The CePAWHS Study: Knowledge about Why and How to Improve Preconception Health

MCHB DHSPS Webcast

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JOHANNIE ESCARNE: Good afternoon, everyone, and thank you for joining us through our technical difficulties. I'm Johannie Escarne from HRSA's Division of Healthy Start and Perinatal Services in the Maternal and Child Health Health Bureau. On behalf of the division I would like to welcome you to this webcast titled "The CePAWHS Study: Knowledge about Why and How to Improve Preconception Health."

Before our presenters are introduced today I would like to make some technical comments. Slides will appear in the central window and should advance automatically. The slide changes are synchronized with the speaker's presentations. You don't need to do anything to advance the slides. You may need to adjust the timing of the slide changes to match the audio by using the slide delay control at the top of the messaging window. A 12 second delay typically provides optimal performance for the audience.

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or organization in your message so that we know where you're participating from. In order to allow ample time for the presentation we'll defer questions to the question/answer session following the presentation. However, again, we encourage you to submit questions via email at any time during the presentations. If we don't have the opportunity to respond to you during the broadcast, we will email you after. On the left of the interface is the video window. You can adjust the volume of the audio using the volume control slider which you can access by clicking on the loudspeaker icon. Those of you who selected accessibility features when you registered will see text captioning beneath the video window. At the end of the broadcast, the interface will close automatically and you'll have the opportunity to fill out an online evaluation. Please take a couple minutes to do so. Your responses will help us plan future broadcasts in this series and improve our technical support. I will now turn it over to Dr. Lisa LeRoy, a senior associate from Abt Associates who will introduce our presenters today. Lisa?

LISA LEROY: Thank you, Johannie. Hello and welcome. This is Lisa LeRoy from Abt Associates and I'm very pleased to introduce today's presenters. This webinar on results from the Central Pennsylvania Women's Health Study is jointly hosted by the interconception care learning community and the Maternal and Child Health Bureau as well as the CDC preconception health and healthcare initiative. I'll briefly introduce the three presenters and if you like you can find more information on each of them in the webinar announcement. They are going to give their -- the three of them will give their presentations and then take questions at the end. Cynthia Chuang is Associate

Professor of Medicine and Public Health from the Penn State College of Medicine. She's a women's health researcher, a primary care physician and mentor for medical students and residents. Marianne Hillemeier is Associate Professor of Health Policy & Administration at Penn State University. She served as co-principal investigator of CePAWHS and she is a pediatric nurse. Carol Weisman is associate dean at the Penn State University College of Medicine and director of the Central Pennsylvania Center of Excellence for research on pregnancy outcomes. She's the principal investigator of the CePAWHS study. She is a sociologist and health services researcher. Thanks and I'll turn it over to Cynthia.

CYNTHIA CHUANG: Thank you. Good afternoon, everyone and thank you very much for joining our webinar. We'll be presenting results from the Central Pennsylvania Women's Health Study today. And the presenters, as you can see, are myself, sin thee -- there are others involved who will be acknowledged at the end of the presentation. Next slide.

Today's presentation will be about strong healthy women, which is an evidence-based behavioral intervention for improving the health of preconception and interconception women. We will cover the following topics today. First the development of the strong healthy women intervention, which first involves a baseline assessment of the target population to determine what the key pre-conception risk factors were in the community to get the proper for mat for the intervention. Two, testing of strong healthy women to provide effective -- to provide evidence of effectiveness and to assess

implementation issues and third, ongoing modifications of the strong healthy women intervention and next steps. Next slide.

So the overall study is called the Central Pennsylvania Women's Health Study or CePAWHS. It's an ongoing program of research to improve women's health and pregnancy outcomes focusing on pre-and interconception women in rural and urban communities. Next slide.

The research objectives of CePAWHS were to one, identify the key risks for average pregnancy experienced and-out comes in the women of reproductive age in Central Pennsylvania. That was phase one of CePAWHS. And two, to design and test an intervention which is called strong healthy women, to reduce these risks in pre-and interconception women. That was phase two of CePAWHS. Next slide.

Here is a county map of Pennsylvania. The shaded area is the 28 county Central Pennsylvania region that was included in CePAWHS. There are three mid-sized cities, Harrisburg, York and Lancaster in this region and a large rural population that includes small towns and isolated rural areas. Next slide.

