Conversation with Dr. Joe Selby, MD, MPH, CEO
Patient Centered Outcomes Research Institute (PCORI)

ACCAHC Research Working Group
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The audio of this dialogue is available here: http://accahc.org/useful-resources

Greg Cramer, DC, PhD, Director Research, National University of Health Sciences, Research Working Group Co-Chair,: It's really great to be able to speak with you as a group together. So if you could just speak for as long as you like and then perhaps work in where you see complementary and alternative medicine fitting with the PCORI in any unique ways. That would be certainly of interest to us. And then we'll open it up to questions and answers. So, OK, Dr. Selby.

Selby: Thank you Greg, and thank you John for the invitation. I'm going to preface my remarks by saying I'm sitting in a hallway of a hotel in the conference center of a hotel where I just did a talk, and it's really nice and quiet now. I hope it stays that way, but if it doesn't, I'll have to apologize. Next thing I'll say is that I was there in Seattle in September of 2011 when Dan and Carlo and John and another one or two people presented to the board of governors, and we really struck by number one, the thoughtfulness of your presentations and how you had embraced comparative effectiveness and seeing that it has a lot to do with complementary and alternative medicine treatments and also appreciated that it has...there's some unusual, maybe particular methodological issues when it comes to studying the kinds of treatments that you employ.

So that was a memorable presentation, and it has stuck with us. And it probably did have something to do with the fact that we called out complementary and alternative medicine in our exceptionally broad [funding announcement]. You'll notice that we have four standing planning announcements out there that...standing means you can apply to them every four months, much like an NIH program announcement.

They are extremely broad. I'll get into what they cover in a minute, but just to say that to even be called out as one example of the type of research we're interested in, it says a lot in terms of all the things that we didn't call out but we'd still be interested in, so it did make an impression, and we do, I think, recognize that there are a lot of important patient centered questions that involve options in their therapeutic areas.

So I thought I give a little, brief update of what happened at the September 2011 gathering and very quickly move to your questions, because that's still my favorite part of the exchange, and I think probably most valuable. But since that meeting, we've been rather busy. One of the things we had to do was to put out what the legislation called our National Priorities for Research.

We put them out in an update this past January, and then opened a two month period of public comment and received about 700 comments, digested them, and filed a revived National Priorities and Research Agenda that went with them. They were adopted at our Denver board meeting in May.

I'm just going to go through the five priorities and explain a little bit about each one, at least the ones that I think are the most germane to your interests and to the kind of research that you do. But you may let me know that I missed the boat or that there are important questions and others.

The first one speaks to individual patients and their decision-making. It's called "Assessment of Prevention, Diagnostic and Treatment Options." This is, you might call it your classic CER. It's how does one treatment compare to another treatment.

We hastened to add in the funding announcement for this priority that treatment to usual care or treatment to no care is a very valid comparison sometimes. All of our research is premised on the fact that the comparisons were practical comparisons of choices that patient face. All of our research has to focus primarily on patients and outcomes.

All of our research has to be comparative. All of our research needs to address practical questions and include primarily outcomes that are of interest to patients. I don't think your world will have any trouble of meeting those two requirements.

In the usual care, no care, no treatment, is sometimes a legitimate option. It's a relevant comparator, if you will. In fact, it even creates a place, I think, sometimes for placebos in the PCORI world, which is a bit surprising. I'm going to move on.

I will say that I think this first priority, the assessment of diagnostic, prevention, and therapeutic options, is probably the main place. It's where the bulk of funding will go. It's, I think, probably where Congress thought we would go with most of our funding, and thus far about 40 percent of our funding is in this area.

The second priority is called, "Improving Healthcare Systems." Right now, about 20 percent of our budget is going into this area. It just reflects what we all know, that having the evidence is not enough, whether you receive your care in an organized system or whether you receive it in an unorganized setting, that is, a setting that is not part of any larger system that puts any thought into caregiver delivery, quality of care, convenience, access, patient education, self-management or any of those things. It is important.

We dedicate a portion of our budget to comparative studies, again, with patient-centered outcomes. The comparators are different things the systems might do or might not do. If you've got patients receiving care under a usual care setting, [indecipherable 0:06:57] with that particular system of intervention being added to the restraints.

That's the second priority and I won't say anything more about that. I'm not sure that much of your interest would be there, although one of the things that falls under this priority and is called out is differences in benefits design.

