



MICROBICIDES AND HIV PREVENTION RESEARCH

GLOSSARY OF TERMS



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This glossary was compiled to serve as a resource and guide to help in the understanding of common terms used in the setting of HIV/AIDS treatment and research. Enjoy.

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A

ABC

The ABC approach to behavior change promotes the adoption of the following three behaviors as central to HIV prevention efforts:

A – Abstaining from sexual activity or delaying the age of the first sexual experience

B – Being faithful or practicing mutual monogamy with an uninfected partner

C – Correct and consistent condom use

Abstinence

Refraining completely from something; in reference to HIV infection and AIDS, it usually refers to completely avoiding sexual intercourse to prevent passing an HIV infection from one sexual partner to another.

Abstract

A brief summary of a research study and its results.

Acceptability

How a product or service fits the physical, social and cultural needs of a user or community. Products and services that do not meet these needs are unlikely to be widely used, no matter how well they work.

Accidental exposure or accidental transmission

Usually refers to HIV exposure or transmission that occurs in a health care setting. Transmission can occur from patient to provider or vice-versa.

Accrual

The process of recruiting participants into a trial in order to reach target participant numbers, or the number of participants enrolled or planned to be enrolled.

Acquired immunity

The body's ability to fight or prevent a specific infection. Can be acquired either actively (by having an infection or recovering from it, or by being vaccinated against an infection) or passively (by receiving antibodies from an outside source, such as breast milk or donated blood components).

Acquired Immunodeficiency Syndrome (AIDS)

A disease of the body's immune system caused by the human immunodeficiency virus (HIV). AIDS is characterized by the death of CD4 cells (an important part of the body's immune system), which leaves the body vulnerable to life-threatening conditions, such as infections and cancers.

Activity

The immediate effect of a drug on a disease-causing microorganism.

Acute

Rapid in onset; the short-term initial stage of a disease. Compare with *chronic*.

Acute HIV infection

The first stage of HIV infection, which can last anywhere from a few days to several weeks. HIV multiplies rapidly and is more easily transmitted to others during this time. See also *primary HIV infection (PHI)*.

Adherence

Following a prescribed regimen correctly and consistently. In clinical trials, the term adherence usually refers to how well the trial participant followed the trial's study drug or protocol.

Adverse event

An unwanted reaction to a pharmaceutical product or intervention. An adverse event can range from a reaction that is less severe, such as a rash or nausea, to something more serious, such as kidney or liver failure. In clinical trials, adverse events among study participants are recorded and analyzed to learn about the safety of study products. See also *side effect*.

Agonist

An agent that binds to a receptor on a cell's surface and promotes a specific cellular activity; a drug or substance that promotes the activity of another drug. Compare with *antagonist*.

AIDS Clinical Trials Group (ACTG)

A clinical trials network funded by the National Institute of Allergy and Infectious Diseases (NIAID) that evaluates treatments and new therapeutic approaches for the treatment of HIV infection and opportunistic diseases related to HIV/AIDS in adults.

AIDS-defining illness

These include a variety of conditions that occur at late stages of HIV disease and that signal progression to AIDS. Many individuals first become aware of their infection at this stage.

Allele

A variation of a gene located at a specific location on a chromosome; each individual organism has two alleles for each trait, which may be the same (homozygous) or different (heterozygous).

AMAG

The African Microbicides Advocacy Group. A coalition of microbicide and other new prevention technology advocates from organizations and institutions based in and/or working in Africa.

Amniotic fluid

The fluid in which the embryo and fetus is suspended within the amniotic sac during pregnancy.

Anal intercourse

Intercourse involving the insertion of the penis into the anus of a sexual partner. Practiced by both men and women. See also *receptive anal intercourse*.

Antagonist

A chemical substance, such as a drug, that interferes with the physiological action of another substance, especially by combining with and/or blocking its nerve receptor. Compare with *agonist*.

Antenatal

Occurring before birth (as in HIV exposure or transmission from mother to infant during pregnancy).

Antepartum

The time period before childbirth (refers to the mother).

Antibiotic

A drug used to treat infections caused by bacteria and other microorganisms.

Antibody

Molecules in the body that identify and destroy foreign (unfamiliar) substances such as bacteria and viruses. Standard HIV tests identify whether or not antibodies to HIV (HIV antibodies) are present in the blood. A positive HIV test signals that antibodies are present.

Antibody positive

Having antibodies against a microorganism, indicating previous exposure to the microorganism.

Antibody test

A test that detects the presence of antibodies in a blood sample. The enzyme-linked immunosorbent assay (ELISA) and the Western blot are the tests typically used to detect HIV antibodies.

Antigen

Any substance considered foreign to the body that can stimulate the body to produce antibodies against it. Antigens include bacteria, viruses and allergens such as pollen. See also *antibody*.

Antigen presenting cell (APC)

Type of immune cell that collects foreign materials (antigens), digests them into small pieces, and displays or presents the pieces on the cell's surface. Other immune cells recognize these pieces and become activated to fight the foreign invader. APCs include B cells, macrophages and dendritic cells.

Antimicrobial

An agent that destroys or prevents the growth of microorganisms such as bacteria, fungi or parasites.

Antiretroviral (ARV)

A drug that interferes with the ability of a retrovirus, such as HIV, to make more copies of itself. See also *antiretroviral therapy (ART)* and *highly active antiretroviral therapy (HAART)*.

Antiretroviral (ARV)-based microbicides

Candidate microbicides that contain ARVs. Some of these employ the same mechanism of action as ARV drugs used in HIV treatment. Examples include tenofovir gel and dapivirine.

Antiretroviral therapy (ART)

Treatment involving a combination of ARVs that together inhibit the ability of retroviruses, such as HIV, to multiply in the body. The antiretroviral therapy recommended for HIV infection is referred to as highly active antiretroviral therapy (HAART).

Apoptosis

A form of natural cell death in which a programmed sequence of events leads to the elimination of cells without releasing harmful substances into the surrounding area. Apoptosis plays a crucial role in developing and maintaining health by eliminating old cells, unnecessary cells and unhealthy cells.

