

# 16th Annual MCH EPI Conference: Plenary III—Challenges to Evidence- Based Public Health Practice December 16<sup>th</sup>, 2010

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WANDA BARFIELD: Good afternoon. We're going to start the afternoon plenary shortly. I just wanted to make some announcements, if you would look at the screen you can see there are several activities that are occurring. The first is the third annual preconception summit that will be in Tampa, Florida, June 12-14 and there is a call for abstracts that has been posted on the website called [beforeandbeyond.org](http://beforeandbeyond.org). So that will be the next one that I think pops up on the screen. Also, there is the western regional MCH epidemiology course that will be June 19-21 in San Francisco. And also tomorrow morning, for those who are waking up bright and early, there will be an environmental scan for invitees for the Division of Reproductive Health and we'll be having an environmental scan board posted outside in the main area at around 10:00. It would be great to get feedback from the conference attendees. If you have any questions about the preconception care either ask Sam, Allison Johnson or Lauren, who are here at the conference.

WILLIAM SAPPENFIELD: Good afternoon. For those of you who know Steve Thacker, you miss notice that I'm not Steve Thacker. We're both very good looking but the hair sort of gives it away. Welcome to challenges of evidence-based public health practice. Dr. Thacker had problems with his slide and was unable to be here so I am the stand-in for today and I will not do nearly as good but I will use his slides and blame it on him. Clearly, the reason we're here is that all of us, at least in all of our careers, have had the challenges of trying to do evidence-based public health practice. What I'm really excited is we're now talking about it as a clear focus with clear processes and clear ways to address it and I'm even more excited that we have the presenters we do today to help us talk about the challenges of doing this. Always good to start out with a definition. The definition that Steve would like to put out is the development, implementation, evaluation of effective programs and policies in public health through applications of principles and scientific reasoning including systematic uses of data and information systems and proper use of behavioral theories and program planning models. What is important is to know when we talk about evidence-based public health it's not about just changing the last word from

medicine to public health. There are clear differences in the two. First is the quality of evidence. Usually an evidence-based medicine is predominantly focuses in on experimental studies. When you talk about evidence-based public health they may use experimental studies but it focuses -- when you look at the volume of literature, when you talk about public health and the evidence that's out there is substantially smaller. The time interval from what you're trying to do from your evidence-based to your-out comes is shorter for medical interventions than public health intervention. The training and doing evidence-based practice, medicine has gone to the point they have certification and licensing and we at this point have no standard certification, though I do notice there are some university out there who might think about that as an idea. The decision making. Usually when you think about evidence-based medicine it is usually decisions made by individuals. Frequently evidence-based public health really focuses on teams and teams' decision. A good example of moving towards evidence-based public health practice is the community prevention services guide and it is clearly done a lot out there for some of us who have been in the field to try to get some idea of condensed evidence. It's even now out in book format for those who have clear interest in seeing hard copy versus electronic, though I tell you I go to their website quite frequently. What is the community guide? It contains systematic reviews, evidence-based recommendations, gaps in the evidence, areas for further study, catalyst for public health collaboration, credible resource for evidence-based population approaches across health topics. It clearly helps us to start talking about what we should be looking at when we talk about evidence-based public health. Currently there are out there 216 topics or recommendations. Of that 107 have recommended approaches, 71 with strong evidence, 36 with sufficient evidence, 1 with not recommended and I think what's really important to note to me is 108 with insufficient evidence. That sometimes our biggest problem in public health is that we come and try to look for that evidence-based guideline and this is the category we frequently find ourselves ending up in. To help talk about this, since the literature is not there, it's not always clearly made out for us are three people to talk about the real challenges. To look at it from a public health policies perspective we have Lauren Smith. To look at it from developing a prevention program we have Dr. Jennifer Culhane from the University of Pennsylvania. And third from a public health practice or a practice perspective we have Dr. Pierre Buekens. They have beautiful pictures and descriptions in their book. I will not spend more time on further introduction but turn this over to our experts. Dr. Smith. [Applause]

Lauren A. Smith: Well, thank you for that introduction and I'm so impressed that so many of you are here, since I know that we are what stands between you and your evening Margarita. So we will attempt to be exciting and provocative to keep you guys awake and interested in this afternoon lull

period. So I'm going to take you through some of what we have been experiencing in Massachusetts in terms of the challenge of implementing evidence-based public policy using safe infant sleep practices as a case study and how we've approached this. So in my comments for you today I'm going to be talking a little bit about SIDS policy recommendation, the epidemiology of SIDS who may not be aware and the disparities in this major cause of post neonatal mortality. There are major implementation challenges. This slide shows the incidence of SIDS deaths by age. You can see that it peaks in the period from around two to three months and trails off during the latter part of the first year of life. As for many of you who may be familiar with this, these are sort of the highlights, the milestones of the back to sleep campaign. In 1992 a first statement was issued that all healthy full term infants should be placed in non-prone positions. For people doing this kind of work it was non-prone. Side and back sleeping were equally recommended. A couple years later the U.S. and CDC launched the back to sleep campaign in 1994. By 1998, four years after that campaign was launched, SIDS deaths had be reduced by 30 to 50% which was a tremendous and very positive result. In 2000, the American Academy of pediatrics issued a more -- I see more specific statement saying that the supine position poses the lowest risk and the side position was somewhat better than being prone but not as good as being supine and most recently in 2005 the AP issued its last policy but I will say for those of you in pediatrics you know there is another policy statement on the horizon that will be happening soon. I tried to get insight scoop to find out what it was but no one was talking. In terms of the back to sleep recommendations in the 2005, it really strongly for the first time specifically recommended supine only sleep. Back only sleep. No longer was side sleep recommended. It specifically, again, this is for the first time, rather, indicated that there shouldn't be bed sharing with an adult and the infant and recommended pacifier use during sleep. In the back to sleep recommendations, identified that in 2010 healthy people goal of having greater than 70% of infants sleeping in the supine position. This slide shows the SIDS rates per thousand live births over time from 1992 through 2003 and the main sort of take-away point from the slide is that at the beginning of this time period, there was a pretty significant rates of SIDS and it decreased overall for Blacks with the dark squares, for Whites with the open squares and this was the overall decrease. The SIDS rate did decrease substantially during that time period. However, there has been a significant and uneven adoption of the message regarding sleep position. Significantly racial disparities persist in SIDS in prone sleeping despite the overall decreases. So what you see in this slide represents, again, from a similar time period from 1993 to 2005 at the beginning of this time period the non-supine, that would include both back and -- I'm sorry, side and stomach sleeping, the rates were actually pretty close for White and Black infants. However, by the end of this time period, although the non-supine decreased

