Woman and Clinical Trials

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OBJECTIVES

• Understand some frequently used terms in clinical trials
• Identify the difficulties that prevent women from participating in clinical trials
• Discuss possible benefits and risks associated with clinical trials
• Disclosures: None
Historical Overview of Scientific, Ethical and Legal Issues

• Historical Framework
• Policy Changes Occurring at the FDA and NIH
HISTORICAL FRAMEWORK

DURING THE PAST TWENTY YEARS THERE HAS BEEN NO INCLUSION OF WOMEN IN CLINICAL TRIALS IN THE UNITED STATES

• In 1977, the FDA and NIH issued guidelines for the clinical evaluation of drugs that excluded women of child-bearing age for potential early stages of clinical studies.
Policy Changes Occurring at the FDA and NIH

• The women movement of the 1960’s and 70’s began to present some results in 1980 when the US Public Health Service established a task force for women’s health.

• By 1990’s, clinical researchers collected information on pregnant women with breast cancer that challenged the traditional plans of care for pregnant women.

• Between 1990 and 2004, cancer complicated by pregnancy increased from 1 in 1,560 to 1 in 1,180 pregnancies.
Policy Changes Occurring at the FDA and NIH

• Many pregnant women faced cancer unsure about the adequate treatment for themselves and their fetus. The Food and Drug Administration approved medication for used in pregnancy. Those medication was related to the cancer issue in pregnancy.
Inclusion and Protection of Pregnant Women in Clinical Trials

• In the history of inclusion we can talk about abuse in medical research, drug tragedies and reactionary federal regulations that had greatly shaped women participation in clinical trials. Two historical events largely defined the history of inclusion:

• The Diethylstilbestrol (DES)

• The Thalidomide tragedies
Ensuring Ethical Maternal and Fetal Protections in Clinical Trials

- Law and Ethics compelled additional protection for investigators studying pregnant women and their fetuses.
- In 2010, the United States Dept. of Health & Human Services and the FDA placed an institutional review board ensuring ethical maternal and fetal protection that required properly designed studies.
Strategies for recruiting and Retaining Women in Clinical Trials

• Addressing logistical and financial needs
• Involving the study participants
• Improved communication
Barriers to women participating in Clinical Research

• Social & economical aspects: Women traditionally consider themselves last; take care of husband and family before themselves; tend to earn less money than men.

• Physical aspect: hormonal, pregnancy
Types of Clinical Research Trials

• Different types of clinical research are used depending on what researchers are studying
Types of Clinical Research Trials

Women Inter Agency Clinical Research Study (WIHS)
• Questions?

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The information presented is the consensus of HIV/AIDS specialists within the SEAETC and does not necessarily represent the official views of HRSA/HAB.

The AIDS Education and Training Center (AETC) Program is the training arm of the Ryan White HIV/AIDS Program. The AETC Program is a national network of leading HIV experts who provide locally based, tailored education, clinical consultation and technical assistance to healthcare professionals and healthcare organizations to integrate high quality, comprehensive care for those living with or affected by HIV.
The **South FL SE AIDS Education and Training Center** within the University of Miami, Department of Medicine, Division of Clinical Immunology, has over thirty faculty members and staff dedicated to caring for patients with HIV/AIDS and includes some of the world’s most renowned researchers in infectious diseases. We have specialty clinics in adult medicine, and obstetrics/gynecology that provide state of the art clinical care for those individuals infected with HIV and other STIs. HIV clinical care is provided by the UM physicians for inpatient care at Jackson Memorial Hospital (JMH) and University of Miami Hospital, and outpatient care at numerous sites on the UM/JMH medical campus. UM HIV faculty also provide off site care at Federally Qualified Health Centers.
The South FL SE AETC includes the following counties: Polk, Hardee, Highlands, Indian River, Okeechobee, St. Lucie, Hernando, Pasco, Pinellas, Hillsborough, Manatee, Sarasota, DeSoto, Martin, Palm Beach, Broward, Miami-Dade, Monroe, Charlotte, Glades, Lee, Hendry and Collier.
The U.S. Department of Health and Human Services (DHHS) has released updated versions of its antiretroviral treatment guidelines for adults and adolescents, and for children with HIV. The new adult guidelines include revised recommendations for first-line antiretroviral therapy (ART) as well as management of treatment-experienced patients. The revised pediatric guidelines include a discussion of very early treatment for HIV-infected infants.