Approved drug

In the United States, the Food and Drug Administration (FDA) must approve a drug before it can be marketed and sold to the public. The approval process involves several steps, including laboratory and animal studies, clinical trials for safety and efficacy, filing of a New Drug Application (NDA) by the manufacturer of the drug, FDA review of the application, and FDA approval/rejection of the application. See also *New Drug Application (NDA)* and *Food and Drug Administration (FDA)*.

Area under the curve (AUC)

A measure of how much drug reaches a person's bloodstream in a given period of time (usually the time between each dose or within 24 hours of a dose). The AUC is calculated by plotting the drug's blood levels on a graph at different times during a set period to form a curve. The area under this curve reflects the total drug exposure in the set time period.

Arm

Any of a trial's study groups, each consisting of participants receiving the same treatment or intervention, or a placebo or no intervention. Most randomized trials have two arms, but some have three arms, or even more.

ASPIRE

A Study to Prevent Infection with a Ring for Extended use. A Phase III clinical trial designed to evaluate dapivirine ring for preventing HIV in women that will be conducted by the Microbicide Trials Network (MTN).

Assay

A test used to detect the presence or concentration of a chemical marker, drug, or microorganism in the blood or other body fluids or tissues.

Asymptomatic

A person with HIV is asymptomatic if he or she shows no signs or symptoms of the disease. This is also the second stage of HIV disease progression and can last for many years after infection. The virus can be transmitted during this stage.

Attachment inhibitor

Class of anti-HIV drugs that prevents the virus from attaching to a new, healthy host cell, thus preventing cell infection. See also *entry inhibitor*.

Attenuated

A term used to describe a bacterium or virus that has been changed in the laboratory so that it is not harmful to people. Attenuated viruses are often used as vaccines because they can no longer cause disease but can still stimulate a strong immune response. Examples include the vaccines against polio (Sabin oral vaccine), measles, mumps and rubella.

Audio Computer-Assisted Self-Interview (ACASI)

A system that allows research participants to privately answer questions via a laptop computer.

Autoimmune

Relating to an immune response by the body against one of its own cells or tissues.

Autoimmune disease

Disease that results when the immune system mistakenly attacks the body's own tissues. Examples include multiple sclerosis, type I diabetes, rheumatoid arthritis and systematic lupus erythematosus.

AVAC

A non-profit organization dedicated to the prevention of HIV. Formerly the AIDS Vaccine Advocacy Coalition, the name of the organization is now AVAC: Global Advocacy for HIV Prevention.

Aviremia

Lack of virus in the blood plasma.

B**B cell**

Also known as a B lymphocyte. An infection-fighting white blood cell that develops in the bone marrow and spleen. B cells produce antibodies. The ability of B cells to do their job may be damaged in people infected with HIV.

Bacteria

Simple single-celled microorganisms, many of which can cause disease; bacteria are classified by their shape (rod, spirochete, etc.), staining properties (Gram positive or Gram negative), and habitat (aerobic or anaerobic).

Bacterial vaginosis

A vaginal condition characterized by an abnormal vaginal discharge due to an overgrowth of certain bacteria in the vagina. Women with bacterial vaginosis have less of the normal vaginal bacteria called lactobacilli. See also *lactobacilli*.

Baseline

An initial or known value (e.g., CD4 cell count, HIV viral load) against which later measurements can be compared.

Bias

When a point of view prevents impartial judgment on issues relating to the subject at hand. In clinical studies, bias is controlled by blinding and randomization.

Biochemical response

A favorable response to treatment as indicated by normalization of certain blood values (e.g., liver enzyme levels).

Biomarker

A chemical or biological signal detected in cells, blood or tissues that can help predict or measure the safety and effectiveness of a therapeutic intervention and/or that correlates with a clinical outcome. The amount of HIV in an infected person's blood, for example, can be used both as a marker of disease progression and as a measure of response to antiretroviral treatment.

Biopsy

The surgical removal and examination of an organ or tissue to aid in the diagnosis and treatment of a health condition. In microbicide research, biopsies may be used to look at levels of study drug or immune responses.

Blind

A randomized trial in which neither the researcher nor the participants know to which group the participants are assigned.

Blinding

Procedure to limit bias by preventing participants and/or study personnel from identifying which treatments or procedures have been administered (i.e., which study groups participants have been assigned to) or from learning the results of test and measures undertaken as part of the study.

Blood-borne

Refers to pathogens transmitted through direct blood-to-blood contact, for example, via shared needles or blood transfusion.

Blood chemistry panel

Set of tests used to measure levels of various substances (e.g., liver enzymes) in the blood.

Booster

An additional dose or doses of a vaccine given after the initial dose to enhance the immune response to the vaccine. Also used as a term to describe a medicine given to enhance another medicine.

Breakthrough infection

An infection caused by the same virus a vaccine is intended to protect against.

Budding

The final step in the HIV life cycle, in which an individual virus pushes out (or “buds”) from a host cell, steals part of the cell’s outer envelope, and frees itself to attach to and infect another host cell.

C**Candidiasis**

Overgrowth of the *C. albicans* yeast, causing infections in the gastrointestinal tract, vagina or other parts of the body. Vaginal yeast infections develop when the normal balance of bacteria (flora) in the area is upset. See also *flora*.

CAPRISA

Centre for the AIDS Programme of Research in South Africa. Conducts research on HIV pathogenesis and epidemiology, treatment of HIV and TB, and microbicides and vaccines for the prevention HIV.

Care, treatment and support

Care, treatment and support encompass the range of interventions necessary to take care of people living with HIV/AIDS, including antiretroviral therapy, treatment and prevention of opportunistic infections, nutritional support, psychological and community and home support. See also *antiretroviral therapy*.

Carrier

An individual who does not show symptoms or have active disease, but carries an infectious organism and can transmit it to others.

Case study

A description of a single individual’s development of disease and/or response to treatment.

CCR5

Chemokine receptor 5 (CCR5) is a protein on the surface of some immune system cells. It is one of two co-receptors that HIV can use along with the CD4 receptor to bind to and enter host cells. (The other co-receptor is CXCR4.)