for both, the difference actually widened. So here we have an example where we had an intervention that actually ended up exacerbated disparities during the period of the intervention time period. So I think that during our discussions we should come back to thinking about things that drive overall changes in a behavior may not be the same approach as needed to close a gap. What you'll notice here is that there was a different timing in terms of reaching a plateau. So you see that both White infants and Black infants have reached a plateau. However, the plateau was different so that the White infants have higher rates of -- the Black infants of higher rates of non-supine sleep and they reached 45%, which in 2001 about four years after White infants reached the same amount. So why do I call your attention to that? That's because there is a cost to that delayed uptake and so what this slide presents and this is from a paper from a colleague of mine from Yale, presents the high cost of a failed public health messaging for this population. If one looks at that rate and assumes that Black infants had achieved that same 45% rate of non-supine sleeping at the same time that White infants had, what you can see is that there were 719 excess deaths that occurred during that time period simply because these Black infants hadn't attained the same rate of supine sleep. So with that as a background, we need to sort of jump into the bed sharing controversy because that really is a hot bed right now. I guess that's a funny pun. It's a significant area of controversy. So this is a relatively recent paper titled why babies should never sleep alone. A review of the co-sleeping controversy and I want to call your attention to the quote in the conclusion here that says the simplistic and scientifically inaccurate and misleading statement, never sleep with your baby, needs to be rescinded wherever and whenever it is published. Hold that thought for those of you who have been sharing that scientifically inaccurate and misleading statement. There is another recent paper that looked at why mothers choose bed sharing, and this came out just last year. And in this study of inner city predominantly African-American mothers, although there was some ambivalence regarding balancing the risks of co-sleeping with not co-sleeping, they did indicate that comments the finding that clinician's advice against bed sharing did not influence the parents decision. That's kind of a big deal because that's who we have entrusted with the task of sharing this public health message is pediatricians. This group of women said that wasn't going to influence their decision but they would like to know ways to increase safety when doing bed sharing. So again, sort of hold that thought, the idea of people rejecting the public health message that had been attempted to be conveyed but instead asking for a different kind of information. So this idea that there are significant controversies regarding bed sharing then is played out in sort of messaging related to that. So here is an example of some public health messaging that is actually from Florida. I don't know if you've seen this, bill, but this is -- this is a real medical examiner and she says I do autopsies. Don't let me be the last

doctor to see your baby. For the message here is never co-sleep with your baby, a pretty unequivocal, very clear message. Here is another one that says for too many babies last year, this was their final resting place. And then in the bottom it says the safest place is in a crib from the City of Milwaukee health department. So clearly this message is no matter what, no co-sleeping. Now, contrast that, if you remember, with that first set of papers that was looking at the idea that mothers weren't going to listen to doctors about not co-sleeping and there was a large group of people who felt like this is not only an important practice but one that should be encouraged. In that context, the Massachusetts Department of Public Health was asked to develop a safe sleep policy by our sister agency, the Department of children and families which is our state welfare agency. And the end result of that process was a pretty clear, we thought, safe policy recommendation, the safest place for an infant to sleep is on his or her back in the same room with the parent or caregiver but in a separate sleep space such as a crib or bassinet. We gave recommended sleep positions, sleep environments as well as bed sharing precautions. And then we go into a little more detail to that. We decided at that point to take a risk reduction approach. That is, to acknowledge that there were very strongly held beliefs around co-sleeping that at least in Massachusetts were going to be hard to change in the short term. And that we needed to at least convey -- we thought it was important to at least convey to those people who were choosing to bed share and who weren't going to be dissuaded by the kinds of messaging you saw before, what things to avoid. So this section of the safe sleep policy talks about essentially acknowledges that some parents are going to choose to do this regardless of what we say and then with a set of sort of recommendations or criteria that really should be avoided in terms of soft bedding, chairs, recliners, doing it when you are drowsy or taking medication, when you are overweight or obese or using alcohol. Some of the challenges with this issue have been the idea that we have a no cost effective intervention that should be easy to adopt. At the beginning of the sleep campaign is when all you had to do is tell people to change the position which they put their baby to sleep and you would be able to affect a dramatic change in SIDS rates, that seemed very attractive. However, we know -- now we know that hasn't played out and there were multiple reasons for that. In focus groups, researchers in this air have done interesting focus groups among inner city African-American and other minority women and found significant skepticism about the mechanism of the development of SIDS or really what SIDS is. And in particular the idea you used the tell us we were supposed to put the baby on their stomach so they wouldn't choke. Now you guys are telling us to put it on their back. You guys don't know what you're doing and changing it on a whim and we'll do what we think makes sense. There are very strongly-held beliefs on sleep position and environment, especially the concern about safety and

preventing choking and that's really played out in a lot of focus groups among mothers. Many mothers believe that co-sleeping is, in fact, protective for the baby. That they'll be able to sort of check on the baby more frequently and make sure the baby is doing well. And that there is better and longer sleep for mother and baby if the baby sleeps with them. And for those of you who have been in the sleep-deprived state of the early postpartum period, the idea of getting more sleep is a very attractive one. And then facilitating breastfeeding. That has been one of the major causes of the controversy around co-sleeping and are there cohorts or sub populations for whom co-sleeping is safer and can be done safely. This important issue of discounting doctor's advice that sleep isn't their domain is one that I did a project in as well. I don't have the time to show you the data right now but the upshot was that there were certain areas that this population of women who were interviewed in WIC centers in five states, there were certain domains they felt like their child pediatrician to talk to them about. Vaccination, feeding, fever control as examples. There were some topics that they were intermediate about. Such as sleep position. Back, side or front. But then there were some like bed sharing that really did not accord any qualification to the pediatricians to be talking to them about. So given the idea that people will be discounting the advice of the folks that we've given the responsibility to communicate this message, clearly we need to be thinking about doing it in a different way. So in terms of what's next, we have in Massachusetts unfortunately seem to be experiencing an increase in infant deaths occurring in couches and recliners. And what's happening simultaneously is sort of some I guess ascertainment issues about whether or not these deaths are called SIDS, whether or not they're called sudden unexplained infant death, whether or not they're called suffocation. So the classification of them has been changing over time. But it does seem that there could be at least a cluster of deaths that are related to sleeping with an adult on couches or recliners especially. We are confronted with the idea, given that idea that there has been this cluster of deaths, with the idea of whether or not risk reduction approach we've taken is the right one. Whether or not acknowledging that there are some people who have these strongly held beliefs and are not going to be swayed by the tombstone picture or medical examiner picture. Is that the right way to go? Or should we switch to a more strict prohibition against co-sleeping in all of its forms and all of its locations. The idea here is what is more effective and for whom and is it possible that whatever choice we make might end up exacerbating or increasing disparities depending on who takes up that message and who doesn't? But clearly, we must redesign our public health messaging to target persistently vulnerable groups. I think that slide that I showed you that looked at the 700 excess deaths due to the delay in reaching the same plateau tells us that we really have to do this sooner rather than later. So that we can avoid this problem going on in the future. So my parting thoughts on

