Robin Mashep: Good morning, everyone; and welcome to today's cyber seminar. This is Dr. Robin Mashep, Director of Education at the PRIME Center of Innovation at VA Connecticut, and I will be hosting our monthly pain call entitled Spotlight on Pain Management. This is a collaboration of the PRIME Center, the VA National Program for Pain Management and the NIH/VA/DoD Pain Management Collaboratory, and the HSR&D Center for Information Dissemination and Education Resources.

Today's session is Pain/Opioid CORE: Works in Progress. I would like to introduce our presenters for today. Dr. Alicia Heapy is Associate Director of the Pain Research, Informatics, Multimorbidities, and Education, COIN, the PRIME Center at VA Connecticut; she's also Associate Professor in the Department of Psychiatry at the Yale School of Medicine and her area of research is pain.

Dr. Sara Edmond will also be joining us; she is a clinical health psychologist and researcher at the PRIME center who specializes in patient-provider communication and improving the delivery of evidence-based non-pharm treatment for chronic pain.

Dr. Erin Krebs is a CORE investigator from the Minneapolis VA Center for Care Delivery and Outcomes Research. She's also a Professor of Medicine at the University of Minnesota and her research addresses clinical questions related to chronic pain and opioid analgesics.

We also have on our call, Dr. Will Becker who is going to be moderating the discussion at the end; he is a CORE investigator at the PRIME Center at VA Connecticut and also an Associate Professor and General Internist at the Yale School of Medicine with expertise in clinical epidemiology, addiction medicine, and pain management.

Our presenters will be speaking for approximately 45 minutes, and then we will have a 15-minute question-and-answer period at the end of the presentation. Please feel free to use the panel on your screen to type in questions; if anyone is interested in downloading the slides from today, you can go to the reminder email you received this morning and you'll be able to find the link to the presentation. Immediately following today's session, you will receive a very brief feedback form; we appreciate you completing this as it is critically important to help us provide you with great programming.

And now, I'm going to turn this over to our presenters.

Alicia Heapey: Good morning, everyone. I'm Alicia Heapey. I'm going to start things off by explaining to everyone what a CORE is, giving an overview of the Pain/Opioid CORE, including our overall goals and some activities, and how you can be engaged with the CORE. And then I'll hand it off to

Doctors Edmond, Krebs, and Becker to provide a deeper dive on two projects that are being conducted by the CORE, and then to answer questions at the end. I should note that I have to leave early for another meeting; I apologize I won't be around for questions, but I'm sure you won't miss me at all. But if you feel compelled to have a--if you have a question for me, you can certainly email me.

So, as was mentioned, the Pain/Opioid CORE has three PIs: that's me, Dr. Becker, and Dr. Krebs. In the context of the CORE, we work closely with a group of operations partners on the development of our strategic plan and identifying research priorities, so those are partners from the National Pain Management and Opioid Safety Prescription Drug Monitoring Program, Integrative Health Coordinating Center, the Mental Health Substance Use Disorder Program; Pharmacy Benefits Management; and that group of our partners is chaired by Dr. Robert Kearns, who used to be the National Director for Pain Management in VA.

I should note--it was left off this slide--we also work with an internal leadership committee which is a group of senior pain and opioid researchers that meet regularly with us to advise us and also participate in the enacting, monitoring, and revising of the CORE strategic plan and CORE activities.

So, what is a CORE? HSR&D has funded four COREs or Consortium for Research in priority areas: suicide prevention, pain and opioids, access, and virtual care. All of the COREs have the same overarching goal and that is to support and accelerate collaborative research that will lead to measurable improvement in care delivered to veterans by doing a couple of things: prioritizing research goals and developing a collaborative network of researchers.

Since COREs are new, I thought I should also say a little bit about what COREs do not do. So, COREs don't determine VA's research or operational funding priorities; though HSR&D or our partners may choose to be informed by our CORE recommendations, we don't act as gatekeepers to HSR&D or operational funding, or write letters of support for IIRs, CDAs, or grants. The CORE is available to you to participate-- in which we'll be talking about today. So, that's just kind of a given and we also do not serve as consultants tasked with doing evaluation work for operational partners, though we could facilitate the formation of partnerships with operations to complete that work.

So, the Pain/Opioid CORE has its own mission and goals. So, although the COREs have these common goals, we've relied on feedback from our research community and partners to identify the specific needs of our community and the best way to reach and address those needs. So, based

on needs assessment surveys and interviews that we've conducted with pain and opioid researchers, operations partners, and early career investigators and fellows, we identified the following goals: overall, fostering high-quality, high-impact and veteran-centered research focusing on improving pain care and reducing opioid harms by building a network of researchers, and promoting multi-disciplinary cross-institutional research collaborations.

