there can be a role and there should be a role for PCORI to play here to help fill in some of the data gaps that exist. Do it in a very “PCORI way” to view patients as partners and bring all the relevant stakeholders together to really capture the most important elements as it relates to cost and burden on patients. I'm really excited for this conversation today. I'm really excited about the work that PCORI is doing in this area.

- **Susan Dentzer:** Thank you so much, Eric, for what you just said about the potential to be really transformative and the real imperative of PCORI would be echoed by our other panelists today, but I want to give them the opportunity to weigh in on that. Gwen, you want to add a few words?

[24:13]

- **Gwen Darien**: Good afternoon, everybody. Thank you so much for inviting me to be part of this panel. I have to say, I'm so pleased with this authorizing language. I agree with Eric that this is truly transformative in terms of doing real and true patient centered research. If you do not measure and collect data on the economic impact to families, to patients, to individuals, you really aren't fulfilling all of the pillars of patient centered research. One of the things I wanted to go back to is the PCORI Annual Meeting and the first panel that Dr. Cook moderated, as well as the closing panel. What she talked about was looking at really eliminating disparities in access to health care and health outcomes. The consideration of the cost burden is key to PCORI’s mission to eliminate health disparities. It's not enough just to address them. It's not enough just to know what they are. You have to know them at a deep level, which is a patient centered level. You also have to understand, particularly with health disparities, how the impact of cost is a barrier to access to quality, equitable, affordable health care. Susan mentioned that in her introduction and in her introduction of me that my organization provides direct patient services to over 175,000 people a year who are having trouble accessing equitable, quality, affordable health care. They're primarily low income. The barriers there are deep, structural, and systemic. This is this is a place where I think PCORI can make a huge difference by identifying that data and helping support and bring light to all of these different barriers and where we're looking at burdens, where we're looking at impact, and how we can really understand that.
- **Susan Dentzer:** Those are two very important sets of comments. Leah, let's start with you.

[26:50]

- **Leah McCormick Howard:** Sure, thank you, Susan, and thank you, PCORI, for having me as a part of this conversation this afternoon. It's so important. And thank you to Eric for your kind words. It's really interesting that we're here talking about this today. I'm so excited that we are because from a patient advocacy perspective for the last decade, many of us have been talking with our communities about the importance of getting coverage, utilizing your health care, and making as informed decisions as possible. But the challenge if you live with a chronic disease or represent a community that's impacted by chronic disease is that having those discussions, making those calculations is not always easy because information is not readily accessible. It is certainly not transparent when you're trying to do this work. I think that this extension of the conversation now to looking at this data is so important. You know, at the NPF, we've been talking for many years to our patient community. We've been around for more than 50 years. One of the things that we know is that all individuals that live with psoriasis and arthritis don't experience the disease the same way. That progression of disease, that journey may be very different for one patient with severe disease, then with another. What those two patients are looking for in terms of outcomes may be different. What they're looking for in terms of treatments may be different. They may be willing to tolerate different side effects. They may be looking for different types of treatment or have different ability to access treatment, either at home or in their physician's office. Factoring all of these issues into the calculation between the patient and provider is so critical when they're sitting there looking at the treatment options that are available to them. I'm thrilled that we're here and look forward to continuing this conversation with the panel.
- **Susan Dentzer:** Thank you so much, Leah. Let's go to Leigh. What would you add to the comments your colleagues have made about the importance of collecting these data to patients, to consumers, to their caregivers?

[29:18]

- **Leigh Purvis** I'd like to start off by echoing all of them in terms of thanking PCORI for putting this together. This is a really important conversation and we're happy to be a part of it. I think in terms of what everyone has been saying and kind of maybe dancing around a little bit is when it comes to health care, unfortunately, you never actually get to clinical effectiveness. You don't get to patient reported outcomes unless the person can access and afford the drug. Cost, obviously, is a huge part of that. That is driving a lot of AARP’s engagement around prescription drugs and health care generally. As much as we like to hope that health care delivery is being driven by what the patient needs and what is going to be most effective for the patient, the reality is cost plays a very big role in what patients are able to access. This is so really important to add this to the conversation. We thank PCORI for bringing it in.
- **Susan Dentzer:** Great, and last but hardly least. Speaking for the large and very important population of persons with disabilities and their caregivers, what would you say to add to your colleagues' comments?

[30:25]

- **Rylin Rogers:** Really it is a joint building on the great conversations that have come before. I appreciated Eric's frame about how the “PCORI-ness” of this is unique and the chance to look at cost and impact more holistically than perhaps in other settings. We know that in able to access care, there are other systems costs that are often creating challenges, particularly for the disability community to get to that entry point. Those systems costs are also painfully part of the equation that families and individuals make around their care decisions. PCORI is unique in its ability to look at things more holistically and allow us to ask the questions in a meaningful way that really drives those decision making at the individual level and gets us the right information to move forward. So, we're thrilled with this step forward and this conversation today. Thanks.

