Rani Elwy: Thanks so much Maria and welcome everyone to our bimonthly Complimentary and Integrative Health Cyberseminar Series that we do as part of HSR&D with CIDER’s help. This is our last session of fiscal year ‘22 and we’re really excited to let you know that in addition to this last exciting seminar, we have a wonderful program of fiscal year ‘23 cyber seminars planned so look out for those announcements in the future. I’m Rani Elwy. I’m based at the VA Bedford Healthcare System. I’m part of the Complementary and Integrative Health Evaluation Center which is a partnership between QUERI and the Office of Patient Centered Care and Cultural Transformation. I’m the Dissemination Director and with us today we have the director of the center Dr. Stephanie Taylor. And we also have the codirector Dr. Steven Zeliadt, both of whom I work closely with and so excited that they’re here to present.

And for those of you who have been regular attendees, you know that we always have Allison Whitehead from the Office of Patient Centered Care and Cultural Transformation with us to present at the end. So just to give you some information on our wonderful speakers, Dr. Stephanie Taylor as I mentioned is director of CIH, the Complementary Integrative Health Evaluation Center. And she’s also the MPI of the project that is being talked about today, the APPROACH study, which is the assessing pain, patient reported outcomes, and complementary integrative health project which is a VA national demonstration project funded by the NIH, DoD, and VA Pain Management Collaboratory. Dr. Taylor serves as the Associate Director of the VA’s greater Los Angeles HSR&D Center of Innovation. And she’s also a medical sociologist, a health services researchers, she’s won the HSR&D Health System Impact Award for all of her work in the complementary integrative health space. And she’s an adjunct Associate Professor at UCLA.

And Steve Zeliadt who is also one of the MPIs of the APPROACH study is the Associate Director for the Seattle Denver HSR&D Center of Innovation based in Seattle. He’s a Research Professor of Health Systems and Population Health for the School of Public Health at the University of Washington. And Steve has been the winner of the HSR&D Best Research Paper Award in the past for his work in lung cancer screening. And his work focuses on understanding the real-world performance of healthcare interventions in veteran populations. Steve is as a Health Economist and really provides just a huge complementary set of skills to our team. So welcome to both of them. I’m so excited that they’re presenting.

For those of you who know Allison, she is the Program Lead for the Integrative Health and Coordinating Center as part of the Office of Patient Centered Care and Cultural Transformation. She provides a two-to-three-minute reflection on these presentations and is also present during our Q&A in case you have questions related to how you might bring anything that you hear in our presentations into your own work. So she can give you a lot of the policy and program aspects of CIH in the VA. So without further ado, welcome to all of you and I’ll pass this over to Dr. Taylor.

Dr. Taylor: Thank you Dr. Elwy. Rani. So Rani neglected to mention she’s on the APPROACH study that we’re going to be talking about, so you can feel free to ask her questions about the study too. I’m kidding. This APPROACH study is again, assessing pain, patient reported outcomes, and complimentary and integrative health therapies. It’s funded by HSR&D. Steve, and I are the PIs. So today I’m going to tell you a little bit about the APPROACH study, but I do want to offer a full disclosure upfront.

For those of you who are attending to learn about the results; the results of innovative health effectiveness, I need to give you a stay tuned message. We’re only halfway through the study and the data are still being collected. Those final, final results aren’t going to be ready for another year and a half. But what we will have today though as far as results is, we will have some preliminary results on integrative health usage and that usage organized by whether or not it was delivered by a practitioner or done by itself and across 18 sites pre-and post-pandemic. So it’s really interesting stuff and we’ll tell you about the study through.

So in general, the study is addressing two mean research questions. The first is, is combining self-care integrative health therapies. So things like yoga, meditation, tai chi. Things that you do-it-yourself. Is combining those things with practitioner delivered integrative health therapies, things like acupuncture, chiropractic care, and massage; is more effective when you combine those therapies at managing pain than just having something done by practitioner integrative health therapy alone? And the other research question we’re asking or addressing is, well, how effective are these individual integrative health therapies? And the outcomes we’re examining across these two questions, it’s predominantly grounded in pain, but then pain related conditions. So depression, stress, physical health, quality of life, well-being, and fatigue.

And why did we even ask this research question about the combination? Well, we’re hypothesizing things that you do yourself, self-care therapies might be more powerful than treatments are done to you. Maybe by activating a feeling of self-empowerment or control over your own health. We’re not sure. We will be examining these possible mechanisms of action, but that’s why we’re studying this. Just a few more details before we get into it. Again, I mentioned it’s HSR&D funding, VA funding and it’s the only VA funded study that is in this incredible portfolio of research studies. It’s underneath an umbrella called the NIH-DoD-VA Pain management Collaboratory.

That portfolio of studies is being managed by the Collaboratory and that Collaboratory has three incredible PIs. Bob Kerns, Peter Peduzzi, and Cindy Brandt out of the New Haven VA in Gale. And our particular study is being conducted at 18 VA sites and they’re the sites that are labeled Whole Health Flagship Sites. Whole health is as I’m sure everybody knows now is a national transformation in healthcare that has been going on for about a decade now. Flagship sites are the sites that received a good chunk of money over a period of years a few years ago. And so there were 18 of them. We chose them to be our study sites. The population we’re examining are almost 16,000 veterans that are new users to integrative health. The people who’ve not been using it for a long time. They’re not experts at tai chi for example. And they also have chronic musculoskeletal pain.

