2018 PCORI Annual Meeting

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Breakout Session
The Promise of PROs (Patient-Reported Outcomes)

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Moderator:
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Discussant:
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SESSION TRANSCRIPT

>> We're just going to get started in a minute or two.

>> JASON GERSON: Okay. I think we're going to get started. We're a couple minutes past 4:00. So good afternoon and thank you for joining us for this session, "The Promise of PROs." I'm Jason Gerson. I'm a senior program officer at PCORI. I'll be moderating today's session. In my five years at PCORI, I've been fortunate to have a role both overseeing methods, projects, focus on PROs. As well as help PCORI think strategically about PRO related investments. They provide high quality and valid data that aid health care decision-making processes. It often uses PROs to ensure that the patient voice is represented in the outcomes of success.

We aim to produce evidence that can be applied in real world settings, frequently our funded studies examine the choices people make about the options for managing a disease with the eye to learning more about the important benefits and harms that attach to options to patients and caregiver's perspectives. It represents an important hallmark of PCORI's commitment to research done differently. PCORI's investments that focus on and sought to integrate PROs can be categorized in three ways. Through CER clinical studies, research studies and research infrastructure projects. In our clinical studies, we look for our investigators to include PROs that reflect what's important to patients to provide rigorous proposals for the collection and analysis of PRO data, and to ultimately generate pro-related evidence that is both meaningful to patients and clinically actionable. We support research that fosters improvement in the analysis and interpretability on PRO data. With our research infrastructure investments, we've included PROs in the common measures that all participating data networks must collect.

PROs are increasingly integrated in other spheres including performance measurement of hospital physicians and EHRs and administrative applications and thereby promoting patient-centered care. Without further ado, I'll introduce our panelists. Dr. Claire Snyder who is the program director building lifestyle -- building lifestyle outcomes and care services research and cancer at the Johns Hopkins -- Johns Hopkins university school of medicine. Dr. Snyder conducts research focusing on quality of life and other patient-reported outcomes can be used to improve the quality of cancer care. She's past president of the international society for quality of life research and served on the American society of clinical oncology quality of care committees and patient-reported outcomes panel.

Dr. Kimberly Gregory is the vice chair at Cedars-Sinai medical center. She's an obstetrician/gynecologist specializing in high-risk obstetrics. As well as patient safety, appropriate cesarean rates. She has served on society of maternal fetal medicine board of directors and various committees for the obstetricians and gynecologists.

Dr. Eleanor Perfetto will serve as our discussant. Her policy work and research primarily focus on patient engagement and health care, including comparative effectiveness, medical product development, patient-reported outcome selection and development, health care quality and value assessment. She was senior director of federal government relations for Pfizer. She has a lengthy bio, so I will stop there.

Just a few housekeeping things. I'll invited Dr. Snyder and then Dr. Gregory to present for 20 minutes. We can take a couple of clarifying questions from the audience. If there are done, we'll just move onto Dr. Gregory and Dr. Snyder will do the same. Without further ado, Claire?

>> CLAIRE SNYDER: Well, it's a real pleasure to be with y'all this afternoon. I want to thank Jason for the opportunity to present. We've heard people say "I'm wearing multiple different hats."

I'm not wearing multiple hats, I need to be two different people today. Because our patient advocate partner was supposed to come and present with me. But due to unforeseen circumstances, she is unable to make it today. So I'm going to start by saying what Alyssa would have said, and I have some idea about this because she and I discussed it. Alyssa is the manager of communication, education, and survivorship as well as being a three-time cancer survivor herself. What Alyssa was going to talk about is the different ways that Patient-Reported Outcomes such as quality of life, the role that they play in her own experience as a patient as well as the work that she does with other cancer patients and survivors. She has no disclosures to make.

And so the first topic that Alyssa wanted to talk about is how Patient-Reported Outcomes such as quality of life can be used to manage individual patients. This is when you go to your doctor's office and fill out a questionnaire and your own data is used along with your laboratory results, imaging studies, and other information to inform your monitoring and management. And what Alyssa sees as a real strength of this is the way that it empowers patients to see where they are and transparency in terms of their progress and their care. She also notes that it promotes shared decision-making and that the data are even more powerful when they can be reported in realtime in the electronic health record.

Another way that Patient-Reported Outcomes such as quality of life can help patients and promote patient-centered care is in the realm of clinical trials and comparative effectiveness research. This is where we're using quality of life outcomes and other patient-reported outcomes to compare treatment A and treatment B from the patient perspective. So not what some lab value says or what some clinician says, but what patients say about how treatments A and B are affecting their functioning and wellbeing. And this information helps both clinicians and patients have a better understanding of the implications of the treatments and can help inform decision-making.

Thirdly, Patient-Reported Outcomes have an important role to play as quality indicators. Many of our quality indicators are things that come from the medical record such as whether someone got an aspirin within 30 minutes or whether they got readmitted to the hospital, but they don't say the patient experience. And this is another important role for Patient-Reported Outcomes to play in promoting patient-centered care. I was tickled this a during the lunchtime session by how many times the term "quality of life" was said. I said, you know, if someone gave me a nickel every time it got said, I think I could do another research project.

So in conclusion, Patient-Reported Outcomes can help promote patient-centered care at multiple different levels. At this point, I'm going to take off my Alyssa hat and become my other than person and discuss the different projects that PCORI has funded that have served to advance the goals of patient-centered care that Alyssa just described.

So I do have a couple disclosures. I've been fortunate to receive research funding to my institution from Genentech and travel support from Optum to attend a conference last year. My objectives for my talk today are to talk about how Patient-Reported Outcomes can be applied at those three different levels to promote patient-centered care, talking about clinical trials and effectiveness research and for evaluating the quality of care. Just to make sure that everyone is on the same page in terms of what I'm talking about when I say a Patient-Reported Outcomes, this is any report that comes directly from a patient about his or her functioning and wellbeing without interpretation from a clinician or anyone else. And they are generally collected using standardized, validated questionnaires.

So one of the applications we've described is the use for individual patient monitoring. I go to the doctor or maybe even before I go to the Doctor, I get sent a questionnaire to complete about maybe my symptoms or how well I'm able to do my regular activities. And then when I meet with my Doctor, he or she and I can discuss, you know, what's going on with me, how I'm doing, what might need attention. So there have been multiple different studies testing this kind of intervention in clinical practice. And one of the studies I want to highlight was conducted by my colleague Ethan Bash back at memorial Sloan Kettering in New York. If you do this routine system monitoring, his system is called STAR, if you do this, you improve patients' quality of life. In his study, 34% of patients regularly reporting their symptoms have improved quality of life whereas only 18% of patients who were experiencing usual care improved quality of life.