References
HHS Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*. Updated April 8, 2015.
TRAINING OPPORTUNITIES

**Preceptorships**
An intensive clinical training program offered to healthcare providers in Florida who have an interest in learning more about the diagnosis and management of HIV/AIDS, opportunistic infections, and co-morbid conditions. Each preceptorship is structured to meet the unique needs of the individual participant based on his or her previous experience, geographic location, and time available. Experience 4 to 240 hours of clinical training at adult, pediatric, obstetric, and/or family practice clinics where care is provided to HIV-infected patients. All training provided is consistent with current guidelines from the Department of Health and Human Services or other nationally recognized guidelines when available.

**Individual and/or Group Clinical Consultations**
Individual and group clinical consultations are offered. Individual clinical case consultation is provided on the diagnosis, prevention, and treatment of HIV/AIDS and related conditions. These consultations take place by telephone, email or face-to-face meetings. Group clinical consultation with case-based discussions include information on pharmacology, clinical antiretroviral therapy updates, drug-drug interactions, and antiretroviral resistance.

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TRAINING OPPORTUNITIES Cont’d

Chart Reviews
The chart review program offers clinics that provide HIV/AIDS care an opportunity to assess adherence to current Department of Health and Human Services (DHHS) and other published guidelines utilized in the care and treatment of HIV-infected individuals. Using a team of specially-trained F/C AETC faculty, a review of selected patient charts is completed to identify the strengths of the healthcare team, as well as areas of opportunity for education and training to support quality improvement efforts.

Web-Based Education (Webinars)
We offer numerous web-based educational opportunities to increase the knowledge and skills of HIV healthcare providers. Our web-based educational opportunities cover a wide range of HIV-related topics. Trainings are provided both as live webinars or on-demand recorded webinars. Web-based education offers participants a way to stay up-to-date on current topics.

Telehealth Case Based Group Consultations
This model uses a live audio-video-based platform (Adobe Connect) to provide educational experiences through the creation of a learning network comprised of clinicians serving HIV/AIDS patients, novice to expert throughout our region.
FOR MORE INFORMATION, PLEASE VISIT:

http://hivaidsinstitute.med.miami.edu/partners/se-aetc
National HIV/AIDS Clinicians’ Consultation Center
UCSF – San Francisco General Hospital

Warmline
National HIV/AIDS Telephone Consultation Service
Consultation on all aspects of HIV testing and clinical care
Monday - Friday
9 am – 8 pm EST
Voicemail 24 hours a day, 7 days a week

PEPline
National Clinicians’ Post-Exposure Prophylaxis Hotline
Recommendations on managing occupational exposures to HIV and hepatitis B & C
9 am - 2 am EST, 7 days a week

Perinatal HIV Hotline
National Perinatal HIV Consultation & Referral Service
Advice on testing and care of HIV-infected pregnant women and their infants
Referral to HIV specialists and regional resources
24 hours a day, 7 days a week

HRSA AIDS ETC Program & Community Based Programs, HIV/AIDS Bureau & Centers for Disease Control and Prevention (CDC)
www.nccc.ucsf.edu
Upcoming Webinars

**Friday, JUNE 10th**
Cultural Competent Care of African American Patients

*Alexis Powell, MD*

**Monday, JUNE 21st**
Retention in Care for Transgender Clients

*Sheryl Zayas, DO*

**Monday, JUNE 27th**
Transitioning HIV Infected Youth to Adult Services

*Ana Garcia, PhD, LCSW*
Need Additional Information?

Contact the South FL SE AIDS Education and Training Center

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Tivisay Gonzalez, Program Coordinator: tgonzalez1@med.miami.edu
Target audience: Physicians, physician assistants, nurses, pharmacists, social workers, mental health workers, nutritionist/dietitians.

The Suwannee River Area Health Education Center, Inc. is a Florida Board of Nursing, Dentistry, Pharmacy, Psychology, Respiratory Care, Occupational Therapy, Nursing Home Administration, Clinical Social Work, Marriage and Family Therapy and Mental Health Counseling and Florida Council of Dietetics and Nutrition approved provider of continuing education. CE Broker Provider ID #50-1922.

This program meets the requirements for up to 1.0 contact hours. The Florida AHEC Network designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credits™.
Thank you!

We thank you for participating in today’s webinar and encourage you to stay on WebEx and fill out the Performance Evaluation after the call ends. This is a HRSA requirement that helps us ensure continued funding.