CCR5 antagonist

Class of anti-HIV drug that stops HIV from binding to the CCR5 co-receptor, a receptor that most strains of HIV need to enter cells. Without the ability to bind to CCR5, HIV entry is halted.

CD4

A protein marker on the surface of certain types of T lymphocytes and other cells. HIV binds to CD4 receptors to enter host cells.

CD4 cell

Also known as a helper T cell or CD4 lymphocyte. A type of white blood cell for fighting infections that carries the CD4 receptor on its surface. CD4 cells coordinate the immune response, which signals other cells in the immune system to perform their special functions. The number of CD4 cells in a blood sample is an indicator of the health of the immune system. HIV infects and kills CD4 cells, which leads to a weakened immune system.

CD4 cell count

Also referred to as T cell count, the absolute number of CD4 cells in one cubic millimeter (mm³) of blood. The CD4 cell count is one indicator of HIV disease progression. A normal CD4 cell count ranges from about 600 to 1,200 cells/mm³; moderate immunodeficiency in adults is associated with a CD4 cell count between 200 and 500 cells/mm³, while severe immunodeficiency is associated with counts below 200 cells/mm³. Many treatment guidelines now recommend starting antiretroviral therapy when the CD4 cell count is between 350 and 500 cells/mm³.

CD4 receptor

A specific molecule present on the surface of a CD4 cell. HIV recognizes and binds to a CD4 receptor and a co-receptor to gain entry into a host cell.

CD8 cell

Also called a cytotoxic T lymphocyte (CTL), killer T cell, or suppressor T cell. A type of white blood cell that is able to identify and kill cells infected with bacteria, viruses, or other foreign invaders.

Cell

The basic unit of living organisms; a typical animal cell contains a nucleus and a cell membrane surrounding the intracellular material, or cytoplasm.

Cell-associated virus

Virus particles that remain attached to or within the host cell.

Cell-free virus

A virus particle outside its host cell.

Cell-mediated immunity

Also referred to as cellular immunity, this is the immune protection provided by the direct action of immune cells. With this type of immune protection, the response to infectious microorganisms is performed by specific cells – such as CD8 cells, macrophages, and other white blood cells – rather than by antibodies. The main role of cell-mediated immunity is to fight viral infections. See also *antibody* and *immune response*.

Centers for Disease Control and Prevention (CDC)

An agency of the U.S. Department of Health and Human Services (HHS) that is charged with protecting the health and safety of U.S. citizens and other people. The CDC serves as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and education activities designed to improve the health of the people of the United States. Commonly referred to as the U.S. Centers for Disease Control and Prevention.

Cervical-vaginal lavage (CVL)

A rinse of the inside of the vagina to collect vaginal and cervical fluids for laboratory testing.

Cervical-vaginal secretions

Liquid discharge that is a normal aspect of the environment in the vagina.

Cervix

The lower, narrow end of the uterus that forms a canal between the uterus and vagina. The cervix protrudes slightly into the vagina.

Challenge

The deliberate exposure of an animal to an infectious pathogen in order to test the safety and effectiveness of potential treatments and/or prevention approaches.

Chemokines

Proteins that serve as chemical messengers to control the activities of the immune system. Chemokines are involved in a wide variety of processes, including the control of infectious diseases, cancers and inflammation. Examples include interferons, interleukins and many other small proteins.

Chemoprevention

Also known as chemoprophylaxis. This is the use of natural or man-made agents to help reduce the risk of or delay the development or recurrence of a disease, such as cancer.

Chlamydia

A sexually transmitted infection (STI) caused by a bacterium called *Chlamydia trachomatis*. The bacteria infect the genital tract and, if left untreated, can cause damage to the female and male reproductive systems, resulting in infertility. See also *sexually transmitted infection (STI)*.

CHOICE

Committed to Having Options and Interventions to Control the Epidemic. A follow-up open-label trial that will proceed if at least one of the products in VOICE is found effective. See also *VOICE*.

Chromosome

A structure of compact, intertwined molecules of DNA, found in the nucleus of cells, which carry the cell's genetic information.

Chronic

Slow to develop, persisting over a long period, or recurring frequently. Compare with *acute*.

Circumcision

A procedure in which the foreskin of the penis is removed that has been shown in randomized controlled trials to reduce the risk of HIV transmission from women to men. In 2007, the World Health Organization and UNAIDS recommended that circumcision be considered “an important intervention” in reducing the risk of heterosexually acquired HIV infection in men. Both health organizations view the procedure as one part of a comprehensive HIV prevention program.

Clade

A group of organisms that are genetically similar and descended from a single parent organism. With HIV, the term clade refers to a group of specific HIV-1 strains within an HIV subtype. For example, HIV-1 subtype M contains clades A through H, J and K. Clades B and C account for the majority of HIV infections around the world. See also *subtype*.

Class-sparing regimen

An anti-HIV drug regimen that purposefully does not include one or more classes of anti-HIV drugs. A class-sparing regimen may be prescribed to save certain classes of drugs for later use or to avoid side effects specific to a class.

Clearance

The removal or elimination of a drug or microorganism from the body.

Clinical failure

The occurrence or recurrence of HIV-related infections or a decline in physical health despite taking an HIV treatment regimen for a minimum of 3 months. Clinical failure may occur as a result of virologic or immunologic failure. See also *virologic failure* and *immunologic failure*.

Clinical Practice Guidelines

Recommendations by panels of expert health care practitioners designed to assist clinicians and patients in making decisions about appropriate health care for specific diseases and conditions.

Clinical progression

A term for the overall progression of a disease as measured by deterioration of clinical outcomes. In an HIV-infected person, clinical progression may be defined as the occurrence or recurrence of HIV-related events (after at least 3 months on an antiretroviral regimen), excluding immune reconstitution syndromes. HIV-infected patients who have a CD4 T-cell count less than 100 cells/mm³ are considered to have a high likelihood of clinical progression.