It also leads to more efficient resource use in his study and then other studies we find that by routinely monitoring patient symptoms, they're ending up in the emergency room less often. His research and my research is done in cancer, but this work has been done in multiple different disease areas. And then what was really exciting about Dr. Bash's study was this discovery that not only are we improving patients' quality of life and keeping them out of the emergency department, but they are actually living longer. So based on the success of his initial study conducted only at Memorial Sloan, he receive PCORI funding to compare symptom reporting to usual care. It's being conducted now in 50 community oncology sites with 1,000 patients with metastatic cancer and he's going to look at similar outcomes. So that study is ongoing, and we look forward to seeing the findings.

There are various resources available to those who are interested in using PROs in clinical practice for individual patient monitoring. Several years ago, the international society for quality of life research released research PRO assessment in clinical practice. What this users guide does is walk step by step through the process of implementing a PRO assessment. It lays out a range of options and their disadvantages, advantages and resource requirements. This is the team that was involved in writing the user's guide. Each person here took primary responsibility for one section of the user's guide, but everyone contributed to the user's guide as a whole. We had both clinician and researchers and the user's guide was summarized in this paper and quality of life research. As I mentioned, the user's guide walks step by step through the process of implementing PRO assessment in clinical practice, starting with figuring out what are your goals for collecting these data in the first place and then figuring out which patients and what setting and how frequently you're going to collect the PROs using which questionnaire administered how and then on the back end, what are you going to do about reporting the results to patients and clinicians making sure that they understand and can act on those results and then evaluating the impact of the intervention.

I'm not going to go through the entire user's guide today, but I wanted to highlight several of the areas where PCORI has supported research to use our use of PROs in clinical practice. This includes identifying aids to facilitate score interpretation. We were fortunate to be one of the first cycle one awardees to study how to predict data results so that patients and clinicians can understand what the scores mean and use them in practice. In the first part of the study, we looked at current approaches for graphically displaying PROs to find out what patients and clinicians found helpful and what they found confusing. In part two of this study, we partnered with patients and clinicians to develop improved presentation approaches. In part three, we tested those approaches for interpretation, accuracy, and clarity ratings. I'm not going to

go into detail on the findings of the research study, but these are the results from parts one and two which have been published. As I mentioned, part three involved an evaluation of their -- of their different candidate approaches use and interpretation accuracy and clarity.

So what we did is a broad scale study with over 2,000 patients, clinicians and researchers, not just nationally, but internationally, as well as one-on-one interviews to get feedback. And, again, I'm not going to go into details on the finding, but three of the four papers that report those findings are published here.

At the end of this project, our stakeholder advisory board said, you've developed an evidence-base sufficient to develop recommendations for best practices for how to report PRO data back to promote understanding and use, but we think you need to engage a broader group of stakeholders to actually develop those recommendations. So we were fortunate to apply and receive meetings and conferences engagement award to conduct a modified Delphi process with patients, clinicians, researchers and end users of PRO data to develop the recommendations for how to present them. So those results just came out three weeks ago in quality of life research. And without going into deep detail about what our recommendations are, there are a few things that I want to highlight.

So one of the recommendations we made for presenting an individual patient's data is that on the Y axis, you should include a display of -- sorry, I'm trying to bring up the pointer, but that's not working. So I'll use the old-fashioned pointer. You should include descriptive labels of what the numeric scores mean. What score is very poor, poor, moderate and very high. A second recommendation is that you should indicate what scores are possibly concerning. We see scores below this line are possibly concerning, so we need to worry about physical function, whereas here fatigue is below the line and not an issue. And thirdly, they recommended including reference values for comparison populations if those data are available. So actually we have some partners in the room who helped us develop those recommendations and we are most appreciative.

So it was easy enough for us to sit in this conference room and say, oh, we'll put descriptive labels on the Y axis and tell us what scores are possibly concerning, but there was this recognition that for many PRO measures out there, we don't know where those label go on the Y axis. At what point do scores become moderate and at what point should we become concerned about them, and how do we get reference values for comparison populations. So fortunately with funding from Genentech, we are currently undergoing a project to develop a methods toolkit which will be a paper series published in the Journal Medical Care in 2019 where we're going to display -- each paper is going to describe different methodological approaches used to address these questions of figuring out where the cut points are, figuring out what scores are concerning, collecting reference data, and implementing this in a way so that patients and clinicians can act on the findings.

The secondary I wanted to highlight that PCORI has supported is approaching for reporting the results. Back in 2013, PCORI held a meeting in Atlanta on the topic of advances in the use of patient-reported outcome measures and Electronic Health Record. In preparation for that meeting, we developed this landscape review of different example case studies of PROs used and integrated in Electronic Health Records. From these 11 case studies, you can see that there was a range of health systems that were integrating PROs and EHRs, a range of patient populations and clinic sites. What came out of that 2013 PCORI meeting, as well as a 2015 national institutes of health meeting on a similar topic, was a call for guidance for how we can help

institutions integrate PROs in their Electronic Health Records. In response to that, PCORI funded the users' guide to integrating PROs in EHRs. It was released in May 2017. This was the steering group that advised on the development of the PRO EHR users' guide and it included a multi-disciplinary perspective of patients, clinicians, researchers and users. And then these are the people who really developed the users' guide. There are 11 different sections. There are 22 people up here. Each section at two co-authors with complementary background and expertise. As before, everyone informed on the development of the users' guide as a whole.

These are the topics that are covered in the PRO EHR users' guide, starting with figuring out strategies for linking the PRO data and the EHR to begin with, and then the considerations around governance, training and ethical legal issues. There are also a number of topics that are relevant from the users' guide as well such as patients and outcomes and information. This focuses specifically on the role of the EHR. So the PRO EHR users' guide and the ISO users' guide are meant to be complementary and they're developed by people that have groups that overlap and ISOQOL was a collaborating partner.

The next topic I want to address is the use of PROs in clinical trials and comparative effectiveness research. This is where we take PRO data that has been collected and might not have been used to form an individual patient's care but was shipped off and analyzed with other patients to help clinicians understand the different treatment options as well as to develop patient individual materials and decision-making all of which can help patients and clinicians work together in a shared sense. We know this kind of information is important because less than half of clinicians surveyed said they actually feel comfortable interpreting quality of life data, but two-thirds really want to improve in doing so. And similarly, we know that patients really value this information and it influences their decision-making.

