CAB Conference Call
July 28, 2011
12:00 EDT
Meeting Minutes

Participants:

Carrie	University of Colorado
Delia	University of Miami
Gloria	University of Florida - Jacksonville
Grace	Westat
Jennifer	University of Colorado
Julie	University of Alabama - Birmingham
Julie	Harvard
Julie	Westat
Lennie	St. Jude's Children's Hospital
Leslie	Texas Children's Hospital
Lori	FSTRF
Mariana	University of California San Diego Hospital Center
Melanie	UMD—New Jersey Medical School
Megan	Westat
Russell	Tulane University
Sherry	St. Jude's Children's Hospital
Theresa	Texas Children's Hospital
Victoria	Westat
Vikas	Bronx Lebanon Hospital Center
Yuri	University of Miami

• WASHINGTON POST ARTICLE

Dr. Russell Van Dyke talked about an article on using antiretroviral medications to prevent HIV infection. These medications are now used to treat HIV infection. There is no vaccine for HIV, so people are looking at other ways to prevent infection. These studies involve sexual transmission. There are two ways to prevent transmission using antiretrovirals. Doctors can treat the infected person with HAART therapy. They can also treat the uninfected person.

These studies focused on continents like Africa and Asia. On these continents, access to therapy is limited. Both studies focused on male-female couples. One study had three arms, the other had two. One study compared using a placebo, using Truvada, and using Tenofovir. The other compared using a placebo and using Truvada. The uninfected person takes one pill a day. Both studies showed a drop in HIV transmission rate. Therefore, it's effective, but not 100%.

There are concerns about toxicity and resistance. This includes using Tenofovir during pregnancy. Tenofovir can lower bone density. However, both studies did not see many side effects. Side effects can occur while taking the medication. There should not be any risk after a person stops taking it. This should always be supervised by a doctor. Other concerns include adherence, availability, and cost.

Dr. Van Dyke said he believes that this could become a standard of care. He is unsure if insurances would cover it. Yuri mentioned Tenofovir gel therapy. It could be turned in to the FDA for approval soon. Dr. Van Dyke talked about the difference between FDA drug approval and approval for different indications. This indication (using antiretrovirals to prevent HIV infection) is not FDA approved. However, doctors are allowed to prescribe medications for other reasons besides what it was approved for first by the FDA. Insurance companies can choose not to cover the cost for this indication.

• APPROVAL OF MINUTES

The minutes from the June 23, 2011 call were approved with no changes.

• INFORMED CONSENT PRESENTATION

Yuri spoke about a presentation on informed consent that he attended at the IMPAACT meeting. Informed consent came about from the Belmont Report in 1976. This created the principles of respect for persons, beneficence, and justice.

Informed consent is a process. It involves a voluntary agreement between the participant and the researcher. It is important for HIV studies. It contains rights that cannot be waived. The researcher must be very familiar with the study. They must be able to clearly explain it to the participant. This includes risks, benefits, and compensation. The researcher must also tell the participant that they may withdraw at any time.

Location is very important in the study. Researchers must find a location that would be private and confidential.

Informed consent forms are only seen by the participant, the research site, and the Institutional Review Board (IRB). Each site has its own IRB. The research site keeps the records that identify the study participants. The study participants' identity stays confidential. The information cannot be shared without consent.

If women are included in studies, the informed consent must have information on pregnancy risks.

• HHS NEWS RELEASE

Julie from Westat talked about the HHS proposal to improve rules protecting human research subjects. HHS is considering changes to the "Common Rule." They have not made changes since 1991.

There is no clear data security protection for IRB reviewed research. HHS wants to make rules to limit identifiers in collected information.

Another issue is research using biospecimens. This research can be done now without consent. This is because researchers strip the specimens of identifiers. Changes would require informed consent to use biospecimens. Another change being considered is allowing all studies to receive Federal protections. Right now this only applies to studies funded by certain federal agencies.

HHS also wants to update the adverse event reporting process. All information would be stored in a single database.

The current rules have vague language on how to write informed consent forms. This could be changed to make specific guidelines. This way the forms are easier to understand.

HHS is also considering stopping IRB continuing review. The IRB could stop review after study intervention.

The summary of proposed changes can be found here:
http://www.hhs.gov/ohrp/humansubjects/anprmchangetable.html
Final comments to this article must be submitted by 5pm on September 26, 2011.

NOTE: The next CAB call will be on Thursday, August 25, 2011 at 12:00 pm EDT.