So phase one of CePAWHS included population-based surveys of reproductive age women living in the Central Pennsylvania women that we saw on the previous slide. This included a telephone survey of 2002 women ages 18-45 in the general population, as well as face-to-face interviews of 288 women ages 18-45 from the

Amish community. The objectives of phase one were to establish the prevalence of multiple risk factors for adverse pregnancy outcomes and to identify sub populations at greatest risk. This information would then be used to inform the strong healthy women intervention in phase two. Next slide.

The survey content included many areas, including health status indicators, pregnancy history, health-related behaviors, psycho social stress and exposures, healthcare access and patterns of care and socio-demographics. I'm going to summarize the findings from the phase one survey in the following three slides. As you can see here, 73% of women had had at least one live birth previously. On this slide we show the percentages of these women who have previously experienced birth complications, including pre-term birth, low birth weight and macrosomia which is large babies. Next slide.

So in this slide, we can see the prevalence of risk factors for pregnancy complications in the CePAWHS sample. As you can see, women in Central Pennsylvania were more likely to have these risk factors that have been associated with pregnancy complications as compared with state level Pennsylvania data and national U.S. data. Women in our sample were more likely to be obese, more likely to have depression and anxiety or depressive symptoms. They were more likely to have nutritional deficits, alcohol use, have binge drinking, they were more likely to smoke than the national population, and there were less likely to be taking folic acid supplementation as recommended. Next slide.

So this slide shows some more risk factors that we found amongst the CePAWHS sample that are risk factors for pregnancy complications. Namely physical inactivity, gynecologic infections and stress. While we found them to be prevalent in our sample there are no state or national level data for comparison on these variables. Next slide.

This slide summarizes some of the other findings from the phase one CePAWHS survey that guided how the intervention would be developed. Some have advocated that interconception women, meaning women who are between pregnancies, are at greater risk for adverse pregnancy outcomes and intervention should be aimed at this group. However, we found that pre-conception women in our CePAWHS sample were often at greater risk than interconception so our study targeted both. Secondly, we found that poor and low income women and less educated women were at higher risk. Our intervention also would target those groups and thirdly, rural women were not at any lower risk than urban women. So they would also be targeted in the intervention. So I'm going to hand over now to Marianne Hillemeier who will talk about the interventions.

MARIANNE HILLEMEIER: Thank you, Cynthia. So armed with this information we moved on to the second phase of the CePAWHS study and that consisted of two components. First we developed a behavioral intervention, which we named the strong healthy women, which targeted those modifiable risk factors identified in phase one which were most prevalent in our population. Then second we tested this

intervention in a randomized, controlled trial with pre-and interconceptional women in rural and urban communities in Central Pennsylvania. So some characteristics of the strong healthy women intervention were that it's a behavioral intervention for small groups, usually between 8 and 10 women. And these women were pre-and interconceptional women. This interveng was designed to be implemented in community settings by lay facilitators. We did this specifically because we thought that it would contribute to the ability of this to be widely disseminated. That it wouldn't require highly, highly educated facilitators but could be implemented by lay facilitators and we'll talk more about our training in a minute. We targeted multiple risk factors simultaneously in our intervention and finally we based it on theories of behavioral change, most specifically the social cognitive approach. That theory assumes that behavior is goal directed and people are capable of self-regulation.

As you'll see in the next slide, our intervention consisted of education, behavior change skills and self-enhancement tools. And so that's in the left box and then in the center you see that we hypothesizeed it would work to increase women's knowledge and the self-efficacy. The belief in one's ability to achieve a goal. And also intention or motivation. So once those factors had been improved, we expected to see health behavior change that would lead to health status improvement and finally the lower right box improved pregnancy experiences and outcomes. Next slide.

This is the logo on the cover of our intervention manual that was developed and you'll see that our curriculum was developed by a team led by two behavioral

interventionists. One, Dr. Danielle Symons Downs who is in the Department of kinesiology at Penn State and Mark Fineberg at the prevention research center also at Penn State. Next slide.

So in the strong healthy women intervention, we had six key content areas. We had behavioral objectives for stress management. Nutrition, physical activity, tobacco, alcohol use and exposure, gynecologic infections and preparing for pregnancy. The next slide.

This is a rather busy slide. You can't read it all quickly but it illustrates the point that in those six key content areas, which are along the left column, there were for each of those behavior change goals overall as in the second column. Learning objectives of which one example is in the third column and behavioral outcomes in the final column. Just looking across the top for stress, for example, the overall behavior goal would be to decrease psycho social stress. Within that one learning objective to be to learn the causes of stress and behavioral responses to stress and a behavioral outcome example would be practice relaxation techniques. We provided relaxation tapes and other information about those techniques. You can see for each one of those six areas we had these goals and objectives listed out. Next slide.