This is a study that my colleague did where he tested how much of an influence quality of life data had on decision-making. And half the group saw -- if you take chemotherapy it's going to have just a little worsening to your quality of life. And in that case, very few people change their mind about whether they wanted chemotherapy. But the other half of the group saw this is going to affect your quality of life a life, you're really going to feel pretty bad. And that changed many patients' decisions. In fact, when you asked patients what -- what information was helpful to them in making their decision about having chemotherapy or not, the quality of life outcome such as physical, emotional, cognitive function were ranked similarly to the toxicity measures in terms of informing their decision-making, although survival had the biggest impact of all.

To promote the use of PROs in clinical trials, we are planning to embark on a new project called the PROTEUS consortium, patient-reported outcome tools: Engaging users and stakeholders. There are multiple different guidance documents out there that help researchers conduct and report their clinical trials in a way that make the PRO information most useful. And we need to make sure that they are implemented and disseminated in partnership with the stakeholder partners. So these are the different tools that have been developed to help the use of PROs in clinical trials. And they include the whole gamut from beginning to end of writings protocol, selecting the measure, analyzing the data, reporting the findings, displaying the results and interpreting them. So this is the spirit PRO extension, SPIRIT is general guidance for how you write a protocol for randomized controlled trials. The PRO extension says this is how you write the PRO parts of it.

Back when PCORI was first formed, they contracted with the international

society for quality of life research to recommend minimum standards for PRO measures to use in patient-centered and comparative effectiveness research. This informed PCORI's methodology manual on PROs, and the information is widely applicable in terms of helping people select measures. A more recent initiative which is being focused out of the European organization for the research and treatment of cancer is to develop recommendations for how to analyze the data. And then just as SPIRIT provides guidance on how to write the protocol, consort provides guidance for how you wry up the results -- write up the results for a randomized control trial and the concept extension says this is how you write up the PRO parts. This also addressed how to do that with clinical trial and comparative effectiveness research studies, and we also have this tool for how to help clinicians interpret and use articles that report on PRO findings.

So finally, I just want to touch briefly on the use of PROs to evaluate care quality. And what this means is that we use PRO data to evaluate the performance of different practices. So these two measures are the percentage of patients whose pain is four or higher and the percentage of patients who report moderate nausea or worse. And so using this example, we can see that our practice is better at controlling pain than practices B and C, but only better at controlling nausea than practice C. So this is useful feedback to give to practices to help evaluate and improve the quality of care from the patient experience perspective.

And several years ago, the American Society of Clinical Oncology decided they wanted to pilot test PRO measures as part of their quality oncology practice initiative. Our Patient-Reported Outcomes panel went through multiple different methodologic performances, surveys and consensus development. And out of that, we developed multiple outcome measure specifications such as control of pain, control of nausea, and control of constipation as well as just a process measure of how good are practices at collecting these data. Because if we don't collect them, then we're certainly not going to be able to analyze them. Building off of that, we -- and when I say we, I mean Dr. Bash -- received funding from PCORI to actually do a prospective multi-center U.S. implementation study to test the feasibility of collecting these PRO performance measures as well as figuring out how to do appropriate risk adjustment.

So in conclusion, I just want to highlight the different PCORI-funded projects that I've described today that are advancing the use of Patient-Reported Outcomes at multiple different levels so that hopefully we are delivering on the promise of PROs for individual patients, for clinical trials and comparative effectiveness research, and for evaluating and improving the quality of care. Thank you.

[Applause]

Are there any clarifying questions?

>> Hi. My name is Liz frank. I have a question about how PROs are published. Because oftentimes in clinical trials, the first clinical trial is reported out, and then at some later time, the PROs are reported out. I'm actually interested in your view about how this affects how clinicians integrate the information from the PROs into how they think about the results of the clinical trial.

>> CLAIRE SNYDER: So thank you. That's a great question. And it's an area where we have attention between trying to put as much of the clinical trial results as possible in one paper versus the journal guidelines that say you only have 3,000 words. In which case quality of life might get 30 of them. And so we're seeing different approaches being undertaken. In some cases, if you have a really big, really strong clinical trial, you can talk to the journal about simultaneous reporting so that the maybe primary clinical trial results are published in one manuscript, but the quality of life results are published in the same issue -- which becomes less relevant in today's online

publication -- but the two papers come out basically simultaneously. So that's one approach that we've seen.

We've also seen that, you know, maybe in a paragraph, you can cover the key points and then there are opportunities for supplementary tables. So we are exploring different strategies for that, but what you've raised is an important issue. So thank you for bringing that up. Great. So we will turn it over to Dr. Gregory.

>> KIMBERLY GREGORY: Now I know why they put the OB/GYN after that because you can see how advanced quality of life PRO measures are and I am giving birth to something in its infancy.

[Laughter]

So first I'd like to thank PCORI for the opportunity to present our work. Implementation of childbirth specific patient reported outcome measures in the hospital setting. Is there an opportunity to improve patient satisfaction. I'm representing the childbirth PRO partnership. These are my disclosures. I was trained to give presentations by telling you what I'm going to tell you and then tell you what I said. So this is what I'm going to tell you. The path -- I'm going to describe the pathway of taking a methods project to DNI phase. So we've developed online PROs which can be used to generate hospital-specific survey reports to change or improve the care processes. Describe why childbirth specific PROs should matter to hospitals. It is being tied to hospital satisfaction. I'm sure in this audience, why it should matter to patients should be self-evident, but our goal was to define what do women want and how often do they get it.

So the seed of this project was a PCORI promise methods project, and we were expanding the PROMIS item bank development to the pregnant population. In that study, we were charged with developing a conceptual framework for childbirth Patient-Reported Outcomes. We did an extensive literature review and identified validated items and put together a survey that -- and we conducted a national online survey of about 2,700 women who were currently pregnant. We wanted to know who wants what and who was defined by the demographics, the clinical status, relevant personality traits and characteristics, their beliefs and experiences and what obviously was the PROs.