translating evidence into policy in general, not specifically to the SIDS issue really, is one thing that was difficult or different for me entering the public health realm was the rapid pace of decision making that is different than in academic life. So the idea of having to have an informed evidence-based decision, say, by 5:00 tomorrow afternoon is different than, say, I have six months to come up with a project and then another three years to implement it and another year to write it up. I'll tell you the results in five years. That doesn't work in public health sort of situation when you have to make rapid decisions. The idea of inadequate information versus certainty. I think that is something that is very hard for people who have been steeped in academics for a long time where they really don't want to talk about their results until they're absolutely sure and they don't want to say one to come out on either side of a recommendation until they're absolutely sure. In public health usually we have to make decisions with inadequate information and we have to make the best decision we can and how do we become comfortable of this idea of decision making with inadequate information? Next would be sort of policy by anecdote. Although the topic of this conversation really is on evidence informing public health policy we recognize there is a significant amount of public health policy that ends up being inactive because of anecdotes, powerful though they may be but not rooted in specific evidence. In our state you have an example of a shaken baby legislation that was very powerful testimony that ended up making this sort of be passed but if one were looking for an epidemiologic point of view, shaken baby wouldn't have been one of them but that's where the focus was based on this emotionally-stirring testimony. Another I think major issue that all of us have to confront is taking small projects that are evidence-based with sample sizes of 200 to 300 or maybe even 400 or 500 and figuring out how to bring those projects or initiatives to scale for an entire population. And I think that we all will have the opportunity to see how this plays out real-time simultaneously with the home visiting project. Hopefully there will be Federal funds to do that but we'll have to figure out how to take evidence-based documented for relatively small groups of families and figure out how to do it for an entire state population and it will be difficult to do. Next is the time chain of impact and this was brought out in the prior set of slides. The work that we do, we don't see the impacts for years and years, which is beyond the electoral cycle of the people who appoint our commissioners and therefore can be hard to get them engaged to make the investment to let us go that far. Then lastly I would say what I call the parallel of intersectional effects. All of you from yesterday recognize that we in public health inherit the failed social policies of the other domains in our state government. So what that means is, our work is predicated on the work that the other agencies and other sectors of government are doing but were not responsible or don't have the authority over their budgets and how the programs are developed. It can be hard to implement policies

in our domain that have a direct impact on what they are doing even though we inherit what the problems are from their domain. That's it. Thank you. [Applause]

JENNIFER F. CULHANE: Good afternoon. And I would really like to thank the conference organizers for the opportunity to address the meeting and I would like to spend the next 15 or 20 minutes talking to you about a project that is near and dear to my heart called the Philadelphia collaborative pre-term prevention project. By way of a brief introduction I'll talk a few minutes while you can look at some of my collaborators on the screen. This is clearly not a project that I can take sole credit for. I had many, many investigators help develop the protocol and actually conduct the study. But my area of interest is really what factors underpin the race ethnic difference we see in the rates of pre-term births in the United States. Prior to this study my work was really in sort of social epidemiology and observational studies. Some of which included collection of biomedical -- clearly biomedical data but also biological samples that we looked at immune systems dysregulations that may be associated with experiences of stressors at both the individual and community level to see if that was a way of explaining this as yet unexplained race ethnic difference in the rate of pre-term births. Well, about six years ago the State of Pennsylvania uses its non-formula fund tobacco money to fund what they call centers of excellence. One of their RFAs was initiated to study reproductive outcomes. At that point we didn't know anywhere near enough to start doing an intervention trial to reduce the rate of pre-term births and clearly we didn't know what to do to reduce the disparity. That was my thinking. But this intervention -- this grant, which was a lot of money, had to be an intervention. So I decided to attempt to work with my group of colleagues and develop an intervention that I felt comfortable doing given that I spent a lot of years saying that we were nowhere near ready or we didn't even understand the factors that were driving the difference so how could we possibly do a clinical trial? So this is a bit about that study. A teeny bit about the outcomes and then I would love to discuss any aspects of the study later. I don't have time to obviously get into the whole details of this study so I'm just drawing your attention to a reference. This is the first paper published from this project that talks a lot about the methodology, the recruitment and retention aspects of the project. So these are the background thoughts on how we actually developed this project. In a nutshell, this is an Interconception intervention where women that were delivering infants at less than 35 weeks of gestation were randomized into either a usual care or an intervention group in the immediate postpartum period and then followed for two years or until their subsequent delivery up to 20 weeks gestation of their next delivery. And the women that were randomized into the intervention arm were assessed across a multitude of risk factors and provided state-of-the-art treatment for those risk factors. As examples, in the area of periodontal disease that I'll

talk more about in a minute, we would do whatever was needed to remediate that condition. Some of our women needed all of their teeth removed and they needed dentures. So we really would do whatever was needed to remediate these risk factors in this population. And then our whole goal, as we'll see, was to reduce the rate of repeat pre-term births in the intervention arm. So how did we come up with what we did? We started by sort of listing out facts, and these are some of our thoughts. First off, we know that the risk factors for pre-term births tend to co-occur. It is very unusual to have a person with one risk factor, be it behavioral, medical, psycho social. It is unusual. Risk tends to co-occur. We also know that many of the risk factors that are associated with pre-term births are also associated with inflammation. So there in fact may be a common physiological mechanism by which all these risk factors actually increase the likelihood of a preterm birth. We also know there is something about the risk of pre-term birth that is retained in the woman across pregnancies. We all know the biggest predictor of a pre-term birth is having a previous pre-term birth. There is something about the host, the woman, that is not pregnancy specific but somehow retained across her pregnancies. We also know that during pregnancy there is a normal shift in the cytokine profile such that women become a bit more TH2 type. More anti-inflammatory and that this is largely the result of the fact that women have to tolerate what amounts to an all graph. There is changes in immunology across gestation. There is some evidence to suggest that when this shift to this TH2 type profile is incomplete, that the woman is at risk for both miscarriage, pre-term birth and in some studies actually still birth as well. It may be initiated by an actual reversal from the TH2 type to a more TH1 or inflammatory state. And that it's possible, we surmise, that women that enter pregnancy with an enhanced inflammatory state for a variety of reasons, may fail to achieve the necessary TH2 dominance, or actually may reach the TH1 or inflammatory threshold earlier in pregnancy. So that the pre-pregnancy state of the mother may have an impact on her ability to have a sufficient alteration in her immune system to maintain the pregnancy to term. And so we also know that every intervention, just about, that's been done thus far to reduce pre-term births, including those that target infections, have largely been conducted during pregnancy and we know that they've largely not been successful. So what we did is we looked in the literature and we found all these risk factors that are both associated epidemiologically with the risk of pre-term birth and have clear evidence that they shift the immune system towards this more inflammatory state. So our aim of the study was to reduce smoking, depression, infection both urogenital tract and periodontal infection, stress and I'll talk about how we operationalized that and receive an appropriate BMI among women who have just experienced the pre-term birth at less than 35 weeks of gestation to reduce markers of systemic inflammation which we measured extensively and to reduce the repeat pre-term