The intervention process consisted of six two-hour group sessions over 12 weeks. Rather than have each one of those sessions concentrate on one of our focus areas, we mixed the topics throughout and most of the topics had small modules given at

each of the sessions. We were -- we stressed active learning including discussions rather than lectures. Certainly discussions and give and take back and forth. Problem solving exercises, physical activity, actual participatory physical activity at each session and active participation in food preparation for healthy meals. And recipes. Each group was facilitated by two lay personnel. They were college graduates and we provided content in the intervention and group dynamics and how to facilitate conversations. We did two-day trainings with our facilitators. Next slide.

The intervention process included motivational strategies from the literature on how to best affect behavior change. One of the first you see there is goal setting using baby steps techniques so the idea being that you would set measurable small goals that could be met in a reasonable period of time and then with that success you move on to set the next goal, that idea. We also used behavioral tracking tools, so log sheets and diaries and various ways to keep track of progress and reward when progress is made. We from the literature we knew that social support would be very important. We implemented a buddy system for weekly phone calls. Each participate had a buddy of another participant identified and speak by phone weekly for support and encouragement and facilitators of the groups also called in between sessions. And incentives were offered. There are little icons on the slide that show we provided multivitamins and pedestrian -- pedometers to people. We gave gift cards to stores that people wanted to use them at. Grocery stores or others in the community. Next slide.

This is a picture of Sara Baker leading -- facilitating a group. And they are using one of the fit necessary equipment, core balls and a good thing we had the picture there because we were usually bouncing along but we got them to sit still for a minute. Anyway, that was a good picture. Other pictures include these images from our hand-outs and from the curriculum. You can see that we tried to be visual and to give people a real sense of things instead of just describing them. For example, in the middle of the upper row you can see that when we talked about portion sizes we could show what a portion size would look like on a plate versus a larger portion side. In the lower right-hand corner another example using the core balls for physical activity. Trying to provide as much as possible ways for people to refer back to pictures rather than just word explanations. Next slide.

So the next thing I would like to talk about is phase two of our second -- which is testing whether the strong healthy women intervention actually worked. We had two hypotheses which guided our study. Our first hypothesis was that women that participate in the intervention will demonstrate significant improvements in several factors, in behavioral intent, in self-efficacy, in health behaviors and health status compared to women in the control group who were not participating in the interventions. The second hypothesis was that more intervention participation would be associated with better outcomes than less participation. So in other words, if people came to more of the sessions, they would have even more improved outcomes than people that didn't come to as many sessions. Next slide.

This is a flow diagram that shows our overall research design. We recruited a total of 692 women. At the top you see. And then before the first step was to conduct a baseline risk assessment which I'll take a little more about later but the idea was that before we assigned them to groups, we took the baseline measure of the variables that we were interested in looking at. Once that was done, then we randomly assigned people to either the intervention group or the control group. Then at the end of the intervention period, both groups came back for a follow-up risk assessment and then following that, there were telephone surveys account 6 and 12 months after that. There were several questions we grappleed with as we thought about our recruitment. Who should we recruit? Should we only recruit high risk women, patients in clinical settings? Are there other ways to go about it? That was one set of questions. Another set is how would we frame the program? It seemed as they we could think about this in terms of reproductive health program, which it does have as a goal to do that. But it could also be framed a bit more broadly as women's health promotion and that is ultimately the way we decided to go in terms of framing to cast a wide net and to Garner maximum interest in our participants. Then another set of questions revolved around methods of recruitment. Did we want to do active recruitment, one-on-one face-to-face kinds of things or other recruitment or a combination? In answer to whom the recruit, for this randomized control trial we recruited women in low income rural communities. So we recruited directly from the community rather than from clinical settings for a couple of reasons. This approach includes women who do not have access to healthcare, so they don't have to necessarily have a regular provider to be part of our intervention and we wanted to reach people no matter what in terms of their

medical care. But we also thought about recruiting women from clinical settings, primary care or reproductive health services and that's another option that could be another way the think about it. But we decided to use the community setting for our initial test. Next slide.

Here is a map you saw a map earlier of the 28 county area we used for our survey in the first phase of CePAWHS. Here we have low income communities within that 28-county area and they're indicated by little purple paws along the way and there were 15 intervention communities. Next slide.