We then got fertilized with supplemental funding from PCORI and the Cohen family foundation and allowed an opportunity to do a follow-up study of 800 women after they delivered. And this gave us the opportunity to ask women did they get what they wanted, how important was it to them if they got or didn't get it, and to describe their experiences and outcomes of childbirth. We were also able to determine gaps in what women wanted versus what they got, and to determine which PROs were predictive of hospital or birth satisfaction. Which leads us to our current project, implementing childbirth-specific PROs in the hospital setting. You can see we're a nice plant now. And the overview of that project, we shortened the survey. We developed a mobile platform in addition to the web version, and it's essentially a feasibility study in ten diverse hospitals in California. And the goal is to sample 3,000 women. We want to be able to demonstrate differences in hospital satisfaction across sites and provide summary report in aggregate about what women want and how satisfied they are, and more importantly provide hospital-specific recommendations for improvement in patient care.

So why should hospitals care about childbirth-specific PROs? Everyone is aware of the 2% withhold from CMS as part of value-based care. And this relies on responses to HCAPS. However, despite the fact that childbirth is the number one reason for hospitalization, there are no childbirth-specific questions on this survey. Many families' first interaction with hospitals is during childbirth, and women

commonly select or direct health care providers for their family members. So hospitals are simply missing an opportunity to impress an important customer. Why should it matter to patients? 90% of U.S. women expect to give birth at least once during their lifetime. There is increasing concern about rising maternal morbidity and mortality rates and disparities in these rates or patient safety issues. More importantly, there's a growing demand for alternative birth sites. We're seeing an increase in home birth and an increase in deliveries at birth centers. More women are bringing private doulas into the delivery room. And they're writing birth plans to personalize and protect their birth experience.

So this is our conceptual model. We hypothesize that women come in with predisposing conditions defined by their personal characteristics, life experiences and clinical risk and that collectively with their own values and preferences, it leads to their preferred childbirth experience. They then obviously go through the birth process and they come out with their outcomes, method of delivery, complications, but ideally what they want is a healthy mom and a healthy baby. And that this collectively predicts their satisfaction with birth and their hospital satisfaction. From our first survey, we did a national cross-sectional survey administered by the Nielsen company. Women were at least 18 to 20 weeks pregnant and all U.S. residents. The sample was weighted to be nationally representative. I'm going to focus the rest of the discussion on this blue category which is the number of women who planned a hospital birth and planned to attempt a vaginal delivery.

So what we found is that for this group of women, there were 39 PROs across 19 domains. The PROs varied by patient characteristics and their values and preferences. Not surprisingly, there were two types of PROs. Things that we're calling universal PROs or items that everyone would most likely want. For example, safety, to be treated with courtesy or respect, and specific PROs. Items that were likely to vary by patient characteristics. An example might be based on whether or not they've had a child before. For example, if this was your first child, you were more likely to want to avoid interventions, to receive information regarding baby care or feeding. You want to breast-feed and you were more likely to want to have a female provider available.

PROs also varied by race/ethnicity. We found in the national survey that white women were more likely to want epidurals, narcotics, or have the baby stay with them. Black women were more likely to want spiritual or cultural needs met. Hispanic women more likely wanted massage or mental strategies for pain management and they were less likely to want intervention. Wanting to breast-feed was very important for the Asian population in this survey. Importantly, these are all things that hospitals can do something about. We develop models for each of the PRO. In the is just one example of one model. These are women who wanted skin to skin. In our survey, 72 of respondents anticipating labor said they wanted the baby placed skin to skin immediately after delivery. However, there were important patient characteristics that were also predictive of this. These women were more likely to have a birth plan, to be confident, to be medically literate, to believe they would do well coping with pain and they had planned to bring a support person with them in labor.

One of the things that emerged in the study is that there were gaps. And we identified four types of gaps in terms of what patients wanted and what they got. So the first gap were women who wanted some service but they didn't get it. Examples were reassurance from the provider, narcotic as a pain treatment option, and information about newborn care. So, for example, for women who wanted reassurance for their provider, if they wanted it but did not get the service, they were less likely to be satisfied in that only 29% of women reported that they were satisfied with their hospital

experience compared to 63% of women who wanted the service and got the service. So we interpret for these PROs, it helps to know in advance if a woman wants these options. The second type of gap is that you wanted -- you didn't want the service, but you got it anyway. An example of that is that you didn't want your partner in the room, you didn't want breast-feeding encouragement, and you didn't want acupuncture as a type of pain treatment. If you didn't want it and you got it anyway, you were likely to be less satisfied in that 28% of the women reported satisfaction.

So for these PROs, it helps no know in advance if a patient does not want these options. The third type of gap is you wanted the service and you got the service. Not surprisingly, if you wanted the service and you got the service you were very satisfied. And that 77% of the women reported satisfaction. Examples were you wanted a massage or you wanted the ability to take a shower or be in a tub to manage your pain. You wanted to be able to feed with breast milk or you wanted to stay less than 24 hours in the hospital. For these PROs, it helps to know in advance if a patient wants these services. And finally, the fourth gap, you didn't get the service. These were ultimately identified as universal PROs. It doesn't matter if you want it or if you said you didn't want it, if you did not get it, you were not likely to be satisfied. So if you did not get these services, only 31% of the patients reported that they were satisfied with their hospital experience compared to over 60% of women if they got these services. So we interpret for these PROs, it's not important to ask in advance. These are services you need to provide regardless of patient preferences.

The variables listed in red, patients were less likely to be satisfied. If the women reported poor or fair mental health, a history of discrimination, a negative previous childbirth experience, they reported that most of their days were stressful or they were worried about the overall birth process. They were less likely to be satisfied with their hospital experience. Similarly for the universal PROs if women felt that they were pressured by providers, family or friends to have a cesarean, they were less likely to be satisfied with their hospital experience. Things that we found out in the antepartum survey, if they wanted and got a massage, they were very satisfied. If they wanted and got nurse comfort, they were very satisfied. If they wanted and got their tubal sterilization, they were especially satisfied. If they wanted and didn't get narcotics. If they did not want the partner in the room, these were things associated with being less satisfied with their hospital experience.

And to develop reports for opportunities for improvement in childbirth services. Lessons that we have learned so far is to be adaptable within reason. One of the things that I've learned about community research is that it's very transactional. Every site has some unique ask, so you need to be prepared for it. We try to accommodate globally, but not at the expense of the integrity of the project. For example, catholic hospitals we were not allowed to ask the tubal ligation questions. We wanted to keep them in the study, and so we fixed this by creating two versions of the survey. Hospital X wanted to know about the postpartum visit. We added the fix but with global responses pertinent across all sites. Hospital Y was seeking magnet recognition and they needed to get nurses involved in the research. Our fix was easy. We included the nurses in the engagement process, offering them opportunities to collaborate and agree to assist them with publications. Finally, hospital Z wanted mandarin and Farsi versions. We have this in both Spanish and English, but we decided we couldn't fix that this time around. So the answer to that one was no.

