

Research on Behavioral Risk Reduction Counseling

Dr. Phil, and his colleague Ann Landers, want to know whether or not HIV behavioral counseling can reduce risk for HIV among African-American men who have sex with men. Project Explore, a study with over 4200 men who have sex with men (mostly white with some African-American and Latino participants), compared an intensive 10-session counseling program with twice-yearly HIV counseling and testing sessions. After following the participants for 3 years, they found that the intensive counseling session and the twice yearly HIV counseling and testing were about the same in terms of the percentage of men in each group who got infected with HIV.

But now Dr. Phil and Ms. Landers want to know if twice yearly HIV counseling and testing is better than nothing at all. They plan to recruit African-American men who have sex with men, between the ages of 18 and 40, go through an informed consent process, and randomize them to twice yearly counseling and testing, the intensive 10-session counseling session used in Project Explore, or testing only at the end of the study. They will counsel everyone at the beginning to practice safe sex and to use condoms for anal intercourse. People will be tested for HIV at the beginning of the study and at the end of the study, and those in the Project Explore arm and in the twice-yearly counseling and testing arm will also receive HIV testing plus counseling every time that they come in. People who have HIV at the beginning of the study will be referred to medical care, and those diagnosed acquiring HIV during the study will also be referred for medical care and won't need to be seen by the study team after they get HIV.

Substance Abuse Research

Mr. Alexander Rodriguez (also known to his fellow students as A-Rod) decided to try a different career, went back to graduate school, and is ready to start his dissertation research to finish his doctoral studies in public health. He has done extensive work in substance abuse treatment and this will be the topic of his dissertation.

Mr. Rodriguez developed a program called the "Don't Do It" curriculum which provides free materials, technical assistance, and training to teachers willing to use it with their students. The Institute has been very successful, largely because Mr. Rodriguez funded much of its writing and implementation with his own funds. Over 500,000 students have now been exposed to the curriculum.

But recently two large universities completed large scale studies of the curriculum and found that it did not change drug use behavior in students. IN fact, there was some evidence that drug use might have increased after the curriculum was implemented.

The Institute for Drug Abuse Prevention wants to continue to use the curriculum, citing problems in the two studies in the literature, and they have been promised funding from the Rodriguez Drug Abuse Prevention Foundation for continuing to implement it.

They propose instead to evaluate the curriculum, and the Rodriguez Foundation accepts their proposal. They will assign schools at random to receive the curriculum or nothing at all, and follow students for 1 and 2 years after the curriculum is implemented. The Rodriguez Foundation wants to be in charge of collecting follow-up data, and also wants to implement urine testing to verify self-reports of behavior.

They propose to do the studies without name identification, and would like also to avoid positive parental permission where parents have to return permission slips. Rather, they intend to send a notice home to parents informing them that the study and the measures are being taken and that they can send a note in if they want their child excused from the curriculum and/or the testing.

Survey of HIV Discrimination in Dental Practices

Dr. Justin Bieber, a young dentist and a faculty member at UCLA (and an out and proud gay man and highly visible gay activist), has always been interested in discrimination against people with HIV. He has designed a study to examine whether or not dental offices discriminate against people with HIV. He plans to call all dental offices in Los Angeles County and ask a series of questions:

- Is your office taking new patients? (if no, end the call.)
- Do you accept dental insurance? (if no, end the call.)
- How many dentists and allied dental personnel work in the office?
- What is their background and training?
- I have HIV. Do you accept patients with HIV? Or I have hepatitis B or I have hepatitis C. Do you accept patients with hepatitis B or C? (Dental offices will be randomized so that 1/3 are told that the patient has HIV, 1/3 are told that the patient has hepatitis B, and 1/3 are told that the patient has hepatitis C.)

He will not reveal the fact that this is a study to the person answering the phone. He will keep track of phone numbers so that he can call offices back when he is unable to reach someone to answer the questionnaires, and can verify the offices that he has called. He does not plan to tell the participants at the end of his call or later that he engaged in a deception in order to do the study.

Microbicide Research in Pregnant and Post-Partum Women

Drs. Kim and Kanye West, and their daughter North (who is on her way toward becoming an eminent investigator in her own right), have designed a study to study whether or not microbicides can protect women from acquiring HIV during pregnancy or during the post-partum period.

