CAB Conference Call
February 27, 2020
12:00 EST
Meeting Minutes

Participants:

Andrea	Jacobi Medical Center
Anisa	Harvard University
Antionette	University of Miami
Carol	Bronx-Lebanon Hospital Center
Claire	Harvard University
Delia	University of Miami
Falon	University of Colorado, Denver
Gena	University of Miami
Gloria	University of Florida, Jacksonville
Haleigh	FSTRF
Jarmel	University of Illinois, Chicago
Jennifer	San Juan Hospital
Joel	University of Puerto Rico
Julie	Westat
Kate	Harvard University
Kimbrae	Texas Children's Hospital
Kylie	Texas Children's Hospital
Latonia	University of Illinois, Chicago
Lesley	Texas Children's Hospital
Liz	Harvard University
Lourdes	San Juan Hospital
Megan	Westat
Morten	Bronx-Lebanon Hospital Center
Raiko	University of Colorado, Denver
Sharry	University of Southern California
Stephanie M.	University of California, San Diego
Stephanie S.	University of Miami
Tracey	University of Illinois, Chicago
Veronica F.	University of California, San Diego
Veronica S. R.	University of Puerto Rico

• APPROVAL OF MINUTES

The minutes from the January 23, 2020 call were approved with no changes.

• ANTIRETROVIRAL (ARV) PRESCRIBING PRACTICES PAPER – DR. KATE POWIS

Dr. Kate Powis reviewed her paper, "Antiretroviral Prescribing Practices Among Pregnant Women Living With HIV in the United States, 2008-2017."

Since 1994, the United States Department of Health and Human Services has put out guidelines about antiretroviral medications (ARVs). The guidelines have information about what kind of ARVs should be used in pregnancy. The guidelines are based on what ARVs are the best at lowering viral load (amount of HIV in the blood), and what ARVs are the safest for the mom and baby. In the guidelines, ARVs are put into categories. The categories are preferred, alternative, and special circumstances. There are also categories for insufficient evidence for use in pregnancy. This refers to ARVs that have not be studied

enough in pregnant women. There is also a category for ARVs that are not recommended for use in pregnancy. These ARVs are not recommended due to safety issues.

Previous research has looked at changes in ARVs over time. However, before this study there were no research findings comparing the guidelines to what ARVs doctors were actually prescribing.

Researchers looked at data from women enrolled in SMARTT from 2008-2017. They looked at the first ARVs women were given during pregnancy. The researchers looked at differences between the following groups:

- Women who were taking ARVs prior to becoming pregnant;
- Women who restarted ARVs during pregnancy; and
- Women who started taking ARVs for the first time during pregnancy.

It was important to look at these groups. This is because the research team could see differences between the groups. For example, many women who were undetectable prior to becoming pregnant would stay on their same ARVs. This may be true even if they were not the preferred ARVs. This may be because the ARVs were working well for those women. Therefore, doctors would not want to switch them off of those ARVs if they were working well.

The researchers looked at which ARVs were prescribed. The researchers looked at the number of pregnancies. Women may have contributed multiple pregnancies to the analysis. Women may have also been in different categories based on their pregnancies. For example, a woman might have started taking ARVs with her first pregnancy, and restarted ARVs during her second pregnancy.

The study involved a total of 1,867 pregnancies of 1,582 women. The researchers found the following:

- 42% of the pregnancies involved women were taking ARVs prior to becoming pregnant;
- 34% of pregnancies involved women who restarted ARVs during pregnancy; and
- 24% of pregnancies involved women who started taking ARVs for the first time during pregnancy.

Less than half of the pregnancies involved women who were given ARVs that were preferred or alternative per the guidelines. A total of 26% were given ARVs that had insufficient evidence for use in pregnancy. A total of 7% were women who were given ARVs that were not recommended for use in pregnancy due to safety concerns.

It is important to understand the data by when women started taking ARVs. Researchers found the following:

- Among women who were taking ARVs prior to becoming pregnant, only 36% were on preferred or alternative ARVs;
- 52% of those resuming ARVs in pregnancy were given preferred or alternative ARVs; and
- 70% of women who were starting ARVs for the first time during pregnancy we given preferred or alternative ARVs. That means the majority of women starting ARVs during pregnancy for the first time were given preferred or alternative regimens.

The researchers found that ARVs with insufficient evidence for use during pregnancy were prescribed to the following women

- 34% of women who were taking ARVs prior to becoming pregnant.
- 25% of pregnancies in women who restarted ARVs during pregnancy; and
- 15% of women starting ARVs for the first time.

Only 5% of pregnancies in women starting ARVs for the first time and 8% of pregnancies in women resuming or on treatment at the time they become pregnant were given ARVs that were not recommended.

The guidelines offer great advice. The guidelines encourage women to have a say about what ARVs they should be taking. Doctors are encouraged to adjust the ARVs if they caused problems for a woman in the past. Doctors are also advised that if a woman developed resistance to a specific preferred ARV, another ARV should be given. Recommendations based on previous side effects and drug resistance only applied to women who had already taken ARVs.

It is important to note that the guidelines changed over the years. This means that woman may have been taking ARVs that were not preferred at the time, but over time, research showed that they were now preferred. For example, the ARVs taken by 88% of women who were taking ARVs for the first time during pregnancy in 2015 ended up being reclassified as preferred or alternative in later years. This means that it ended up being safe for these women despite being unknown at the time. These included darunavir with ritonavir, atazanavir with ritonavir, rilpivirine, and tenofovir.