birth rate in the intervention cohort. So why the interconception period? There is a lot of talk about pre-conception, interconception care and it is hopefully not just the flavor of the day. That it actually -- people actually begin to embrace that the overall health status of the mother, be it from the time she's a child or potentially a fetus have an implication for her reproductive Life Course. So what we do know is that interventions in pregnancy have had very little efficacy. Is it because of the timing? Is it because of the intensity? Why is that? Because in theory a lot of these things seem like they should work. As we mentioned is that the best predictor of a pre-term delivery is a previous pre-term delivery. These are just data to support that claim. We see to the far my right -- is that women who have had two previous pre-term births, about 52% in their next pregnancy, have a pre-term birth. This is drastically reduced to about 14% in this study for women that have had two previous term births. In the MSMU progesterone trial in the usual care group, the women that did not get the progesterone, we see that about 50% of the women that had a pre-term birth at less than 32 weeks also had a repeat pre-term birth. There is very clear indication that risk is retained across pregnancy which would mean that women that have had a pre-term birth represent a unique sub group of at-risk women. These are the interventions that we selected. Maternal stress. I'll tell you a bit about why physiologically in a minute. Housing instability and inadequacy and health literacy. Most of these women had sick babies and had stress navigating the healthcare system. In terms of housing, we moved people. We paid first month, last month security deposits. We paid back mortgages, we fixed roofs, we put in new stoves. We paid heating bills for women who had their heat shut off. We spent a lot of money trying to stabilize housing. In terms of periodontal disease, we could not include people with moderate -- with mild periodontal disease, that would have been practically everyone. We used moderate to severe periodontal disease as our threshold and we did, you know, deep cleaning and root planning. We did removal of teeth. We got people dentures, whatever. Urogenital tract infections. We screened and treated for urogenital tract infections -- we looked for major depressive disorder using a skid and we offered women cognitive behavioral therapy, supportive counseling, medication. We worked hard to remediate depression. We did a lot with BMI. We tried to get heavy women thin and thin women heavier. Women with BMIs of less than 19 are at risk for spontaneous pre-term births. We worked on smoking cessation. Both women what quit before pregnancy and smoke through their pregnancy. We tried to get women to stay quit or to quit smoking. This is how these things are related to inflammation. We do know that maternal stress in the literature shows about a 1.5 to 2 fold -- women that have a lot of stress are two times as likely to have a pre-term birth even after adjustment for other biomedical and behavioral risk factors compared to their non-stress counterparts. The interesting thing about stress is that it affects

the immune system in an extremely complicated way. I think a while ago people thought -- generally would say stress is immunosuppressive. That's way too monochromatic and too complex. This is very simplified for sake of time. We do that these things may systemically actually shift the TH1 and TH2 type balance to a more TH2 type profile helpful in pregnancy. What's really interesting is that at the local level when people have looked at lung, gut, etc., it really looks like that -- the same chemicals actually produce more pro-inflammatory environments. We have this complex systemic versus local issue in pregnancy, and so there is some indication that stress is inflammatory, at least in local tissue. In terms of infection, we know that many urogenital tract infections are associated with increased births. Conferring risks of 1.5 and 4 depending on the study and the infection and we know that infection can affect the fetal membrane to produce alpha beta 68. Many pro-inflammatory cytokines. Infection is definitely an inflammatory risk factor and has a lot to do with early pre-terms, those prior to 30 weeks of gestation. Smoking confers a risk of 1.2 to 2. And we know that women that smoke have markedly elevated rates of interleukin 6 reactive protein if you measure it compared to non-smokers. BMI. This is a complex situation because BMI is associated with CRP and interleukin 6 as measured in serum. One would think that women that are obese would have higher rates of pre-term births, spontaneous or otherwise compared to their thin counterparts but, in fact, that's not really how the data look. Thin women, women with pre-pregnancy BMIs of less than 19 have significantly higher rates of spontaneous pre-term births compared to their obese counterparts. A paper recently didn't show that marked an increase. So BMI is curious in this sort of infection/inflammation picture. The thin women are the ones that are at risk and the heavier women are the ones that are more inflamed. That's sort of complex. I really didn't know what an inflammatory state depression is, but it really is -- it's probably what underpins the association between depression and cardiovascular disease. The epidemiological association between stress and pre-term birth is inconsistent. Some women who are depressed have 2 to 3 times rate of pre-term births. This is measured with the CDS. We did a clinical diagnostic exam, the skid on participants so we looked for real depression. We know that depression causes reduced natural killer cell activity which actually remits with -- as depression remits. We know that cytokine levels are associated with depression. And we know that treatment with immune activators like gamma interferon clearly cause depression as well as TNF alpha and treatment with antidepressants counteracts this effect. So we know that all the risk factors we picked, and those were just them, have this potential pathophysiology that culminates in this inflammatory mechanism. What did we do? Before women were discharged from their postpartum hospital stay, someone from our staff approached them in the hospital, asked for their consent, acquired permission to get their medical chart, conducted a survey, randomized them,

