Moderator: So, our first presenter is Hayden Bosworth who’s going to be presenting telemedicine cardiovascular risk reduction Veterans. They’re a CITIES trial.

Hayden Bosworth: Good morning everyone. Let’s just jump right in here. So, I’m going to talk about a trial that we just completed and it’s using pharmacists to implement focusing on individuals with cardiovascular risk that are at high risk. One of the pieces of why we looked at the pharmacist was looking at trying to figure out where there better ways to provide care given some of the limitations and competing demands in the primary care setting. So, \_\_\_\_\_ [00:00:50] using phone calls and I’ll go through more detail. This occurred with the outpatient setting using as I said, a clinical pharmacist.

 Our objective for this study was to look at a comprehensive risk factor management intervention delivered by a clinical pharmacist could reduce cardiovascular risk and we assessed it through the Framingham Risk Score. And secondary outcomes were blood pressure and lipids over twelve months. So, the setting was a primary care setting. The inclusion criteria as you can see, greater than forty years of age at baseline. Part of that was in terms of calculating the Framingham Risk Score and that we wanted to at least a higher level to start off with. Individuals had to be engaged with the healthcare system so we operationalized that as one visit to the primary care.

As you can see we defined poor blood pressure control as greater than 150. At the time when we started this study the LDL guidelines and so we used individuals who are greater than 130. One lesson with all this is what happens over a long period of time with a trial, how things change and how you adapt. You’ll see that adaption is really the fundamental aspect of this trial. So, I’ll come to that. It’s just a cliffhanger for you all.

In terms of study flow we identified approximately thirty-four hundred individuals and then we contacted twenty-one hundred and randomized four hundred and twenty-nine to the education, which I’ll mention momentarily, and then the pharmacist intervention. Let me talk a little bit about what the intervention was. It was supposed to be twelve months and every other month with a clinical pharmacist calling the patients. It was focusing on med management with hypertension, diabetes and hyperlipidemia. The clinical pharmacist was able to make changes in regard to the medication and was able to follow up with labs, if necessary, as well as put that into the EMR. We can talk later but it’s one of these issues do you do the fishing or do you teach people how to fish. In this case the goal was initially trying to do the fishing if you will, with the pharmacist taking that responsibility.

In terms of just cholesterol, just to go quickly, it was using at the time as I said, looking at LDLs, low density lipoprotein, and basically we created an algorithm for medication for individuals with a goal of trying to get below 100. Blood glucose. Not everyone was diabetic but for those that were we basically tried focusing on self-monitoring or as you can see, focusing on oral hypoglycemic medications. One of the lessons we learned early was that it was really hard to do glucose monitoring particularly if insulin was initiated over the phone. That was another part of the project that we ended up having to change because the amount of time that was required trying to explain this and trying to support somebody to do this over the phone. We focused on ADA [PH] guidelines at that time so as you can see, less than 7% A1C.

One aspect which is based upon some of our prior work is the use of home blood pressure monitoring so we trained individuals how to use that. We instructed them to use it every other day and we then we’ve previously used and algorithm that if values are greater than 135/85 for those who are nondiabetic and those who are diabetic slightly lower. We received about a five point change in this population and so that was what we used over a two-week average. We usually say do it every day but if they gave us four measurements over that period of time we documented that’s pretty valid to if necessary, make changes. The other parts of the intervention was just self-management. It was a tailored behavioral intervention focusing on knowledge, risk perception, smoking, diet and exercise. If there’s opportunity later if there are questions I can go into greater detail regarding those components.

The education control group got material at baseline in six months. This was generic information and not tailored to where they were but basically trying to help them support reducing CVD risk. Our analysis, as I mentioned, were primary outcomes looking at risk as measured by Framingham. We looked at differences over a baseline six and twelve months. The surprise here was we had a pharmacist who was the interventionist and unfortunately got sick and was disposed of for approximately six months which really had a pretty big impact on the trial itself. It was more of an efficacy trial but in many ways represents what the real world is. You can’t control when people get sick. Subsequently, we’ve tried using multiple people as backup when we do this. But, no one got all twelve calls and we defined compliance as completing at least five phone calls. We, fortunately, have a very good statistician that used a complier average causal effect analysis and I’ll talk a little bit about that but able to kind of account for the high and low compliance. You can’t just simply say well somebody’s compliant or not. How do you account for that?

In terms of just demographics this generally represents our population and again as you can see the CVD risk board, down there, represents a thirty-two percent likelihood of mortality over the next ten years. So, really a reasonably sicker population but also subsequently in pretty good control regarding blood pressure despite us trying to get those people who had a greater than 150/100 over the last twelve months. The other part is low literacy level. Approximately thirty percent low literate. Okay. So, just to kind of frame the engagement, eighty-two percent completed the baseline to twelve month follow-up. As I already mentioned the mean number of calls completed was only 3.6. So, we were trying to reach them every month. Only thirty-four percent got all five or more calls. Then, the median time spent on the counters ranged from thirteen minutes to forty-one minutes. The more forty-one minutes in general was when we started focusing on trying to do insulin management over the phone which just took too much time.

