10:45am-12:15pm – Outcomes Panel 1: Working with Multiple Health Behaviors (**Qualitative** Results).

Each project might address (10-15 minutes): 10:50

1. **Which behaviors did you intervene on?**
    a. The Mediterranean Lifestyle intervention targeted diet (specifically the Mediterranean diet), stress-management, physical activity, smoking cessation, together with different types of social support for maintaining improvements.
    b. This particular clusters of behaviors WAS amenable to a multiple behavior interventions,
2. **Describe your intervention (20 words).**
    a. The intervention began with a 2 1/2-day retreat to provide an experience of the new lifestyle, build camaraderie, and teach program components. Immediately following the retreat, the women began attending 4-hour weekly meetings that lasted, on a faded schedule 2 years. The weekly meetings consisted of an hour of physical activity, an hour of stress-management, a Mediterranean diet potluck and the last hour the women broke up into three smaller support groups.

3. Why did you choose these behaviors?
    a. This trial targeted postmenopausal women with type 2 diabetes who are at risk for CHD. Effective lifestyle management, especially diet and physical activity, is a core issue for diabetes control and prevention of CHD.
    b. They are modifiable lifestyle-related health risk factors and they tend to cluster
    c. And, there was a reasonably good knowledge base on each individual behavior in this cluster and methods for intervention

4. The reason we chose a multiple rather than single risk factor trial was that:
    a. As we got more and more into our work with comprehensive lifestyle interventions we realized that multiple risks are the norm in our target population (women with and at extreme risk for coronary heart disease), which suggested to us that the women could benefit greatly from a program that recognized this
    b. There was a progression our own work. Russ, Lisa and I had been working with diabetes populations for several years and had begun addressing both diet and exercise. We began reading about Dean Ornish, working with men with heart disease, who demonstrated reversal of coronary lesions and he added smoking cessation, stress management and social support to diet and physical activity. So, we decided to replicate his design first in a pilot study targeting postmenopausal women with heart disease, then with women with type

2 diabetes in the Mediterranean Lifestyle Program, and our latest effort with a Latina sample at KP in Denver.

c. I think historically, scientists have shied away from real-world, multiple-lifestyle interventions, in part because of perceived problems with recruitment and retention, treatment fidelity, the burden of intervening on multiple risk factors, time and expense, and dissemination. Studies of this kind are difficult but necessary in developing behavioral programs powerful enough to truly help people prevent or cope with chronic illnesses.

d. Other investigators were dubious of the intensity, and the generalizability. **When we proposed this program, everybody told us we'd never get anybody to sign up. When we got people to sign up, everybody told us they'd never attend. When we got people to attend, everybody told us it wouldn't change anything. When we got people to change, everybody told us it was because they wanted to please the interventionists. The bottom line is that this is a really powerful program, even with all its problems.**

5. How intensive was your intervention from the participant's perspective?

a. **Our intervention targets 5 health risk behaviors and consisted of a retreat to teach program components and weekly 4-hour group meetings. The program lasts for 2 years on a faded schedule.**

b. On the face of it, such a program may seem demanding for staff and onerous for participants. In fact, it IS demanding for both. The women expressed concern in the beginning. Once they go through the retreat, the women become so bonded to the program and each other they gladly invest time for the program, expressing gratitude for the opportunity to learn and practice healthful habits, and to make social connections with other women struggling with similar health issues.

c. After 6 months, Mediterranean Lifestyle program began fading to every other week, and at that point we re-randomized half the women to stop attending weekly meetings, and instead receive the remainder of the program with an interactive computer program. We practically had mutiny on our hands. The women had become a family, and we were villains ripping families apart.

d. Again in our Viva Bien program at the Institute for Health Research at the Denver Kaiser Permanente, (where Russ, Lisa and I and our colleagues are now replicating the Mediterranean Lifestyle program with Latinas), at first we wondered, "How will these busy women with these chaotic lives, ever get free to attend 2 years worth of 4-hour weekly meetings?" What we got was completely counterintuitive. The women in Viva Bien might have even more drama in their lives than

the Oregon women, and though we aren't re-randomizing half of them to a computerized intervention, as we are now beginning to fade the meetings to every other week, the women are panicked about the loss of contact with the program.

e. Our Viva Bien support group leaders thought that the 4 hour weekly meetings would be impossible, and that the women would have to get off early from work to attend the program, that they just couldn't do it. Now they are shocked about how people make it happen, time is not an issue, now they want more time if anything. Once the women experience the retreat and get bonded through the weekly meetings, asked if in future programs we should cut the time of the weekly meetings, the women say that initially they felt like 4 hours a week was too much, now they feel they would be giving up too much if it was shorter or we cut out anything.