started the smoking intervention for those women randomized to the intervention group that met criteria and they scheduled the first one month postpartum visit which is very a very extensive evaluation of their risk profile was conducted. For the data collection visits, women in both arms were then seen at 6, 12, 18 and 24 months, or at 20 weeks of their subsequent pregnancy if they actually achieved pregnancy. At the postpartum data collection visits we did face-to-face survey. We repetively screened for periodontal disease and sent women to the dentist if they got periodontal disease. When they didn't have it at one month and had it at 12 months we would offer them the intervention. We collected vaginal fluid. A lot of peripheral blood, urine. We did a lot of measurements. Got their blood pressure and we did -- we reduced what I would call traditional barriers to participation. Women had transportation. The clinic was open late in the night, on the weekends. We took care of childcare. So we really tried to eliminate all of the barriers to participation. In terms of recruitment down at the bottom, or in sort of the middle line you can see that about 82% of the women that we approached consented to participate. There was clearly selectivity with white, older, educated privately insured women less likely to participate in the project. They were randomized to intervention and usual care with about 560 women in each group. These are the sample characteristics. We can see that most of the women were single. Many were on Medicaid and about 70% were of Black race ethnic group. These are the prevalence of the risk factors. 75% of the cohort had housing inadequacies. 55% had moderate to severe periodontal disease. Depressive symptoms, 45%, which is using the screening CESD but as you can see two lines down only 31% met criteria for clinical depression. 38% of the women either smoked when they found out they were pregnant but then spontaneously quit during their pregnancy or smoked through their entire pregnancy. We called that smoking positive for everyone. 35% had a urogenital tract infection at one point in the screening, at least. 23% had low literacy and 19% had low BMI. These are the percent of women who had multiple risk factors. You can see that not that many women had just one risk factor like we talked about in the beginning. If women had multiple risk factors we let them choose how -- which risk factor they wanted to actually work on first and they were offered intervention for all of their risk factors. What we know is that in the intervention group, you can see that there was a wide range in people that accepted the intervention if they screened positive. It's not at all surprising that 92% of the women, for example, that had a housing inadequacy actually accepted the intervention because we really literally gave people checks, etc. We got 83% of those women to participate. Infection had such a high participation rate because we used observable therapy mostly and we gave women medications right there in the clinic or we drove them to their house if they needed us to or what have you. You can see that it drops from there with only 29% of the

smoking eligible women actually participating in the intervention. And I hate to say it, but it's true. I think two women quit smoking in the entire study. So these are some selected findings that we know that exposures that are associated with adverse outcomes are moderately prevalent and they co-occur. There was a very wide range of participation across interventions. Even with all traditional barriers to care actually addressed. We think that, you know, volunteering for treatment, so say you say I'm offering a smoking cessation program and people come into your clinic to actually participate, and even at that point you randomize them to two different types of treatment. This is a much different situation than what we did, which is we randomized people that weren't volunteering. We went out and found 50 smoking women and asked them if they would participate in a study. They weren't volunteering in any way. I think this has a lot of implications for public health because it's likely that women that really need these interventions are those that are going to be less likely to actually volunteer. So how one takes a program that works let's say with volunteers, and then actually implements that in the real world to people that need it but don't actually volunteer is a really interesting question. So a colleague of mine is actually working in this cohort to try to figure out why some of the women didn't avail themselves of care when we tried to reduce all of these traditional barriers. And she's coming up with the fact that very complex decision making that may seem irrational from the outside makes perfect sense in some of the context of these women's lives and it is our problem to figure out systems that can respond to these differential needs. Her research is showing that racism, housing challenges, insufficient resources, multiple burdens and emergencies play a role in these everyday lives and influence participation in projects or programs on a daily basis. And that we need to become aware of and document and address the way that various institutional structures, rules and ways of doing business create additional burdens for already stressed women. So in some we see that targeting a single risk factor may be insufficient. I think that's a real challenge in doing evidence-based work. You know, the timing of the intervention is critical. Pre-natal care may be too late. The baby inappropriate to evaluate the outcome of a subsequent pregnancy. It may be -- interventions may not work lock step like we hope. That doesn't mean that they don't work if we look for different dependent variables. We have a big problem with really at-risk women may not participate in programs and projects and I think that's a big, big burden on the public health community to figure out how to reduce barriers that are complex and we may not even understand. Even if an intervention works, like go back to the example of women volunteer for smoking cessation project and then you randomize them into different types of interventions and one intervention works better than the other, you say this works, but it may not be able to be successfully implemented in women that don't volunteer. So I think what we mean by works

is really important. We need more research to understand the complex barriers that we see to participation in these programs. And finally, although I didn't talk about it here, the unfortunate outcome is that the gestational age distribution in the usual care and the intervention group is identical. So we did not change the rate of repeat pre-term birth in the intervention arm. Thank you. [Applause]

PIERRE BUEKENS: Well, thank you, Bill, for the invitation. And very nice to see my friends in the room. Many I have not seen for some time. Let me try to follow these two very impressive presentations which have in common that it is not easy to change behaviors and indeed I think that we need to deliver innovations, but also we need to find, you know, innovation in the way we deliver things. So it is deliver of innovation and innovation of delivery are the two challenges we are facing. And by innovation, I don't mean only new devices. I mean new idea, any guideline, anything you want to diffuse. And one example, you know, is the guidelines to try to decrease C-section rates. She presented C-section rates in Florida and trying to decrease them. About 20 years ago I was really impressed by a randomized cluster trial which was published in Canada where they compared three -- two different ways to try to decrease C-section. He compared it to really not doing anything new. So he randomized 16 hospitals, eight hospitals were in a control group where nothing different than the usual practice was done. In four hospitals, he implemented feedback, which is really informing the obstetricians and the midwives and the house practitioners about the C-section rates, and trying to provide feedback about those rates and see if that would decrease the C-section rate. Something we do all the time. We compute data, we send them back to the hospitals and we hope that it will change something. He compared that to having an opinion leader in each hospital. Really actively trying to change things and to work with his or her colleagues to try to convince them to decrease the C-section rates. And what you can see on these slides is that there was basically no difference in trends of C-sections between the control group and the feedback group. So what we do most of the time, which is just to send the data back and hope that people will suddenly wake up, be embarrassed by their irrational C-section rates and decrease them doesn't seem to work. What was really striking is that the group where an opinion leader, a leader in the hospital, decided to change things, in that group there was a sharp decrease in C-section rates. So I kind of remember that because it's one of the few randomized trials trying to compare different ways to change typical behavior. I liked it because it was a trial, a cluster trial, and because it was really challenging what I was doing, which was just to publish rates and to send them back to the -- to my colleagues. So keep that in mind and I think it inspired our team when we decided to do another trial, which we published recently, and it was entitled behavior intervention to improve obstetrical care. The problem is that in Latin America where we work most of the time, us in the U.S., us in Europe, us