- **Susan Dentzer:** Great. Well, thanks to all of you. We're going to now begin to creep into our conversation about the "how" and the "what" of collecting these data and capturing these data. I want to ask you all to think about the opportunities for capturing the cost burden and the economic impact for patients, for caregivers, and consumers in the PCORI funded studies, in particular. What are the challenges that you see in doing that? Some of you have already alluded to the challenges of acquiring these data, but let's begin to talk a little bit more about those, especially in the context of PCORI studies. To the degree we can have this conversation, the decisions that you think are going to be helped by having the relevant cost and economic data. And of course, that's what's going to be most important. It's not just having the data, it's actually using it to make decisions around care and of course enabling those communities to make appropriate decisions also around care. Rylin, we're going to start off with you on this one. Thinking about this from the standpoint of the disability community, the opportunities (in connection with PCORI studies), the challenges, and the decisions that you think could be informed.

[33:01]

- **Rylin Rogers:** The biggest opportunity is really in that spirit of PCORI that we can take a step back and we can focus on what is the most relevant data. Its patients, people with disabilities, families and caregivers that can frame the questions in a meaningful way, in the spirit at PCORI. When we think about this in the disability community, it is a unique opportunity to really challenge that paradigm of rigor versus relevance in terms of the data that we're collecting and the data that we're using to make critical decisions. This is a real chance to take that step back and start asking the questions in the most relevant way. We can also challenge the economic impact narrative that presumes a steady state of systems. In the disability community, we often refer to the "disability tax:" those real costs in productivity, daily life, and actual economic costs of living as a person with a disability in America. Some of those costs are based largely on our systems and not on the individual or the care that they need. We make assumptions about how do we move forward? Those assumptions are frequently in a steady state environment. Is this a chance to look bigger and really think about what do we need overall? We can think about those impacts and those chances to use the data to drive decision making against silos. It can be more than just a clinical decision. Often cases, it can be something tied to educational access, to employment, to community living, and even something as concrete as transportation.
- I think the other piece is that I would encourage us to hold onto our considerations about the types of data that we collect and whether it's qualitative or quantitative, particularly when we're thinking about individuals with intellectual and developmental disabilities. Too often, the data that we're using to make decisions about outcomes and their care is based on the caregiver report and not the perspective of the individual themselves. This is a real chance to make sure that we're creating a balance and collecting both pieces of data so we're getting a fuller picture about quality and impact and cost from the individual's perspective.
- Finally, in the disability community, I think I would be laughed out of town if I didn't say out loud that too often we're not collecting the data. There are giant gaps around the status of health. What's happening in terms of access for people with disabilities? The current pandemic has laid many of those gaps bare and this is an opportunity to really look at that again and make sure that when we're planning to consider these options that we're including all people with disabilities.

- **Susan Dentzer:** Great. Well, thank you. I promised I would ask you a couple of follow up, so let me do that now. You used the phrase "rigor versus relevance." What did you mean by that?

[36:17]

- **Rylin Rogers:** Often in the disability community we hear that we can't ask that question or get the answer to the question, because the data's not rigorous enough. One of the things that's attractive about PCORI is that partnership. Can we ask it in a different way? Can we be selected in a different way? Can we be really creating a new set of data that is rigorous enough, instead of just those assumptions that there are barriers to the data? Thus, we can't ask the question or we can't collect and move forward. We've really been making significant progress as a community and including the voices of individuals with disabilities at all level of research. This is a real tipping point where we can sort of move beyond some of those challenges.
- **Susan Dentzer:** Can you give us an example of a data set that might be relevant, if not rigorously, collected?

[37:17]

- **Rylin Rogers:** My brain just went on explosion overdrive because I thought about basically all of our Medicaid billing data and how too often an individual's disability status is not clear in there. You may have assumptions by treatment codes and whether to include that to move forward or not. That's a piece that comes to mind. We do have a history where we are just excluding individuals with some types of disabilities, particularly folks with intellectual and developmental disabilities, as study participants because of perceived limits and their ability to be meaningful participants in the study. Or we are instead relying on a caregiver report, instead of individual. Those questions about how do we get to that true voice, that true perspective, and using all data to move forward.
- **Susan Dentzer:** The other phrase that you used was "the need to challenge the economic impact narrative." What exactly did you mean by that?