Clinical trial

A research study that uses human volunteers to answer specific questions about the safety, efficacy and medical effects of a specific treatment or intervention. Carefully conducted clinical trials are regarded as the fastest and safest way to find effective treatments for diseases and conditions and to improve health. The clinical trial process includes Phase I, II, IIb, II, IIIb and IV post-marketing evaluation.

Cohort

A group of individuals in a study who share a demographic, clinical or other characteristic (e.g., age, study site).

Co-infection

Infection with more than one virus, bacterium or other microorganism at a given time. For example, an HIV-infected individual may be co-infected with hepatitis C virus (HCV) or tuberculosis (TB).

Coitally dependent

In HIV prevention, the requirement that products are used or regimens followed around the time sexual intercourse occurs. Compare with *noncoitally dependent*.

Coitus

Sexual intercourse, especially between a man and a woman.

Colony-stimulating factor (CSF)

A cytokine responsible for regulating the production of white blood cells; types include granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), and macrophage colony-stimulating factor (M-CSF).

Colorectal

Refers to the colon and rectum.

Colposcopy

Examination of the uterine cervix or anal canal using a lighted magnifying instrument (colposcope) to identify abnormal cell growth or evidence of damage/inflammation, and, if necessary, remove a tissue sample for biopsy.

Combination therapy

Two or more drugs used together to achieve optimal results in controlling HIV infection. Combination therapy has proven more effective in decreasing viral load than monotherapy (single-drug therapy), which is no longer recommended for the treatment of HIV. An example of combination therapy is the use of two nucleoside reverse transcriptase inhibitors (NRTIs) plus a protease inhibitor (PI) or a nucleoside reverse transcriptase inhibitor (NNRTI). Compare with *monotherapy*.

Community Advisory Board (CAB)

A group of community members (e.g., care providers, advocates, people living with HIV/AIDS) who provide recommendations regarding clinical research.

Comparison trial

A type of clinical trial in which two or more experimental therapies or interventions are tested against each other or against existing therapy or interventions.

Compartment

A separate structural portion (e.g., of the body or of a cell); a distinct area or part of the body, which may or may not have a discrete physical boundary; in pharmacology, an area of the body where a drug is metabolized.

Complete blood count (CBC)

An inventory of the cellular components of whole blood, including red blood cells (e.g., hematocrit and hemoglobin), various types of white blood cells (e.g., granulocytes and lymphocytes) and platelets.

Computed tomography scan

Also referred to as a CT scan. A method of visualizing the soft tissues of the body using X-rays.

Concomitant

Accompanied by or occurring at the same time; concomitant therapies are those that are used together.

Concurrent sexual partnerships

Having more than one sexual partner at a time. The practice raises the risk of contracting HIV and is increasingly recognized as a significant factor in the high prevalence rate of HIV in Africa.

Condom

A sheath made of latex or polyurethane that is worn over the penis to prevent pregnancy and/or the spread of HIV and other sexually transmitted infections; the “female condom” is an internal pouch worn inside the vagina or anus. See also *female condom*.

Condom migration

A term used to describe the act of abandoning condom use in favor of another, less efficacious method, such as a partially effective vaccine or microbicide. Also called 'condom substitution'.

Confidentiality regarding trial participants

Refers to maintaining the confidentiality of trial participants including their personal identity and all personal medical information. The trial participants' consent to the use of records for data verification purposes should be obtained prior to the trial and assurance must be given that confidentiality will be maintained.

Confidence interval (CI)

Research results often include a point estimate of an effect as well as a confidence interval. A confidence interval refers to the range within which the true result lies, and is expressed with an upper and lower limit.

Confounder

A factor that can influence a trial or experiment, leading to outcomes that improperly skew the results.

Congenital

A trait present from the time of birth.

CONRAD

An organization focused on research, product development and clinical evaluation of products and methods that provide contraception and/or prevent the sexual transmission of HIV/AIDS and other infections.

Control group

The standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given a standard treatment or intervention, or a placebo.

Controlled trials

A control is the standard against which experimental observations may be evaluated. In clinical trials, one group of participants is given an experimental drug or intervention, while another group (i.e., the control group) is given either a standard treatment or intervention for the disease or a placebo.

Core

The inner protective coat of protein that surrounds the genetic material of most viruses. In HIV, the core is mostly made up of the p24 protein, which surrounds two copies of HIV's genetic material.

Co-receptor

A protein on the surface of a cell that serves as a second binding site for a virus or other molecule. Although the CD4 protein is HIV's primary receptor, the virus must also bind to either the CCR5 or CXCR4 co-receptor to get into a host cell.

Cross-immunity

A state in which immunity to one organism serves to protect an individual against a different but related organism.

Crossover

A trial design in which the therapy (or intervention) given to study groups is switched during the course of the trial.

Cross-reactivity

A process by which an antibody responds to an antigen other than that which originally stimulated its production.

Cross resistance

The phenomenon whereby HIV resistance to one drug prompts resistance to other drugs in the same drug class. See also *drug resistance*.

Cross sectional study

A type of study that involves the collection of data at a defined time. Often used to assess the prevalence of a disease or condition in a particular population or to answer questions about the cause of disease in a population.

Cross sensitivity

A drug reaction that may occur again with the use of a different, but related, drug.

Culture

A laboratory method of growing a microorganism or living cells or tissue in a medium that promotes growth.

CXCR4

Chemokine receptor 4 (CXCR4, also known as fusin) is a protein on the surface of some immune system cells. It is one of two co-receptors that HIV can use along with the CD4 receptor to bind to and enter host cells. (The other co-receptor is CCR5.)

Cyanovirin-N (CV-N)

An anti-HIV protein being developed as a microbicide to prevent HIV.

Cytokine

A protein produced by white blood cells that acts as a chemical messenger between cells. Cytokines can stimulate or inhibit growth or activity of immune cells and are essential for a coordinated immune response. Cytokines include the interleukins and the interferons. See also *interleukin (IL-2, IL-7)* and *interferon (IFN)*.

Cytology

The study of the structure, function and pathology of cells.

Cytopathology

Disease, disorders or the destruction of cells.

Cytopenia

Reduced number of cells, in particular, blood cells.