So to be pertinent to the topic at hand is what is the future of this, we want to be able to define improvement strategies. For example, we think it will be easy to tell hospitals that they should provide universal PROs to all women. However, information

gained from the antepartum survey, mental health, prior experience with adverse birth outcome or everyday stress, would help hospitals identify vulnerable patients based on the antepartum survey and perhaps we could develop training or educational programs for staff in order to help women get what they want. We also could develop referral options for patients. For example, women who want a VBAC or vaginal birth after cesarean, if that hospital does not offer that service, that woman probably should not be delivering there. That should be found out.

Potential next steps would be to integrate the PROs into the EMR or develop a childbirth registry. We would love to see this nationally administered and then we would be a tree. We want to have providers intervene directly with the vulnerable patients and to further refine and validate and propose this as an NQF performance measure. Importantly, we've completed steps one through five in the PROMIS pathway. And at the conclusion of the D&I project, we will have completed step six and seven of the NQF pathway, evaluating the PRO measure in the target population and comparing aggregate data across hospitals.

So I hope I've done what I said and shown you how you can have a vision and in the methods project and take it to the D&I phase. We've developed online PROs which hopefully can be integrated into the EMR or administered other ways and used to generate hospital-specific survey to change and improve the care process. I've demonstrated why it should be important to hospitals, value-based purchasing is tied to hospital satisfaction. Hospitals should want to satisfy their number one customer. And why is it important to patients? Women know what they want. They don't always get it. And not getting it matters. So you can learn more. I can tell you what I've learned is that I need to break down and get a Twitter handle. I'm open to questions, but before I'd like to acknowledge my academic research team who is listed here and the childbirth PRO partnership who is an integral part. They were a part of the first proposal. They attended monthly meetings, help with the item selection. They've been part of the second proposal. They helped us reduce the survey, and now they're participating in either monthly calls or the weekly calls for the people on the ground collecting the data. Thank you.

[Applause]

If there are any clarifying questions -- great.

>> Thank you. I'll invite Claire and Eleanor to come up. We'll have Eleanor make some remarks. Do you want to sit or do you want to stand?

>> It's late in the day. Wow, it's bright up here. Thanks very much. I do have some comments on what we heard and just some comments in general about what's going on in the PRO field.

So our theme is the promise of PROs. I want to be sure that I zero in on this issue of the promise because I've been -- I've been at this area of PROs for a very long time now. My gray hair gives away how long this has been. I actually am working in PROs long enough that I remember what they were called before PROs which is this umbrella term of quality of life or wellbeing. It was actually in 2000, I believe it was or 2001, I might have that wrong. It was there the date of the birth of the term PROs, Patient-Reported Outcomes. And it was a meeting where Lori Burke who was at the FDA stood before a crowd giving a presentation about what the FDA's perspective was on this because they were getting so much of this data that was being reported to them. And companies wanted it put in their labeling. It was a mishmash of all of these things. Sometimes it was function, sometimes it was preference, sometimes -- and she coined the phrase at a drug information association meeting in New Orleans. I remember this very clearly because right after she used the term and everybody in the

room wrote it down, within probably weeks there was suddenly changes to people's titles within the pharmaceutical companies, and they became the manager, director, team leader, blah, blah, blah of Patient-Reported Outcomes. It just took off from there. If you actually do a literature search on the term PROs, you would see it went up exponentially from that date because it became the common term to be used.

We still have a lot of confusion about PROs and what that means. And I actually, over the last ten years that we've had Patient-Reported Outcomes enter our lives with PCORI and the advent of the discussion about getting -- things that are most important to patients, being patient-centered -- there's confusion in terminology of what's a Patient-Reported Outcomes and what's a patient-centered outcome. Next Wednesday, my organization the National Health Council is actually holding a webinar for our membership who are very interested in PROs. And I'll tell you why. But we're doing a webinar on is there a difference between patient-centered outcomes and Patient-Reported Outcomes. The answer is yes there's a difference, they're not the same. They can be the same, but they're not necessarily the same.

I think one of the big things we need to contend with to really realize the promise of PROs, and I'm saying promise with an E at the end, we have to be sure that everybody understands the terminology and we Harmonize the terminology because there's just a lot of confusion out there. When we talk about something being patient-centered, as you all know because of the meeting you're at, it's what's important to patients, what they care about. Sometimes that's a PRO. Sometimes it's not a PRO.

And let me give you an example. The FDA in the last five years has held voice of the patient meetings. It's a meeting about a specific disease where patients come in and talk about their experience with having that disease and the treatments for that disease. When they -- when they have these meetings, it's on a specific topic. One of them was on chronic fatigue syndrome. There were a lot of people there -- of course the expectation was that these patients would talk about their fatigue, lack of productivity, their pain, there's some days they're unable to get out of bed, their depression, their anxiety. That was all expected. Patients asked for a biomarker. The FDA said why do you want a biomarker. They said because my husband, my family, my employer, my friends don't believe I'm sick. If I could get that test done that shows I have a positive test for this, I could prove to them I'm really sick. That stigma they have with their disease was so powerful that they want add biomarker. Think about that. It's very patient-centered. Patients want that. They believe it will help them and it will help them contend with their disease and deal with it. It's not a Patient-Reported Outcomes, but it's patient-centered.

All of the other things, fatigue, lack of productivity, all of those things are Patient-Reported Outcomes. And they are, in fact, very important to patients who have that illness. But those are the Patient-Reported Outcomes versus fatigue which is a patient-centered outcome, but not a Patient-Reported Outcomes. So we have to make sure that a lot of -- that people understand this. That the patient community understands this. One of the reasons why they're so interested in getting involved in this is because we are seeing an initiative from the FDA that they've kicked off over the last ten years with much more emphasis in the last five years and that's the patient-focused drug development initiative. How do we get patients more involved in medical product development and how do we make medical product development more patient-centered. Because of that they're writing guidance documents right now. They're scheduled to come out over the next four years. The draft is already out. It came out earlier this year. FDA already collected comments on that. The first one will be final early next year. They've released two other drafts in the last couple of months, drafts

two and three. Both of those are on clinical outcome assessment.

What is clinical outcome assessment? For those of you who aren't familiar with the term, it's what FDA refers to as umbrella term for Patient-Reported Outcomes, clinician reported outcomes, and performance outcomes. In the next year, there will be three guidance documents that will be coming out addressing patient-centered medical product development. And two of those guidance documents will be specifically on clinical outcome assessment. Those two replace the one that I believe Claire showed earlier. That's the 2009 document.