And we do that by really developing research networks, cultivating partnerships, and developing infrastructure that allows the research community to work more efficiently, identifying priority research areas for investigation, developing mentoring structures for early-career investigators, and then disseminating our work from our community to patients, partners, and other researchers.

I wanted to say a little bit about our area of focus; sometimes there's confusion about what our focus is: is it opioid reduction, opioid treatment, addiction, or pain? It's really purposefully quite broad and inclusive; so, we're interested in interventions for pain that includes pharmacologic and non-pharmacologic interventions, including behavioral interventions, physical therapy, complementary and integrative health interventions. In addition to that, we're interested in pain care delivery models of pain and opioid-related practice and policy initiatives such as the Opioid Safety Initiative, and the management of opioid dependence and Opioid Use Disorder.

So, this slide shows some of the activities that we are conducting to meet our goals. We don't have time to talk about these; we will be giving an overview of a few of these activities in this presentation to give you a flavor, but I just mentioned a few things. At the left here identifying our research priority areas is an important thing that we do; the foundation of that work is really using the recommendations of two recent state-of-the-art conferences sponsored by HSR&D, one on opioids and one on non-pharmacologic treatments for chronic pain; and building on that, we have additional activities that help us further investigate or identify priorities within this area. So, we will be talking about our Delphi Consensus Study that, I think, illustrates how we've taken these sorts of priorities and advanced them.

Developing and cultivating partnerships. So, as I mentioned, we meet regularly with our partners and our internal leadership committee; we also engage with veterans through our veteran engagement panel and Dr. Krebs will be talking about that a little bit.

We're invested in building research networks for providing infrastructure and I'll be saying a little bit more about that because these are ways that you can be involved with our CORE that we want you to know about,

and that includes strategic priority area workgroups, and the funding of Rapid Start projects. And then, of course, we're interested in disseminating the impacts of our community, taking high-impact findings, and disseminating those in a patient-friendly way, and to the wider research community and clinical community.

So, for our CORE workgroups. Our CORE supports several workgroups: these are time-limited, product-focused workgroups that come together around specific projects or to produce specific products or tools within these areas. The ones that we have up and going now are Medication for Opioid Use Disorder which is chaired by Dr. Adam Gordon; this to identify and promote effective implementation strategies for MOUD. We have a workgroup on MOUD Use in Perioperative Care; the co-chairs are Dr. Hickey and Dr. Becker. Its objective is to survey evidence related to buprenorphine in perioperative settings and publish expert recommendations. We have a Mentorship of Junior Researchers Studying Pain and/or Opioids workgroup that is chaired by Dr. Matt Bair; really, its focus is to support professional networking and mentorship and connect early-career researchers to senior researchers; and we also have a Heterogeneity of Treatment Effects in Pain- and Opioid-Related Research workgroup that's chaired by Dr. Kelli Allen. It's really about understanding factors that predict patients' response to pain treatment using state-of-the-art statistical methods.

These workgroups are open to engagement from the research community; if you'd like to know more about these workgroups or interested in potentially joining, I'd invite you to send an email to Brian Coleman, he's our CORE coordinator and he can provide you with more information or connect you with a workgroup chair that's of interest to you.

We also have a Rapid Start funding program that provides funds to support research in our pain and opioid priority areas; attached here or noted here are two publications that outline the recommendations of the two HSR&D SOTAs that I mentioned, that kind of clearly define our priority areas. We provide funding for projects of up to one year that are likely to meaningfully inform future applications for funding as a VA study or to answer priority questions. Within this mechanism, we do give preference to early-career investigators and investigators who are not located at HSR&D Centers of Innovation or COINs; those researchers have access to infrastructure already and we like to provide this assistance to those people who are not located at those centers, although not exclusively.

So, this is a list of our awardees from last year. And so, we had 30 applications last year; these were the five that we selected. I should note that four of our awardees were not located at a point and all but one are

either early-career investigators or have primarily a clinical role and are starting down the research pathway.

As far as our Rapid Start Program, we will be continuing in 2021; as a matter of fact, we will release our RFA tomorrow. So, I should say we are interested in applications that support HSR&D career development applications or other submissions that focus on veteran populations, applications that promote collaborations with clinical or operations partners in high-priority areas, or secondary analysis of previously collected data. PIs have to have a 5/8ths VA appointment; if the applicant is a fellow, they should have a mentor who has a 5/8ths VA appointment.