everywhere else, many ineffective or even dangerous interventions are used all the time while at the same time effective practices remain under utilized. No different from what is happening in the U.S. In Latin America the situation is often really concerning. For example, and I have prepared this slide for another doctor because he published a fantastic review on the lack of -- a long time ago. But despite what he published a long time ago, if you look at the episiotomy rates among pre-med in hospitals in Latin America and other parts of the world, you see they're extremely high. Close to universal in many, many places like Argentina and Uruguay. So as you know, this is completely against the evidence we have. If you look at the Cochran review and you look at the trials which have been comparing selective use of episiotomy. Only do one when you have a good reason to do it, to universal or routine use, you see that all the trials -- you know, have, you know, they are on the left-hand side of the no effect line. All the trials show that it is better to do selective episiotomy. The study published in 1993 is the largest trial and really showed that also. So the literature is really clear, you should not do routine episiotomy but people do. At the same time if you look at the hospitals which are part of our network in Argentina and Uruguay and if you check if our colleagues do active management of the third stage of labor you see that most don't. The vast majority of the hospitals, they do not use active management. They do not inject oxytocin just before the delivery of the placenta. They have a passive approach to facilitative labor. They do episiotomy but not active management. The Cochran review, the results of all the trials are very clear, you have to do active management. You decrease hemorrhage by 50 percent per at least if you do active manage: it's a clear case. As you can see all the dots are on the same side of the no effect line. So there is no debate. You have to do this. Yet we don't. And this is not specific to Latin America. In many parts of the world we don't. So we wanted to check if we could do something about that and we wanted to evaluate an intervention to really increase the use of two evidence-based practices, selective reviews of episiotomy saying we want to cut less and active manager of the third stage of labor which is we want to inject more oxytocin during the third stage of labor. We wanted our colleagues to cut less and -- we are always the bad guys always saying you have to do fewer C-sections, fewer episiotomy. You have to cut less but you can do something. You have to inject more. So we combined the two. Now, which behavior intervention? Well, you know, I'm not a behavioral scientist at all, so I went to see my colleagues in behavioral sciences and I told them I want to do an intervention to make sure people use these guidelines. And she said okay, so what is the intervention? Well, I'm going to do training. I'm going to do what I'm doing with you, I'll invite them to a conference where they are going to learn how to read Cochran systematic reviews and they will develop their guidelines and then they will go back to their hospitals and she said that's fine, what's the intervention? I said well that's the

intervention. No, that's teaching. Teaching doesn't change behavior. And then she told me, you know, not using a bit of best practices, it's an addiction like smoking. You can tell people that smoking is bad for their health and give them all the data you want, they will probably not stop smoking. You have to do more than that. So we looked at the behavioral sciences literature and decided that we wanted to do a multi-faceted, comprehensive intervention combining seminars but also detailing active involvement of early adaptors, reminders and feedback on the rates. But the key point here was really the involvement of opinion leaders. Opinion leaders were developing the guidelines and then diffusing them. And we trained these opinion leaders to develop guidelines based on the evidence but we also trained them to do this academic detailing and to do that, we used the same trainers that the pharmaceutical companies were using in Argentina and Uruguay to train their sales. They now, how to diffuse them and they don't do passive diffusion. If you look at what pharmaceutical companies do, they identify opinion leaders, they try to pay them well if they can, you know, they mobilize them, then they try to have them change the behaviors of their colleagues. They do commercial detailing by seeing the ones who are not ready to change one by one and trying to change their behaviors. Then they identify the ones with the prescription practice. They invite them to a night of dinner with the opinion leaders, you know? And then they send them reminders, you know? And then they keep monitoring their prescriptions, you know? And they keep bugging them. So pharmaceutical companies know how to do this and they use science to do this. And they are successful. So we really decided with the help of our colleagues on behavioral \*\*\*\*\* to create an intervention very similar to what pharmaceutical companies do. We randomized 24 hospitals in Argentina and Uruguay. 12 control hospitals. The frequency of \*\*\* before randomization we went to each hospital and we did exactly what I'm doing right now. We presented all the evidence to everybody. The Cochran review, showing that if you don't do active management, women will bleed. These are the ep east -- I thought people would change behavior and we would have no trials and we did that. And actually what happened is that people didn't change behavior. Our baseline, you know, there were still doing a lot of episiotomy and not active management. We categorized them in hospitals in Argentina and Uruguay and as you can see, the randomization worked well. It was very balanced between the two groups in terms of teaching hospitals, in terms of large hospitals and in terms of active management, which you can see here was 4% in each group. Then what happened? Well, I'm used to publishing negative trials. That's what I do generally and -- [Laughter] And it is okay because I try to show that, you know, actually an intervention is ineffective and you should stop doing it. I make a living of doing these trials. So I was shocked when we broke the code and when I saw the results from this trial because the effect was huge. You can see

on the top of this slide you see that that baseline there was no difference in terms of oxytocin. You see at the end of intervention the dotted line there was still no change. Almost no change in the control group but almost everybody in the intervention group adopted the intervention. And what you can see also is that one year after the intervention, the difference was still the same, even though we went back to all these hospitals and told them what happened and we offered them all the package so they could do this program, but we didn't mobilize them and they didn't do it. Episiotomy, among all births included and you can see that in the intervention group it went down but not in the control group, not at all. So we told them before the randomization, we give them all the information, nothing change. But in the group using this aggressive approach that pharmaceutical companies use there the impact was really very strong. And what you can see also is that the impact was very homogenized. You can see that oxytocin, and all the hospitals changed. So the impact was really homogenous among all the intervention hospitals. So what I learned from that is that we have to be very aggressive if we want to implement guidelines, or any change. There is no reason to believe that it was so difficult to have people stopping smoking. They would be so easy to have them accepting something like using evidence-based guideline. All these interventions need to be diffused in an aggressive way. And also believe that evidence-based public health, like evidence-based medicine, should be evidence-based. That we need to test these interventions to diffuse and implement evidence-based practice by doing randomized control trials. So I kind of respectively disagree with the first slides showing that public health evidence should be mostly based on observational data and experiment. I think we can very often do randomized control trials. They might be more often community randomizations of individual trials but we can and we should do it also about ourselves, just different ways to diffuse and to implement. Because it's very surprising that look at all the evidence-based public health and evidence-based medicine there are very few trials to see this evidence-based movement is actually effective. It is often not tested in a randomized fashion so we have to do to ourselves what we do to our colleagues and compare different ways to diffuse. Thank you. [Applause]