f. Another of our support group leaders mentioned how interesting it is, and the women themselves have mentioned that, women from such different backgrounds in the support groups have become such good friends. Women who never would have been connected in any other way, or if they met in other circumstances, would not have become friends, and now have such a bond. They are all Latinas, but there are huge SES differences. The women have such a strong personal connection when so they are so different from each other.

g. It is possible that this type of bonding occurs because of the multiple components. Here they are exercising together, eating together, practicing stress management together, and then they have opportunity to talk and debrief. We wonder if the support group bonds would be as strong as if the women hadn't been through all the different program aspects together; this kind of bonding can happen with athletes on a teamor in a war unit, where you sleep in the same barracks, get mad at same drill instructor and a powerful bond is created.

h. Another of our group leaders mentioned that what they go through in our program is very intimate; they see each other sweat, cry, fall asleep, snore. They begin to know each other intimately. We don't think they would be as close if they were attending an hour meeting once every three months and not trying to accomplish so many lifestyle changes together.

i. If they came one time they would not make these bonds, they wouldn't be contacting each other outside the group and find themselves worried and caring about each other lives. They are now family, they think of each other as family.

6. Participant burden, Did the multiple risk factor approach place a high demand on your participants? Did they lose attention or interest? Answering this both in terms of intervention and measurement issues:

   a. Problem solving is used in the support groups to work with feeling overwhelmed by the program, acknowledging that when people make lifestyle changes they can get discouraged, noting that this is why the

group support is available to help them with motivation levels, which are driven synergistically by the level of success and support, and is also a key component toward keeping the women engaged and excited about making positive changes in life.

7. Is it easiest or best for people to make multiple changes at once, or to make them one at a time?
    i. **I do think that certain health behavior changes serve as a gateway to overall healthful lifestyle change. I am defining gateway behavior as a behavior that, when intervened upon, has a positive influence on other behavior changes. In our sample there is preliminary evidence that points toward this possibility as diet, and physical activity, and to a lesser extent support and stress management were somewhat related. Examining the effect of single behavior change interventions on other health behavior changes is a first step to further develop knowledge regarding potential gateway behaviors. The one behavior that seemed to stand out in our analyses at all time points was Physical Activity and it seemed to become more strongly associated with the other behaviors at 24 months.**
    ii. We think that with diet, physical activity and social support, a simultaneous approaches work best because diet and physical activity can have synergistic effects. If you have a successful work out, you feel more like going ahead and sticking to your healthful eating plan (the opposite can work also). And this has been corroborated anecdotally by the women. But in the MLP the support group also needed to be simultaneous, because in the group the women learn the problem solving skills so they can deal effectively with obstacles as they arise. So the program components are set up to work in tandem.
    iii. But there certainly might be other ways to do this
    iv. It is also possible that treating multiple behaviors may have a positive effect due to the multiple exposures to the principles of behavior change. But we haven't tested that.
    v. There are some key behavioral constructs and processes that are common to the targeted behaviors so multiple-risk factor interventions could be designed to efficiently involve key common elements such as setting goals, identifying obstacles to achieving those goals, identifying strategies to reaching the goals, marshalling supportive resources in a more efficient fashion

8. And, while the efficacy of goal setting is generally accepted, the question of whether it is better to formulate easily achievable goals or more challenging goals remains unresolved. In the context of a multiple behavior intervention perhaps it makes sense to set more easily achievable sub goals. On the other hand, theory suggests that more difficult goals will lead to more behavior change and better outcomes, at least until the goals become impossible to attain.
9. **What are the cost, and time intensity issues?**
   a. This was an intensive intervention that continued for 24 months and the costs of ongoing group meetings added up to a large sum over time.
   b. **We have done an explicit cost and cost-effectiveness analysis to determine how costly the Mediterranean Lifestyle Program intervention is and how that compares to alternatives and other diabetes and CHD treatment options.**
      i. **The costs of our program are much less than those of the Diabetes Prevention Program and Look Ahead (which relies on highly trained leaders and medications.**
      ii. **The costs are vastly lower than coronary bypass surgery, which consumes more health dollars than any other medical procedure in the U.S.**
   c. **Both the cost and the cost-effectiveness estimates are relatively high compared to lighter touch programs.**