There may be ways to study the benefits design to the extent that they vary in providing coverage for different complementary alternative therapies.

The third priority is communications and dissemination research. That essentially recognizes the fact that if the information doesn't get out, doesn't get made available to patients and clinician decision makers, it's not going to have an impact.

If patients and clinicians don't improve the ways in which they communicate with each other, even having the information there is probably not going to meet the [indecipherable 0:07:54] test. The sharing of that information and of the decisions that follow it, that is the most important thing. We don't really know the best ways of doing that yet.

Again, these studies are comparative; they focus on outcomes that are important to patients. That's priority three, communications and dissemination research.

The fourth priority is addressing healthcare disparities. This priority recognizes the fact that, just like comparative effectiveness recognizes the fact, that particular treatments don't work the same way for everybody.

Patients have different preferences for communication and learning, different preferences for outcomes sometimes, and different preferences for different kinds of treatments. Beyond that, the same treatment administered to different patients may not have the same effectiveness.

All of these kinds of observations are part and parcel of disparities research, but they also are part and parcel of comparative effectiveness research. We basically dedicated some money to studies that are comparative but they build on this disparities research, comparative effectiveness research literature, in ways that are designed to reduce or eliminate disparities.

We're particularly interested in interventions here, the need to reduce or eliminate disparities. That's the fourth priority. Like the third and second, I'm not sure that you would naturally be drawn to those, but there could be some ways in which you build some standard patient preferences for treatments or outcomes into your research and study modules.

This fifth one is, I think, again, highly responsive potentially. It's called "accelerating patient care and outcomes research." It's about infrastructure, it's about improving research methods, it's about building clinical databases, and engaging patients in those databases.

I think there, you and a lot of other people that CER will also find opportunities there specifically dedicated to some of the pre-work that goes into getting ready to do a comparative effectiveness study.

If you wanted to do some descriptive work on patient preferences, if you wanted to develop an instrument for measuring outcomes, if you wanted to pilot some kind of an intervention that would later be the subject of the comparative study, you may well find funding in this announcement, and I will tell you that this announcement is not quite out yet, but it will be out by the end of this month. This is an announcement that responds to our fifth priority and funding methods. That is what I wanted to say about the funding that is out there.

Dollar wise, there was 96 million dollars available, in the first round of funding. There will be roughly that amount for the second round, which is due November 30th, it's a little hard to say exactly how much will be available each time. There will always be a sizable amount, but I don't know that it'll always be that amount every four months going forward.

Catch any good idea, any condition, any treatment modality, that's what these announcements are about. We're also starting a process of research prioritization, which is going to lead eventually to stakeholder-driven decisions on PCORI’s part to put particular amounts of money into specific

areas. So if we get a lot of interest in a particular area by our website or one-on-one discussions with patients or patient organizations, clinician organizations, healthcare systems, we might well be convinced, and we'll do this in concert with advisory panels, to put some specific target for PCORI dollars toward a research area.

So, in 2013 and beyond, you can expect that in addition to the broad announcements, you will see targeted announcements. Some of those could well be related to your area of interest as well, and it speaks to the need for you to stay engaged and give us your ideas and talk with us about the key questions in this area.

The last thing I'm going to say, and it's just a little bit about what we demand in our research. I don't think it's going to be a big stress for you, but it is unusual and distinctive. And that is that we put a lot of stock with patient engagement. We think that having the patients and...

We think it's very important to have patients and the other end users of research, so clinicians or the caregivers of patients would predict certain conditions, involved in the research from the beginning. If you are an applicant, we're going to want you to tell us in your application how you have incorporated patient input and caregiver input into your research team. Typically, we'll be looking for a member of the research team who represents those communities and who is going to be an active participant in your research as you're drafting the proposal, and as you're conducting your research and as you're disseminating the research.

So that's a distinctive feature when we review the applications. We have several patients and other stakeholders on the review team. I mean, as much as 30 percent of the [indecipherable 0:14:04] is non-technical patient and stakeholder reviewers, so that's another difference.

The other difference is that the application itself is split into eight portions, and in those eight portions, you present the evidence that helps us review your project according to PCORI funding, [indecipherable 0:14:27] period, so the big difference with PCORI is that we are, almost to an extreme, we are interested in the likelihood of impact of the research upon practices.