Microbicide research in general has been somewhat promising. A study in South Africa (the Caprisa Trial), for example, demonstrated that the use of the microbicide before and after intercourse reduced HIV infections by about 30%. Pregnant and post-partum women were excluded from the trial, but women during pregnancy and the post-partum period are at increased risk for HIV infection. Some studies estimate that the incidence rate (the percentage of uninfected women getting infected with HIV during a year) is 8-10%. Thus, protection during this period would be very very important.

The Drs. West have designed the following study. Women who are pregnant or in the post-partum period will be recruited to the study and told that they will be participating in a placebo-controlled trial. Half of the women will be randomly assigned to receive placebo, and the other half will be assigned to the tenofovir gel microbicide. The women will be enrolled in the study for two years, and will be asked to come to the clinic every 3 months where they will receive a medical exam and be tested for HIV. Those who are diagnosed with HIV will be referred to the local medical clinics for care and will no longer be followed in the study. At the end of the two-year period, the two groups will be compared and the participants will be told about the results and referred to local medical care.

Reducing HIV Transmission from Mothers to Babies During Breastfeeding

Dr. Stefani Joanne Angelina Germanotta (also known as Dr. Lady Gaga), an eminent HIV prevention researcher with projects all over the world, has designed a study to determine if it is possible to reduce HIV transmission from HIV-infected mothers to their infants during breastfeeding. Breastfeeding accounts for about 30-40% of HIV transmissions from HIV+ mothers to their infants. Formula feeding can prevent transmission, but is not safe in many settings because the water supply is not safe. Dr. Germanotta has developed a pill that, when put into water, can clear the water of all contaminants and make it safe so that the infant does not develop diarrheal disease. Recent studies have also shown that triple combination therapy with anti-retroviral medications can prevent most, if not all, transmissions of HIV from mother to child, even during the breastfeeding period. But she also knows that not all women who are breastfeeding choose to stay on anti-retroviral medications and thus wants to prove that her pill will also be effective in reducing mother to child transmission by providing clean water for mixing formula.

Her study design is as follows. Women who are HIV+ and pregnant will be recruited into the study just prior to delivery. Entry criteria are HIV+, willing to participate in the study and sign informed consent, and willingness to be randomized to one of the study conditions. As part of the recruitment procedure, women who enroll in the study prior to delivery will be promised a place in the regional hospital birthing center (quite often there are not enough available spaces), and a midwife birth attendant and are also told that a physician will be on call should there be complications with the delivery.

The informed consent document outlines the study design which says that women will be randomized to receive either combination anti-retroviral therapy, the pill to clean the water to mix with formula, or both. Women given the pill to clean the water to mix with formula will be expected to engage in exclusive formula feeding.

Mothers and infants will be followed for 12 months. The endpoint of the study will be HIV-free survival. Thus, the two groups will be compared on whether or not their infants are still living and whether or not they are acquired HIV.

Women will be required to attend follow-up sessions every month, and they will be given a free medical exam for themselves and for their infants, and will be given first access to hospital and medical facilities should they or their infant require it.

Research on Male Circumcision

Observational studies in sub-Saharan Africa showed that countries with high male circumcision rates had low rates of HIV. Based on this evidence, three randomized controlled trials were conducted—in Kenya, Uganda, and South Africa—and demonstrated the efficacy of male circumcision in reducing transmission from an infected female to an uninfected male.

Dr. Chris Paul, team physician for the LA Clippers and also on the faculty of UCLA, wants to do a study to understand whether the same protection demonstrated in reducing HIV transmission via vaginal intercourse also works with anal intercourse, thinking that this could be another way to protect men who have sex with men (MSM) from HIV infection. At the same time, he wants to study whether or not the protection works in reverse, namely does male circumcision reduce transmission from an infected person to an uninfected person.

He proposes a study whereby he will recruit HIV+ uncircumcised MSM and randomize them to one of two conditions. One of the entry requirements is that they be partnered with an HIV- partner. One condition will receive circumcision right away, and the other group will be delayed in receiving circumcision until it can be determine whether or not circumcision is protective against HIV transmission. The groups will be followed for 2 years and the rates of HIV infection will be compared at the end of the two years.