Cytoplasm

The gel-like substance that composes cells and lies outside the cell nucleus.

Cytotoxicity

Poisonous or harmful to cells.

Cytotoxic T lymphocyte (CTL)

Also known as a killer T cell. A type of white blood cell that bears the CD8 surface marker, and targets and kills cancerous cells and cells infected with viruses; the action of CTLs is coordinated by CD4 cells via the production of cytokines.

D

DAIDS

See *Division of AIDS*.

Daily monitored adherence

A strategy to ensure adherence to a prevention regimen, in which a health care provider or other observer watches a patient take each dose of a drug. See also *directly observed therapy*.

Dapivirine

Also known as TMC-120, a non-nucleoside reverse transcriptase inhibitor being developed as a microbicide that is formulated as both a vaginal gel and an intravaginal ring to prevent HIV.

Dapivirine ring

An intravaginal ring developed for preventing HIV in women that contains the antiretroviral dapivirine and releases the drug slowly over time.

Data Safety Monitoring Board (DSMB)

An independent committee of community representatives and clinical research experts that reviews blinded data while a clinical trial is in progress to ensure that participants are not exposed to undue risks. If the DSMB has any safety concerns, it may, at any time, recommend that the study modify its procedures or be discontinued. In addition, the DSMB may recommend halting the trial if there is compelling evidence for a product's effectiveness or if it becomes clear that the trial cannot determine whether a product is effective. See also *Independent Data Monitoring Committee*.

Definitive

Conclusive, unquestionable; a definitive diagnosis is made by detection of an organism (e.g., virus or bacteria) via culture, biopsy or other procedure.

Dendritic cell

A type of antigen-presenting cell that picks up foreign substances from the bloodstream and presents them to other parts of the immune system, which activates an immune response against the foreign invader. Dendritic cells are present in skin (where they are often called Langerhans cells) and the lining of the nose, intestines, lungs and genital tract. See also *antigen-presenting cell (APC)* and *antigen*.

Deoxyribonucleic acid (DNA)

Chemical structure that contains the genetic instructions for reproduction and protein synthesis for all cells and for many viruses.

Desensitization

Reduced sensitivity to an antigen or drug, typically achieved by administering a small amount of drug and gradually increasing the dose.

DEXA

See *Dual Energy X-Ray Absorptiometry Scan*.

Diagnosis

Determination of the existence of a disease or condition; diagnosis generally involves the evaluation of an individual's medical history, clinical symptoms and/or laboratory test results.

Diaphragm

A small latex or silicone dome/cup that covers the cervix (the lower part of the uterus that connects to the vagina). A diaphragm is a form of contraception that prevents pregnancy by covering the cervix and blocking sperm from entering the uterus. Clinical trials have shown that diaphragms DO NOT protect women from HIV infection.

Directly observed therapy (DOT)

A strategy to ensure adherence to a treatment regimen in which a health care provider or other observer watches a patient take each dose of a drug. This strategy is used with diseases like tuberculosis (TB) and HIV infection, in which adherence is important for effective treatment and to prevent emergence of drug resistance. See also *daily monitored adherence*.

Discordant couple

A couple in which one person is infected with a sexually transmitted infection (such as HIV) and the other is not.

Disinhibition

In HIV, the idea that people may be more likely to engage in risk-taking behavior because they perceive themselves at low risk of contracting HIV.

Division of AIDS (DAIDS)

A division of the National Institute of Allergy and Infectious Diseases (NIAID), a component of the U.S. National Institutes of Health. DAIDS was formed in 1986 to address the national research needs created by the HIV/AIDS epidemic; to increase basic knowledge of the pathogenesis, natural history, and transmission of HIV disease; and to support research to promote HIV detection, treatment, and prevention. See also *National Institute of Allergy and Infectious Diseases (NIAID)* and *National Institutes of Health (NIH)*.

DNA vaccine

An experimental vaccine approach in which one or more genes encoded for specific antigens are injected (via plasmids) directly into the body, thereby stimulating an immune response.

Dose escalation

The gradual increase of drug dosages to determine the amount that delivers the best balance of high efficacy and acceptable side effects.

Dose-ranging study

A clinical trial in which two or more doses of an agent (such as a drug) are tested against each other to determine which dose works best and is least harmful.

Double-blind

See *blinding*.

Double-blind study

A study design that ensures neither the participants nor the researchers know which group of participants are receiving the test product and which are receiving a placebo. This means there is less potential for bias. Only after all of the data have been recorded (and in some cases, analyzed) do the researchers discover who had received the test product and who had received the placebo. In doing this the results are considered “unblinded.”

Douching

Using water or a medicated solution to clean the vagina. Douching can mask, or even worsen conditions such as bacterial or yeast infection of the vagina. Even more seriously, douching is associated with increased risk of pelvic inflammatory disease (PID) and associated with increased risk of an ectopic pregnancy (probably due to PID). See also *pelvic inflammatory disease*.

Downregulation

Reduction of the rate at which a process occurs or a substance is released, etc. Compare with *upregulation*.

Drug absorption

The passage of a drug through the mucous membranes or skin.

Drug class

A group of drugs that share common properties, such as mechanisms of action. See also *mechanism of action*.

Drug-drug interaction

A change in the way a drug works when it is taken with another drug. The effect may be an increase or a decrease in the action of either drug, or it may be a side effect that does not normally occur when either drug is taken alone.

Drug interaction

An effect that can occur when one drug is taken with another drug or when a drug is taken with particular foods. Possible effects include changes in absorption from the digestive tract, changes in the rate of the drug's breakdown in the liver, new or increased side effects, or changes in the drug's activity.

Drug resistance

The ability of some micro-organisms, such as bacteria, viruses and parasites, to adapt so that they can multiply even in the presence of drugs that would normally kill them.

Dry sex

Refers to the practice of women using various agents to “dry out” the vagina before sexual intercourse. This practice is often based on cultural beliefs, but can inadvertently increase the risk of HIV transmission because condoms break more easily from the friction and a dry vaginal wall can lead to tears and lacerations during intercourse.