Our sample size goal is 5,600 veterans by April next year. Well, we’re going to exceed that. We’re so thrilled. We’re relieved. We already have almost seven…we have 6,800 baseline participants. And the strong majority of those are making it to our six-month follow-up. So we’re going to be exceeding our goal. Our trial design is what is called a pragmatic trial design. We chose this number one, it was this requirement of the RFA. But really the attractive aspect pragmatic trials is for when randomization really isn’t feasible or desirable because it means withholding some care in an existing healthcare system.

And for those of you familiar with pragmatic designs, you’ll be familiar with the notion that there are eight different ways in which a trial can be pragmatic. And each trial is rated on how pragmatic it is. So Steve’s and my trial is considered the most possible pragmatic trial design. We’re not touching a thing; we’re not doing anything. We’re only reaching out and speaking with the sites to learn what they’re doing. We don’t have our fingers in the pie at all. Our data, we’re not collecting data directly using data. We’re using data that’s currently being collected by the Office of Patient Centered Care and Cultural Transformations Veteran’s CIH Experience Survey. And again, as I mentioned, the study results will be out in 2024.

Moving forward. So this is just to orient you on what we will be talking about today since we will not be talking about the final results. We will sort of give you a glimpse on how it’s going with study enrollment through that survey that I just mentioned. And we have completed two years of invitations to almost 16,000 veterans. It was an intensive invitational process. As I mentioned a moment ago, we’re going to have outcome data. We’re following people longitudinally over six months and we anticipate having over 6,000 veterans in our sample. We’re going to talk about how we sampled those people and we’re going to tell you about how we found that most people over the past two years who were starting integrative health, have significant chronic pain. We’re also going to talk…that middle bullet is veterans aren’t using a lot of integrative health. We’ll show you some numbers on that.

And then will turn to Steve and he’ll really get into the weeds with what we’re doing with this pragmatic trial design. He’ll talk about the natural patterns and variation that we’re seeing, and he’ll talk about the sources of those variation. We can do this without our killer amusing team. We have top scientists at four of the VA’s across the nation. As I mentioned, Rani our host of this cyber seminar series is on that team. It’s really, really a crackerjack team. We also relied heavily on our study advisory board. We reached out early on to leaders in the field that were researchers and practitioners in each of the therapies that we’re examining to really help us understand what would be an appropriate dosed study.

So since we’re not administering dose of integrative health, this is a pragmatic trial. We’re looking to see veterans who are receiving integrative health therapies. Really the question in the field is, well, what is the right dose? There is no consensus out there. So we relied heavily early on on leaders in the field to help us think through that question of what is an innovative health dose. And we’re going to be reaching out to those experts when we near the end of the study when we have some data to talk to them about.

As I mentioned, this is one of the trials in that infamous NIH-DoD-VA Management Collaboratory. For those of you want to learn more about it, here’s the link. Just Google pain management collaboratory and read until your heart’s content. Now I’m going to get into the study details. I’m going to talk first about the veteran CIH experience surveys. I mentioned this is not our survey. It’s the VA Office of Patient Centered Care and Cultural Transformation Survey. But just to confuse you, CIHEC, I’m going to be wearing my CIHEC hat now, not my APPROACH at. CIHEC the Complimentary Integrative Health Center that Steve and I run that Rani mentioned at the beginning of the call, we partner with VA OPCCT to do a whole host of projects. And one of the projects we’re doing with them is helping them with the survey with helping them design it and manage it. So I’m going to put on the CIHEC hat here and talk a little bit about this survey because these are the data that we’re using in the APPROACH study.

So their survey is predominantly electronic. It’s being conducted over web. Veterans who don’t feel comfortable with the web, we offer them a phone option. It’s being administered by an external survey group of crackerjack survey group that we’ve used for years down in Los Angeles. Again, we’re serving veterans over a four-time month, so baseline one month, three months, and six months we’re talking to them about…or we’re interviewing them about their integrative health use and their outcomes. Patient reported outcomes. We’re asking about use over the last four weeks and about four weeks before that. And again, these are the six therapies that we ask about. Excuse me. I’m doing the wrong button here. There we go.

So here’s just…sorry you guys. This is very small. This is just a snapshot of what we’re asking when we are trying to ask about integrative health. So for the six therapies, first we asked them, did you do any the following therapies in the past four weeks or are you about to start? And again, Steve will get into this. But we’re asking are you about to start because we see some indicator in the EHR that they have been signed up or they may have just used some sort of integrative health therapy. So if they say yes, I used it in past four weeks. then if it’s chiropractic care or acupuncture or massage, so practitioner delivered things we asked them, well, where did you get it? Did you get it at the VA or did you to get it in the community? And then we ask them how many visits they got with the VA provider and how many visits they got in the community.