      In case someone wants to know the costs of MLP:
      Total intervention costs were estimated at $211 061 ($148 022 direct costs) or
      $1295 per MLP participant relative to usual care ($908 direct costs). This translates to $3808 per average change in coronary heart disease risk as measured by an average 1-point reduction in hemoglobin A1C. Relative to other measured improvements, this corresponds to $2345 per unit reduction in body mass index and $644 per unit improvement in Problem Areas in Diabetes Quality of-Life Self-care Summary score, and a $196 per-gram reduction in intake of saturated fatty acids as noted by the Food Frequency Questionnaire. A significant portion of the direct costs were related to the resources used during the recruitment phase.

   d. There are other practical and public health implications of our results. Our participation rates may be influenced by the fact that participants were not charged for the program. If it were to be widely adopted, either patients or their health plans would have to pay, which could reduce participation.

e. On the other hand, participants in this study had to agree to randomization, and to complete lengthy surveys and biological assessments, which would not be required in clinical settings.
f. **Certainly alternative or less-expensive approaches could be developed. The women who participated in this trial were at extremely high risk for further CHD-related diseases, which are major causes of health care expenditures as well as mortality. For them, a program with this level of intensity may be warranted, as the overall cost of the intervention is considerably less than invasive surgical or even some intensive pharmacologic or cardiac rehabilitation interventions.**
    i.
g.

10. In terms of what we would like to do differently next time,
    i. One limitation of the Oregon program was that intervention effects were not as strong 12 and 24-months as they were at 6 months.
    ii. When you think about medication for chronic illnesses most of the time you don't start taking the medications every other week, and then once a month. You don't get to eat a healthful diet every other week or once a month.
    iii. So the question is how to keep people doing these difficult multiple heath-related behaviors over the long term with less intensity and lower costs? What we are trying that is new with Viva Bien (besides adapting to the Latin culture) is a revision of the support group component of the intervention in an attempt to strengthen participants' use of social-ecological resources and maintain their use over time.
        1. We introduced a variety of activities in the support groups that we did not explicitly include in the Mediterranean Lifestyle program
            a. Sessions focusing on negative self talk
            b. Problem solving
            c. Asking for support
            d. Behavior chains
            e. Contests like a 10-day no sugar club
            f. Restaurant activity
    iv. The other thing is whether or not this is generalizable; so we could see if there is a less intense way to capture the essence of the bonding that occurs as a result of the retreat, and the weekly meetings, including the structured support group experience and still target multiple risk factors
    v. We need more studies addressing the additive and/or synergistic effects of our interventions

vi. It would be interesting to compare the all at once approach with sequencing the introduction of each behavior and then also examine "spillover effects" of change in one lifestyle behavior on change in other behaviors.

vii.

11. Do people only have so much motivation and they can't spread it around? Do you have to use your motivation on basically one thing at a time?

    i. We haven't studied this directly, and my answer to this is just based on what we hear in the support groups. The program seems overwhelming at first, but the women feel so much better once they begin doing all the pieces, that it actually leads to doing more and more. I think it really helps that they come to the meetings every week and actually practice each part of the program, and they keep meeting and practice for longer than a lot of programs.

    ii. The other things we have heard from the women is what is nice about the program is that you can find something to be successful at; while we teach all the program components simultaneously, if may be they are not ready to do the diet, there are all these other pieces they can be working on. We don't kick them out if they don't make all the changes perfectly and all at once. The idea also is that being successful in one behavioral area can foster development in another area.

    iii. Some women are ready for certain changes and some are not but with the large group format multi behavior change allows for that heterogeneity; a woman who is not ready for pa but the woman sitting next to her is doing well in that area and she sees another person having some success with PA; that experience might help that woman begin work on the other areas.

    iv. And the breadth of improvements was striking. The MLP produced consistent and significantly greater improvements than the UC in all of the four diverse CHD behavioral risk factors targeted—eating patterns, physical activity, social support, and stress management. There were too few smokers to analyze tobacco use effects. It is difficult to produce lasting improvements in single behavioral risk factors, and the demonstration of sustained effects on both multiple behaviors and potential underlying processes has been encouraging.