We don't care nearly as much as other funders about the fact that it might shed light on the inner workings of some processes. We don't want to discover new biological mechanisms in this research. We don't want to test innovative methods just for the sake of testing innovative methods. We want research that, because people are asking for it, because it addresses widespread uncertainty, because preliminary data suggests that the findings could really surprise us and change the practice.

For any of those reasons, we think the research is more likely than average to...If it turns out that we expect it to change practice and to change practice broadly, to be disseminate-able, to be implementable and once you could change the practice to improve outcome.

We are looking for impactful research. One very self-serving reason that that's the case is because we're trying to make the case by 2017 that PCORI should continue, that our approach to research, to comparative effectiveness research, to patient-engaged research makes a difference. We are really bent on funding research that has a chance to make a difference.

I'll stop, and hope some of that was new news, and hope you have some questions.

Cramer: Thank you very much Dr. Selby. Does anyone have any questions? Just state your name and go forward. I'll start it off. Dr. Selby, our group is frequently discussing research, talks about whole systems research, whole practices research. For example, how would a venture [indecipherable 0:16:48] physician approach a patient and treat a patient versus standard medical care, et cetera.

It's kind of broad outcomes and broad approaches. Practice-based research networks frequently come up in our discussions and as ways for us to collect meaningful information on those types of practices and comparisons.

Do you have any thoughts on whole systems, whole practices research, where that might fit with PCORI, if it does or not? And practice-based research networks as a mechanism, as a method to look at these kinds of questions?

Selby: I will start with the second part of your question and then maybe ask you a question about whole systems research. In terms of practice-based research networks, we -- and when I say we I mean both PCORI staff but also PCORI board of governors and also the balancing committee -- are all three very interested in what we call or think of as building comparative effectiveness research infrastructure.

Practice based research networks are one very prominent type of research infrastructure that we're interested in. We think it's important because, first of all, this research needs to be based in practice to be relevant in the first place. We want this research to come from practice.

So to be capturing that data in an efficient prospective fashion is a really good thing. VPRNs, especially VPRNs that can be linked longitudinally to outcomes are just great. So actually we'll have a funding announcement related to infrastructure in 2013. One thing I will tell you all about this, and here I'm asking myself well, did I mention this already or whether it was in the talk I just gave, I think it was in the talk I just gave, but we are particularly interested in infrastructure that engages the patients in the governance of the infrastructure and in the use of the infrastructure.

Much of the infrastructure that has been built over the last 10 or 20 years is based on electronic health records, and those are great because they do capture real world experience of people. But as any of you who work with them know, they don't have any patient reported measurements or almost none. I mean, we have smoking status, for example, but little else. And we think that most patient center research is going to need some patient reported outcomes.

And notice I didn't say all patient centered research needs patient reported outcomes. I don't think that's the case. [indecipherable 0:19:58] question. But often times, they are an important part of the picture and most of these data infrastructures that are built on the EHRs, claims data, and health plan data, and health system data, don't have that and don't have a great way of getting it at the moment.

Similarly, they don't have any kind of built in interest in patient community participating in research, so you may have just as bad and difficult a time recruiting these folks into trials as you do elsewhere in the world.

So we are interested in an infrastructure that has patients really engaged and actively participating and contributing and using the infrastructure. Participating and actively participating -- I would include providing patient reported outcomes and also, you know, being on record as being interested in being contacted about clinical trials as appropriate.

So we're very interested in infrastructure that goes that extra step, and incorporates patient participation and governance.

That's the infrastructure question, and PBRNs would be a great place to do that, because their practices are close to the patients, and it should be possible to put together some kind of patient networks linked with the bigger network.

Now, back to this question of whole systems research. I'm not sure that I understand whether you're talking about healthcare systems or whether you're talking about the body of the human being as a system.

Cramer: That's a good question, and one that we frequently need to clarify. We're actually thinking of -- we use the term to talk about whole, complementary and alternative medicine systems of approach. For example, naturopathic medicine physicians approach patients in a unique way. A lot of times part of the interview history is very detailed and comprehensive, diet and that sort of thing. Treatments are tailored to the patient, and the same with chiropractic care, and Ayurvedic, and et cetera.

It's been difficult, and historically there have been challenges in CAM regarding clinical trials where we need to reduce to a very defined diagnosis, and a very defined treatment. A lot of our practitioners feel that we really miss the boat with randomized clinical trials, because their practice is so much different than what these trials really look at.