[38:29]

- **Rylin Rogers:** I think about often in a care setting or in a clinical decision that the question is the cost of the medication versus the outcome of medication. But the complexity for an individual is often much bigger than that. It can be even the cost of time and receiving the care and partnering with a physician team around the care, beyond the cost of the medication. It's missed work time scenario. The other piece, and Leah mentioned earlier, is the access to information in order to make decisions. So, if you're an individual with a different learning need, or literacy level, or an intellectual disability, are you getting the information about the cost of care, or even the options of care in a way that you can access it? And if you're an individual that relies on family caregivers as part of your decision team, are all members of your decision team getting that information, and are all of their factors part of the decision? The complexity of human lives and experience is often much broader than this sort of smaller discussions about "Does X drug give you a better outcome than Y drug and is it worth $30 more?" For folks that are living with complex disabilities and lifelong disabilities and the caring environment, the factors are often just exponentially more involved than that.
- **Susan Dentzer:** You're essentially calling for a very holistic look at costs.
- **Rylin Rogers**: Yes. In a word. Yes.
- **Susan Dentzer:** OK, great points. So, let me go to Gwen next. Gwen, build on some of this, particularly thinking again about the challenges, the opportunities, and the kinds of decisions that would be helped. We could tie it back to what Rylin just said about taking a holistic look and how do you pull all that together.

[40:38]

- **Gwen Darien:** That was great, Rylin. I really appreciated that conversation. I think that oftentimes when we talk about financial impact, we're talking about the impact of medical care. But what we're really looking at is the impact of health care. The number one reason that people call the Patient Advocate Foundation is transportation. That's one out of many, many, many reasons. But transportation is a huge issue. Or, the impact on caregivers, when caregivers have to take time off from work and whether they can afford unpaid time off or whether they lose their jobs.
- Tradeoffs are a critical issue to look at. What kind of tradeoffs are people making? Over my 25 year advocacy career now, I've been doing a lot of work looking at tradeoffs and I look at them from the lens of a patient advocate, but I also look at them from the lens of the three time cancer survivor. So my first diagnosis was as a young adult and I chose to pay all my medical bills and I incurred pretty relatively long term debt for my personal costs, like my food, my housing, and whatever else I could charge on my credit card. But I always paid my medical bills first. We have so many patients that do things like cut their medication in half because they have to make a decision between their health care and feeding their children or families. I think these are really critical issues that Rylin has brought up.
- When I was thinking about this panel, I was reading a lot about what we've just done. We've done a significant (four years' worth) of a body of work on conversations about cost of care and integrating cost of care. Costs not just as in medical costs, but a holistic approach to cost in both the patient's daily life as well as the burden on the clinicians and the systems. One of the things that I thought about was this transformation. I'm thinking about words because Rylin brought out a lot of really important words. We used to talk a lot about "risks and benefits" and we've now started to transfer that conversation to "harms and benefits." I think that's a really critical point as we're looking at costs. It is not a coincidence that one of the most often talked about areas and areas of intersection between health care providers and patients and patient advocates these days is in this framework of financial toxicity. We didn't talk about it as financial impact. We talk about it as toxicity. Financial impact, financial harm, is the toxicity to the family and individual patient and the community. It's also toxicity to people who are partners in their patients' health care. We have learned a tremendous amount about cost of care conversations and about where they differ in different patient populations.
- I'll just give you one brief example, so everybody else has a chance to talk. But we just did two community workshops on measurements around conversations about cost of care. The project that's funded by Robert Wood Johnson Foundation and in partnership with Avalere who really developed the measures and our role was to ensure that they were patient driven and patient centered. We did two workshops, one in the Mississippi Delta and one on the south side of Chicago. There were significant differences in those two populations. Almost everyone was insured in both populations. In Mississippi, because it's not a Medicaid expansion state and because we're talking about rural Mississippi, the access barriers to equitable care were phenomenal: driving hours to go to the hospital, not having any kind of resources. The people there want to be on Medicaid. They wanted to be able to have their family members eligible for Medicaid. Then, we went to Chicago and the south side of Chicago, which is a Medicaid expansion state. What most people talked about there was wanting to be seen as people, rather than identified by their insurance. They talked a lot about the transition in insurance. There are so many different facets to this that we could go down and talk about. The opportunity PCORI has now is to look further interrogate these questions and look much more deeply into the

impact and especially to look at the impact across the country, in different communities, different diagnoses. We do deal with people with disabilities, but we primarily deal with people with very serious and chronic and disabling illnesses, so they become disabled by illness. The conversation about cost of care is often a barrier to even getting in the door of health care, let alone making a choice of their care plan.

- **Susan Dentzer:** So I want to ask both of you and your colleagues could join in. What types of measures do you think researchers could consider to begin to capture these perspectives you've been talking about as they are conducting their patient centered outcomes research. Is it measures like financial toxicity? Just to make up a hypothetical, this study shows that intervention A is superior to intervention B. But intervention A is so much more expensive than intervention B that it does produce greater financial toxicity. Is that the kind of thing you're talking about being captured and if not that, what?