12. Is it your sense that there were other mediators or moderators, environmental, or psychosocial factors that interacted with your intervention; or that might intrude on the multiple behaviors- e.g. depression?

    a. Regarding moderators, or variables that show significant interaction effects with the intervention MLP data, we tested a boat-load of variables and none interacted with treatment.

b. Anecdotally, the group had a very high rate of stressors including children in jail, lawsuits, deaths in the family, major illnesses, in both our Oregon and Colorado samples. These things affected attendance.
c. In terms of mediators, our results showed that changes in the social-ecological resources mediated intervention effects on diet, exercise, and some biological outcomes
d. We think that supportive resources were activated by our intervention in a key way. For over 20 weeks, MLP participants met with other support group members and leaders to help them express feelings, to mobilize active coping with illness-related problems, and to encourage group support for health-related problems and solutions.
    i. Although it would be tempting to attribute changes in social resources solely to the social support group component of the MLP intervention, the study was not designed to evaluate each intervention component independently. It would have been premature (and very costly) to design a study to evaluate the four individual components of MLP before establishing that the comprehensive intervention affected the mediators and outcomes.
    ii. Even though the largest program effect on mediators and outcomes occurred at the first follow-up, some mediational effects were found at the 2-year follow-up for the model of fat intake and for the model of physical activity.
    iii. It has been suspected for a long time that the link between social support and mortality might be explained in part by health behaviors. People who are embedded in supportive social relationships take better care of themselves. That mechanism can be mobilized in interventions such as the one tested in the current study.
    iv.

13. Are intervention effects diluted?
    a. If the intervention promotes concurrent action in multiple behaviors, it may be overwhelming to the participant and result in poor adherence.
        i. Results of the Mediterranean Lifestyle Program suggest that many of the challenges associated with a multiple-behavior intervention may be successfully overcome. We delivered an appealing, intense multi-behavior program to a relatively high and representative percentage of older, chronically ill women. The program consistently produced significant improvements compared to usual care encompassing all of the four diverse CHD risk factors targeted:
            1. eating patterns, physical activity, social support, and stress management.
        ii. While some of the changes were small (i.e., servings of fruit and vegetables increased by only .5 servings) and of debatable

clinical significance, the intervention succeeded in changing multiple behaviors.

14. Do you see larger increases in one behavior and less on another?
    a. Our strongest effects were with diet and physical activity; stress-management was our weakest effect.
15. If only have so much time, do you want to employ a weaker intervention across multiple behaviors?
    i. It is hard to imagine how weak an intervention really can be and still be effective.
16. Do multiple behavior interventions have to take more time?
    i. In terms of MEASURES: A limitation of the multiple risk factor trials is the relatively large number of measures, that are necessary. In part this is because many of the available tools either do not assesses all of the domains of interest, or if they do, they are not of sufficient brevity to be practical when paired with the other outcomes.

17. If multiple behaviors were targeted, how did you handle sequencing?
    a. See above and note that We threw the entire program at them beginning with the retreat. So can't really comment on this one.
18. What were your 1-3 key QUALITATIVE lessons learned
    a. Co-occurrence of multiple unhealthful behaviors anything stand out?
    b. Did the targeting of one cluster of behaviors relate to other non-targeted behaviors?
        i. We didn't target weight loss per se, and while we were of course interested in A1c, a measure of diabetes control, it is not something you can explicitly target in a behavioral intervention. But both of these outcomes were significantly improved at 6 months, but there was not a strong or consistent relation with the individual behaviors, or clusters of behaviors
        ii.
    c. Did success in changing one or more lifestyle behaviors increase confidence or self-efficacy to improve other risk behaviors that individuals had low motivation to change?
        i. Self efficacy was one of our stronger effects, but we have no way to evaluate whether or not it affected other risk behaviors as we didn't measure them.
19. Given limited contact opportunities for health promotion, do you support the notion that it would be ideal if interventions could simultaneously improve multiple risk behaviors relevant to an individual's health profile?
20. If multiple health behaviors are targeted for change, are there challenges regarding increased behavior change demands and program complexity?
21. Was there an increased overall positive impact on an individual's health?
22. Intervention approaches specific to multiple behavior change which may facilitate greater adherence and overall change.
    a. Sequencing change goals

b. Matching intervention strategies to individuals' psychosocial characteristics. Are there possible psychosocial constructs that may be targeted in multiple vs. single risk factor interventions that make success more likely?
c. Adaptive designs
d. Are the intervention participants more likely to change one risk behavior relative to another?

23. After your current experience what do you think would have the given the biggest bang, and what could you have done differently to sustain changes over time?

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i. Hard when we start going every other week and then once a month, very hard on the ladies, that their connection is starting to be severed, their connection isn't the same when they fade, it takes a toll, you can see it becomes harder for them; they all talk in the beginning about how it will be easier on them when we go to every other week, but then when that time approaches to begin fading they feel like we are severing their ties
ii. The women are exploring ways to continue meeting on their own, one group pulled together all on their own, and got a reduction in a Y membership so they could continue meeting and exercising.