The participants in our intervention had to meet the following eligibility criteria. They had to be ages 18 to 35 at enrollment and as a side note -- a footnote there, that age group does account for over 85% of pregnancies in Central Pennsylvania. And we went for the -- that age group because we felt that that was the group that was most likely to account for pregnancies and would be likely maybe to become pregnant after our intervention so could reap the benefits there in terms of improved reproductive health. Another eligibility criteria was that they reside in the target area. That they were not pregnant at enrollment. That they were either pre-conceptional, having never had a child or interconceptional, in between pregnancies. They were capable of becoming pregnant. They couldn't have had a hysterectomy or tubal libation. All of our materials were in English so we did exclude non-English speaking women but we hope to include them in future versions of our study. Next slide. These are just illustrating some of the recruitment materials. Again just to note that you will see that

we sort of frame things as women's health, a broad brush women's health approach. Next slide.

Our recruitment methods were tailored to the communities with the help of a local steering committee consisting of people from the community that helped us figure out what would be the best ways to reach people in those communities. In each one of our communities had an organizational partner to help us. We used both active and passive methods. You'll see on the slide the active methods would consist of one-on-one recruitment at social service agencies such as WIC programs, at schools, at daycares and at shops. Passive methods included presentations in the agencies or schools. Kiosks at local health fairs and farm shows, inserts in utility bills, which was a suggestion from one of our community partners and proved to be a very good way to recruit people. And post cards to parents in subsidized childcare. Next slide.

This slide shows for one particular community what percent of the participants came as a result of the various kinds of recruitment methods. It is not -- I'm not really showing you this to say that one was better than the other or the particular percentages, but just to show you that we did get participants from a variety of different methods and that having a lot of different methods seemed to be the best way to go. Next slide.

This slide shows our enrollees compared with the general population in the counties from which they came. As I mentioned earlier, we were trying to -- we were hoping to recruit women that were -- tended to be in low income communities and be at higher

risk, say, for that reason. And so if you look here in the column -- so we're looking at demographic techniques, poverty, education, race, ethnicity, marital status, health insurance and in the county as a whole in the first set of percentages you see the general characteristics and then among our enrollees you'll see for everything except education less than college we were able to recruit more of our target population that were more low S.E.S. More minority and more rural women. For example, just to look at one across the poor and near poor in the counties overall, about a third were poor or near poor and in our enrollees we were close to 2/3. We were very successful in getting our target population. Next slide.

Our risk assessment consisted of behavioral and biological markers. We administered a questionnaire that women answered and we helped women that needed help with -- if they had problems reading or understanding the questionnaire. This questionnaire covered health status health behaviors, psycho social stress, access to healthcare and other characteristics. We did anthropometric measurements. We measured blood pressure and we also did a finger stick for non-fasting blood glucose and lipid panels. Next slide.

Here is the fully filled out flow sheet of how we ended up in terms of our numbers. As I mentioned before, we had 692 total women enrolled. We were particularly interested in helping as many people as possible to benefit from our intervention so we intentionally, when we randomized people we randomized 2/3 to the intervention group and 1/3 of them to the control group as you see on the second level of that diagram.

That allowed us to reach women with the intervention but still have enough people to compare to to see if the intervention worked. On the third line you see something called FURA. That's follow up risk assessment. In both the intervention and control group about half of the women completed that follow-up risk assessment. Some weren't able to come to that assessment but even then you see the arrows down to telephone information. We did follow up and got information from many of them. Looking at those that actually completed the follow up those were the base end for the number for some of the biomarker studies and in general our analysis are based on women that, an average, attended 3.9 of the six sessions. Next slide.

We just say a little bit about retention. We did, as any time you have an intervention and that it lasts for a period of time, retention is a potential concern and we did have some drop-out. They tended to be younger women and to have lower educational levels that those who remained in the study. This slide indicates that one major problem was forgetting the session and record keeping to know when to come. One solution that we started to institute and will be in future work will be to increase between session contacts by group facilitators and make better use of email and telephone contacts. Another issue we noticed was lack of childcare was a major barrier for women. Providing on-sight childcare is an important solution. I'll turn it over to Carol Weisman to continue.

CAROL WEISMAN: Thank you, Marianne. This is Carol. Next slide, please.