And then for those therapies where people are doing some sort of self-care like tai chi or meditation or yoga, we asked them about classes. So did you do classes or sessions in person or at home on your own? Did you do with it with the provider? VA provider, community provider. We’re trying to really get details on these things because we have a feeling that these different modes of receiving care may matter for the effectiveness or their quality. So we wanted to control for that. A little bit about the enrollment of how we’re taken that survey and we’re enrolling it in our APPROACH study. So again, we have 6,800 veterans who’ve responded. It represents a 35 percent participation rate, response rate for those people we sent an invitation to. And for those of you who are interested in how did we get to that 35 percent, it’s pretty decent. We’re very thrilled.

We offered veterans two dollars in mail. So we sent them two dollars with an invitation. Or we didn’t, the survey company did. The collective we. And then we followed up or they followed up with an email invitation from the VA Office of Patient Centered Care and simultaneously mailed at the same time. And again, the six-month completion on survey data are being analyzed right now and we are thrilled to find out that of the people who started at baseline, completed baseline surveys, 94 percent of them are completing the six-month survey. That’s just insanely high. And again, we had the crackerjack…I think I’ve said crackerjack three times in this presentation. That’s odd. We’ve had a great survey company advised us that really the way to snag these people at the six-month, if they’re not responding to the survey to offer than the 10-dollar bill or 10 dollar…I think it was a gift card as a last chance incentive. And we really think that’s what worked. So wanted to reveal how we got that.

Some sneak peek results on what we are finding in the six-month data for what people are using, so almost half of the people in the sample so far, 48 percent are using things that are done to them by a petitioner only. They’re only doing chiropractic or therapeutic massage or acupuncture. They’re not doing self-care things at all. Now nice percent are doing only self-care therapies. Only tai chi or meditation or yoga. They’re not doing anything that’s being done to them by a practitioner. But 40 or 39 percent are doing some sort of combination of practitioner and self-care or what we call dual care.

We’re thrilled with that. That’s exactly what we wanted to see. A very high number of people using dual care. And that’s something that the VA is hoping will happen. We can’t really…we hope that patients…we. The collectively we again. Hope the patients really try some self-care therapies instead of completely only relying on practitioner delivered care. And then in the margin in the slide, you can see the four percent of our sample were ineligible for our study. So that’s great. I think Steve this might be you now. I’m going to pass the baton back to you.

Dr. Zeliadt: Okay. Yeah. I’m going to talk a little bit about the weeds of how all these people were sampled and the names were sent down to the survey company. So every week and we…you know they talk about the COVID problem. We were supposed to go into the field about a year before we were…right as COVID was beginning and we kind of waited a little while like everyone hoping that COVID was going to be a two week, or a three-week delay and it turned out to be longer. And then we saw things close down a little bit and we’re like, hm. What’s going on here? So we were a little bit delayed in that and so a lot of this and the survey kind of changed a little bit to try and really capture some of those at home tele modalities that were being delivered in more detail. So it’s sort of very interesting. But it really informed among sort of launching a survey what happened.

So then we talk a little bit about the first 20 weeks of survey sampling. And what did, we had some analysts go every…I think they started on Sunday night to crank through the CDW data, define people who had just started CIH in the previous week. Because sometime in the week before, they started CIH and they hadn’t had any CIH as we could tell in the EHR, in the VA EHR in the prior six months. So the early part of…or when we kind of started COVID has been going on for a while, so there were quite a few people we were finding as the chiropractic and acupuncture and the referral programs were starting up again that were kind of new users or restarting users at these 18 sites. But that endeavor of building the code to look for needles in a haystack of finding all these new CIH users was quite the undertaking. Click on the slide, and then I can advance. Yes.

So of the folks that we invited, and this is the data of the people we actually found an example, so these are the patients that are going to have chronic pain which I’ll tell you about in a second. This is the 15,800 invitation that were sent down. This is a little bit of the flavor of the types of CIH that we were finding as their new use in the medical record. So about 84 percent of the sample population, their name sent to the survey company has just started some kind of practitioner delivered care. And you can see over here on the right side that a lot of that was community care. So there was a lot of chiropractic and a lot of acupuncture care and a lot of it was in the community.

And we also looked a little bit about the self-care modalities if they were attending in person classes or by tele and a lot of it was by tele. There was some in person still going on in the first 20 weeks of the survey. And here’s a month of practitioner delivered care. Kind of a summary. About two thirds of it were, we found a new community referral for acupuncture or chiropractic or massage therapy. And then among the self-care modalities, about two thirds of it, 68% of it were tele.

And then it was talking about, we really wanted to focus on patients with chronic pain. And when we started this survey, we had no idea how many of these patients who were starting CIH would have chronic pain. I think we thought it would be a pretty small number. And I talk a little bit about how we did that. So we had to rely on what we were seeing in the EHR in that past week, we found this new chiropractic referral and we looked to see if you thought the patient had pain. And we had two ways of doing it. Our preferred way of the way guided by the Pain Management Collaboratory is this sort of algorithm to…and I’m talking about the 20,000 veterans that we kind of saw in that first 20 weeks of those new CIH users. And using that definition that’s sort of the more… definition, we found that date in the past week when a chiropractic referral or a visit happens.