We call that whole systems, we've been, and John Weeks has really been very active in helping define these terms, so we call it disciplines research. Whole systems research is what we've been using to say, you know, compare how doctors in naturopathic medicine treat a patient with diabetes, versus usual care, or versus a doctor of chiropractic medicine, et cetera. So does that answer your question, then?

Selby: Yes. And your answer takes me back to the evening in Seattle, where I appreciated that night your emphasis on the patient as an individual and the treatment assignment, the treatment choices, so closely linked to who the person was and to what the purposes were. So I would say that I think we could be very interested in that. I mean, it might lend itself to a comparison of the whole system approach to the usual care, but it might take something more sophisticated. So I'm glad to hear that you've got some methodologists, statisticians, in your group, on the phone today, because it may take methods that are beyond the usual just comparing the average or the modal response in [indecipherable 0:24:35] groups.

I don't know that I have anything more to say about that unless you have additional questions. I will just repeat, though, that I think that kind of question is a type of question we have a lot of interest in. If you're going to do your way to study that...convinces the study section that the methods would work. I think the notion that you are tending to individual patient differences and

tailoring your treatments according to it is a pathway that PCORI seems to be very interested in -- giving the right treatment to the right patient. That part sounds very attractive.

John Weeks, ACCAHC Executive Director and RWG staff: Greg, I wonder if there's somebody who might have a follow-up on that topic that's sitting there.

Richard Hammerschlag, PhD, Founding Co-Chair, RWG, Scholar, The Institute for Integrative Health: I'd be delighted to follow-up. From an acupuncture perspective, the overwhelming amount of research is done simply by acupuncture as an individual modality, whereas that's not a reflection of clinical practice. So the idea of the whole system is to build into the research all of the modalities that the patients actually receive in clinical practice. You don't simply look at just the whole system of care but, as you said before, it's so important to look at the patient's history and not bringing a whole system of care simply to treat one isolated condition of the patient.

When we did our TMD study, it was staggering to see how many co-morbidities people with TMD present with from fibromyalgia to depression and headaches and GI problems.

The treatment is geared not only to the particular condition that you're studying, in this case TMD, but also to how the patient presents. It's definitely a dual approach with the whole system of care and the whole patient.

My question, if I might, given the amount of usage of CAM and, of course, CAM is such a broad topic. CAM is not just a thing, but the whole spectrum of CAM. Given the national surveys that show the percentage of usage, I wonder if PCORI has considered earmarking a corresponding percentage of funds specifically to look at composite effectiveness of CAM versus conventional care.

Let me just have one second, I'll tell you a funny story, quickly. This medical colleague of mine when we were doing a study of comparing acupuncture and herbs to hormone replacement therapy for endometriosis related pelvic pain. He liked the term "traditional Chinese medicine" so he started using the term "traditional allopathic medicine." So we've compared to T.A.M.

Selby: Mm-hmm, yeah.

Hammerschlag: In any case, my question is, is there any consideration within PCORI to earmarking a certain percentage of research funding specifically to look at CAM versus conventional care?

Selby: OK. So good, now I'll take the questions in the order you ask them. So back to the systems of care, one thing that's very important to emphasize is that PCORI is, number one, not interested in a particular condition. We will not earmark a portion of our money to study cardiovascular disease or to study epilepsy or to study irritable bowel syndrome. I'm quite confident we'll never do that. We have these broad announcements now that allow you to just propose anything and we have anticipated some targeted high priority investments but they're not going to be about treating diabetes or treating depression. One of them might be about specific questions on diabetes, just as one of them might be a specific question about a CAM therapy.

But we are also, at the same time, extremely interested in what we've come to call cross cutting questions -- so questions that cut across people with multiple conditions or with some things that would be applicable to people with multiple conditions.

Pain is an instance of an often-cited example. Medication adherence is another one. Multiple chronic conditions is another one. Those kinds of things all cut across a wide range of conditions and problems.

I think from that perspective, that perspective of PCORI having a particular interest in cross-cutting questions, I think that your question about a whole system approach, about studying a population that expresses a range of conditions, either as an option to a narrow spectrum of, as you call, a traditional allopathic medicine or to an expanded portfolio of complementary treatments where the best treatment is chosen after considering the patient's individual characteristics and needs. That's an interesting contrast, and I think you could easily fall into, you know...could do well in the review in response for broad announcements.

Now, your second question is, "Do you think we might ever set aside a portion of PCORI funding for studying complementary and alternative medicine ?" It's not impossible, I would say, but thus far the board has been reluctant to do this.