I'm going to be talking about the evidence that we have that the strong healthy women intervention actually works. These are the statistical analysis we use to analyze the data. I'll go through it quickly for the statisticians in the audience. We used an intend-to-treat analysis conducted with analysis of variant. The baseline measure on our outcome measure was controlled for. We're taking into account where women started prior to the intervention. And the follow-up measure on each of these three variables is the dependent variable. We used the general linear model. Ordinary logistic regression, depending on the form of the depending variable and in all of our pre, post analyses that I'll show you in a moment we controlled for age and educational attainment. The reason we did that is when we conducted analyses to try to understand which women were retained in the study and which tended to drop out, we found that younger women and women with lower educational level tended to be our drop-outs and so we have controlled for both of those variables in our pre/post analyses. Next slide.

This slide shows you the at statistically significant effects. These analyses were conducted on 362 women who did complete the follow-up risk assessment as Marianne indicated in an earlier slide. So these are our main findings. In the category of self-efficacy, we found that the intervention was effective in increasing women's self-efficacy for eating healthy foods. It was also significant for increasing women's internal control of birth outcomes. That is their perception that they can indeed control the process and outcomes of their pregnancies. With regard to the behavioral intent measures, the intervention was significantly effective in predicting or in producing

eating healthier foods or intending to eat healthier foods, I should say, and also the intervention was effective in increasing intent to become more physically active. Regarding actual behavior changes observed, the intervention was effective in increasing women's reports that they read food labels for nutritional values, that they consumed a daily multi-vitamin that contained folic acid and that they meant the recommended exercise guidelines that were prevailing at the time. Those guidelines were for 30 minutes or more of moderate or strenuous physical activities on most days of the week. These are our significant pre-/pose changes in the 362 women measured over a total period of approximately 14 weeks. Because that was the interval between baseline risk assessment and follow up risk assessment. Next slide.

This slide shows you our analyses for pre-post findings with regard to our bio marker assessment. Here you will see we found no significant differences between the intervention and the control group. But if you look closely you'll see that for most of the variables on this slide, the trend moves in the right direction. For example, looking at weight in pounds. There was a slight reduction in wait attributable to the intervention over the 14-week period although this didn't change statistical significance. We tend to think that one of the reasons that we did not achieve significant findings with regard to the biomarkers because our follow-up period was only 14 weeks. In future studies we intend to use a longer duration for follow-up prior to measurement of the biomarkers in order to try to capture changes in these indicators. Next slide, please.

This slide shows significant effects for our outcome variables. As Marianne mentioned earlier one of the hypotheses was more intensive participation in the intervention would improve findings. So this slide is showing you the effect per additional intervention session attended out of the six total sessions. So each additional session attended significantly increased self-efficacy in terms of control in birth outcomes and behavioral change with regard to reading food labels. Using relaxation exercise or meditation to manage stress, and using a daily multi-vitamin containing folic acid. The one thing I would like to point out at this juncture is that many of our key findings pertained to the domain of nutrition, folic acid supplementation and physical activity levels. We have conducted some additional analyses that I also want to point out. We looked for moderation effect. That is, we asked the question, does this intervention appear to work better for certain subgroups of women? For example, less well-educated women versus more highly-educated women or pre-conceptional women versus interconceptional women and we found no evidence of moderation effect in our sample. Second, based on the follow-up surveys that we conducted at six months and 12 months post follow-up, we looked for maintenance of changes. And we found that the intervention effect on folic acid use was maintained over the 12-month follow-up period and intervention participants had lower body mass index or BMI at 12 months follow-up compared with controls. So again, thinking back to that none finding with regard to weight measured in pounds. While we didn't see weight reduction over the 14 week follow-up period, looking out 12 months we did find lower B.M.I. in intervention participants compared with controls. Finally, some of the pre-and interconceptional women who were part of this randomized control trial did go on to

become pregnant and have a live birth during the 12-month follow-up period. So we were able to examine the outcomes for those births that did occur during that time. All together there were 54 births. We found no difference between the intervention and the control group with regard to having a pre-term birth or a low birth weight baby. This is not surprising because those are at the population level rather rare outcomes and our sample of live births at 54 is quite small. But we did find that women in the intervention group had lower pregnancy weight gain than women in the control group. So those women who got pregnant and delivered a baby during the 12-month follow-up period and had participated in the intervention group had lower gestational weight gain than women who did not participate in the intervention. And again, this is a finding that is very exciting to us and does make sense given the previous results I reported that the intervention did seem to impact nutrition and physical activity. Next slide, please.