And then we looked in the EHR to see if they had ICD10 codes related to muscular skeletal pain. And then we also looked to see if they had medical rating scores that were greater than four or higher. They have at least two of these in the prior year separated by at least 30 days. This is a pretty restricted definition. And we found that about 27 percent of the folks that were started CIH had met that criteria. Well, as I said, we were kind of starting a little bit late and COVID was happening and had seen all these new CIH users. So we were trying to make up a little bit for some lags and you tried a looser algorithm. So we just kind of said, well, all the new CIH users are starting, maybe we could just sample on did they have any pain. So any flag for chronic pain in the past year. And many more of the veterans met that, so about 80 percent of the veteran starting CIH sort of had at least some flag chronic pain in the prior year.

And then we had some survey data come in. So we have the baseline survey data come in for a sample of these patients and we found that among the patient that sort of met that looser algorithm, 92 percent of them reported on our first screener question in the survey that they had paid most or every day. And so we were a little bit shocked by that. That loose flag in the EHR really corresponded in this population to a pretty heavy burden of chronic pain. And as expected, the more restrictive EHR definition was a little more precise. So 96 percent of those patients sort of also said the same thing that that they had chronic pain most or every day. But it was sort of interesting. We did stick with that more complex definition for most of the survey. We didn’t relax it too much. We had a lot of survey…a lot of new users to sample from and we were a little afraid of running out of money for this survey. But I thought that would be interesting data to share with you and kind of folks thinking about this in the field about these new CIH users that pain is really an important indicator of why they’re starting CIH.

So now I’m going to talk a little bit about all the amazing data that we have. So as Stephanie said, we have the survey data that covered these four-week periods over a whole six months. And we also have all of the EHR data and the community claims data. So this is a little bit on the frozen sample of people that we have all six-month surveys back for. So we have baseline of one-month, three-month, and the six-month surveys. And it’s pretty interesting trying to harmonize and understand what their full CIH use was. As you can expect, there’d be things that we would not know about in EHR. So if they’re going yoga at home on an app, that’s not something that we would find in the EHR.

And also if they’re paying for acupuncture, or chiropractic, massage therapy out-of-pocket or at least some other insurance, that would be things that aren’t showing up and there would be a EMR records. And so we’re spending a lot of time kind of processing and digesting all of this data to kind of really look at the patterns of all the different modalities that folks used over this six-month period. I talk a little bit about this in some other presentations, so we have all kinds of crazy ways to go in query everything we can find in the EHR about how these modalities might be showing up. And for therapies like chiropractic care, there’s CPT codes, there is the VA billing codes, the CHAR4 codes.

The Whole Health program has designed a lot of health factors and other kind ways of attaching the organization to some records and notes. Their note titles and location names and chiropractor care has a stop code. So we can look for all these different ways and find these things. What the chiropractor care then diagram here shows is that the CPT codes are great. You use that and everything overlaps. So you can pretty much rely on CPT codes to really identify chiropractic are. For things like meditation, not one coding strategy really captures it all. So there’s some health \_\_\_\_\_ [00:26:41], there’s some of VA billing codes, there’s some note titles. And so we’re using all those different modalities to try and capture that the patients were identified using…participated in some kind of meditation activities.

And then we have the survey data. So we have all the ERH data over that six-month period and it sort of maps to these four-week periods from the survey data that Stephanie was talking about. with all this detail about did they get it in the VA. Did they use it at home. Did they pay for it out of their pocket if they used acupuncture or chiropractic care \_\_\_\_\_ [00:27:15] therapy in the community. And sort of the incredibly rich detail they’re we’re kind of overlaying the two together. And we’re finding some interesting thing. So this is a microscope on acupuncture and so we really focused on the EHR and the billing…the community billing codes for acupuncture. So if it was paid for by the VA, we have those codes that we get back. There’s a little bit of a delay \_\_\_\_\_ [00:27:45], but this sample, we think that we’ve pretty much have captured the bills that have come back the VA has paid for. And so and then we have the survey data.

And this focuses here just on the initial baseline period, not the full six-months just so we can be super precise. And so on the survey, about 265 people said they used some kind of acupuncture that was paid for by the VA or in the community…in the VA or paid for by the VA. And then on the survey, that didn’t always match. So overall, the concordance was about 90 percent. And then we’ll look at in a little bit more detail just among the people who responded positively to using some kind of acupuncture that was in the VA or paid for in the community by the VA. So we found 265 instances where veterans used that.

And in the same four-week period, we asked them about their use and interestingly, not all, there’s 171 of those veterans that we found bills for did not report on the survey that they used it. So in the survey they said they had not used acupuncture. It’s a pretty high rate of discordant among use. And there were also some veterans who said that they used acupuncture buy a VA provider or paid for by the VA in the community. Ninety-one of those veteran and we did not find billing codes or codes in EHR for those veterans. Now Stephanie, \_\_\_\_\_ [00:29:25] back to you. But you have some interview data that you talked to these veterans a little bit about….

