

Taking Care of Our Health Taking Care of Our Communities

Community Education Group

SCALES

Houston, TX

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Why are we here?



African Americans are disproportionately represented among AIDS cases nationwide

- In 2003, African Americans accounted for (49%) of the AIDS cases diagnosed in the United States, while 12.3% of the population.
- The rate of AIDS diagnoses for African Americans was almost 10 times the rate for whites.
- The rate of AIDS diagnoses for African American women was 25 times the rate for white women.
- The rate of AIDS diagnoses for African American men was 8 times the rate for white men.



HIV Transmission in African Americans

- Among African Americans, a majority of cases are transmitted via sexual contact (homosexual and heterosexual).
- Since the beginning of the epidemic, 30% of AIDS cases were MSM%, 24% were heterosexual contact.
- 39% of cases have a history of injecting drug use (IDU). There is a strong correlation between IDU and heterosexual transmission.



In Summary

HIV can be prevented.



HIV Vaccines



Key Messages



- Currently, there is no HIV vaccine available.
- HIV vaccines being tested in humans do not contain HIV; therefore, they cannot cause HIV infection.
- An HIV preventive vaccine will only work on HIV negative individuals.
- The best long-term hope for controlling the AIDS epidemic is the development of safe, effective, and affordable preventive HIV vaccines.
- A **comprehensive** approach to vaccine research includes the partnerships of prevention, care/treatment and research.

What is the potential impact of a HIV preventive vaccine?

- Preventing infection in most people
- Preventing infection in some people
- Eliminating virus after a short period of infection
- Controlling persistent infection to delay or prevent AIDS
- Reducing the infectiousness of an infected person, thereby reducing transmission to others



Why Should African Americans Know About HIV and other Clinical Trials?

- Important to know about health choices
- Drugs might effect African Americans differently
- More African Americans die from health problems than other groups of people
- To help the community, our families, and our friends



The Tuskegee Syphilis Study

- Tuskegee Syphilis Study
 - Approximately 400 African American Men
 - All had syphilis prior to study
 - Study lasted 40 years from 1932 - 1972
 - Scientists wanted to know what would happen to the body when syphilis was not treated
 - Never treated the patients even after a cure was discovered



What Good Came from Tuskegee Study

- Alerted government and community about the pitfalls of medical research and studies
- Pushed the government to make new laws to protect people who are in studies or research



What is a Clinical Trial?

It is a study done to find new and better ways to:

- Keep people from getting sick
- Find out what is wrong with a person's health
- Cure a person of their sickness



Who Pays for Clinical Trials?

- Doctors
- Hospitals and clinics
- Groups that give away money - Foundations
- Voluntary groups
- Drug companies
- The government
 - National Institutes of Health
 - Department of Defense
 - Department of Veteran's Affairs



Where are Clinical Trials Done?

- Hospitals
- Universities or colleges
- Doctor's offices
- Community clinics



Types of Clinical Trials

- Prevention Trials
- Treatment Trials
- Screening Trials
- Quality of Life Trials



Prevention Trials

- Look for ways to stop the disease from happening or returning
- Includes medicines, vitamins, minerals, or changes in how we live
- A Vaccine is an example



Other Types of Clinical Trials

- Treatment - looks for new drugs or treatments to cure an illness
- Diagnostic - looks for better ways to test for an illness
- Quality of Life - looks for ways to help people who are sick live more comfortably or better