WILLIAM SAPPENFIELD: Being an epidemiology I would like to take a quick poll. How many of you feel adequately challenged? We go from here we have a clear evidence base and an evidence base recommendation, but a substantial population who don't use it and a substantial minority who don't use it and we aren't reaching that group and so what's next? We move on and really discouraging where this whole idea that we should be moving the pre-conception health, that's the way to go and someone just took every one of the major ideas I could think of that you would want to do in pre-conception health, and guess what? I'm not saying all. There is still opportunity for you. But I'm just saying they

took my biggest measured ones I would have thought of and in a budget from the public policy percent effective I'm not going to have any time soon and move on you have some of the best educated people. You have doctors and you can lay out clear, solid evidence and they still don't do it. And that you have to do marketing PLOYS that drug companies do to get them to do it. As we talk about our discussions and questions there are two directions. We could really solve in 15 minutes the problems about sleep position, about preventing pre-term birth and getting doctors to do the right thing, or we could really talk more about and discuss more about the challenges doing evidence-based public health. As I open it up for questions and for discussion, I would like us to focus more on the challenges of evidence-based public health and less on solving these other problems which would probably take more than 15 minutes. The floor is open for questions for a discussion and for debate. Please, introduce yourself and then--

QUESTION: Hi, I -- I just want to comment on the speakers, I think you did a great job and I want also to refer to -- I have two comments so I don't forget. The first one is that I think we have forgotten that public health is both -- I was telling them yesterday -- both a science and an art and that bottom line of public health is change. We want people to change their behavior for better. We talk about demology and all that, and then there is how we get people to change their behavior. There is a lot there. I think most people confuse social marketing with health education. They are two different things. Health education, you're just telling people what to do, you know what's right, which they already know. So that doesn't change anything. Social -- you look at the behavior and see what can I do to make and create the change in behavior. We should try to transition from health education and give people the information but also try and initiate change. And that is my first comment. The second one is talking about innovative ways and thinking outside the box about funding and all that and I want to commend her for saying that risk reduction is the way to go. People will do what they will do and if you don't look at yourself inside their shoes and tell them don't -- [inaudible] -- if you're in a situation where you are -- what can you do to reduce that? And I just want to commend what you said. The last thing I want to say is--

WILLIAM SAPPENFIELD: Why don't we stop there so others. Two is plenty. Thank you.

>> Okay, thank you.

WILLIAM SAPPENFIELD: Someone want to respond?

QUESTION: I have a question for Dr. -- [inaudible]. The recommendation of non-bed sharing and both of them seem contradictory to breast feeding. [Inaudible]

LAUREN A. SMITH: That's a great question because clearly that is the -- one of the underpinnings for the controversy about things that happen when the recommendations came out in 2005. That the recommendations were going to undermine the efforts to increase breastfeeding. One thing to note is that looking at groups of women who are particular risk for having their babies die of SIDS also have and who do co-sleeping who have higher rates of co-sleeping have low rates of breastfeeding. So in certain groups of women the co-sleeping is not associated with breastfeeding. In that way, you can think that for some women co-sleeping is associated with breastfeeding and for other women it's not. Certainly for the women who aren't breast feeding. Although I think everyone should. For the women who aren't there is not really a rationale for co-sleeping in any sense. So I think that's one way of looking at it. I think the other issue is that the -- we need to have an additional understanding of for which sub population that connection is the strongest and is there a way that we can tailor our messages and our individual level counseling with that acknowledgement? But again I think we have to understand that for many people and as a clinician I -- that was why I got this idea of asking whether or not people were going to listen to what we said, for many people the idea of talking to them about their sleep position and sort of sleep environment is not something they even want to hear from their pediatrician. How to reduce the risk, not whether or not they should do it at all.

QUESTION: I'm from Nebraska. I had a quick comment. I look forward to seeing the continued results of this for Dr. Culhane. If you think of the Life Course model there was all that period before you got to those women that you can't effect and how are you we going to see the results play out over their future Life Course? Look forward to that long term view. In terms of Bill's challenge in terms of what we get from the other two presentations in terms of evidence-based, I believe and it's been shown that moms -- most moms love their babies and given all the practical considerations, they are making what they feel is best for the health of their baby and the physicians are making decisions that they feel are in the best interests of their patients. So as we are trying to get people to adopt evidence-based practices, it is on us and kind of like the first comment on social marketing, how do we fit that desire to do what they truly believe is best with what we truly believe is best? And I think that's the conflict.

Lauren A. Smith: That's a great point. One thing I would respond to what we've been wrestling with is this idea of when -- in what situations do you try to take the risk reduction approach and in which situations do you try to take a complete prohibition approach? An analogy would be the use of car

seats. We don't say it would be nice, you know, try to use car seats but if you don't put the kid in the back seat. We don't say that. We say, you know, all infants and kids under certain age need to be in a car seat and we're really clear about that. So I think what I'm sort of -- wanted to put out there was this idea at what level of evidence and in what situations do we switch which kind of approach we make and the sort of tolerance we have for sort of alternative or non-concordance \*\*\* about what our recommendations are? We don't have a clear understanding of when we need to be in one way or the other.

QUESTION: I'm from the University of South Florida and I really enjoyed all your presentations. Thank you so much. In thinking about evidence-based public health, I think part of our challenge is that we get whetted to our ideas that we think make sense and so by the time we get around to testing those ideas we've already been married to them. So it's really hard to divorce ourselves. If you think about pre-conception care, we have this entire movement and we're all gearing up for this and we haven't tested it and yet it sounds really good and it feels really good and it's the right thing to do but we've never tested it. So I think we have to look at ourselves and say, you know, this is a good idea but let's test it early on before we get so far down the road and we're so heavily invested in it. Then we're doing the catch-up thing to prove that what we did is working and we come up to the ideas of why and how it didn't work as opposed to saying maybe the way we're thinking of it isn't the right approach. I'm not putting down pre-conception, I'm using that as an example before you guys stone me. But you can get on the list of all the things we thought were really great things and it should work and we really like it but then by the time we test it, it is years after it's been ramped up and disseminated widely. I think we have to look at our own selves in the mirror and say what's the best approach to how we practice public health?

>> I would add to that we also need to be careful with what recommendations we start putting out until we clearly have what level of evidence. Bill.

QUESTION: First I want to thank the panel, too. I thought it was great. What I would respond to your challenge, Bill, of thinking about how to improve public health evidence-based access, I want to point out and I thought this whole conflict has been very exciting on this point. I want to just get us thinking about two different paradigms that relate to this. So evidence-based practice, is it science or is it engineering? Just point out to you this is an issue in quality improvement world. They're struggling with is there quality improvement? Is that science, the quality improvement do you have different approaches? I haven't -- I think of this both at science and engineering. How are we going to achieve what we want to do? I'd be interested in the panel's thinking about this. I think for public health we

have to be open to a wider range of thinking about how we make progress, how we help people, how we improve things and we need to think about both of those approaches. Some of us are totally whetted, you could hear the debate on the stage a little between, you know, when you summarized in the beginning what is public health evidence and clinical evidence? I think we need both the science but we also need the engineering that's quality improvement and I think we have to think about both. It doesn't solve this problem but it broadens the way we approach this kind of a topic. I do think we haven't thought a lot about engineering in our narrow focus, which I like the science, but I think we've not given enough thought to how we improve things, which really is actually kind of an engineering. Both of them very successful in our country.

