

LinCS 2 Durham CC Meeting

March 14, 2011

Durham County Public Library, Downtown Branch in the Auditorium

6-8pm

Facilitator: Randy C. Rogers

Note taker: Alexandria Horne

Attendees:

Community Members: Tonya Stancil, April McCoy, Kendra Batten, Chris Reed, Noah Powell, Caressa White

Research Team: Kia Caldwell, Kate MacQueen, Debbie McGill, Natalie Eley, Malika Roman Isler, Michelle Laws, Marcus Hawley, Eunice Odhiambo, Alexandria Horne, David Jolly

Special Guest: Dr. Tim Mastro, FHI, Inc.

CAPRISA 004 Study Highlights presented by Dr. Tim Mastro

- 1994 AZT was given to pregnant women to prevent HIV transmission to children.
- First microbicide to show evidence that it works
- Use of antiretroviral before the exposure could prevent sexual transmission of HIV
- First gel effective for women
- First study jointly funded by the US and South Africa
- First study led and designed by African scientists
- 95% retention rate
- The women can have the control of protecting themselves
- This is the first step, but they would like a second trial.
- Could prevent 1.3 million new HIV cases and over 800, 000 deaths

Prevalence of pregnant women in rural Vulindlela (slide)

- 1 out of 10 16 years old girls have HIV
- By the age of 25, 50% of women are infected with HIV

Tenofovir Gel

- BAT 24 gel use
- Used once before sex (insert up to 12 hrs. before sex), and then within 12 hours after sex. Not used twice in 24 hours.

- The gel did not show any resistance. Also in the study the women had to be on birth control to limit any negative effect of the drug on the fetus with the product

Question: In different parts of Africa, it is a rumor that if a male is infected with HIV and has sex with a virgin, he can be cured from HIV. Is this true?

Answer: Dr. Mastro shared there was not truth to this myth. Kate responded she had heard this myth but she didn't think that this was an issue in this community.

Question: Was it common to use other forms of STI (sexually transmitted infections) treatment? Was there access to other forms of prevention?

Answer: Condom promotion was in the project. Women were screened for other STIs and pregnancy during the course of the study. STI education, and HIV prevention education was provided, as well.

Question: Was the study 24 months?

Answer: The women could stay on the product for two years. Katie shared some women stayed on the gel for three years.

Question: Was the study halted because it was so successful.

Answer: The study remained during the lifespan of the study, as outlined in the protocol.

Findings:

Reduced infection by 39%. The women who used the product the most had a rate of 54%. Also, it had a 51% prevention rate for herpes simplex 2.

Questions: Are there any plans to do a similar study in the US? I am thinking about the cultural differences especially with African American women.

Answer: Currently, there is not a similar study in the US. There are safety studies, to make sure that there is no harm. It needs to be a large population of HIV cases to challenge the product. ISIS study is being looked at to study acceptability, education.

Question: Were questions asked about the health status of their partners?

Answers: The men were not a part of the study. 50% of the women were already infected with herpes so you could presume that 50% of the partners were also infected.

Question: Are there effort to use the same technology for anal sex?

Yes there are for men and women. Rectal sex reported by the women was very rare.

Question: Could the placebo cause any rates of infections?

We believe it is very safe and there is no active chemical, and it is almost like KY. It may have served as a barrier to potential infection.

Question: What was the frequency of follow-ups?

They came in every month.

Question: How was the study able to have such a high retention rate?

High community engagement, consultation, good customer service by the clinics, and monetary incentives contributed to the high retention rates.

Question: Women commit themselves and then the study ends. So what happens?

The women are not getting the product now. If there was availability the women on the placebo would have gotten the active medications.

Question: For the ones that did get pregnant how did you track to see if the product didn't harm the fetus?

Women come in every month, and received a urine test. The study followed the women throughout their pregnancies to make sure that their children were safe.

Question: In the first study, it said that there was one death?

She was struck by lightning.

Question: What happened when their partner found out they were in the study?

There was a hand full of social harms. There was a case when the partner became angry: they were able to bring in her partner to resolve the issue. One case a woman got fired from her job, but she continued to stay in the study. I can only think of one case when a woman dropped out of the study. (Kate)

Question: Did their partners know that they were enrolled in a study?

Many women reported that they told their partner they were in the study; however, they did not always tell them what the study was about. (Kate)

Question: Were the men more receptive because they were getting compensation from the study?

I am not sure.. I am not sure how much control the men had over the women. (Kate)

Question: How did you follow-up? Was there a code name for the study?

This was a very sensitive area. They wouldn't identify themselves as HIV researchers and there were no long detailed messages left with study participants.

Question: What kind of work did you do in the communities to help eliminate some of the distrust?

The community leaders came to the study, the researchers were also members of the African community, ongoing outreach and a strong community presence made a positive impact with establishing trust.

PrEP Initiative

This study was done with men who have sex with men (MSM). The idea was for a study participant to take a pill before they engaged in sexual activities.

- Half took the active medication. One pill a day
- Half took the placebo
- High level of follow up
- Received other HIV prevention items.
- 100 participants became infected
- Effectiveness- 44%
- 73% effective of men who took it 90% percent of the time
 - Pill counts
 - Drug levels
- No moderate to severe toxicity
- There was no resistance

Question: When do you stop using the placebo when it has proven that it works?

The drug for MSMs is beyond that (Truvada). The CDC should be approving it, and open it for distribution very soon. In some cases, there isn't enough data to approve this method. And it is a very long and difficult process to be approved.

Small Updates:

An executive decision has been made to table the TAB at this time, until we have more representation from the target population. We will re-visit this opportunity, based on the need and reception from the target population.

Making sure that LinCS 2 Durham is being responsive to requests made versus being self-promoting at extended invitations in the community.

Carissa White: (presentation at Russell Memorial Church)

Make sure we assess the community's readiness about research. I don't think they were ready to hear about everything LinCS 2 Durham is endeavoring to do. I believe we lost our audience. We need to understand what they are wanting and not push our agenda, especially with the body of faith community.

ISIS did use community involvement before they spoke about what ISIS wanted to do. It is important to build a transparent relationship.

Michelle:

We need to tap into faith community members (religious leaders) who have a significant influence on various segments of the community. Michelle used Minister Rhonda Royal Hatton, as an example.

Tabling agenda items:

CC's Compensation and Involvement

Upcoming CC Meetings

Monday, April 18th, Stanford L. Warren Library in Rm. 1, 6-8pm

Monday, May 16th, Stanford L. Warren Library in Rm. 1, 6-8pm