The project budgets range from 10 to $30,000; these are one-year projects. The submission deadline is the 15th; as I mentioned, we are releasing the RFA tomorrow; it is emailed to a list including everyone who gets our newsletter already, COIN and center directors attendees at pain research working groups, and ACOSs of research at all facilities. But if you're not sure that you're on that list and you want to ensure that you receive the RFA, you can send an email to Brian Coleman, and he will definitely add you to that list.

So, I am going to transition hand this off to Dr. Sara Edmond. In this section, we want to highlight the Delphi study that's being conducted as an exemplar of what the Pain/Opioid CORE can do. First, it's a spin-off of work from the opioid SOTA, this particular issue was highlighted as one that would benefit from concentrated collaborative downstream effort. Second, it spans issues relevant to several of our priority areas; and lastly, it's a highly interdisciplinary effort that's being advanced by some of our very promising junior researchers like Dr. Edmond. I am going to hand it off to her.

Sara Edmond: Thank you, Alicia. So, I'm going to talk about our Delphi study that examines the challenges of applying the DSM-5 Opioid Use Disorder criteria to patients on long-term opioid therapy for chronic pain. And I want to start by thanking my collaborators on this study: Will Becker, Jamie [Pomerance], Jenny Snow, and Raymond Van Cleef; as well as a thank you to the Delphi study participants.

I'm going to start with a brief background about why there are challenges in applying the DSM-5 OUD criteria to patients on long-term opioid therapy, and then I will describe the methods of our Delphi study along with some preliminary findings. So, patients prescribed long-term opioid therapy for pain are at risk for adverse events related to opioids, including worsening of pain and function, poor health status, and Opioid Use Disorder. And the current VA, DoD, and CDC guidelines

recommend tapering if benefits do not outweigh harms of continued opioid therapy.

One significant challenge in clinical research and policy spheres is if and how to apply the DSM-5 Opioid Use Disorder Criteria to patients receiving long-term opioid therapy for pain, for whom the harm of opioid therapy may be outweighing the benefit and that tapering may be indicated. And this isn't a new problem, and it's been written about in the past--and I've listed some people who've written about it in the past--but we still don't have a great solution.

So, here, I've listed the diagnostic criteria for OUD in DSM-5. DSM-5 summarizes OUD as uncontrolled use causing adverse consequences, and lists these 11 criteria; you have to meet at least two criteria of these 11 for a mild OUD diagnosis; and if you're prescribed long-term opioid therapy, tolerance and withdrawal cannot be counted. The challenges in applying these criteria mainly center around the difficulty of ascribing negative consequences to pain versus to opioids, as well as the fact that many patients on long-term opioid therapy actually have very controlled use of opioids, but nonetheless, are experiencing poor function.

I want to start by saying that as I talk about this new diagnostic entity, I'm going to call it "Condition X" because we've not yet named it, though I know others in the field have suggested some names. So, some experts believe that a new diagnostic entity is necessary and should be developed to facilitate better care; they argue this population may be large, the clinical problem is urgent, and a new diagnostic entity could facilitate better epidemiological and clinical research, improve clinical management and patient outcomes, decrease the overuse or misapplication of the OUD diagnosis, and could facilitate a focus on better pain care.

At the same time, other experts believe that a separate diagnostic entity is not needed and may, in fact, be harmful. And as I said, this dilemma is not new and it's been the subject of debate for nearly a decade, but it has newly intensified in this current era of opioid de-implementation and the observed adverse effects, and this was discussed at the 2019 SOTA highlighting the problems with clinical care research and policy and that led to the suggestion of the Delphi study.

For those of you not familiar, the Delphi methodology was developed by RAND; it involves exploration of the topic and generation of consensus by convening subject matter experts; it uses anonymous input, sharing of that input, and then voting to mold consensus on a topic when possible. So, for this Delphi study among a group of experts, we aim to first explore perspectives on the merits of creating a new diagnostic entity; and second, to develop consensus on its diagnostic criteria. So, we

invited invitees to the SOTA to participate as our Delphi panelists and all of them were subject matter experts in either pain, long-term opioid therapy, Opioid Use Disorder, medication for Opioid Use Disorder, and/or research, and they represented multiple disciplines including general internal medicine, psychology, addiction medicine, addiction psychiatry, nursing pharmacy, pain medicine, neurology, clinical epidemiology, health services research, and health policy. We had 51 people accept our invitation to participate and complete at least part of Round 1 one of our survey; 44 who finished the Round 1 survey; and then 23 in Round 2, and 21 in Round 3, and I'm going to go into some more details about that.