DSMB

See *Data Safety Monitoring Board*.

Dual Energy X-Ray Absorptiometry (DEXA or DXA) Scan

A painless test that uses low energy x-rays to measure the mineral content of bones. DEXA scans are commonly used to test for changes in bone, particularly in women.

E**Ectocervix**

The portion of the uterine cervix projecting into the vagina. On average, the ectocervix is 3 cm long and 2.5 cm wide.

Effectiveness

The measure of the success of a treatment for a particular disease or condition or an intervention to prevent a particular disease or condition; effectiveness refers to how well treatment or intervention may work in real life settings.

Efficacy

The ability of a treatment to produce the desired effect on the disease or condition being treated. Efficacy refers to how well an intervention works under controlled situations, such as in a trial.

Emtricitabine

Generic name of FTC. See also *FTC*.

Emtriva

Brand name of FTC. See also *FTC*.

Endemic

A term that refers to diseases associated with particular geographic regions or populations. For example, malaria is endemic in tropical regions of the world where mosquitoes carry the parasite that causes malaria.

Endogenous

Originating within or produced by the body.

Endometrium

Refers to the uterine lining, the cells that line the uterus, and the inner layer of the uterus. In reproductive-aged women, this tissue is shed monthly in response to the hormonal changes during the menstrual period. The endometrium then grows back and slowly gets thicker and thicker until the next menstrual period when it is once again sloughed off.

Endoscopy

A method of examining the interior of a body cavity or hollow organ (e.g., esophagus, stomach) using a narrow, flexible instrument (called an endoscope) that conducts light.

Endothelium

A layer of cells that line blood and lymph vessels, the heart and various body cavities.

Endpoint

General term for a measurement used to analyze results of a clinical trial. A common endpoint for an HIV prevention trial is HIV infection. Each trial participant who acquires HIV during the study represents an endpoint.

Enrolling

The act of signing up volunteers into a study. Generally this process involves evaluating a participant with respect to the eligibility criteria of the study and engaging in the informed consent process.

Enrollment criteria

Factors used to determine whether a person is eligible to participate in a clinical trial. Inclusion criteria are conditions a potential participant must meet in order to be eligible to participate in a clinical trial. Exclusion criteria are conditions that disqualify a person from participating.

Entry inhibitor

Entry inhibitors constitute a class of antiretrovirals designed to combat infections that are increasingly resistant to older therapies. They are designed to disrupt the ability of HIV to enter a host cell through the cell's surface by targeting the gp120 or gp141 proteins or the CXCR4 or CCR5 receptors.

Env

The HIV gene that encodes the proteins of the viral envelope; also refers to the protein (Env) produced by this gene.

Envelope

The outer protective membrane of HIV that is composed of two layers of fat-like molecules called lipids. HIV uses specific proteins embedded in the envelope to attach to and enter host cells.

Enzyme

Protein molecule that speeds up a chemical reaction in a living organism. An enzyme acts as a catalyst for specific chemical reactions, converting a specific set of reactants (called substrates) into specific products. Almost all processes in a living cell are carried out by enzymes.

Enzyme-linked immunosorbent assay (ELISA)

A laboratory test used to detect the presence of antibodies in the serum. ELISA is used to screen for HIV infection; a positive result indicates that antibodies are present, but results should be confirmed with a highly specific laboratory test called a Western blot. See also *Western blot*.

Epidemic

A disease that has spread rapidly through a segment of the human population in a given geographic area.

Epidemiology

The study of the frequency, distribution and behavior of diseases within populations.

Epithelium

The protective covering of the internal and external organs of the body, including the lining of blood vessels, the vagina and rectum, glands and organs. In addition to its protective properties, the epithelium also provides a surface to absorb and secrete chemicals needed by the body.

Epithelial cell

One of the closely packed cells forming the epithelium.

Epitope

A particular segment of an antigen that the body's antibodies can recognize and bind to.

Equipoise

A state in which an investigator is genuinely uncertain which arm of a clinical trial would be more beneficial. Provides the ethical basis for clinical research.

Eradication

In terms of an infectious disease, the complete removal of a pathogen (such as HIV). Although eradication of HIV is currently not possible, antiretroviral treatment can control the disease through the suppression of viral load.

Ethics committee

A committee of experts who review and monitor clinical trials to ensure that they are ethically conducted and that the rights of study participants are protected. Ethics committees are similar to Institutional Review Boards.

Ethnography

The study of individual cultures through observation, interviews and questionnaires. Considered a qualitative method of research.

Etiology

The cause of a disease or adverse medical condition.

Excipient

An inert or slightly active substance used to give a drug a certain form or consistency; a substance used to convey an active drug.

Expanded access

Refers to any of the U.S. Food and Drug Administration (FDA) procedures that allow distribution of experimental drugs to participants who are failing on currently available treatments for their condition and are unable to participate in ongoing clinical trials.

Experimental drug

Also known as an investigational drug. A drug that is not approved by a regulatory agency, such as the Food and Drug Administration (FDA), for use in humans or as a treatment for a particular condition.

Explant culture

The growing of microorganisms, tissue cells or other living matter in a specially prepared nutrient medium.

Ex vivo

Outside of or removed from the body of a living organism.

F**False negative**

A test or procedure result that incorrectly indicates a negative or normal result when an abnormal condition is actually present.

False positive

A test or procedure result that incorrectly indicates a positive or abnormal result when no abnormal condition is actually present.

Family Health International

See *FHI 360*.

Fat soluble

Capable of being dissolved in lipids; fat-soluble compounds are not easily excreted by the body. Compare with *water soluble*.

Female condom

A thin pouch used during intercourse to prevent pregnancy and reduce the risk of sexually transmitted diseases. The closed end, which has a flexible ring, is inserted into the vagina, while the open end remains outside, partially covering the labia. See also *condom*.

FemPrEP

A Phase III clinical trial that was designed to evaluate daily use of the antiretroviral Truvada for preventing HIV in high-risk women in Africa.

FHI 360

Formerly known as Family Health International. An international public health and development organization managing research and field activities and building local capacity to address development problems in 55 countries.