So in summary strong healthy women intervention significantly improved attitudes and behaviors related to nutrition, folic acid supplementation, physical activity and stress management. And increased internal control of birth outcomes and lowered B.M.I. Next slide, please.

This introduces you to CePAWHS phase three, the phase of work we are in now. Based on the findings that we have shown you, we did modify the strong healthy women intervention based on a couple of things. Including participant feedback, focus groups that we subsequently conducted with low income urban women, and new

information that was published since we began the study. Based on these things, we've modified the intervention to cut some uncomfortable role play exercises that our participants told us they didn't enjoy. We added physical activity strategies for women who live in urban areas. We added chicken recipes as alternatives to fried chicken as part of the food preparation portion of the intervention. We emphasized reducing tobacco exposure rather than actual cigarette smoking in order to make that part of our intervention relevant to more of the women who participated. We increased our content on intimate partner violence as a stressor because that emerged in our focus groups as an important topic to address more fully than we had in the original form of the intervention. And we have included weight management information consistent with the 2009 Institute of Medicine recommendations regarding weight gain during pregnancy. Next slide, please.

The next steps for us in the research are noted on this slide. We very much would like to replicate the strong healthy women intervention in a trial focused on low income urban women who receive care in safety net clinics. We did submit a grant to the CDC for that. It was approved for funding. It was not funded but we hope to obtain other funding to do that study. We would like to conduct a randomized control trial focused on overweight and obese women. Particularly women at risk for diabetes because our findings with regard to nutrition and physical activity and weight management are so exciting and we have an N.I.H. grant pending review now on that topic. And we very much would like to encourage replications of the strong healthy women intervention in other communities. Next slide.

With regard to replications, the strong healthy women intervention is now available to other sites for purposes of research. With the users agreement from Penn State. We just want to stress for purposes of research, because we're still uncomfortable making this available to other sites who may believe it will be effective in their particular communities or populations. The strong healthy women intervention to date has only been tested in low income rural communities in Central Pennsylvania and we just don't want to overstate its effectiveness without some additional research. But those who would like to use our intervention for research would be asked to sign a use's agreement in which they would acknowledge the study, follow the strong healthy women protocol that we've created and evaluate its effectiveness and share the results in the Penn State investigator team. Next slide, please.

So what would you need to implement the strong healthy women intervention? Permission to use it from us as just mentioned would be one thing. The other is capacity to train a group of facilitators in use of the protocol. We did that quite intensively for the lay facilitators who implemented the protocol in our trial and so we have some very good experience in how these groups facilitators can be trained. You would also need a convenient site in which to implement the intervention and we would recommend that that site would include free parking, space for childcare and kitchen facilities. We don't necessarily mean a fully equipped kitchen with granite countertops but at least a kitchen that has refrigeration, some method of cooking, either a microwave oven or a stove, and space to demonstrate the cooking that is part of our

intervention sessions. And lastly, capacity to conduct a pre/post evaluation. At a minimum and to include a usual care control group, if possible. Next slide.

What we can provide to sites who are interested in replicating the strong healthy women intervention are the following. First of all, the protocol manual for conducting the intervention, which includes all of the materials and hand-outs required to do so. We can provide the evaluation instrument for pre/post assessments of attitude and behaviors and we can provide consultation on facilitator training, recruitment method. Implementation, evaluation and/or data is available. This is how to contact us if you have interest in this or obtaining other information about our study. We have a website. It's http://www.womenshealthcoe.psu.edu/. That stands for center of excellence, and you may certainly email me directly. I'm the principal investigator of CePAWHS. Next slide.

Many of the things that we showed you today in these slides have been previously published. I've listed some of the key publications on this slide, but all of our publications are listed and are available with a quick click on our website. We are still working on some additional publications to report the 12 month long-term findings that I mentioned a few minutes ago. Next slide.

With this slide, I would like to the CePAWHS co-investigators. It is a large, multidisciplinary team cross cutting several divisions of the Penn State university and

other organizations and all of these individuals contributed substantively to our work. Next slide.

With this slide I would like to acknowledge some collaborating organizations. In addition to Penn State, the family health council of Central Pennsylvania actively participated in this study, assisted with recruitment and facilitation of the intervention. Franklin and Marshall College assisted with the first ever, as far as we know, population-based household interview of Amish women with regard to their health. And lock haven University of Pennsylvania participated in the detain of the intervention and in subject recruitment and lastly we have a continuing CePAWHS steering committee consisting of community representatives from all 28 participating counties and we gratefully acknowledge their assistance in helping us interpret our data. Design our intervention and develop recruitment techniques in the local community. Next slide.