The researchers looked at reasons why women were given preferred or alternative ARVs. They only looked at women who were starting ARVs for the first time or restarting ARVs. This is because there was usually a good reason for women who were already taking ARVs to continue their ARVs. Among women who restarted ARVs, the average reason they were given a preferred or alternative regimen is because they had a viral load greater than 1000. In this case, they were twice as likely to get preferred ARVs than women who had a viral load under 200. The researchers want to study this finding more in the future.

The researchers also looked at women who were starting ARVs for the first time. The average reason for getting preferred or alternative ARVs was timing. Women who had babies before 2014 were much more likely to be given preferred or alternative ARVs than those between 2014-2017. This might be because there are many more ARVs available now.

The researchers found some other interesting information. They noted some "regimen switches." Regimen switches happen when a woman started on one ARV during pregnancy and then changed to another. These switches happened in 14% of pregnancies. Researchers found that the following women had an ARV switch:

- 19% of women who were taking ARVs prior to become pregnant;
- 12% of women who were restarted ARVs during pregnancy; and
- 8% of women who were starting ARVs for the first time during pregnancy.

Other interesting findings included "regimen intensification." This means the ARV regimen was increased during pregnancy. This included adding another ARV, or increasing a dose. For example, integrase strand transfer inhibitors are sometimes added because they lower viral load quicker than other ARVs. Only 10% of women had this happen. Researchers found that the following amount of women had a regimen intensification:

- 12% of women who were taking ARVs prior to become pregnant;
- 9% of women who were restarted ARVs during pregnancy; and
- 6% of women who were starting ARVs for the first time during pregnancy.

Researchers did not look at whether women had a prior side effect from a specific ARV (such as headaches or upset stomach). It is possible that some women were given certain ARVs because of side effects.

Overall, researchers found that the ARVs doctors prescribed to pregnant women living with HIV did not match well with the recommendations. Even though some ARVs were not preferred or alternative, all were approved for adults. This might mean that there is not a lot of research in pregnant women.

Therefore, it takes longer to see if an ARV is safe and will work well in pregnancy. More research is needed.

Dr. Powis asked whether CAB members felt they were given a choice of ARVs to take during pregnancy. **Lesley** talked about ARVs in pregnancy. In her first pregnancy, she did not have a choice. **Lesley** stated that if she had another pregnancy, she would want to use the same ARVs she took before since she knows they work. **Kim** talked about ARVs in pregnancy. **Kim** stated that women who found out about their HIV status during pregnancy may be too nervous to ask about which ARVs to take. Many women may just go with whatever the doctor says first. It may be hard to ask questions. **Sharry** talked about ARVs in pregnancy. **Sharry** stated that she felt her doctors knew more about all the ARVs than she did. She liked that her doctors helped her choose her ARVs.

Stephanie M. asked whether the researchers thought about whether ARVs were covered by health insurance. **Dr. Powis** explained that every ARV in the guidelines is covered by the Ryan White HIV/AIDS Program.

Megan asked about how often the guidelines changed during the study. **Dr. Powis** explained that the guidelines changed nine times from 2008-2017. This means researchers had to measure for that in analysis.

Dr. Powis talked about next steps for the study. The researchers want to focus on women starting ARVs for the first time during pregnancy. Researchers want to do more studies to understand why so many women starting ARVs during pregnancy were given ARVs with insufficient data. It could be because doctors know more than the guidelines. It could be because of women's preferred interests. Researchers want to learn more about where women and doctors are getting their information. They also want to help doctors help women understand why a regimen might be the right fit for her.

• PHACS CAB NEWSLETTER, JANUARY 2020 EDITION

Stephanie M. talked about the PHACS CAB Newsletter, January 2020 Edition. The newsletter followed a theme of "Undetectable = Untransmittable (U=U), adherence, and relationships." **Stephanie** thanked CAB members for submitting articles for the newsletter. **Liz** thanked the CAB members for all their hard work on the newsletter. **Megan** thanked the CAB members for sending in so many different articles for the newsletter. **Lesley** thanked the CAB and PHACS for providing a space for CAB members to share their stories. **Sharry** thanked the CAB for putting together the newsletter.

• SITE CAB UPDATES 2020

Stephanie M. invited CAB members to share about their site CAB plans for 2020. **Sharry** talked about her site CAB. The site CAB is putting together a care package for newly diagnosed participants. The site CAB came up with the idea based on things they wish they had at the time they learned about their HIV status. The care package will include resources, inspiring quotes, and information about rights of people living with HIV.

Kim talked about her site CAB. Several site CAB members will be participating in the annual AIDS Walk in Houston, Texas.

Stephanie M. talked about her site CAB. **Stephanie** stated that her site is now signed up as a U=U partner. This means that the site endorses the U=U message from the Centers for Disease Control (CDC). Many site CAB members will also be participating in the "A Woman's Voice" conference. The conference will include many topics around women living with HIV including U=U. **Veronica F.** thanked **Stephanie** and the CAB for choosing U=U as a theme for the newsletter. Many site CAB members had not previously heard about U=U.

Stephanie S. talked about her site CAB. **Stephanie** stated that they have two new members looking to join the PHACS CAB conference calls.

Joel talked about his site CAB. **Joel** stated that they have a new member, **Veronica. Veronica** introduced herself to the CAB.

Gena reminded CAB members that the United States Conference on AIDS (USCA) is scheduled for October 13, 2020. People can apply for scholarships to attend the conference starting on March 30, 2020. **Megan** encouraged CAB members to apply. **Megan** reminded the CAB that the conference is not funded by PHACS.

NOTE: The next CAB call will be on Thursday, March 26, 2020 at 12:00 pm EST.