In terms of primary outcome, as I mentioned, our baseline was a thirty-two percent likelihood of mortality. In six months you can see unfortunately in both arms, decreasing. But, as I would just point out here, and this is preliminary data. This is using this complier’s analysis. But we found about a 5.7 percent decrease in mortality which is clinically meaningful but it did not sustain and I think part of that is just a lot more missing data in the back end. In terms of secondary outcomes, similarly decreased but nothing really clinically meaningful except within the case again here, about a 3.5 which is pretty minor and nothing much with the cholesterol. So, in conclusion, the lack of findings may be, again, only thirty-four percent got greater than five of the planned twelve phone calls so the full dosage was never implemented. It’s always difficult to know how much time to spend regarding behavior over the phone. That was, on a monthly basis, I don’t think for this population probably was the most intensive. Again at baseline, as I mentioned. There was, despite our chances and efforts, the population was reasonably controlled regarding at least the blood pressure and LDL.

So, the Framingham risk score is race, gender and diabetes yes or no. Some of the factors are not the most modifiable and that may not have been the best outcome. There was also the potential for coinvention going on. In summary, the intervention didn’t approve overall risk related to education control but in sensitivity analysis we do some indication that there was an impact at six months at least and did not persist at twelve months. This is our group and acknowledgements and the rest of the teams. Thank you.

[Applause]

Hayden Bosworth: Oh all right. I’m told that I have five minutes for questions. Yes Sundar. Apparently we’re being televised. I don’t know why.

Sundar: Very nice talk. I was curious about the proportion of missing data you had in six and twelve months and what you did for that.

Hayden Bosworth: I’m sorry what was the last part?

Sundar: How you accounted for that.

Hayden Bosworth: That was that case analysis that I mentioned there. It’s trying to account for individuals that had more data versus those that don’t. You can’t just simply look at engagement, yes or no. Because there was also an issue regarding timing. So, the people in the beginning of the study, before the pharmacist got sick, were more likely to get exposure. The other issue is in a trial you have to make sure there’s fidelity. There’s a potential difference in fidelity early on so the analyses try to account for that. Steve.

Steve Ash: Hey. Steve Ash [PH], Palo Alto. So, I can call it an implementation problem and you seem appropriately disappointed, just like I would be if that had happened. Could you put this in context of the general telemedicine literature? Do many of them have implementation problems? Have most of them been effective in behavioral change?

Hayden Bosworth: Yeah. I mean, the more I’ve done this the more I see that there’s nuances. To answer there is no yes or no. I think the role of the clinical pharmacist is still probably less developed. I think there’s issues regarding the cost of them. I think that they’re not necessarily used consistently across. A side note, would be we generally find more effective results with nurses because they’re much more likely to follow fidelity as I already eluded. The pharmacist started doing insulin titration over the phone. We planned that but realized that when you have a pharmacist you can’t just stay in that box. No offense to anybody who is a pharmacist. But, I think we’re doing this trial now for CKD, chronic kidney disease. I think for really, really challenging individuals it’s probably appropriate. Trying to figure out dosages of the interventions. So, something like this I don’t think we would follow up and probably use a pharmacist moving forward.

Steve Ash: Thank you.

Carri Nelson: Hi. Carri Nelson [PH] from Seattle. I had a question about what training the pharmacist got in behavioral change counseling. Or, what was the strategy there.

Hayden Bosworth: Yeah. So, motivational interviewing everybody uses it. We went through that training. So, she practiced with patients and we followed and looked at it and we followed fidelity in terms of tape recording the conversations and things. I think we never give them enough training to do behavioral work so I think that’s always ongoing. Most of the material here was scripted. So, if they follow the directions we were pretty good and there was tailoring based upon levels of motivation and things like that. But if there was somebody really saying I just don’t want to do it I think we were probably somewhat challenged in that respect.

Carri Nelson: Thanks.

Hayden Bosworth: Thanks.

Jeff Colgern: Hi. Jeff Colgern [PH] from Ann Arbor. I just also have a follow-up clarifying question about the clinical pharmacist and who exactly that person was. Was that somebody who was embedded within a pact and thus was there at the potential for them also to be interacting with the control patients? Looking for other potential explanations for your null findings.

Hayden Bosworth: Yeah. So, she was involved. The people knew who she was. She had practiced previously but we pulled her out of the clinical responsibility given the amount of time that was required initially for the intervention. I think that a piece would be that most of our other trials that have been more successful have had individuals who were embedded within that. I think there’s a trust issue and some other issues that go on with that. So, the problem is you still have some of the issues regarding the amount of detention and how do you protect their time. Here we just wanted to, as I said, frame it as an efficacy which I guess we’re now in an implementation, I don’t know. Given the challenges that we’ve experiences. But, I think if they were in the pact the issues of contamination would be something we’d have to consider.

Jeff Colgern: Okay thanks.

Hayden Bosworth: Thanks.

[End of audio]