Lastly, I would like to acknowledge our funders, the Pennsylvania Department of Health funded our work through a tobacco settlement grant between 2004 and 2008. Since then CePAWHS' activities have continued to be funded three the Penn State social science research institute, CCSI and high mark. And with that, I thank you very much for attending the webinar and we look forward to answering any questions you may have.

JOHANNIE ESCARNE: Thank you, Dr. Weisman. We have now entered the question/answer portion of our webcast and the first question is can you please translate the statistical results for people who are not familiar with coefficient or P values?

>> Happy to do so. Somehow we anticipated this question. The slides that I showed you reported either odds ratios or coefficients that report the strength of associations. And the odds ratios in the pre/post intervention effect slide, which was slide number 40, is really the key slide. And this slide is basically showing you that the interventions increased the likelihood of these outcomes approximately two or more times over the control. So, for example, if you participated in the intervention, you were about twice as likely as women who did not participate in the intervention to feel self-efficacious with regard to healthy eating, to have high internal control for birth outcomes, to intend to eat healthier foods, to be more physically active, to read food labels and to meet recommended exercise guidelines. You were 6 1/2 times more likely to use a multi-vitamin with folic acid. So we're increasing the likelihood that women have these attitudes or engage in these behaviors through the intervention.

JOHANNIE ESCARNE: Thank you for that explanation, Dr. Weisman. I have not received any other questions as of yet but some people may be typing them in as I speak. So are there any final comments the presenters would like to make as some questions come in?

>> Just that if people have questions about the statistics, about the content of the intervention or about anything else we've mentioned, we are more than happy to take questions by email at any time.

JOHANNIE ESCARNE: Okay. Thank you. Some questions have come in.

>> Okay.

JOHANNIE ESCARNE: Will you report separately or combined results for organizations who decide to replicate an agreement with Penn State?

>> I think what the question would be is say one or two different organizations each would like to enter into an agreement with us and would like to replicate, would they have to public their results together or could they each public them separately and I would think that could be separate. That we would want -- certainly we would want the particular organization that did it to be able to publish the results of what they did, absolutely.

>> Yes, if that question had to do with the rights of publication, organizations would certainly retain their rights to do that and to use their data.

>> It wouldn't have to be lumped in together from everybody else. You would envision at looked at two or three as well but it wouldn't just be lumped together so you couldn't understand which site was which.

>> The main issue is that we at Penn State would like to keep track of who is using the intervention so that we can have a sense of how it is working in different communities and also that we can be helpful to others but it also helps us to know the results of others' experience using it.

JOHANNIE ESCARNE: Thank you for that clarification. Did those who did not complete the intervention still complete the follow-up risk assessment?

>> If the question is did some people who did not attend all six sessions of the intervention, did they come back for the follow-up risk assessment, yes, some did. That's why we were able to conduct the analysis of dose response because many participants in the intervention did not complete all six sessions. On average, they completed 3.9 sessions. Those who followed up with the risk assessment is how we were able to conduct the dose analysis.

JOHANNIE ESCARNE: Thank you. Here is a comment and a question. It is thank you for a wonderful presentation on this exciting work. I liked the emphasis of self-efficacy and can you say a little bit more about that?

>> Well, self-efficacy as you know refers to people's confidence in their ability to engage in specific behaviors. And in our study, we measured self-efficacy with respect to each of the behaviors that we were trying to impact in our intervention. So, for example, for nutrition we had a measure of your confidence in your ability to eat healthy foods as measured in a multi-item scale. A set of questions. For physical activity we measured through multiple items, women's confidence in their ability to engage in physical activity every day. Or to reduce periods of physical inactivity. For stress management, we measured confidence in ability to use certain stress relaxation techniques that were taught during the intervention. For alcohol avoidance we measured self-efficacy for avoiding the use of alcohol in certain situations where it might be available or substituting non-alcoholic beverages for other beverages. Without going through the whole list we had a measure of self-efficacy that was specific to each of the behaviors that we were trying to address through the intervention and the self-efficacy items for which the intervention had a significant impact included those related to eating healthy foods and the belief that you could control the course and outcome of a pregnancy.