Dr. Taylor: So our team was really puzzled and concerned frankly about what was going on. Why were we not seeing a tighter match for some of these integrative health therapies between what they’re reporting in the survey and what we’re seeing in the ERH. As Steve just pointed out, the worst-case scenario of discordance was for meditation mindfulness too. So we interviewed…our team interviewed 30 people who reported that they had used meditation, or we saw in the EHR they had meditation, but it didn’t match up with the survey.

So 30 people and we asked them, what did you use? When did you use it? Did you use it? Trying to get at why there was discordance. And we found out that almost half, so 14 of those 30 three people had actually used integrative health but it was just that the timing was different that was shown in EHR. So the EHR may have not caught up yet and it reported in the survey that they had just used, or they had used meditation. So that’s one reason. The timing was off. Another reason for the difference was that their visit had been canceled. Two people said they just…their visit had been canceled. There was a little bit of rescheduling and cancellations.

Obviously, there’s challenges that we’re seeing with community referral be recorded in a timely fashion in the EHR the huge lag in that. So that is another reason for why we would not see necessarily complete concordance. Ten patients told us that they didn’t remember getting a particular…that meditation that we saw was recorded in the EHR. And we’ve talked to a few people, and we’ve found that sometimes meditation or mindfulness is being given as part of a larger class like say a food class, diet class, and we’re going to start and we’re going to have a moment on mindfulness about food. And recipients may not realize it was mindfulness or it was coded as mindfulness. That’s the loose aspect of some these codes being given.

And we did find out then also that four people just had incorrect survey information. So 4 out of 30 is not terrible. And these other reasons for discordance are not shocking. It’s very hard to get a very high degree of concordance, but we are thrilled we did get a high degree of concordance in these other therapies. So this is just sort of a word of caution to those of you who are looking at meditation or setting meditation in the EHR. Just know that it’s not necessarily completely accurate. It’s probably not surprising. Okay, back to you Steve.

Dr. Zeliadt: So we have a wealth of data and are trying to figure out how to really figure out what detailed CIH therapy patients participate in over time. So now I’m going to talk a little bit about what we’re going to do with the data. So we have that sneak peek result as Stephanie pointed out. We have about 47 percent who kind of are going to be assigned to the practitioner only arm in about 39 percent of the samples that are going to be assigned to the dual care arm. And these are the two primary groups that we are trying to compare. Now ideally, they would’ve been randomized. So we would’ve enrolled veterans and then randomized them and said, you have to get dual care and you another group, you can only get practitioner care. You can’t participate in any self-care modalities. Well, that was not useful. That was not something that the healthcare system was at all going to want for veterans.

So we are trying to figure out how to overcome that challenge and one of the things that was especially happening early on in these flagship studies was that they were building these amazing programs to really encourage dual care. And so they had a lot of kind of infrastructure being built and pathways to really encouraging dual care. And so we were going to take advantage of that, especially at the time that these programs starting early then then hopefully over the course of the study we were hoping that by the end of the study—this is before COVID happened­—that 80 or 90 percent of patients coming in for chiropractic care would be connected to some kind of dual care or self-care therapies as well as getting chiropractic or acupuncture care.

And so we were going to take advantage of that so that natural variation over time and those sort of pushes and nudges to get dual care. And so those thick black lines are a little bit about of our surrogate for randomization when you take advantage of that that kind of tendency to do that look at look at these and health economics will be sort of marginal patient \_\_\_\_\_ [00:34:41] variable analysis. So this is what we’re seeing and it’s not surprising that using methods of finding new yoga or tai chi users in the VA, these self-care folks that there’s not a lot of them, but a lot of them go on over the six-month period to also use acupuncture or dual care. So that group is pretty small. It’s sort of going to serve as an exploratory group so we can look at those patients who are only using those therapies, but our primary focus is on these first two groups.

And so here’s a little bit of the data. So the red dash line is when the survey began. And so the survey began in April of 2021. So a little bit almost a year into the giant COVID pandemic. And so the data before that line is sort of early on in the flagship experience and you can see these amazingly increasing trends. So these are patient starting practitioner care and over time as they’re building the self-care therapies and building up acupuncture and the other programs, a lot of these patient were starting to get connected into dual care. And then COVID happened, and you can see things start to go down.

The rates of combined dual care, the rates of actual use of practitioner care kind of didn’t drop off completely, but they did go down quite substantially. And then the rates of dual care really kind of changed over time. It adds a little bit of natural variation to the study so that’s sort of nice. It’s not the variation I think we were hoping for which would be by the end of study they’d all be…this plot goes up to about 30 percent. So some of the sites that are the highlights of dual care combined with practitioner care are in the 15, 20 percent range. Think we were hoping that it would all be about 80 or 90 percent by the end of the study. Kind of starting off of with these lower numbers and going to be quite high.