First-line therapy

The preferred initial standard treatment for a particular disease or medical condition.

Flora

The bacteria and other microorganisms that normally inhabit a bodily organ or part, such as the intestine or vagina.

Flow cytometry

A method of analyzing cells in which certain cell properties are detected as the cells flow in a narrow stream of a measuring device.

Food and Drug Administration (FDA)

The U.S. Department of Health and Human Services (HHS) agency responsible for ensuring the safety and effectiveness of drugs, biologics, vaccines and medical devices. The FDA also works with the blood banking industry to safeguard the nation's blood supply. Commonly referred to as the U.S. Food and Drug Administration.

Foreskin

The retractable fold of skin and mucous membrane that covers the head of the penis, protecting it when the penis is not erect. In many cultures, the foreskin is removed at birth or adolescence through a process known as circumcision. See also *circumcision*.

Formulary

A list of regulatory agency-approved or available drugs.

Formulation

The physical form in which a drug is administered. Examples include tablets, capsules, liquids, topical creams and ointments and injectable solutions. A single drug may be available in multiple formulations.

FTC

Generic name is emtricitabine and brand name is Emtriva. It is a nucleoside reverse transcriptase inhibitor drug approved for use as part of combination antiretroviral therapy for HIV.

Fusion or entry inhibitor microbicides

Name of a class of candidate microbicides that block non-specific cellular receptors so that HIV and other sexually transmitted infections cannot attach to and infect target cells. Examples include PRO 2000, Carraguard, cellulose sulfate and VivaGel. See also *entry inhibitor*.

Futility

When efforts to achieve a result are likely to fail. In the context of a clinical trial, futility occurs when the study is unlikely to be able to determine whether a product works due to low accrual, low retention, low adherence, changes in sexual behavior, or lower than expected HIV incidence in the study population. A data safety monitoring board (DSMB) may stop a trial early for this reason.

G**Gag**

The HIV gene that encodes the core proteins of the virus; also refers to the protein (Gag) produced by this gene.

Gender inequality

A phrase typically used to describe the second-class status women hold in many societies affected by the AIDS epidemic. Inequality often leaves women unable to negotiate sexual situations, increasing the risk of acquiring HIV.

Gene

A short segment of DNA that acts as a blueprint for building a specific protein. See also *deoxyribonucleic acid (DNA)* and *ribonucleic acid (RNA)*.

Gene expression

The production of a particular RNA and gene product, or protein.

Genitourinary

Pertaining to the genital and urinary organs and their functions.

Genotype

The specific genetic makeup or "blueprint" of an organism; genotypic resistance testing determines whether an organism's genetic structure contains certain mutations likely to make it resistant to a drug. Compare with *phenotype*.

Genotypic assay

Also known as Genotypic Antiretroviral Resistance Test (GART). A test that determines if HIV is resistant to particular anti-HIV drugs. The test analyzes a sample of the virus from an individual's blood to identify any genetic mutations that are associated with resistance to specific drugs. See also *drug resistance* and *mutation*.

Gestation

The period of development in the uterus from conception until birth; pregnancy.

Global Campaign for Microbicides (GCM)

An advocacy organization focused on microbicides and other user-controlled HIV and STI prevention options.

Glucocorticoid

One of a family of steroids (e.g., cortisol) that influence metabolism, help regulate the immune system, and exert an anti-inflammatory effect. See also *corticosteroid*.

Glycoprotein (GP)

It is a small unit made up of a sugar and a protein molecule, often part of a cell's membrane; glycoproteins make up the envelope of HIV.

Good Clinical Practice (GCP)

An internationally agreed-upon set of standards for the conduct of clinical trials, including rules for handling data, protecting confidentiality and maintaining proper laboratory practices.

Good Manufacturing Practice (GMP)

A set of guidelines to be followed in the testing and manufacture of pharmaceuticals. The purpose of GMP is to safeguard the health of patients.

Good Participatory Practice (GPP)

Guidelines for biomedical HIV prevention trials that are designed to provide systematic guidance on the roles and responsibilities of trial sponsors and trial implementers towards participants and their communities.

gp120

A glycoprotein on the HIV envelope that binds to CD4 receptors and chemokine co-receptors (e.g., CCR5, CXCR4), enabling the virus to enter host cells.

gp160

Glycoprotein 160. A precursor of HIV envelope proteins gp41 and gp120. gp160 is cut by an HIV enzyme called protease to form gp120 and gp41.

gp41

Glycoprotein on the surface of HIV that acts as an anchor in the viral envelope to hold gp120.

Gram stain

The most common diagnostic tool used for gonorrhea and other bacteria. With this test, bacteria either stain purple (gram-positive) or red (gram-negative).

Granulocyte

A type of white blood cell particularly important in fighting bacterial infections.

Granulocyte-Colony Stimulating Factor (G-CSF)

A particular cytokine that stimulates the growth of granulocytes, a type of white blood cell.

Granulocyte Macrophage-Colony Stimulating Factor (GM-CSF)

A particular cytokine that stimulates the production of granulocytes, a type of white blood cell.

Gravidas

Pregnant women.

H**Half-life**

The time required for half the total amount of a substance or drug to be eliminated from the body.

HEC placebo

The hydroxyethyl cellulose (HEC) placebo is considered the “universal placebo” and has been adopted as the standard placebo in many microbicide trials.

Helper T cell

See *CD4 cell*.

Hematotoxic

Poisonous to the blood or to blood-producing stem cells in the bone marrow.

Hepatic

Pertaining to the liver.

Hepatitis

Inflammation of the liver; hepatitis may be caused by several factors, including viruses (hepatitis A, B, C, D and E), toxic substances, heavy alcohol use, and the use of certain drugs; hepatitis symptoms may include fatigue, loss of appetite, abdominal tenderness, jaundice and elevated liver enzymes (ALT and AST).

Hepatitis B (HBV)

A blood-borne viral disease of the liver. Hepatitis B becomes chronic in about 5-10% of infected adults and 90% of infected infants; untreated chronic HBV can lead to cirrhosis and liver cancer. Standard treatments are interferon, 3TC and adefovir; a HBV vaccine is available to prevent HBV infection.