Pierre Buekens: To the previous comment, I agree that quality assurance is really about making sure that the evidence is used in the field but here from a more dual perspective I'm still getting -- I'm still kind of wondering what happened with the last 30 years? 25 or 30 years ago public health was the field which was data driven. And clinical medicine was based on impressions and, you know, case reports and then there was a revolution. The evidence-based evolution in medicine where people started doing trials and doing systematic reviews and so on and it didn't happen at the same pace in public health so we have to catch up and we have to face it. And then the next step is how do you use the evidence on the quality assurance. Still saying that randomized clinical trials should be limited to medicine and not public health is committing suicide and killing our field.

WILLIAM SAPPENFIELD: It goes back to the two questions early on. Are we doing the right things? Are we doing things that are effective and are we doing things right? Are we actually doing those things we know we should be doing and do we know how to do them?

QUESITON: I think this is a fairly broad \*\*\*I can discussion. As we move our field forward we need to be thinking about our paradigms and how we think about evidence.

QUESITON: My name is John of the local health department in San Antonio. Dr. Anderson of the CDC said of her health statistics a few years ago wrote a people of SIDS deaths and he said basically there is no difference between SUIDI and SIDS death. SUIDI we don't know why the kid died. SIDS death is we really don't know why the kid died. The rates aren't going down. It's actually going down. When you add in deaths for co-sleeping, which we think well, you know, the reason the child died is because he was suffocated, well, we really don't know sometimes. And so if you really look at it, these numbers are not going down and yet we tell people they are and so what is the overall impact in our ability to be

believed and to have an impact when it's really -- if you really look at the data, you can see that SIDS deaths are going this way and SUDI deaths are going this way and it's a matter of shifting the case definition in order to be able to show that the data is going this way.

LAUREN A. SMITH: I hear what you are saying about the diagnostics shifts between categories. I alluded that that was an issue, although there is something to be said for the difference in a situation where a child is, you know, in a situation where they are in a crib or bassinet alone and they are put down alive and the next time the person goes back they're not. I think there is a difference in sort of thinking about the fact that -- the co-sleeping deaths, for example, that we're seeing the cluster of in Massachusetts. Not saying that you couldn't have the same sort of respiratory drive depression but if you have the idea the kid got wedged between the couch pillows, that to me is a different issue. So the idea that the other sort of deaths are going up doesn't necessarily in my mind undermine the effectiveness of the fact -- as a no-cost intervention by helping a subset of infant deaths. I think that there is still something to be said for that and I -- the only other thing I would say about that, why is it that this completely free intervention hasn't been as uniformly affected but I still think we have to address that at our level in thinking about how we do.

WILLIAM SAPPENFIELD: We're running out of time. I would really like to focus more on effective public health, evidence-based health practice more than one of the topics.

QUESTION: Emory University and I have a small technical question with a straight forward answer for Dr. Culhane. Why did you randomize after you obtained consent instead of before you obtained consent? Wouldn't it have given you more of a greater challenge how to address the hard to reach population if you had randomized first and then sought consent?

JENNIFER F. CULHANE: We can't randomized someone who hasn't consented. Consent to the project and then there is a pre-determined envelope that the interviewer opens right there and says nobody knows if she is in the intervention or a control group. It's all pre-determined and so once the woman consents, then right in the hospital the envelope is opened and it says you are in the intervention or usual care. I don't see how one would change.

QUESTION: I would like to talk with you afterwards. Thank you.

QUESTION: I'm from Birmingham. -- [inaudible] my answer is yes. Thinking yesterday's panel and today's panel Lisa Berkman was in Birmingham to share free lessons from her previous studies placing

people in the context chromosome sensitive etiology in the Life Course, studied subgroups and interaction effects in the trials. She shared three lessons. My interpretation is for physicians to become powerful persons in the community, those popular opinion leaders, physicians, supervisors, mentors and professors are powerful opinion leaders so they will make change in the local practice, make it sustainable. For me to learn from this I went to -- an IH funded project to learn venue based IV risk reduction among female sex workers. I learned those powerful opinion leaders have been tested in other displays HIV with -- for two decades. So my answer is yes, MCH people we can learn from other things for better public health practice, evidence-based practice. Thank you.

WILLIAM SAPPENFIELD: Thank you. You are the last person.

QUESTION: Thank you very much for the opportunity. I know there were two and I'm three. I really appreciate that. I have liked the evidence-based practices for a long time. I think they're very important structural differences. Evidence-based medicine is extremely well ruled. It is based on the harder data. It is easier to do trials. It is easy to define the fields on risk information, intervention, diagnosis and prognosis. It is based on very, very wealthy fine epidemiology methods and that's why the explosion in the area of evidence-based medicine at the same time of explosion of clinical epidemiology. So I think that it -- the main difference to the public health practices is has been embedded in the training curriculum of clinical \*\*\* and -- physicians and nurses is a requirement but public health it has not. We're taught epidemiology, we're not really taught how to use those tools to do what has been done in clinical practice. In clinical practices we went all the way around and we took epidemiological tools and went back to physicians and clinicians and taught them how to use the literature and how to differentiate what is good and bad and how to judge on them. So if you go as a clinician that has learned how to practice evidence-based medicine they will say I use a five-step approach. The first one is these and the second one is these. I do these, these, these. The second one these and these. If you ask the average or most of the public health practitioners that the practice is area based they say oh yeah. You say how do you do it? Well, you know, I have this paper for my intervention and these other for my program but I believe that we have lagged behind in the ways. I agree with Pierre's comments. We're 20 years behind from the field of clinical practice in developing a systematic approach to actually practice public health based on areas. And the second thing is I do agree that we have opportunities through clinical trials in public health but they are much more difficult to -- it is much harder to measure the outcomes. It is much harder to measure the variables, the associations are soft and based on soft viral data. So it is very, very logical to understand, then, why are we having so much difficulty despite

the paradigm of progress in evidence-based clinical practices into evidence-based public health practices? I think that we have to start thinking more not only outside the box but maybe from the beginning and start avoiding the paradigm of trying to use the paradigm of evidence-based clinical practices and try to develop something like that for public health because clearly the two things are way different and we really need thinkers on not interventions, not topics, but really what public health evidence-based is. That's my comment.

WILLIAM SAPPENFIELD: Thanks. Let's just take one minute to just thank our panelists for coming. They did an outstanding job and we really appreciate you guys coming. [Applause] Have a good evening.