They are more drawn towards, on the one hand, these broad announcements that don't give out anything. On the other, these very targeted, very specific announcements which go after something much narrower than, for example, all of complementary and alternative methods...so I won't say never, I just say if somehow this comes to the patient through the advisory panels with a lot of stakeholder backing, they may turn around and say that's good.

We'd recommend that PCORI fund it and PCORI might have an announcement someday, might get into this. But I would say the chances are not great, just like I don't think we're probably ever going to set aside a portion of our money for the study of the applications of genomics in clinical medicine, even though it's an area that has actually a lot to do with PCORI in that it, again, is focused on individual patient differences and personalized medicine.

So it's probably not an earmarked amount of the PCORI budget. If our budget was much bigger, we'd divide into groups and tackle a bunch of these problems, but I think we're going to end up being more discriminating than that.

Cramer: Thank you Doctor Selby, and thank you Doctor Hammerschlag for clarifying what we mean by whole systems. And I'm sorry I left out acupuncture in some of my examples and that was not intentional at all, but very good discussion. Anyone else have a question for Doctor Selby?

Carlo Calabrese, ND, MPH, Co-Founder, Naturopathic Physicians Research Institute, Research Working Group Co-Chair: I have a question. This is Carlo Calabrese. I understand it's very challenging to consider the methodologies that take into account the whole system, whole person, individualized kind of treatment that we're referring to when we use the term whole systems or discipline specific research. But I was wondering if you might have some rubrics that PCORI might be considering under which the issue that we're talking about can fit. I mean in particular, for example, a patient comes in with multi-morbidity. We take a "holistic" orientation to that. We apply bio, psycho, social model, and I think what I'm saying is in different ways, true

across the CAM disciplines. We then devise a multi-agent, multi-intervention treatment. We are interested in very broad outcomes. We are interested in the impact of our intervention on overall health.

I'm wondering, given the premises that we're starting from, are there rubrics -- and I really am looking for language here -- that PCORI might be interested in pursuing this?

It's the multi-agent individualization and particularly the outcomes for a holistic orientation. This is almost completely contrary to the necessarily reductionistic way that over the last 100 years, we've built the medical model.

I think we have new tools to look at new things. I'm wondering what language can we be advocates for with PCORI and with methodologists that your agency might be responsive to.

Selby: It's a good question, and I think it builds on the last question. I think a couple thoughts. One is that one of the challenges, I think, is to identify the right outcomes measures when we do a comparison of whole systems approaches, this multi-modality, individualized approach to a population of patients who have been experiencing a broad range of symptoms and conditions and illnesses. What is the best outcome to help us determine whether one group is, on the whole, healthier than the next?

So I think there's room for you to make contributions there that would develop measures and a rationale for those measures. The thinking behind those measures...Having the measures, I think, would make it more inviting to being thinking about the trials or the comparisons.

But there really may be some primary methodological research that's needed to pin down measures.

As you know, a lot of these measures just are not very sensitive. At least they haven't proven sensitive in more traditional analysis. They haven't picked up big differences. So taking the theory, and your experience, and what you see with patients into the mix might lead you to some modifications of current notions of how to measure health, and wellbeing, and cultural status, et cetera, in ways that would leave us with better tools for measuring the outcomes.

Having said that I do think that, particularly with all these questions about coverage these days and about cost and management of people with multiple co-morbid conditions, for all of those considerations, it seems to me that an approach that says, "Look, we've got a population of patients that we think we have a better way of providing a range of services to. It could be compelling.

But I do think that one first steps is going to be, tell us which outcomes you've measured to show that you did make a difference. I hasten to add here that we can't measure cost, or cost effectiveness, so somebody in your group may say, they say, well, I think we could show that by offering this multi-modal portfolio of treatment options, we could actually get patients better quicker, and they'd end up using less and cost less.

We are capable, and we do offer studies that measure healthcare resource use. We are interested, we can measure that, but we can't measure cost for those. Put that on the table that I think, identifying the outcome and then, thinking about a real world comparison, it could lead to a study that we'd be very interested in.

Again, I'm talking about the process of choosing the studies that, pretty much like in NIH's purview. In general, the one's that go to the highest, according to the study section, are the ones that will get funded. There may be some capacity for us to add another consideration or two in the final study decision, but we have certainly struggled with the scores that the applications get in the review sections.