This diagram shows the flow of our study, all of which involved online surveys. So, the first survey had 51 participants who at least answered our first question which was meant to be a screening question, and that was should there be a diagnostic entity distinct from but not replacing OUD, that pertains to patients on long-term opioid therapy for chronic pain? 44 people answered all of Round 1; 31 answered all Round 1 and screened in and thus were invited for Round 2, and I'm going to start by talking a little bit about that screening question and the results there.

So, Round 1 resulted in 38 participants or 75 percent of our sample saying, "Yes, we need a new diagnostic entity," and 13 participants or 25 percent of our sample saying, "No, we do not need a new diagnostic entity." We asked why or why not to all of the participants, and that provided a lot of qualitative free-text data. We used rapid qualitative analysis to summarize the data and compile a thematic codebook, and then we perform thematic coding and analysis to distill our findings and identify representative quotes. Our analysis is still in progress but I wanted to share just a few preliminary themes and quotes to give you a flavor of what people said.

So, among those who said, "Yes, we need a new diagnostic entity," some of the most common themes in their answer to why included the idea that a new entity would facilitate research and access to treatment, and that patients with Condition X present differently from patients with OUD; specifically, participants noted that the behavioral and social consequences of opioid use for this population are distinct from the consequences described in DSM-5; and that when working with these patients, it's often difficult to determine if the problems they're experiencing are caused by pain or caused by opioids. Two quotes to illustrate these points are first, "Long-term opioid therapy patients are not good fits for traditional evidence-based addiction treatment, because they don't fit the profile of patients with OUD who have been studied. We need a new category so we can better understand these patients and create, evaluate, and disseminate better treatments for them." Another panelist said, "The current OUD diagnosis does not adequately capture

the range of presentations that are encountered in clinical practice; while some may clearly meet the current criteria, others fall into more of a gray zone that is nuanced where no labels fit well or is helpful in conducting patient care."

On the other hand, 13 participants or about 25 percent of that initial survey group, said, "No, a new diagnostic entity is not needed." They were asked why not and some of the most common answers included the idea that OUD and Condition X are biologically indistinguishable and therefore they don't need to be distinct categories; the belief that a new entity would be an artificial distinction and then thus contribute to worsened stigma; and then they provided thoughts about better ways to address the issues with the current problem such as modifying the DSM-5 criteria, addressing stigma related to OUD in more direct ways, or conducting additional research to determine if Condition X is truly distinct from OUD.

And a few quotes from them include, "From a brain perspective, it shouldn't make a difference whether opioids are prescribed or illicit; if a use disorder develops, there's something going on that requires a diagnosis and treatment." Another person said, "Rather than coming up with new diagnostic labels, I feel providers need to take the time to honestly explain to their patients the iatrogenic effects of long-term opioids." And finally, "Perhaps, we could draft different consequences for people with complex dependence and remove the exclusion of tolerance from the chart."

So, as I mentioned, we're currently finalizing our qualitative analysis and we plan to submit a paper for publication based on our findings.

Meanwhile, we continued on with the rest of the Delphi study to explore the possibility of creating a new diagnostic entity and now I want to talk a little bit more about the rest of the data we collected from that 75 percent of respondents who said, "Yes, we do need a new diagnostic entity." So, these participants were asked a series of additional open-ended questions about the new diagnostic entity, and then 31 percent of them completed the entire survey and agreed to be contacted for the next round.

The Round 1 open-ended questions that we asked included, "Please describe a person who would be diagnosed with Condition X; how did he or she present; what were they prescribed; how did the course of treatment go; what behaviors manifest themselves over time, how is this person different from a person with OUD?" And we asked, "How would you differentiate Condition X from OUD?" Please complete the sentence, "Condition X is defined as _____; please list the diagnostic criteria for Condition X." And then we asked a couple other questions

about the gradations of severity, the relationship between Condition X and OUD, treatment options, and potential names for Condition X.

We used rapid qualitative analysis to summarize the free text open-ended answers and identify distinct concepts; we then performed a content analysis to assess concept concentration and generate potential diagnostic criteria. So, from that analysis, the most common potential criteria that came up included having chronic pain and being prescribed long-term opioid therapy, which I think sort of defines the population rather than is a distinct criterion; and then the other criteria that were common were poor functioning or long-term opioid therapy is not working well, difficulty tapering, so things like the patient is resistant to tapering or deteriorates when a taper is attempted; patient beliefs that contribute to the maintenance of long-term opioid therapy, so the belief that nothing else works or the desire to continue taking opioids despite lack of benefit and/or identified harm, and tolerance, and withdrawal.