>> CLAIRE SNYDER: Didn't actually show it, but I referenced --

>> ELEANOR PERFETTO: The 2009 document on patient-reported outcomes, that one's going to be obsolete in the next year. The 2009 specifically on Patient-Reported Outcomes will be replaced by two guidance documents that are on clinical outcomes assessment. There will now be an overwhelming -- I see a tsunami coming of patients having to be or being approached to be involved in more and more of the PRO and clinical outcome assessment development. And so they have to be prepared for that and we're trying to be sure through my organization that the patient community is prepared for this promise of PROs or the promise of clinical outcome assessment that will truly be patient-centered clinical outcome assessment. These documents all say you don't begin to do any of this until you talk to the patients about what's important to them first. So you'll see that there's -- this is going to be a tremendous shift. It's come about because of what's happened with 21st century cures. It's in the legislation. It's why FDA is doing it. It's going to have a tremendous impact on researchers, patients, on the industry, and the regulatory pathway. We're going to see a lot more of this in labeling which is what the FDA work is all about.

So for the -- for us realizing the promise of PROs, I think it's making sure we all have a really clear understanding and we harmonize the terminology so that everybody's on the same page of what we're talking about. A couple of things that I wanted to mention about Claire's presentation. There were so many things that hit home for me. Back in 1999-2000, I worked for a small company using item response theory to develop Patient-Reported Outcomes that we were using them. We were doing the kind of work you were talking about. Making sure the report that came out of it was interpretable by patients and their clinicians. We were doing sophisticated things, collecting data using Gallon instead of Nielsen, but same idea. We were doing it with pharmaceutical industry funding. They were interested in funding a lot of this cutting edge work. The problem that we ran into, when we tried to get it implemented in the patient care setting, we had a lot of difficulty doing it. There was no business model for it. The organizations that we were working with had -- didn't have the impetus to pay for it and there was no one demanding to get it paid for. Insurance companies, large group practice, none of them, there was no business model for them to collect these data and use it in practice.

And I see that here we are 18 years later and now all of a sudden, things have flipped. The business model is changing. They have some motivation to do this. Quality measurement has so much to do with that. But also there's -- it's just a change in culture and thinking about care. So that company that I was -- small startup company that I was working for in 2000 where we couldn't really find anyone to sell this to except for pharmaceutical companies because it fit their business model but didn't fit the care delivery business model, that little company is now part of one of the largest insurance companies in the United States. So they're finding a way to use that information and the business model is flipping. That's a very important thing that we have to all understand. Unless somebody's going to pay for it, the reality of life is it's not

going to get done.

I'll stop there. I think those are probably the most important things that come out of this. How do we integrate it into the system. Part of realizing that is getting it paid for. The other is how do we make sure everybody understands what are we talking about, how do we do it right, and how do we get it implemented.

>> JASON GERSON: So we have a little under half an hour remaining. I want to open it up to the audience for questions so folks or the panels if you have questions for one another. So please feel free to come up. Introduce yourself.

>> University of the Pacific. Thank you for the presentation. I have a question for Dr. Gregory. You mention that you declined translating the PRO into Asian and Farsi. As the only Chinese in the room -- maybe not the only. I just thought that I'd like you to elaborate on the challenges of translating that in other language. I understand there are some things at issue, but also want to hear about the solution -- possible solution.

>> The challenge is money.

>> [Off Mic].

>> KIMBERLY GREGORY: We got the Spanish professionally translated. Then we had to make sure it was at a eighth grade level. Then we had to focus group test it. So -- you know, not being a Spanish speaker but having been in enough for the focus groups to understand Spanish is not Spanish is not Spanish. So you had to come up with -- you know, which dialect you were going to ultimately go with. So we would love to do a mandarin version and actually at Cedars, I'd love to have a Farsi version. I'm optimistic that we will be a tree and there will be other versions someday.

>> [Off Mic] more inclusive [Off Mic].

>> KIMBERLY GREGORY: I will say the translation isn't the most expensive part. It's the fact that you have to have another -- I have to do another set of programming in that language. That's where the cost comes actually.

>> JASON GERSON: Over here.

>> Yes, hi. My name is Jacqueline. I'm a heart patient and a volunteer patient advocate and also a patient rep for the adaptable clinical trial for aspirin. And I'm just really excited to learn more about PROs and especially about -- and I want to learn more about the challenges that -- the biggest challenges for incorporating PROs into clinical care and particularly for cardiovascular care because I'm a heart patient and I have a rare heart disease. My condition has been diagnosed in only about one in 17 million people. And I've always thought about, you know, how can I find out more about symptoms and concerns that other patients with rare types of heart diseases have and what I have in common with them because a lot of my symptoms are, you know, they're rare. I've talked to other patients and they have some of the same symptoms, but I can't find much information on these issues. I just wanted to know what are some of the major roadblocks into incorporating these things into clinical care and cardiovascular care. I can relate to what you were saying about the vocabulary and terminology. Just sitting here, I thought patient-centered issues were automatically Patient-Reported Outcomes issues. So I got a little confused just hearing what you were saying that those could be very different.

>> CLAIRE SNYDER: So thank you for the question. I think we are seeing an evolution in the field which should be encouraging because there are some barriers that we've really made great progress in overcoming and others that we need now to address. But I've been in this field long enough that when we first talked about using PROs in clinical practice, the idea was ridiculous. How were you going to have the patient fill out a paper form, and then someone was going to have to score it, and

somehow you were going to have to get that information to the doctor or part of the clinical team. You know, so the encouraging part is that to a large extent, the technological challenges have been addressed. Now we're at the next level of challenges.

And I would -- from what you've said, I would highlight three things. One is making sure that the questionnaires we're asking patients are relevant to them. And that becomes particularly challenging when you have very rare diseases, but there again are advances in the field called adaptive testing where you can cherry pick or the system is smart enough to know which questions to ask which person. So there's another frontier that I think we're going to cross.

And then a lot of what my own and my collaborators were focused on is making sure once you've collected the data, you know what the scores mean, and you can do something about them. So those are the ones that I would highlight. I'm not sure whether other members of the panel might add.