[47:24]

- **Gwen Darien:** I think there are multiple parts to this. There is the measure around looking at outcomes and effectiveness and what different treatments cost and what the comparison and their efficacy is. Underling that, what is important is understanding that a conversation like that makes people feel like you're offering them lesser care. If you're talking about what high value or low value care is, you have to be really concerned that you're not just making people feel as if you're giving them lesser care because of who they are and what they can afford. And this is where bias comes in, and it's not implicit, it's very explicit bias. Whether it's biased because of racial ethnic identity, whether it's biased because of insurance, socioeconomic status, educational status. This is a really critical piece to address. What we found was that the measures didn't resonate so much with the patients. What they were really looking for was building a relationship of trust. Look at building a relationship in which they were given information as transparent as possible. Nobody expects that their health care providers are going to understand everything and they are happy to speak to the business person. They're happy to speak to patient navigators and to really be seen. I think there are some foundations of these measures that we need to address. One of the things that's come out loud and clear is that the idea of screening for financial toxicity makes many people uncomfortable because of what screening typically means. If you normalize it as an “assessment” rather than screening, it can be something that patients use and their health care providers use to facilitate this discussion. I didn't answer you precisely. I went underneath it. There's so many things to continue to look at before we jump into the quality measurement or outcomes, process measurement space. Rylin, do you agree?

[50:09]

- **Rylin Rogers:** That’s the real issue. Before we can pick nuts and bolts measures, it’s the bigger context and the relationships that patients and families have access to and the real conversations about the inequities that exist for us based on who we are, where we live in this country, what our employment status is and how that relates to our access to coverage. We have made progress in terms of access to coverage. We have big challenges in terms of ensuring that all people have adequate health care financing. It’s different than having health care financing. Those barriers and challenges that underlie our system are the foundational piece before we can get to that true quality measurement discussion.

[51:10]

- **Eric Gascho:** I want to bring it back to the idea of kind of looking at this holistically, as well. I think it could be relatively easy to say intervention “A” has a high likelihood of financial toxicity because it as a high cost and high out of pocket cost, but it also may reduce the likelihood of surgical intervention. If it's something that does or does not require you to take time off of work, to get your treatment on a regular basis transportation to get to it. I just want to be careful to say that I think that it's a good start to be thinking about this and financial toxicity, but you really have to make sure you're looking at it from the whole picture and what the impact may be on the patient and their family as well.

[51:54]

- **Leah McCormick Howard:** Eric, I think that's such a great point. You know, we've been talking about this in the disease world for many years about what kind of ideal outcome is when you're on treatment, what the optimal outcome is, what we're all kind of shooting for. The NPS has done quite a bit of work in this space with some recommendations for providers and patients. I think one of the things that really came through in those conversations when we actually talk to patients (and I can't stress enough how critical that is to actually be having conversations with patients directly) is what costs matter to them and how they're making those decisions. But what we found is, in some instances, even a late increment and improvement in terms of efficacy of a therapy, for example, maybe something that a patient as willing to pay for. So let me give you a quick example: If you have psoriasis coverage on your skin and you have it on your face or on your genital and it's a particularly challenging case where you've tried several different types of therapies and your provider offers you a new medication that is believed to possibly address that issue, but it comes with a higher cost. You may be willing to pay that incremental increase in cost because of the expected potential outcome of that therapy. Where again, another patient experience in the disease differently, who's looking for a different set of outcomes, may not necessarily see that equation the same way. So I think it's critical to be talking to patients about what matters to them. The one other thing I just want to throw in here to remember is that in many cases these cost calculations are not being made by one person, independent of everyone else in their life. So if I have a chronic disease like psoriasis, I may have someone in my family who has some other chronic disease. We're trying to manage the cost of a number of therapies in my family. So, we have to remember that these calculations don't occur in a vacuum. I appreciate the word holistic that we've been using here today. I think it really does very much applies to the conversation and the challenge that patients are facing when they're making this decision.
- **Susan Dentzer:** Great. I do want to take a moment to remind the audience that we invite you to submit your questions to us for the panel as we go. We will have time for some questions at the end, but we also would like to take up questions as they come in and see most pertinent to the topics we're discussing at that time. So please feel free to input your questions into the platform for us. To that end, we do have a question that has come in asking: When we talk about health care costs and social costs, how do we distinguish best between those? As we're thinking about this holistic cost approach, who has given that some thought about how we think about both of these pipelines, the actual health care related costs of a particular intervention as distinct from social costs? Eric, has that one cross to your desk?