Some of the other categories included adherence to the opioid regimen or misuse of opioids; other criteria of OUDs, so we got things that were the criteria of OUD but sometimes phrased in a way that contributed that attributed the symptoms to pain. So, for example, we saw important social occupational or recreational activities are given up or reduced because of pain. We also saw themes around the way that patients were coping with their pain, hyperalgesia and psychiatric systems.

And so, based on our analysis, we generated 31 potential criteria to use in the Round 2 survey, all of which were mentioned by at least two Delphi participants. This is just to remind you of the study flow, so that Round 2 survey was sent to the 31 people who streamed in and completed Round 1. We received 24 partial responses and 23 complete responses to that survey, and this is an example of how the Round 2 survey was structured. So, for each criterion, we ask, "To what extent do you agree that each of the following criteria should be included at the future criteria of Condition X?", and we ask participants to answer on a 7-point Likert Scale. We also asked participants to indicate their preferred wording for items and to provide suggestions for alternative wording if they did not like the wording you provided; and then finally, we asked participants to write proposed names for Condition X.

So, for the Round 2 results, the most highly endorsed criteria in Round 2 included benefits of long-term opioid therapy no longer outweigh the harm; difficulty tapering, when a taper is attempted the patient exhibits psychological or physical symptoms such as withdrawal, a painful or depression; does not meet criteria for Opioid Use Disorder for DSM-5, that does not have at least two DSM-5 criteria not including tolerance and withdrawal caused by opioid use; and exhibits tolerance, might ask for a higher dose with motivation seeming to be a desire for pain control;

or dose was escalated over time by a provider and then maintained at a high dose.

We also asked participants, "Do you believe that Condition X and OUD can co-occur?" And interestingly, the Delphi Panel was split 50-50 on this question, and so this is something we'd like to continue exploring in the future. And as for names, we're still working on it; the most well-liked names included "Iatric Opioid Dependence," "Prescription Opioid Dependence," and "Complex Persistent Opioid Dependence." And at the same time, all of those names were disliked by some participants and we got a lot of qualitative feedback about how important the name is and reasons for disliking names such as not liking the phrase "Use Disorder" to be in the name when referring to taking a prescribed medication.

So, moving on to Round 3, we used the Round 2 results to generate our Round 3 survey. Based on qualitative feedback in Round 2, we added three items to our original 31; and then we presented group statistics along with an individual's response from Round 2 to each participant and asked them to re-rate their response.

So, this is a visual of how we did that. The top picture is a very detailed instruction infographic made by Jenny Snow; and then the second screenshot--the second picture shows how we presented that group and individual data to each participant, and then had them re-rate each item using the drop-down box; and we've received responses from 21 out of our 23 Round 3 participants, and are still analyzing that data so stay tuned.

In terms of next steps, a lot of it is writing up what we've learned, so we plan to write a protocol paper; we're also planning to write a pair of essays from experts on the pro and con side of the debate, about whether or not this entity is needed. As I mentioned before, we're going to write up the qualitative analysis of the free-text answers to that why or why-not question, and then, of course, we'll write up the main results of the Delphi study.

As you can imagine, our work is definitely not done after that, so we plan to convene a smaller workgroup to look at research priorities and clinical recommendations regarding Condition X, and we want to include stakeholders such as patients in our future work.

Thanks so much. I think I'm going to hand it over to Erin, and then probably save questions for the end.

Erin Krebs: Hi, all. This is Erin Krebs and my task today is to talk about our Veteran Engagement Panel. This panel was developed specifically for the Pain/Opioid CORE and really, my objective is to give you a sense for

how this panel was developed in the mission so you can determine whether this is a good fit for you. Because really, this Veteran Engagement Panel--which I'll just call the VEP--from here on out, was really developed to be a resource for pain and opioid researchers in VA. This is not a CORE--this is not something we want to keep to ourselves in the CORE, we want this to be used by a lot of different people.

So, I'll just start by walking through what this group is, how it was formed. This was something that we knew we wanted to do as part of the CORE objectives from the beginning, and we started with recruiting individual veterans to participate in the panel. I'm showing you on the slide, our flyer that we distributed through probably many of you and others who helped us get the word out across VA. Our goal was to develop a diverse national panel of veterans, so we wanted people from multiple different VA sites across the country; and we were looking specifically for veterans who had personal experience with at least one of the CORE focus areas, and we defined this for the veteran's purposes, as chronic or persistent pain, opioid pain medications, and opioid addiction or suboxone. That's just how we described it, and we just asked people to self-identify themselves as having a personal experience with that.