And this is a picture of what’s going on with that smaller group that’s starting self-care. So they start self-care, and this plot is a different scale, so some of these places…almost everyone starting self-care…well, about half of the patients starting self-care kind of go on to use acupuncture or chiropractic or some practitioner care over time. And you can see the sort of variability across the 18 sites for that. And this is another picture about just kind of seeing what happens. So some sites have some pretty strong dual use programs and are really nudging a lot of patients into dual care and other places. Especially places that still rely on a lot of community referrals. Those patient don’t tend to get as much dual care over time.

Okay, I think this is close to the end here. So we can get some questions and discussion. So some of the take-home messages Stephanie said, the six-month survey data are going to be coming in through April and so summer of 2023 we will start to have some outcome data about the value and differences in outcomes for patients who combine self-care with practitioner care compared to just practitioner care alone. There’s a lot of interesting challenges to figuring out how to really capture detailed CIH use especially these modalities like at home use and use of apps.

And so, I think the survey company did an amazing job of giving us guidance in developing the survey about how to really measure some of those kind of…those use patterns. And there are some caveats about using the EHR as the only source of CIH utilization. Okay, I think that’s it. And there’s some additional…there’s some papers about the methods and details about the study. Claudia has a paper that just came out kind of describing sort of the tele CIH patterns during the COVID pandemic at these 18 sites which is really interesting. And if you have any questions, email us. Allison, do you want to take it over?

Allison: Yeah, I’m happy to. That was fantastic. I have had heard this presentation about this project many times but it’s still always fascinating. So hi everyone. Just a few notes. Just a reminder that this all, all this work, all the work of all of our CIH initiatives are a part of our Whole Health system transformation in VA. And so complimentary and innovative health approaches whether they’re provider delivered or self-care, it’s all a part of the Whole Health system alongside conventional care as well. And as we talking about, this study was really looking at veterans with chronic pain and we know that is a condition that impacts so many veterans both inside and outside the VA. And then just a couple notes to make too as Stephanie mentioned, this data has really been focused on those 18 flagship sites.

But we know that the Whole Health system transformation is really expanding beyond that and that all medical centers have some form of complimentary and integrative health approaches and have some at least components of the Whole Health system happening. And then also something that Steve pointed out and almost maybe could be whole other cyber seminar is just the coding and the tracking and the pulling of this data and how complex that is. And so it’s been so great to work with the CIHEC team on kind of digging in and thinking about that. And so I know I’m sure there’s a lot of questions coming in. I already see some in the Q&A, but just wanted to pop on and say hi and say thank you. It’s always a pleasure to work with this amazing team. And I’ll be here in case there’s any of those policy and program questions.

Rani Elwy: Thank you so much Allison and thank you also Stephanie and Steve for that great presentation which I also love hearing about. Because all of those meetings where we tackle a lot of the questions that are actually coming up in the chat make you realize how productive all of that has been and the great work that you’re leading. So the first question we have here is, how are you asking the self-care questions? Which I did have to smile at because I know that that’s been a conversation that we’ve had many times. The question says, I wonder if a patient is doing an exercise taught to them by a provider or the patient thinks that is provider delivered care. So I wonder if you can elaborate on that aspect.

Dr. Taylor: Sure. We don’t really ever ask the patient are you getting a self-care thing or a provider care thing. We specifically…ask and I think that’s Julie Olson who said, she showed up late. Yeah, Julie right before you joined, we showed the actual question. And we asked the veterans, did you use acupuncture, therapeutic massage, chiropractic care, yoga, tai chi, meditation mindfulness. Ask them specifically and then if they check yes, then we ask them more details. We knew they would not know what provider meant. I mean, I barely know what provider meant so be real specific.

Rani Elwy: And other question is, are we able to share survey questions? I know a lot of the questions we asked were already validated items.

Dr. Taylor: Yeah, so this is where Steve kicks me under the table from Seattle. I’m down here in L.A. and his response would be, well, if Stephanie Taylor would get the paper out, then it would be in public domain. So yes, that is on my first priority now that I’ve me some other deadlines is get the paper out. We want to share…Rani is part of the…one of the most important people on developing this survey of how to assess integrative health. It was a very laborious process. We developed it with the intention of helping everybody in the field. I mean, this is really hard to do, and we want integrative health therapy to move forward, and so we’re happy to get this out ASAP. Just hang tight.

Dr. Zeliadt: Remind them about all the amazing work that you’ve done for years before this with the Veteran Insight Panel and sort of the validation of these items and all the little things that were in there about 15 minutes and other little things to make sure that it really is…the word make sense and that veterans really will understand what we mean by meditation or yoga.

Dr. Taylor: Yeah, thanks Steve for that shoutout. Rani and I have years of experience of integrative health therapy survey work and interviews, and so we just put all of our…that’s why we have a great team. There’s many of us on the team with that experience, so we met many many times over probably two years, a year and a half to really hash out this survey. So it’s a labor of love, but it’s based on what we know and based on our experts that we mentioned. Our advisory board. They really really helped us think about how to ask these questions. Thanks Steve.

Allison: Rani, I see a question. Sorry. I’m just going to jump in. I see a question. I just want to make sure we don’t lose it that’s a little bit more of sort of implementation or programmatic one. So Dora asks, do veterans find it easy to navigate within the complementary medicine options that they can have throughout the VA? Is it easier or not? So that’s a really great question. And I would say, that’s always sort of a work in progress on our end in terms of communicating out and really having a good understanding of what services are happening where.