[55:38]

- **Eric Gascho:** We recently had a round table talking about improving health inequity. One thing that stuck me more than anything is else is that we know there are a large number of inequities in our health care system, and they are reflected in our society as well. We can all come together to improve the health care system across the board, but many factors come in to improve management of their condition. I don't have a great way to distinguish the two because they are so intertwined. It’s important to remember to focus on all of those factors and not work in a vacuum. I'd love to hear what Gwen would have to say on lot of the other support that you provide as well. It's a lot of that kind of gets more into the social cost as well. We recently had a roundtable of folks talking about improving health equity and one thing that stuck with me, probably more than anything else, is that there are a large number of inequities throughout our health care system. Many of those are reflected in society as well. What really stuck with me is that we could all come together and completely solve every issue within the health care system, 100% improve equity across the board. Let’s say we're causing 30% impact. When they come into a health care setting, many factors will impact how much the health care system is going to be able to help them manage their condition. I don't know that I have a great answer of how to differentiate it. The social drivers on health have a huge impact on health. I think it's important to remember to kind of focus on what we can focus on, such as what PCORI is undertaking here. But certainly want to make sure that we're considering all of those factors as we're not operating in a vacuum here.

- **Susan Dentzer:** Leigh, I want to ask you about your work and monitoring drug costs and drug prices. It seems that the cost data that you're monitoring is a little bit more discrete, isn't necessarily that cross cutting holistic cost model that we've been describing. So, first of all, take that one on. Do you agree about the importance of looking at some of these discrete costs, not going to the holistic level? It sounds like that would be a perspective that you would bring to this conversation.

[57:56]

- **Leigh Purvis:** It is, and it kind of speaks to my original thought, which is, you know, if you're looking at cost, that really can be the deciding factor, in terms of whether someone gets treated or not. And it's driving a lot of the focus on prescription drugs. Right now. We've been tracking prices since 2004, and frankly, the trends are not changing much specific to the population that I represent. We're looking at drug, but on average, are costing about $7000 a year for a brand name drug, over $50,000 for a specialty drug, and that is just a lot of money, whether you're talking about out of pocket for the entire system. But when you do look at it more on the consumer side, you're looking at out of pocket costs, and that is a huge issue, especially when you're looking at the fact that these prices just keep getting higher. We're hearing more and more stories about people who are just choosing not to take their dogs with prescribed. You're hearing about people who are taking a different type of trade off where they're not paying for their prescription drugs, or they're not paying their rent. But if you look at just broadly, you can look at the surveys, and about one in four people have found it difficult to afford their prescription drug and three in ten didn't take them as prescribed. That is a problem. Obviously, you're not getting treated if you aren't actually taking the treatment. Unfortunately, when you look at current events, we're hearing about more and more people who are facing job loss, they're facing lots of health care coverage.
- The problem is going to get worse which is why we're paying so much attention to it. The other thing to keep in mind specifically with prescription drugs, of course, is that unlike a lot of other health care services, pretty much everyone uses prescription drugs. Once they reach a certain age older, adults use more than four on average. So it really is an issue that affects everyone and that is why it really is important to focus on these very discrete aspects of it because they do have such an impact. If you’re looking at cost, it can really be the driving factor on if someone gets care or not. We have been tracking prices since 2004, and the trends have not changed much in the population I represent. On average, drugs are costing them $7,000 for a name

brand drug and over $30,000 for a specialty drug. That's a lot of money. Prices are constantly getting higher. People are choosing not to take their drugs as prescribed. This is a different type of tradeoff. They're not paying for their prescription drugs, they're not paying for their rent, and they have to make a decision. The surveys show that one in four people have found it hard to afford their prescription drugs and one in three didn't take it as prescribed. You're not getting treated if you're not taking the full treatment. With the current events, people are losing insurance and jobs and we're paying a lot of attention to it because it is going to get worse in the grand scheme. Pretty much everyone uses prescription drugs, and once you reach a certain age you're taking more than four on average. These discrete costs have such a large outcome impacts in the grand scheme.

- **Susan Dentzer:** I want to move on to this question of collecting the relevant data points. If PCORI researchers are going to be asked to capture data around costs and economic impact, they need to know what types of data and analysis should be conducted that will be most meaningful and most useful in the decision making process that presumably people will follow once they have access to the PCORI funded research. So again, to kind of think about what are those relevant data points, we've talked both on both sides of this already. We've talked about the holistic data approaches, capturing tradeoffs, etc. We've also talked about discrete data, out of pocket costs. Help us think through an offer to PCORI, how we begin to refine these discrete data points. Let's take that first piece that we were talking about earlier, this kind of notion of holistic cost. You can't capture everything, right? Otherwise, a simple PCORI funded study would go on for 15 years. But if we're going to try to capture the really relevant data points, let's make this very concrete, what are those discrete data points that we could start to collect?