There was an application process that was started by a phone call to a research associate here in Minneapolis; and then for people who were interested, we asked for a written statement of interest; then we followed up with a telephone interview with CORE engagement staff. And the goal here was to identify a diverse group, and also make sure that we were recruiting people who could kind of complete these steps without too much trouble. So, we wanted people who were not necessarily experts in applying to like federal government jobs or research jobs--that wasn't the goal, but at least being motivated enough to write something, email it, and then complete a telephone interview.

We ended up selecting 12 members, and finalists were identified by our CORE engagement group, and then the members were selected by consensus of our CORE internal leadership group. In the end, our 12 members reside in nine different states, and all of them expressed that they had personal experience with at least two of the three focused areas I mentioned.

We have VEP members with really varied professional work and volunteer experiences, and this was purposeful. So, one thing we did not want was a group that was dominated by kind of professional patient advocates, and we also did not want the group dominated by people who already had healthcare or research experience, we really wanted a range. And so, we actually capped the number of health professionals who could participate--I think we have two or three--and we aimed, again, for diversity. So, 7 of our 12 members are men--that was purposeful--about

half are white, and then they are distributed across the age group. So, you can also see most of them are VA healthcare users, that was also something that we predetermined; we thought it might be useful to have a small number of people who were not VA healthcare users because that's a veteran perspective of interest, but we did want most of the group to have experience with VA healthcare because most of our research and questions focuses on VA healthcare. And vast majority with chronic pain, a personal history of opioid use; and 42 percent of the group with self-report reporting personal experience with Opioid Use Disorder.

So, of course, our panel development process was delayed by COVID; this was something that we were--I think we selected our panel members about a year ago, and the goal was to have a spring orientation face-to-face meeting, get to know everybody; and that did not happen. So, ultimately, we convened the group virtually and had a total of about five hours of virtual orientation spread out over three meetings in summer and early fall of 2020.

And just so you know, we generally use these orientations to be sort of a mutual orientation so that the research team is really getting to know the Veteran Engagement Group and the Veteran Engagement Group is getting to know the research team and process. So, introductions were a big part of this, getting comfortable as a group. Other topics, obviously technology review, since everything is being done virtually these days; we do have formal membership and confidentiality agreements. This is a paid group as well; so, these are not study participants, these are partners and consultants, so making sure that those relationships are clear.

The group was provided an overview of VA research as well as CORE goals, and CORE stakeholders really talked quite a bit about medical research constraints, regulation, IRB, this kind of thing that is very important. An ongoing part of the VEP, not just in orientation, is really development of, I think, group norms, and reinforcing those, sharing information in the group, privacy/confidentiality expectations, and then, of course, practicing effective feedback and communication.

And an important part of the VEP is really ongoing evaluation and reflection. So, this is something that happens with every meeting, not just in the orientations and processes are sort of actively reconsidered and according to the feedback.

So, I'm going to switch gears just a little bit to what it might be like working with the VEP, because this is something I hope many of you will consider. Basically, there are three steps to doing this: the first step is initial planning. And here, if we get a word from an investigator of interest, that investigator will meet initially with CORE staff to develop the key questions for the VEP; then there will be a pre-VEP prep session,

the CORE staff writes a facilitation guide as a draft, and then the researcher and the CORE staff do a dry run and finalize materials based on the discussion. Then the VEP meeting is the third step; and here, the CORE staff actually facilitates the meeting, the researcher or research team attends kind of in a guest capacity, mostly observing just being able to get that feedback, but not running the meeting itself. And then, afterwards, the CORE staff provides notes and an executive summary to the researcher.

So, this is just showing you some of the questions you would be asked if you wanted to use the VEP. This is part of our pre-planning process, really getting a sense for what kind of feedback is desired and, of course, many of these may be the case right. So, doesn't necessarily have to be just one thing; and then we do ask questions really that are helpful for the VEP to understand your motivations, the reasons for the research, and provide the best feedback that they can; really understand, why are you interested in this area of research; what makes you passionate about the topic; as well as things like who you want to enroll in your study, what you're going to ask participants in your study to do; and why you think your study might be beneficial to those who choose to join.