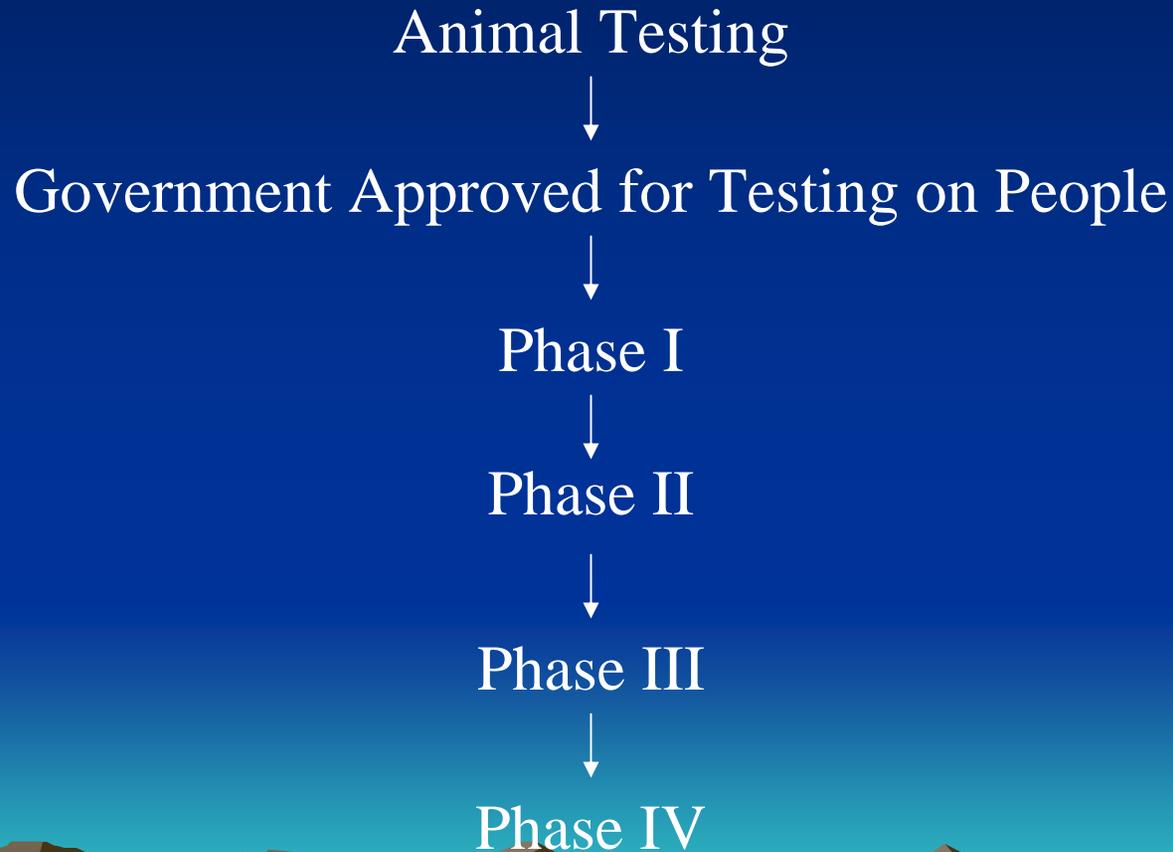


Clinical Trials - Risks

- Patient may get sick from drug
- May not be helpful
- May require more time:
 - Trips to the doctor
 - More treatments
 - Hospital stays
 - Different or complicated drug requirements



Steps for New Drugs or Treatments



PHASE I

- First test on a human
- Looks at best way to give the drug (with a shot, a pill, or intravenous)
- Looks at how much of the drug to give
- Looks at how safe or unsafe the drug is
- A small group of people participate (< 100)
- Most risky or dangerous



PHASE II

- Continues to test safety of new drug
- Looks at how well the new drug or procedure cures the sickness
- More people are needed - 50 to 500
- Usually safer than phase I trials



PHASE III

- Test drug or procedure against other treatments to see which is better
- Thousands of people are tested
- Safest test of new drug
- If the drug passes the test, it can be used by everyone



PHASE IV

- Drug is being used already
- Researchers are watching the drug for safety and other ways to use the drug
- Patient usually does not know they are being watched or studied
- Doctors are usually paid to watch how the new drug is effecting the patient
- If problem happens, the drug can no longer be used



Is There a Possibility of Becoming HIV Infected When Testing Candidate HIV Vaccines?

- It is not biologically possible to become HIV infected with experimental vaccines.
- Vaccines DO NOT CONTAIN complete HIV virus, either live, weakened or killed.

Institutional Review Board

- Law says all studies on people must have an IRB
- A group of people that includes:
 - doctors, statisticians, people from the community, and others
- Separate from the people doing the study
- Purpose:
 - Make sure study is not taking advantage of the patient
 - Makes sure the rights of people in study are protected
 - Compares the good and bad of a study





WESTERN BLOT TESTS

Vaccine-induced antibody responses can be distinguished from infection-induced antibody responses by Western blot.



What is a Protocol?

- A study plan or how the study will happen
- Written by the doctor or researcher
- IRB must say it is ok or approved
- Plan includes:
 - Types of people who can be in the study
 - How often a patient will be test
 - What medicines will be used
 - How much medicine will be given
 - How long the study will last



Informed Consent Form

- Reason for the study
- What the patient must do in the study
- The good and bad parts of the study
- How much the study will cost
- Person to call about the study
- Place for patient to sign



Questions to Ask

- What is the reason for the study?
- Who is going to be in the study?
- Why do researchers/doctors believe the new treatment will work? Has it been tried before?
- What kinds of tests and treatments are involved?
- How does the new treatment compare to old treatments?
- How will the study change my daily life?



Questions to Ask continued...

- How long will the study last?
- Will I need to stay in the hospital?
- Who will pay for the study?
- Will I be paid back for money I use?
- Who will take care of my health after the study?
- How will I know the treatment worked? Will I be told the results?
- Who will take care of my health?



Be Prepared!

- Plan ahead!
- Write down questions to ask
- Ask a friend or relative to come with you to talk to the doctor
- Listen carefully to what the doctor says to your questions
- Bring a tape recorder
- Make sure the study is IRB approved



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Thank You