And so in addition…I forgot to mention, in addition to all the work that we’re doing with Stephanie and Steve, internally we also can pull data from the corporate data warehouse just to kind of see where the encounters are happening. Where the uniques are for different complementary integrative health approaches. So we have a better understanding of where everything is happening. We do have Whole Health points of contact at facilities as well as various complimentary and integrative health providers. And so I think it probably depends sometimes in terms of where the veteran is or how they’re coming into the system in terms of how easy or not it is for them to navigate. But I’m always open to feedback and thoughts and input on how we can make things even more clear. So thank you for that question. I think that’s just really important, so I wanted to make sure that was voiced.

Dr. Taylor: I want to go back to something that was just asked, and I really am not clearly awake yet. When we’re talking about the survey design process, it wasn’t our survey. It was the Office of Patient Centered Care and Cultural Transformation Survey on which Allison works. She is the lead of the Integrative Health Coordinating Center. So we met every other week with Allison and her experts to really hash this out and make sure we got the wording right. So you’re sitting here looking at the people who labored extensive over it. So want to make sure Allison. Thank you.

Rani: And Allison, I’m always for you to jump in and see the questions and answer them, so thank you. I’m going to go back up to the pragmatic design question which I know Steve will be so excited about too. And I was actually going to bring up something related to this so I’m glad that the question was asked, which is just, can you say more about the pragmatic design? This question asks, do you have a treatment and control group? I’ll leave that there. But I also wondered when you answer that if you can also talk about just the different aspects of making this a pragmatic trial. You didn’t mention the PRECIS. You don’t have to do that, but just maybe something to help to describe how we know something is more pragmatic than not.

Dr. Zeliadt: Maybe I’ll just slide back to the slide here. So some of the key elements of the pragmatic trials are that you don’t kind of consent patients and restrict the eligibility criteria in a way, kind of screen them out and say…you kind of find just the perfect population that might be amenable to the exposure or will to participate in the exposure under study. You kind of try and build it for all the possible people who might actually participate in it. And so we did that by letting everyone who’s actually participating in these modalities be the sample that is being studied.

So there was no exclusion criteria other than they had to have chronic pain most or every day at the time of starting CIH. But that was a huge amount of the veterans. What we’re concerned about is that the veterans who might naturally use dual care seek out dual care in addition to practitioner only care might be different. They might be more motivated. They might be sicker. They might have more complex chronic pain. And so in the randomized design, we would have perfect balance on that. But what we will have is these patients, these sort of the margin…they call them on the margin. These marginal patient who were nudged who used dual care who without that nudge, without those changing the underlying structures, without changes in difference in availability, or access that is created by the program who would not have used it without those nudges.

And so we can’t point at those patient directly. We can’t say Mr. Jones here was a nudge patient and Sally Jones here was a non-nudge patient. But through math, we kind of find these marginal patients and kind of see given the strength of the nudges and the strength of these black bars kind of going to these different modalities, we can see how many of those patients on the margins were judged who otherwise wouldn’t have been. And they provide this more pure sample that’s really from sort of some of those underline selection biases. It’ll give us an answer, so we’ll see overall when we go to analyze the trial. We’ll look at the results directly as they receive the care and then we’ll use sort of this \_\_\_\_\_ [00:49:34] variable approach to see if accounting for some of the underline selection bias, do those patterns change. Do they go away? And understand more about these sort of…on the nudge patients on the margins who use dual care who otherwise would not have used it without those structures in place. I hope that answers the question.

Dr. Taylor: Yeah, I also wanted to add in case anybody is reading…interested in learning more about pragmatic trials, what Rani is referencing was the PRECIS]. So if you Google P-R-E-C-I-S-2, it list the eight aspects of what the pragmatic trial is. And really briefly, I’ll just say eight words. The eligibility of the patients. The recruitment. The setting. The flexibility of the intervention being delivered. The flexibility of how well people are adhering to it. The primary outcome. Primary \_\_\_\_\_ [00:50:32] analysis. So it’s every aspect basically of a study. You can be ranked on how pragmatic it is or not. So just Google PRECIS-2.

Rani: I just put it in the chat.

Dr. Taylor: Thanks Rani.

Rani: Yeah, no I should’ve done it before since I mentioned it. But yeah, it’s just a…and I think…I didn’t have a second to get it, but I think there’s been some updates and people are really using this more in the implementation science space too. So you’ll definitely want to…if you’re interested in this, look more into it. We don’t have any more questions are, but I had one that I wanted to just sort of bring up, a comment and a question which is, one thing that I really loved about being part of this project is just witnessing how nimble you can be in a very complex project. So you mentioned when we got those survey results, we were concerned, and we sort of pivoted and did these interviews which were really helpful. And a lot of times people either don’t think that way in a research project because this is research project. So they don’t think that way in a research project or they don’t feel like they have the permission to do that. And I wonder if you could say a bit more about how that thinking came about about the need to do that and just how critical it was to make sure that our methodology was right along the way.