[01:01:43]

- **Gwen Darien:** I want to mention that it's not in my bio but I am also the chair of the Patient Engagement Advisory Panel at PCORI. I'm honored to be doing it and these are the kind of discussions we want to be having. I want to tie it back to medical, non-medical, and social costs. There are so many different ways to look at it. There are also structural issues that are more societal and community oriented. There is a study out of the University of Chicago, Northwestern and the University of Illinois Cancer Center about high risk pregnancy and what the episode of care was. Every single cost was factored into a discrete episode. What were the transportation costs? What would it cost to use public transportation, parking cars, water from the vending machine, babysitters, meals? What is the cost of the copays for health care providers and medicines? They came up with an overlay to help women understand the cost over this period of time. These were primarily low-income women, who are high risk pregnancy. You need to identify some period or episode of care. Many of us have ongoing episodes of care. Personally, I paid $10 a day for 30 days of radiation. What happens if you need a babysitter or eat at the hospital? One of the health care providers I spoke to recently assumed that bundling all of the appointments at once would be better, but that's not necessarily true and she never asked the patient. The economic impact for the patient at one time was too high. Looking at the full cost is a crucial part of the cost conversation. As a patient advocate and as a patient, Leigh's comment about adherence makes the hair on the back of my neck stand up. Adherence makes it go up about halfway. Adherence is an essential part of this cost conversation. It's often because of the tradeoff and the cost barrier.
- **Susan Dentzer:** OK, so, in the case of a holistic cost approach, can you describe that example from pregnancy, Gwen? Are you saying to bound an episode as much as you can and look at the cost along the continuum of all the costs?

[01:06:05]

- **Gwen Darien:** Milliman did a study a few years ago looking at episodes of cost on lung, breast, and colorectal cancers and you saw where the spikes of cost are in terms of pre-diagnosis, just diagnosed, and treatment. You can look at it in a way that's meaningful to the patient experience of care.
- **Susan Dentzer:** We have a question from the audience. Leigh, if we thought about the need to collect some of these more discrete costs, what would you think about comparing out-of-pocket costs for a therapy by the type of insurance coverage that the person has? Comparing these out of pocket costs by effectiveness of health outcomes that are also identified as important that patients. Would that be an appropriate way of thinking through, at least in terms of discrete costs, what might factor into the PCORI funded studies?

[01:07:35]

- **Leigh Purvis:** I think out-of-pocket costs can play a big role in assessing a patient's ability to access the treatment they need. Effectiveness is also important, but the challenge is that we are in an incredibly complex health care system. There is a great deal of variability in terms of what sort of out of pocket costs are associated with a given treatment from insurer to insurer. We're not necessarily privy to those decisions made behind the scenes. It can be hard to link effectiveness in out of pocket because insurers are making decisions on a variety of different factors that again, unfortunately, we're not privy to. So I think it's incredibly important to have both of those data points, but it could be difficult to kind of directly link that you.

[01:08:32]

- **Leah McCormick Howard:** The other thing I would throw out here is based on the earlier comments on side effects, there are costs that are hard to find on a spreadsheet in terms of the impact of one treatment versus another. We need to look at patient's lived experience with the disease. For example, there are some older systemic agents and old cancer therapies for psoriasis, and those therapies leave them in a fog. They're rundown and unable to function. Looking at things like absenteeism and presentee-ism are critical. If you have to hire a babysitter or have food brought to your house after infusion, those are not easy to capture. Providers need to have this conversation with their patients in determine their long-term care because those are important factors to consider.
- **Susan Dentzer:** Well, thank you, Leah. And I also want to ask you to address a topic that you brought up earlier as well which is disparities, even within a group of patients. You've talked about different ways psoriasis manifests and the treatment choices and costs. How do you think about segmenting different types of data that's used within a different disease state? How would you think about segmenting the different kinds of data that would be collected across the spectrum of patients?

[01:10:52]

- **Leah McCormick Howard:** Eric talked about this at a recent National Health Council meeting. The same topic has become a really important dialog. It is incredibly challenging to talk to patients about their disease sometimes. We shouldn't talk about data that we have as a first step and we need to talk to the patient about what's important to them in terms of collecting the right data. When we're talking about data, we really should never start jumping in talking about the data that we have, but really make sure we're taking that step back to say to patients "Are we collecting the right data? Is this the data that speaks to the information that you need to make decision?" Similarly, I would say the same thing to payers and providers. "Are these the data points that you need to design coverage? Are these the data points that you need to work with your patients to make treatment decisions?" We need to talk to providers and payers the same way as we talk to our patients in asking if these are the data points that are needed to design coverage and empower patients to make treatment decisions. Psoriasis costs aren't bundled like pregnancy. Phototherapy is a long-standing, effective, and safe treatment and is great for young or pregnant people, but the problem is that the person is paying out-of-pocket costs with the specialist dermatologist for every visit, and it could be three times a week for 10 weeks. The systemic, more aggressive agent may be bundled and therefore a lower cost to the patient. I also appreciate the mention of transportation, especially to access specialists and for patients who live in rural areas.