That was the pre-VEP kind of process. I just wanted to show you a little bit about our post-VEP meeting process. This is a standard part of our process for the VEP meetings; we provide feedback to the VEP about the information they give and how it was used; and so, this is something--a process we actually developed with help from the Wisconsin Network for Research Support, that's a University of Wisconsin-based research group with a lot of really great expertise in engagement methods.

And this slide I'm showing you here is an example from PCORI-funded voice trial that I lead; so, this is not from the CORE VEP, but we use a very similar process, and it's just reviewing the topic from the meeting, summarizing the feedback that the VEP gives to the research team, and then providing the VEP with information about what the research team did with the feedback. And this is just to make sure that all this work isn't going into sort of a black hole for the engagement partners.

So, we have completed four VEP project reviews so far; I think there's another one scheduled this week and this is just brief information about the topic. So far, really the VEP has focused on a couple of meetings focused on recruitment; one was specifically going over a recruitment phone script, another more recruitment materials in general, and then a couple of meetings focused on intervention components, a decision aid, and any text messaging system. So, a variety of different kind of topics in pain and opioid research would be appropriate for this group.

In the future, obviously, we plan to continue consulting on individual investigator projects, and we've also expanded a little bit into some clinical VA pain management initiatives; Dr. [Sanbrink] [00:43:02] with a roll-out, and the VEP is eager to work with that as well. We are hoping to really formally encourage the participation of our CORE Rapid Start project investigators. Alicia mentioned how many of those are not located at COINs; often now COINs do have their own engagement group, but this is a group that may be helpful for people without access to an engagement group at their center, or if they're just simply looking for more focused engagement from a veteran group that has personal expertise with pain and opioids.

We're developing a CORE website, and that will really feature the VEP, including their biographies and information about their background; so, the VEP is helping us with that. And then, moving forward, we also anticipate that the VEP will have a big role in supporting the CORE translation and dissemination efforts.

So, this is the end of my oral presentation, and I know we're going on to the Q&A session now, which, obviously, can focus on questions you might have about any aspect of this presentation on CORE. But I would specifically really welcome any questions you have about whether the VEP would be a good fit for the questions you might have or anything about that process; because, really, I just hope to drum up interest in collaborating with the VEP.

Thanks so much.

Robin Mashep: Well, I just want to thank our speakers; these were incredible presentations and the breadth of what all of you are doing for the VA is just really tremendous. And you can go ahead, Dr. Becker, and start the Q&A session; if you can just give me two minutes to wrap up at the very end, that would be great.

Will Becker: Thanks, Robin. So, yeah, do folks have questions about either the Delphi, or the VEP, or the CORE in general? The floor is open for any and all comments or questions.

Erin Krebs: And Will, I do see one question about the VEP in the Q&A box, so maybe I'll just start with that?

Will Becker: Oh, yeah. Because I don't see it.

Erin Krebs: So, a question, "What was the total number of veterans who applied to be members of the VEP? You mentioned a few factors that were considering when selecting the members, but was there a set of criteria used for the selection process?" And yes, so I will say there was a set of

criteria used for the selection process. Specifically, diversity was an important aspect of this, so we explicitly were aiming for approximately 50 percent female representation and this was, in part, due to evidence that group participation of women, in particular, is inhibited when the numbers of women in a group are too small; and the same, I think, is true about smaller racial or ethnic groups as well. And so, we did not have -- we aimed for about 40 to 50 percent minimum of women--we did not have specific quotas for other groups, but we're just looking for balance. So, we didn't want a group that was dominated by any one racial, or ethnic, or age group; and so, that was certainly factored in.

The other aspects of this were just the, I think, communicating in groups, a lot of our interview questions focused on how do you talk with people with whom you disagree; how do you have productive conversations? Because unlike the Delphi panel that was discussed today, the goal of the VEP is not to reach a consensus; we actually were really seeking different views, and so we hoped that we would have a group that had different views but the ability to share differences in a constructive manner. And specifically, we actually asked about whether people had any particular concerns about working with people; for example, with an addiction. Because if someone expressed a significant bias against addiction to the extent that they felt that they couldn't work with those people, that would be a disqualifier for the group.

And then in terms of the total number who applied, we actually have not publicized that information because this was more--this is really like a job interview process rather than a research selection process, and so people were not selected for reasons that included on maybe not being a good fit, but also just simply having too many, for example, older white males based on the demographics of the veteran population, and wanting to speak diversity. So, a variety of reasons people weren't selected, but I don't actually know the total number who applied.

Will Becker: Thanks, Erin. It looks like there may be another question, I believe related to the VEP, but I'm not 100 percent. Do you say there was the research publicly published or sent to providers to ask their patients?