>> ELEANOR PERFETTO: So my organization is the National Health Council. For those of you who don't know what that is, we're a membership organization, but the members are not individual people. They're organizations. So our members include names you would recognize, the American heart association, the American diabetes association, American cancer society, et cetera, et cetera, all those groups. We're a group that exists for them for cross-cutting issues. Patient-Reported Outcomes and clinical outcome assessment has become a cross-cutting issue because they're all getting involved in the development of these tools for their constituents, for the patients that belong to their organizations.

That's why we provide the support for them on that.

We spend a lot of time making sure they understand the terminology. To address the confusion you're expressing, you're not alone. There's confusion everywhere. Essentially the way we describe it for our organization, the terminology that we use in the glossary we have is that a lot of information is provided by patients. And we call it patient-provided information. And that's a big umbrella term. And underneath that are Patient-Reported Outcomes and outcomes with those health outcomes. What are the long-term health outcomes you're looking for. Quality of life, wellbeing, physical function, mental function, social function. In other words, do I have pain, can I get out of bed, can I take care of my kids, can I go to work. Those are the kinds of things under Patient-Reported Outcomes as opposed to a preference. I prefer this kind of treatment to that kind of treatment. I would trade off these side effects in order to have this level of a drug that works for me. What's the tradeoffs. That's other patient-provided information.

Some of those things that patients provide are -- they're answers to questions. So it is patient-reported and they're reporting that information.

But they're not things they care about. That means they're not patient-centered because they're things that they don't care about. What we have to be careful of is in the past -- and I can tell you this because I saw it, I worked on it, I experienced it -- in the past, many of the questions that we ask patients that are part of older measures that are used out there are questions that came from doctors and not from patients. They were things that were important to clinicians. They weren't important to patients. So some of those older tools that are out there might ask a patient 12 questions, 24 questions, 36 questions. And they're all questions about things the patient couldn't care less about.

Well, it's patient-reported because the patient did answer the question, but it's not patient-centered because it's not something the patient cares about. So we want

them to be both. We want them to be a question that the patient is reporting and only the patient can report on that. Only you can tell somebody how much pain you have. I can't look at you and say, I'm going to rate you as a ten because you've got that much pain. It's only something that can come from the patient and it's patient-centered because you care about pain for your illness or your ability to function for your illness. We got to make sure to realize the promise of these measures for the future, they have to be things that patients are caring about.

>> KIMBERLY GREGORY: Thank you so much. This is great and very timely for me. I was just invited to be on a panel about PROs and I thought I totally understood until you --

>> ELEANOR PERFETTO: Call me, we'll talk. And come to my webinar next Wednesday.

>> I'll be on it. Thank you.

>> JASON GERSON: We'll go over here.

>> Hi. May name is joy. I'm an OB/GYN. I actually work with your friends at QMCC a lot and at ACOG. I'm also on the advisory committee for the black women matter alliance. So we are working on what we term patient experience metrics. So to go back to your earlier thing about definitions and language, we spend a lot of time talking about outcomes, but when we look at the experience that women, especially black women have in obstetrical care, that impacts health. There are global standard for care and global standards for abuse. We have not created a metric in the U.S. context for either one of those things although we know they impact care. We also know there is a need for some type of quality improvement based on how the experience of care happens to you.

So do you know of any studies around experience and the difference between PRO, patient-centered, all of that. I'm here to learn.

>> Let me throw a wrench in everything. 21st century cures legislation got passed last year. What happened was -- I have to figure out how to --

>> I'm here. I'm ready for it.

>> Yeah. Sometimes when legislation gets written on the hill, they -- they have the best intent, but they don't use the right words. And so the words that got used in the legislation was patient experience data. There's nothing wrong with that, but our -- when you think about I don't want to know just a patient's experiences, I want to know a lot of other things. Well, they use the term patient experience data as the umbrella term for everything. And so like I said, in our glossary, we say patient-provided information because that's a bigger, broader term which could be experience, preferences, outcomes, all those things.

Right now, we're going to suffer for a little while longer because it was written in the legislation. It means the FDA has to execute on it that way, therefore FDA is now calling it patient experience data also. But they are using it as an umbrella term for all those things. And so it -- it will remain confusing because it's now in legislation where it's been codified.

But -- so when they're using it, they're saying patient experience, they really mean anything. It could be experience with care, it could be experience with a disease, experience with a treatment. It could be outcomes, preferences. That doesn't help you. It doesn't help me.

>> Amen.

[Laughter].

>> JASON GERSON: Over here.

>> Hi. Great panel. I'm Megan Lewis from RTI international. Great

presentations. My questions for Dr. Perfetto, but whatever you all think as well. You said that things flipped. I have noticed that things have flipped in the field. They've flipped in the federal government for different agencies. Some of it's related to legislation. I personally think it's because of PCORI, but I have a bias. What do you think flipped? What is leading to this big change in how we think about measurement and the values and the priorities in this area?

>> I'd like to think that it's because of PCORI and because of the National Health Council because we've been working hard on this for the last ten to 15 years. PCORI's been working hard on it. I think also we have seen a change in the advocacy community. Patients are now much more empowered. You know, this started 40 years ago with the HIV movement. Other organizations learned from what was going on in the HIV community. Patient advocacy organizations, patients are much more empowered. We have the technology now for patients and patient groups to communicate with their constituents in a way that they've never been able to communicate before. So I think it's a lot of things that all came together at once. I also think that within government agencies like the FDA, there were some ah-ha moments like the idea of why do you want a biomarker. It was so -- something that they never realized.

But once it happened, they drank the Kool-Aid and understood how important it really is. Now it's just kind of infiltrated.

>> I also think that because we're trying so hard to be more transparent, it's just more obvious that people are not satisfied.

>> Right. Right. Exactly.

>> Thank you.

>> I am post --

>> [Off Mic].

>> I'm post doctorate fellow. My question is about how can we maximize evidence of the patient-provided data compared to these kind of biomarkers, hitting back on the example Dr. Perfetto provided. The patient experience was not varied by society and the family and this patient want the biomarkers. And actually this hits on my main question and concern. Most of the patient-reported outcomes are not valued at clinical level and at policy level as this kind of biomarkers and these kinds of things that can be measured evidence. How can we maximize evidence. Is it related to measurement issues? How can we maximize these to influence decision-making at clinical level and policy level?