- **Susan Dentzer**: I want to go to Eric next to draw out a bit on the National Health Council's efforts. First of all, describe in a little bit more detail for us about what role you think PCORI should play in advancing or improving this process, particularly with respect to garnering information about costs and the economic impact on patients?

[01:13:54]

- **Eric Gascho:** Leah touched on this when talking about the need to engage patients, and how it's done across the continuum of stakeholders. At a high level, this is a core set of measures that a variety of stakeholders should be using. One of the challenges that we've found is that many of the measures we see used in clinical research and value assessment and coverage decisions are using different measures and done with varying levels of patient input. I touched on how important it is to bring the patient perspective in to all these different areas. In an ideal world, this should be done very early on and should all be measuring the same thing. What are the outcomes that matter to patients and how does this treatment impact those outcomes? Even within a pharmaceutical company that might be doing this level of work, the clinical and commercial teams aren't always talking to each other and often recreate work. We've seen examples of these core sets being developed but they're using old measures that may not capture the patient perspective. They may not go back and fill it in with the patient perspective. If we're all trying to measure the same thing, and we're all trying to show whether or how there's an impact that matters to patients, then that should be done during clinical development. PCORI can address that in convening stakeholders who have a role in that process and measures and ideally the FDA has a role to play as well. I know that obviously, their focus is on improving the products are safe and effective. It should always be that. But I do think there's also a convening role for FDA as they are currently doing a set of measures that are focused on clinical outcome assessment to bring in all of these perspectives, to bring in all the stakeholders to ensure that the data that we're collecting. It's not just relevant for regulators that can be relevant for everyone downstream as well.
- **Susan Dentzer:** I gather it goes without saying that those outcomes would include costs such as direct costs to patients, as well as some of these tradeoff issues we've talked about earlier?
- **Eric Gascho:** They have to. We've heard so much today about how so many parts of the intervention impacts patients based on clinical and other costs, patient's adherence to them, and tradeoffs. In any level of research and determining what's important to patients, cost has to be a consideration.
- **Susan Dentzer:** Well, I want to advance to a question about patient engagement. We think about patient engagement that Gwen in her work now with PCORI is front and center there. That's obviously front and center for PCORI work. Having advanced the notion and really proven out the notion that engaging and involving patients in research makes research much better, much more relevant. As we think about ongoing patient engagement around these issues of cost, you all have more or less addressed that in not leak or even more direct ways, but as we think about how PCORI funded research do that. How should they best go about that? Again,

we've talked a bit about some of the broader elements of costs that you all think should be considered, but thinking about how you get this done effectively in the context of a book or a study becomes really important to think about. So, love to hear your thoughts on that question. And let's start with you on, Rylin.

[01:18:19]

- **Rylin Rogers:** I love that question because I think it's a challenge. I talked earlier about how critical it is to hold all the participants involved. When we're thinking about patients and family members, it's important to recognize that it's not just the patients, it's all of the complex needs of the family. Who's involved in that conversation? We need to make sure that there are differing perspectives of the individual stakeholders within a family or caregiving unit and that they are heard and accounted for, particularly people with intellectual or developmental disabilities. It also comes up in this space when we're dealing with issues of transition of youth and young adults with medical complexities and disabilities. How do we hold the different challenges and priorities around cost from that perspective?
- The other part that is really important and will take some planning and thoughtfulness is around access to information. How are we framing this in plain language? How are we recognizing the diversity of the country around literacy level, language, and preference? How do we engage in this conversation so that we are at a foundational level creating and designing different types of research that are representing the reality of all American communities? That's access to information. In some cases, it's access to information across the digital divide. We need to make sure that we're not excluding tribal communities and communities who don't have access to a patient center because of distance. That intentional planning will make this so successful.
- **Susan Dentzer:** OK, great, Well, I just wanted to take a brief moment to summarize some of the really important themes that have come through our conversation today, before I leave you all with a final question. All of you have used the word transformative, or imperative, or some equivalent of that. And how important it is to begin to capture these data, this type of insight, into PCORI funded studies. So, obviously, no argument there. How we go about that is going to be a complex endeavor. As all of you have said, there are going to be more discrete ways of looking at certain costs and much more holistic ways of looking at costs. And all of you have more or less said that there is a strong case for both. And again, it's going to depend very much on what the underlying issue is in the given PCORI funded study that is underway. So very important point of guidance that PCORI is going to have to give researchers is about how to frame the cost issues, even tying back in some instances to particular studies. So you've left us with that. You all talk, very importantly, about the broader context in which patients and consumers live their lives, whether that's their economic situation, various other disparities that they may be faced with, their access to care, etc. All of that has to be taken into account. You just all discussed the very important notion of patient engagement. Patients have to be at the table in deciding what these cause factors should be addressed, and this is not going to be a one and done issue. Right? Things are going to evolve over time. As treatments and therapies evolve over time, but also as we begin to capture more data and frame these questions, probably what all of us think ought to be collected in terms of data and how it should be put to use will evolve.
- With that, we just ask you very briefly, what in your view will success look like for PCORI? Let's say, five years from now, if all of these issues are used in the context of framing these costs and economic impact issues for researchers in the context of studies. We don't have very much time, so we just ask you all to make very brief comments. What would success look like if we were back here five years from now talking about all of this? Leigh, let me start with you.