>> And I would just add that I think the way we tried to build self-efficacy was through imparting knowledge about what healthy eating consists of and what -- I as well as the demonstrations and practice during the session. That was the idea that if you actually practiced something and learned how to do it one-on-one in the small groups, that then you would be more confident to do it on your own later and feel that you had the ability to do it.

JOHANNIE ESCARNE: Okay. In the CePAWHS studies were partners of women included in any way?

>> That's a really interesting question. They were not and that was another design issue that we had a long debate about. And for this initial trial the reason we decided not to include the partners and not to build in some modules or some activities that would require a woman to bring her partner to the session was that we didn't want to exclude women who did not have partners at the moment and we also -- what was the other reason, Marianne?

>> I think we did not consent the partners. Even though we understood how important social support is and tried to build it t in the buddy systems and things. We went back and fort. It was a tough one to choose which way. Anyone in a research study would have to be consented and be a participant themselves and we were really focusing on the women but we realize that's important and need to keep thinking about that.

>> Uh-huh. Excuse me, Sara Baker would like to jump in and also say something.

>> I just wanted to say also that I think part of the issue there as well was the randomization. And women were being randomized and encouraged to come to the baseline study with friends or family or partners. But they were not necessarily guaranteed to be randomized into the intervention portion. That would have been a

different study design. Zbl okay. Did you by any chance follow up with the participants to ask which of the commonents of the intervention were most compelling for them to change their behaviors?

>> Yes, we did that. We actually conducted a participant feedback study in which we contacted selected women based on the degree of participation and the intervention. We recontacted women who were very strong participants who attended virtually all of the sessions and we recontacted women who participated in only a few sessions to ask them what activities they liked the best, which ones they didn't like, which ones they thought were most effective. Those findings help guide the modifications that we made to the strong healthy women intervention following the original trial.

>> We also interviewed facilitators as well and what did people seem to enjoy and say? As a follow up to the previous publishing question, this participant wanted to know would Penn State help with the results publishing?

>> I work with people in developing manuscripts, absolutely, we'd be thrilled to, yes.

JOHANNIE ESCARNE: That's all the questions I've received so far. Is there anything else any of the presenters would like to say in case one or two participants are still trying to type things in.

>> Just thank you for the opportunity to present and it is great to have people that are interested in this area. We are very excited about it and moving forward. We would really like to facilitate in any way we can the dissemination of this intervention to other communities.

JOHANNIE ESCARNE: Great. I think this may be the final question. We'll see. Can you share what you found on those follow-ups that you -- that we spoke about a little bit previously?

>> The follow ups with the participants?

>> Correct.

>> It was interesting. There were issues such as the length of the intervention that we had no consensus about. We had participants who said this was great, can you make it 10 or 12 & others who said three was enough. For the study that we are proposing for overweight and obese women, we are proposing more sessions to concentrate more heavily on nutrition and physical gift factors. Other than that the main ones were the ones I mentioned when I showed the slide. There are some rose -- they had included that made some women uncomfortable probably because they were being asked to disclose aspects of their health or behavior that they were uncomfortable doing in a group setting. So we removed those. We mod filed -- we expanded content

related to interpartner violence and modified contact relating to tobacco exposure. Those are the main ones I'm remembering. Anyone else?

>> Sara Baker. Just in case that last question was in reference to another previous question regarding the follow-up risk assessment, there was a question earlier about those who participated in the follow up risk assessment who didn't complete the evaluation. I think it might be helpful that completion of the intervention was not defined by participating in all six of the intervention group. So one was considered having participated in the intervention if they only came to one intervention. That was rate. We had -- as Carol has missed. They were still considered participants. They were not lost -- right, randomized intervention but they were not lost unless they simply didn't -- they were randomized intervention and didn't show up at all. They were considered lost unless they actually came to the follow-up risk assessment and we did have the rare participant that never attended an intervention but came to the follow-up risk assessment.

>> Which means that I think our findings are on the conservative side because they include -- the intervention effect includes some women in that group that never did receive, not many, one or two. If everyone had gone to all the sessions we expect we have had more strong changes.

JOHANNIE ESCARNE: Well, thank you for that clarification. I believe that is all the questions that we have. So on behalf of the Division of Healthy Start and Perinatal

Services I would like to thank our presenters and audience for participating and our contractor the Center for the Advancement of Distance Education at the School of Public Health at the University of Illinois at Chicago for making this technology work. Today's webcast will be archived and available in a few days on the website mchcom.com. We encourage you to let your colleagues know about this website. Thank you and we look forward to your future participation in webcasts.