>> I think we're -- I think we're going to enter into an era where there will be less skepticism of the patient-reported outcome measures because of what's going to be happening with the guidance documents and that there's more -- there's going to be more acceptance. I actually also believe that as we move into the future and we see patients being engaged at the earliest points in time so that we have a patient perspective on the natural history of the disease, the important symptoms, all of those thing will now be feeding into research, the research that my colleagues do. It will also be feeding into the clinical development plans that medical products will be creating so that we're going to reach a point where in instead of it always being the biomarker that's the primary end point and always being the pro that's an experimental end point or secondary end point. The PROs and those other COAs will become the primary end points because they should have been in the first place. I think we're -- it's not going to happen tomorrow, but we're going to reach that point where we'll be resolving some of these issues just simply because the paradigm has shifted.

>> Just to add a complementary perspective, I -- I'm a PRO researcher. I'm

dedicated to PROs, but I -- I never set up a competition of PROs are better or worse than something else. So I think each of the pieces of information provide a piece of the puzzle. And so it starts that the biomarkers are useless. Measuring PSA is valuable. It just doesn't tell you the whole story for a man with prostate cancer. That's always something I try to emphasize is the valuable information we're getting from multiple sources including the PROs.

>> Just won't be a second class citizen anymore. They're rising up.

>> JASON GERSON: We have about ten minutes left. We'll take these questions for the people at the mic.

>> I'll go quickly. My name is Allison Hall. I'm a professor of health policy at UAB in Birmingham. My question is for the OB/GYN researcher. I was struck very much some of the measures you talked about had to do with things that the health system could do to make lives or that birth experience better for women as opposed to what goes on, I would suppose, at a clinical level. I teach people who are going to run hospitals. So getting a massage or setting a policy in place where people's partners may or may not be in the hospital room seems to be a high level kind of activity or a management activity, if you will.

So talk to me about -- and we're talking also about parsing out Patient-Reported Outcomes, patient-centered outcomes, quality of life, all of these things. It seems a lot of the things that women were reported to you had -- were more sort of the management challenges and less about what goes on at the clinical level. I didn't hear you talk about pain or depression or fatigue. So can you sort of speak to the fact that you sort of had these different kinds of measures coming out of your study?

>> They were there, but it was hard -- I was trying to encapsulate some of the important points in a living room conversation. We do have a publication out that talks about the antepartum findings and we just got a postpartum paper accepted yesterday. I'm happy to discuss it offline more, but that information -- or those types of variables did come out as being important.

>> Hi. I'm Valerie Frazier. I'm with the IBC international consortium. I'm a research advocate and a cancer patient survivor. I see this as really important for cancer patients in clinical trials. It's another piece of the puzzle because as I attend so many meetings and I've been out there for 11 years now. And that piece is missing, you know, we know what's missing, the patient input. But there's a lot of discussion that sort of dove tails in with this that I'm hearing. Because as -- I'm an inflammatory breast cancer survivor. But as patients with cancer live longer and they're on maintenance therapy longer, there are not so many trials that provide information on how to handle that maintenance therapy longer.

So I see this -- you know, there's discussion on dose modification, various things with regard to this that would lower toxicity and patients -- I even heard from a prominent researcher about a month ago that he wants to do a study to look at dosages of all clinical trial drugs because basically they can work at a third of the dosage, but nobody's ever looked at that. And my own doctor told me that my drug, when it was originally tested -- he was one of the original doctors on that -- they actually knew it worked at a lower dose, but they gave it at a higher dose.

So I see this as all sort of coming together, that if patients can have input into this, that they're going to have to look at that data. And it really will lead to precision, more personalized medicine in trials and then, you know, outside of that. And that's our struggle. I mean, that's, you know, with precision medicine, we really -- the struggle is there for patients now. But I see this as a little diamond in the rough. Thank you.

>> JASON GERSON: Thank you.

>> I only have one comment and that's you're dead-on with everything that you said. This woman that's standing right here, you should talk to her.

>> I know Valerie.

[Laughter].

>> Patient advocate foundation and also new member of the patient engagement advisory panel for PCORI. So I keep on forgetting to say that's part of what I'm doing here. This is my third day as a member.

But I wanted to add a little bit to Eleanor's history in drawing back the lens and then just -- and refer back to something that we heard in the plenary. And that is that the -- in terms of biomedical -- in terms of biomedical and research advocacy, the women's -- the breast cancer movement certainly learned from the HIV/AIDS movement. What we can't forget is what they learned from the women's health movement about autonomy and from the disability rights movement about autonomy. So the disability -- the sort of -- the sort of value statement of all advocacy, nothing about me without me, comes from the disability rights community. And the transparency of what -- of what Valerie was talking about and everybody else in terms of what is the impact of medicine, much of that comes from the women's health movement and what they were doing around birth control.

But I'd also like to -- but I think that it weaves back very well into what we've been doing -- at what has been talked about at this meeting. I think it was Eric Hess talking about do you want health care that is for you or health care that is with you. If we mix -- if we marry autonomy with patient -- with what patients' desires are, patients' reported outcomes are, and what the impact of the treatments that we're all taking -- and I'm a three-time cancer survivor -- we have a much more powerful story that has much more -- much more potential for impact.

>> Well said.

>> JASON GERSON: I think there was -- did you want to -- maybe we'll weave that one in, then.

>> I didn't think there was time for me to ask a question. My name is Laurel. I'm a former and member of cancer research alliance, I think that's what they call them now. I wonder if the PRO CTCAS, the common terminology criteria for adverse events, when that's provider reported and then provided -- or the patient-reported, how oftentimes is that actually compared since apparently that's a validated measure and I'm not sure how many are validated.

>> So that's a great question. And so the development of the PRO CTCAE was again to provide this new perspective traditionally in clinical trials, it was clinicians who were raiding the adverse events, the side effects that patients were experiencing. And what we found is that if you ask two different clinicians, you didn't get the same ratings for what the patient was going through. And when you compared what clinicians reported to what patients reported, what they reported was at a much lower frequency.

So, again, to provide complementary information, the pro CTCAE was developed so that for the things patients can report themselves such as pain, but not things such as low neutrophil count, that they could provide this information. Now, interestingly, the clinician reported data are more predictive of certain things and the patient-reported data are more predictive of other things.

And that just goes to my point of they're providing different perspectives and complementary information. But they -- they don't match. You don't get the same answers.

>> I understand that. And then they also have disease-specific questionnaires, PROs, so that we keep them within, you know, the same area that patient would really

truly have input in and not on other areas. Thank you.

>> JASON GERSON: So we are right at 5:30. I want to thank our panelists and thank the audience for your attention and questions. We'll stick around for a few minutes if you have specific questions you want to ask. Otherwise, thank you.

[Applause]

[Session concluded at 5:31 p.m. ET]