[01:23:30]

- **Leigh Purvis:** Hopefully, we will see improved patient and provider communication and patient satisfaction. Patients and providers are finally having informed conversations about their treatment options and we're starting to have those needed conversations about potential tradeoffs

[01:24:10]

- **Leah McCormick Howard:** I'm going to be bold and say success would look like patients who have better access and ultimately achieving better outcomes. I don't ultimately think we have a data problem. I think we have an input problem. The attention brought to PCORI by this issue could hopefully accelerate the work that many of us have been doing to have these conversations and jump farther ahead.

[01:24:42]

- **Gwen Darien:** If we're looking at a bolder outcome that is consistent with PCORI mission and values, that would be to make a huge headway in eliminating health care disparities.

[01:25:08]

- **Eric Gascho:** Well, first of all, I hope this has been helpful because I feel like it leaves folks with more questions than answers but this certainly underscores how complex this issue is. I'm glad PCORI is taking this on. I would agree with Leah that isn't a data issue but a measurement issue. Success to me would be bringing the community together to define the metrics that we can use to capture all the complexities that were mentioned today into PCORI studies.

[01:25:55]

- **Rylin Rogers:** I think success for me would be a greater number of patients, including people with disabilities, being empowered to make good decisions about their health care and treatment based on all factors, including economic factors.
- **Susan Dentzer:** Well, I want to thank all of you. You have clearly given the PCORI and the greater community of PCORI-funded researchers a lot of important food for thought. This is not a one and done. This will be an ongoing conversation, but I was very pleased today, on behalf of PCORI. Now, I'm going to hand this back to Andrew to close out the conversation this afternoon.

Closing Remarks

[1:26:37-1:28:30]

- **Andrew Hu**: Great. OK, thank you Susan and to all the panelists for such a great discussion. The questions I received from the audience are tremendously helpful. I think a lot of questions are more work for us to do, but that's what we're here for, so we appreciate the time that I've been put into it. I just want to note that we did receive a few questions that we couldn't get to today are more focused on the methodology standards. We fully intend to capture the questions that were asked in this process and what we'll do our best to address them. As I mentioned, there are the other two pillars that are all focused on methodology standards. Just as a quick close, I want to remind folks that tomorrow there will be another webinar, similar to this one.
- Tomorrow, we will be having a conversation with the individuals representing payers, or purchasers, providers, health systems, and the pharmaceutical industry to hear their input and perspective. If you're able to, we hope you'll join us for that. Lastly, the webinars, as I mentioned, are archived and will be made available on our website.
- If you can't catch it tomorrow, we hope you can follow up after the fact. And lastly, just a couple of dates that I want to make sure you're all aware of. As I mentioned, the comment period for the proposed principles does close on Friday, November 13th, so please get them in, if you have

any comments before then. And just to thank everybody again. I know I speak for Dr. Cook and the rest of the PCORI team, and Susan, the panelists, the audience, for joining us today. We appreciate everyone's engagement, and look forward to continue working with you all on this topic feature. Thank you everybody and have a good rest of your afternoon.

Appendix: Q&A Chat Questions

Last Name	First Name	Question
Fee	Florence	How will the economic cost/burden data collected as part of a PCORI trial, be interpreted and used in study findings? E.g. if a study on integrated medical-behavioral care shows that patients and caregivers shoulder a considerable burden of coordination & communication of PHI info between medical and behavioral professionals, in the absence of those professionals doing that themselves, will study draw the conclusion that offering integrated care relieves pts/caregivers of this large burden in addition to improving patient health outcomes and such integrated care should therefore be encouraged, despite its incidental added cost to practices, e.g. in patient registries, upgraded EMRs, inter-professional protocols development?
Peschin	Sue	What do the panelists think of comparing out-of-pocket costs (OOP) for a therapy by type of insurance coverage so patients will know how much they will be responsible for, and/or comparing OOP costs by effectiveness of health outcomes identified as important to patients?
Pun	Ting	How do you distinguish social care cost and health care cost?
Pun	Ting	How to equate the cost from different impacts? Would PCORI set up standardize cost for example for days of absent from work? What about say “future” savings from a preventive intervention?
Rogers	Beverly	When you talk about health care costs, are you including the rising costs of drugs?
Silveous	Elin	May I suggest you define a Twitter hashtag for tomorrow? TY.