William Meeker, DC, MPH, President, Palmer West, RWG Member: Dr Selby, hi, I'm Bill Meeker. I'm an NIH grantee or I was, I should say. It was early on the NCCAM's advisory council. It's a follow-on question to what you just said, basically, which is the reviewing process. I believe I understand that at this point I think the CSR [NIH Center for Scientific Review] is doing the reviews but the organization is adding some folks to those panels. But I think...

Selby: Not anymore though, not anymore. That was to get around a pilot project.

Meeker: The concerns were, though, that having NIH review panels who are not used to this type of research, I'm going to say design and approach, I guess is a better word, review these things. There was some concern they would not really understand that we weren't after mechanism or explanatory power here, we were really looking for practical sorts of applications. Of course, if that's not happening, maybe you can explain how we're going to be able to, if PCORI is going to be able to ensure that they have the right kind of reviewers looking at these proposals.

Selby: Let me go into that a little bit in detail. You're right that for our very first round, which was called the "PCORI Pilot Projects," we worked with CSR and they basically formed the study sections, we contributed some members. We insisted that there be three patients or other stake-holders on each review panel. So a 25 person study section, there would be three patients or stake-holders on it. They got very little training and most people felt like it seemed about like a typical NIH review. When we analyzed the data in the end, we found that the overall scores came out to be most closely related to the individual criterion scored for the analytic approach.

Just like in all of NIH's reviews, just like all our first reviews, they study a section and then they get around and they talk for three minutes about the research question and for 45 minutes about the analytic methods.

That was one of the reasons that we were really inclined to move away. We wanted to change the review criteria dramatically. We wanted to change the composition of review panels quite a bit. We wanted to come out with a differently scored and right set of applications.

Instead of having five review criteria, we have eight, and the most important one of the eight, we hope, will be the one on the likelihood of impact. We don't want to fund research because it's going to shed light on a mechanism of action. We don't want to fund research because it gives us a new innovative method for the first time. We want to fund research that is, in fact, practical but answers a practical question that has a likelihood of changing practice.

We have eight review criteria to the five, and one of the ones that will rate the highest is this likelihood that it will change practices. We've worked with the patient, the stakeholder reviewers, we've worked with the technical reviewers, to try and get them all oriented towards that criteria. What's the likelihood that we will change practices?

I think, and you are right that there is every reason to be concerned that it's going to be the same old, same old. We are working, really quite diligently to look at the review data, and to keep cleaving it until we begin to see that the review process is yielding a somewhat different set of processes. We still have to meet rigorous methods, but they can't be rigorous methods without questions that don't matter.

Meeker: Great, that's excellent. If I can just follow up with one more. Dr. Selby, can you tell us at this point whether or not people from the Integrative Medicine in our communities will be able to be appointed to those review panels? How does that work?

Selby: You just go to our website to apply to be a reviewer. I wish I had data. I don't have data on how many of the reviewers have that in, that I've got data on, but I can probably get it for you. No, there's every opportunity to be a reviewer whether you've reviewed before or not. You can apply to be a technical reviewer if you feel that you've got the research chops to do that, but you can also apply to be a clinician reviewer, a stakeholder reviewer.

Anybody you know who does CAM can apply to be a clinician reviewer. We want the perspective of clinicians. [indecipherable 0:45:06] the perspective of CAM clinicians would be very interesting.

We want the perspective of a broad range of people with research expertise, most certainly including that of CAM practitioners who have research expertise.

All you do to sign up is go to PCORI.org and there's a place to sign up to be a reviewer. We will always be needing reviewers so we would love to have you.

Meeker: Outstanding. Thanks for that, Doctor Selby.

Cramer: Yes, thank you, Dr. Meeker, for those excellent questions. That's a very neat...I think those are great answers for our community, Dr. Selby. Just a word about Dr. Meeker's also president of Palmer Chiropractic College West … OK, we have time for maybe one more question. Anyone else?

Weeks: This is John, Greg. Nobody else is going to ask it. I think the specific question that Martha first put forward and then Richard followed up with...it was Martha, if you're there, I'd love to have you handle it, but it's something that's been a question in our relationship with PCORI from the beginning, which I'll use my language and then one of you quickly correct me please...

Martha Menard, PhD, CMT, Adjunct Assistant Professor, Georgetown University, RWG Member: I'm here. I would say that the definition of comparative effectiveness research, has traditionally been defined fairly narrowly, and often in a way that has excluded a lot of the CAM disciplines, because they are not considered to have demonstrated effectiveness. I'm wondering, how exactly are you going to define comparative effectiveness research?