Erin Krebs: So, if this was about the VEP, I'm going to guess it was about the recruitment information maybe. What we did was we tried to disseminate that through a variety of channels including the pain research working group and other members of the VEP and the CORE, just kind of sending out materials to different VA facilities across the country. Again, the goal of diversity, since we wanted to make sure we had people representing different parts of the country.

So, it wasn't probably--we didn't put it on LinkedIn or anything like that, it was more of a word of mouth and since the goal was to identify people

with experience with chronic pain or with Opioid Use Disorder, we really tried to make sure that the flyers were put up in places where people may see the flyers who were most relevant.

Robin Mashep: Well, I have a question and for some reason, the Q&A box is not working for me probably because I'm a panelist. I had a question for Sara Edmond. I was curious about--and maybe I missed this--about whether you have information about the providers who participated in the question about whether they felt that there should be a separate diagnosis for the long-term opioid patients, and whether there's something about kind of working specifically with that patient population, I would assume would suggest that those provider participants would have answered differently than, say, providers who worked with other substance-using populations.

Sara Edmond: Yes, thank you, Robin. That's an excellent question. So, we did collect, in the Round 1 survey, information about the gender, race, and discipline, training background of our participants. I have not had a chance to look at that data to see if the people who said yes versus no differed by any of those characteristics; but our general sense is that yes training background or experience working with patients differs; and this, again, is my impression without having looked at this data, I think that addiction psychiatrists or people who tend to work with Opioid Use Disorder patients in more traditional addiction settings tended to be more likely to say, "No, we don't need a distinct diagnosis," and general internists or people who tend to work more closely with patients with chronic pain tended to be more likely to say yes. But again, we have that data, I haven't looked at it, but that was my general impression.

Robin Mashep: It'll be super interesting to get into that data and look at it more carefully. Thank you.

Will Becker: It looks like we have another question about the VEP. "Any plans to expand the size of the VEP or to have additional groups, Dr. Krebs?"

Erin Krebs: So, I will say that this is--so, our group that developed a VEP here at the Minneapolis VA, we've had some experience from prior projects with a similar VEP structure and we felt that ten to 12 participants is probably about the right number; you want a group that is big enough to have diversity in perspectives, but not so big that it's hard to actually get your voice heard. And so, I think that--so, ultimately, we recruited 12 with the hope that we would be able to maintain a group size of at least ten.

We're not actually planning on more VEPs at this point; I would say, at this time, it seems like this group is really coming together and it's going to be a very productive and effective group; and so, our focus is on supporting the development of this group. If we have more business than

the group can handle in the future, I guess that would be something that we could consider, but I also know that a lot of--I think VA is really getting the message with veteran engagement and sort of the movement toward patient engagement and research broadly. So, this is far from the only veteran engagement group in VA; I think this one is just a little bit of a niche because it has this particular focus on pain and opioids. So, I think we're filling the niche pretty well, but certainly, if demands exceed ability to handle, we could consider more in the future.

And then I noticed that Agnes Jensen, who's a project manager here and a Navy veteran who's been really involved and expert with engagement activities, she's just commenting too that we did do some Facebook outrage outreach at VAs, and then reached out to multiple national veteran organizations and military organizations as well. So, we tried to have a pretty broad net in terms of identifying those numbers.

Will Becker: Thanks, Dr. Krebs. It looks like, Robin, I do not see any additional questions.

Robin Mashep: Thank you for passing it back to me. I just want to thank all of our presenters: Drs. Alicia Heapy, Sara Edmond, Erin Krebs; thank you to Dr. Will Becker for finally doing the final wrap-up and discussion, we really appreciate all of your efforts in creating this CORE for the VA, the breadth of what you're all doing in terms of creating this infrastructure support and really having a vision for the VA and where they should be going including veterans in this vision and in what you're doing in terms of mentorship, and trying to bring up young researchers who can fill in the gaps, it's really quite extraordinary.

I also want to thank our audience. Thank you so much for your attendance today and for writing in with some great questions. Just one more reminder to hold on for another minute or two for the feedback form; if you're interested in downloading the PowerPoint slides from today, you can go to your reminder email from this morning; if you'd like to find slides from our past presentations, you can do this by searching on VA cyber seminars archive and use the windows to find things for spotlight on pain management.

Our next cyber seminar will be on Tuesday, March 2nd and we will be sending registration information out around the 15th of the month for that. And I just want to thank everyone again for attending this HSR&D cyber seminar and we hope that you'll join us again.