Dr. Taylor: Steve, do you want to take that? I see you pausing.

Dr. Zeliadt: The understanding what these exposures are, so what it really means use dual care is really important. And so really trying to quantify that through the survey mechanism and kind of learning what we’re learning about how to do that is important. I think also that…I’m just reflecting back on all the conversations we had as COVID started and we’re like, oh my God. We’re about to go in the field. Oh, no. All the chiropractic care is shutting down. What are we going to do? And then watching the dual…the tele programs just really spring up was sort of fascinating and how to really think about that. And I think what that…how the exposure has changed from how the study was originally conceptualize and how care like CIH care in general has changed in the last couple of years and what we’re really measuring is really kind of a very interesting perspective.

Dr. Taylor: I also wanted to add…I think Rani, this is a great question that you asked, and I want to make it clear to everybody that this is not your typical study. A typical study is very controlled, has a randomized or not intervention. It’s very simple. The decision is usually made very much at front, and you just execute it. What Rani’s point out is that this is the most dynamic experience research study I have ever participated in because of its pragmatic nature. We’re learning things along the way, and we have to change. We have to adapt. It’s not for the faint of heart, but it’s very exciting. And so it’s really been a real lesson for me.

Rani Elwy: And this is related to the IRB question that was just posted and you know, yes, we have a research study. But there are some operational components to that. So I don’t want to know if you want to answer how the IRB piece works in this.

Dr. Taylor: Well, the IRB is just very straightforward because it is a research study and basically you consider it a secondary data analysis. We happen to be using Allison and Ben Coogler’s survey. But it’s a straightforward research study.

Rani Elwy: There are some things that we’re doing that…we didn’t talk about the site visits. Did we talk about the site visits? Yeah, we have some site visits which went virtual in this project where we’re understanding more about how sites are getting information to veterans about the different complementary integrative health opportunities that they have at their site and those are more on the QI operational front. And there’s another question about, in terms of the pragmatic trial aspect, curious of a randomized encouragement design considered. Steve, you want to take that?

Dr. Zeliadt: Yeah, we definitely consider that trying to ask the sites if they’d be willing to randomized patients on Mondays and Wednesdays where you nudge all the patients coming into the acupuncture clinic to also get tai chi. And there was some conversation about trying to structure and get that set up and I think that was a little bit of the goal of more of those traditional…well, I don’t think that’s necessarily traditional, but a different kind of randomized nudge. And given just the scope of all the different sites and the things that we’re changing and then what happened during COVID, that just became untenable to do.

And also, the IRB issues related to that where patients would be randomized to that also raised…there were some challenges with that concept as well. But so we’re kind of relying on just sort of underlying sort of variation that’s happened in part because of COVID and in part because of just the hiring and other accessibility issues at the different sites. So there’s a lot of noise there or a lot of signal. A lot of variation there for us to take advantage of. So that’s sort of…instead of having it being purely randomized, but a little bit of that is why the study is so large. So they talk about it in terms of efficiency. That kind of design would be more efficient. You’d have to fewer study subjects here in order to have enough power. To kind of find those marginal patients, you have to have a very big sample size, which fortunately, the recruitment and the nine-month participation is really helping us with.

Dr. Taylor: I want to say something about Steve’s design and something about a question somebody posted that I didn’t realize the full nature of the question. The full nature of the questions is about the IRB. Did they have a hard time understanding what a pragmatic trial was? Absolutely. We had to have multiple conversations with them. It was insane the amount of education we had to give. It was very scary. Very tough. But we made it through. so yeah, when you guys…if you’re doing pragmatic trials, just know you’re going to have to do a lot of handholding and explaining. Then I wanted to say something about Steve’s nudge design. The instrument \_\_\_\_\_ [00:57:35] analysis. The reviewers when they reviewed this proposal, they called his designed elegant. So although he describes it as a difficult thing, and I want you to know that the methodologist and them reviewing it thought it fantastic. So it’s difficult, but fantastic.

Rani Elwy: And I just want to add that…just to add onto Dr. Taylor’s question. Although, there was no randomizing on encouragements, one of the reasons why we’re doing site is to understand more about what the sites are doing themselves to encourage. And there have been papers presented on sort to what we are learning from the sites. And so some that will be published soon, so that’s kind of our way of understanding what was happening de novo in the sites in terms of those encouragements. But we are at the top of the hour, and I just want to say thank you to Stephanie, Steve, Allison. So great to have you here to talk about this and to let people know that, when we start up again in fiscal year ’23, our very first presentation in November is actually switching from a Thursday to a Monday. November 14th. This is the one and only time we won’t be on a Thursday. It’s just due to scheduling. And Maria is going to give you some instructions for the end of this cyber seminar so thanks to everyone.

Maria: Thank you everyone for taking the time to prepare and present for today. For the audience, thank you everyone for joining us for today’s HSR&D cyber seminar. When I close the meeting, you’ll be prompted with the survey form. Please take a few moments to fill that out. We really do count and appreciate your feedback. Have a great day and stay safe.