Selby: I will tell you that we have a definition on our website of a patient centered outcomes research, and I think that it very definitely leaves the door open for any kind of practice that is, any kind of, therapy, that is in use. Our question said basically, what are my options, and what are the harms and benefits of those options? It is an interesting question. I think you are right that some definitions of effectiveness require that you are comparing treatments that at least have previously

had their efficacy proven, so at least you have had a refined clinical trial that this was proved to be better than placebo.

We have never said in anything that we've written that that is a requirement. While I don't think we would take a comparison of two things that have never been proposed for treating a condition, just off the shelf or off the wall, I think when you have something that reflects good practice and you want to compare it something else, whether you're comparing it to usual care, in which case perhaps you are testing both the efficacy and effectiveness at the same time, or whether you're comparing it to some other therapy, I think they'd both make it through. This is a question I haven't thought at great length about, but I don't believe that...There's nothing we've written that says, "This gets crossed out because you have to be efficacious to make it into our comparisons." That's about as much as I can say. Go ahead.

Menard: If I'm understanding you correctly then, you would not exclude a discipline or practice, particularly if you could show that it was in widespread use by a patient, by a client, just because it has not demonstrated efficacy in a previous study done.

Selby: Yeah. I think that you could. I think that you're distracted looking at one reason that hasn't shown "true efficacy" is that it's very difficult to design the right kind of study to do it and to show that.

Menard: Going back to some of the earlier comments about whole systems research, if you look at traditional Oriental medicine as a whole system of practice, you're talking about a very complex intervention with multiple components. One of the issues in that randomized control trial approach has wanted to link every component out into separate parts, which makes it, one, very difficult from a practical point of view, but you're also losing the synergistic effect of the intervention as a whole.

Selby: Right. Right. I think there's a lot of sentiments today across a lot of areas, certainly the area of fitness research, that would support the idea that multi-sectoral interventions of all types are of interest to us, even if they don't have built into the study design the capacity to tease out the effectiveness of each component. Partly because it would just be impossible, sample size wise, and partly because these different components may interact with each other in ways that really don't allow you to tease it out. I think that same kind of thinking, I'm talking about in the setting of a multicomponent system able to [indecipherable 0:51:49] and manage chronic disease, but I think the same kind of thinking applies to this whole system approach, which is that we're not really talking about one of the components of this approach that didn't work, we're talking about whether the whole system when applied to the population makes a difference. I think the same argument would hold.

Often as you see these multi-sectoral interventions compared to each other or compared to usual care and if it works people come along afterwards and begin trying to see, "Well, could we strip it down a little bit, maybe make it a little more affordable? This is on the systems side more than the CAM side. Even in that world of systems, it's not the rule that you've got to prove that every component has efficacy before you put them together.

Menard: Thank you very much.

Selby: I hope that was helpful.

Cramer: Well, we've come to the end of our time. I just wanted to thank you, Dr. Selby, for taking the time and spending the time with us, giving very through and thoughtful answers to our questions, and for your comments. I think many of them were... I certainly learned a lot from what you said, and I think it would be very useful to all of us.

Selby: Let me just say in closing, I enjoyed it, too, and I hope I didn't talk too much. And let me invite you both to look at some emails. Let them be sure to apply, but also, by all means, get yourselves and get your clinician colleagues to join our review panel that studies [indecipherable 0:53:41] . And I think it's a good way to get their perspective represented there.

Cramer: Oh, thank you. That's one of the notes that I underlined several times and put stars beside. I think that is a really good mechanism to get us involved. Does anyone else have a comment that they feel they really need to make at this point or if not...

Weeks: I was just going to add that I think that is a place where we can do a little organizing work through ACCAHC, Dr. Selby. This is getting more of our people to show up on the review side to put their names in, and so we'll get that information out through our networks. [crosstalk]

Selby: [I'd do a] little check and see if we have data on the many hundreds of clinicians who have signed up and the technical researchers, too, and see if I've got any data on how many of them are CAM practitioners and CAM researchers.

Weeks: Very good. [crosstalk] I'll check with Desiree about that and get back to you, but I think that we'll put the word out through our networks and hopefully we'll show some more people signing up. Thank you also.

Selby: Thank you so much. Bye-bye.

Cramer: Bye-bye, thank you.

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