Hepatotoxicity

A general term for liver damage. Often caused by drugs, including those used to treat HIV infection.

Herpes Simplex Virus 1 (HSV-1)

A virus that causes cold sores or fever blisters on the mouth or around the eyes and that can be transmitted to the genital region. The virus can become latent (inactive), in which symptoms disappear. Stress, trauma, other infections or suppression of the immune system can reactivate the latent virus, and symptoms can return. See also *herpesviruses*.

Herpes Simplex Virus 2 (HSV-2)

A virus that causes painful sores around the anus or genitals. The virus can become latent (inactive), in which symptoms disappear until the virus is reactivated. HSV-2 may be transmitted either sexually or from an infected mother to her infant during birth.

Herpesviruses

A family of viruses that includes several individual members, including herpes simplex viruses 1 and 2 (HSV-1 and -2), cytomegalovirus (CMV), varicella zoster virus (VZV), Epstein-Barr virus (EBV), and Kaposi's sarcoma herpesvirus (KSHV or HHV-8). Each of these viruses can cause disease in humans.

Heterozygous

Possessing two different alleles, or gene variants, at a given site on a chromosome. Contrast with *homozygous*.

Highly Active Antiretroviral Therapy (HAART)

The name given to treatment regimens that aggressively suppress HIV replication and progression of HIV disease. The usual HAART regimen combines three or more anti-HIV drugs from at least two different classes.

Histology

The study or examination of body tissues; histological improvement refers to improved tissue health.

HIV

See *Human Immunodeficiency Virus*.

HIV-1

The type of HIV responsible for the majority of HIV infections worldwide.

HIV-2

A virus that is closely related to HIV-1 and that also causes immune suppression and AIDS. Although the two viruses are very similar, immunodeficiency seems to develop more slowly and to be milder in people infected with HIV-2. The majority of HIV-2 cases have been found in West Africa. Not all drugs used to treat HIV-1 infection are effective against HIV-2.

HIV Prevention Trials Network (HPTN)

A worldwide clinical trials network established by the National Institutes of Allergy and Infectious Diseases (NIAID) to develop and evaluate the safety and efficacy of nonvaccine HIV interventions designed to prevent the transmission of HIV.

HIV RNA

See *viral load (VL)*.

HIV shedding

See *shedding*.

HIV test

The standard HIV diagnostic test looks for the presence of HIV antibodies in the blood or in oral fluid. HIV antibodies are molecules produced by the body once it detects the presence of HIV. The production of HIV antibodies does not happen immediately after exposure to the virus. The period after infection, but before production of antibodies, is called the window period. During the window period, an HIV test may be negative. It is possible to test negative despite the presence of HIV in the body. There are several different kinds of HIV tests used to screen for the presence of antibodies. See also *window period*.

HIV Vaccine Trials Network (HVTN)

An international group of scientists and educators formed in 1999 by the National Institute of Allergy and Infectious Diseases (NIAID). The main goal of HVTN is to find a safe and effective preventive HIV vaccine.

Horizontal transmission

A term used to describe transmission of a disease from one individual to another, except from parent to offspring. For example, HIV can be spread horizontally through sexual contact or exposure to infected blood. In contrast, spread of disease from parent to offspring is called vertical transmission. Compare with *vertical transmission*.

Hormone

A chemical produced in one part of the body and passed through the blood to another part of the body to regulate its structure or function. HIV infection and AIDS can affect the production of hormones and cause imbalances in hormones, such as estrogen and testosterone.

Host cell

A living cell invaded or capable of being invaded by an infectious agent, such as a bacterium or virus.

HPV

See *human papillomavirus*.

HSV

See *herpes simplex virus*.

Human Immunodeficiency Virus (HIV)

The virus that causes Acquired Immunodeficiency Syndrome (AIDS). HIV is a lentivirus, in the retrovirus family, and two types have been identified: HIV-1 and HIV-2. HIV-1 is responsible for most HIV infections throughout the world, whereas HIV-2 is found primarily in West Africa. See also *Acquired Immunodeficiency Syndrome (AIDS)*, *retrovirus* and *lentivirus*.

Human Leukocyte Antigen (HLA)

Also known as major histocompatibility complex (MHC). Found on the surface of almost every cell in the body, HLAs are proteins that play an important role in controlling the immune system by identifying substances that are foreign to the body. The type of HLA proteins a person inherits from his or her parents is important in identifying good matches for tissue grafts and organ transplants. Some HLA types are associated with either a faster or slower progression of HIV disease.

Human papillomavirus (HPV)

A virus that causes various warts, including plantar and genital warts. Some strains of HPV can also cause cervical cancer.

Humoral immunity

Term used to describe the body's antibody-based immune response, as opposed to its cell-based immune response (cell-mediated immunity). Humoral immunity involves B cells, which produce antibodies against foreign invaders.

Hyperosmolar

Pertaining to an increased concentration of salt and sugar solutes in the body's fluids compared to cells. The imbalance causes water to leave cells, making the cells shrivel up like a raisin.

Hyposmolar

Pertaining to a decreased concentration of salt and sugar solutes in the body's fluids compared to cells. The imbalance causes water to enter cells. With too much water, cells can explode.

Hypothesis

A supposition or assumption presented as a basis for reasoning or argument, or as a guide to experimental investigation.

I**IAVI**

International AIDS Vaccine Initiative. A global not-for-profit organization working to ensure the development of a safe, effective and accessible preventive HIV vaccine.

Idiopathic

Without a known cause.

IDMC

See *Independent Data Monitoring Committee*.

IDU

Acronym for injecting drug user(s), and refers to individuals who use needles/syringes to inject drugs. This is a major risk for HIV infection in many parts of the world.

Immune complex

Term used to describe an antibody bound to an antigen.

Immune response

How the body recognizes and defends itself against bacteria, viruses, and other substances that may be harmful. See also *cell-mediated immunity* and *humoral immunity*.

Immune system

The collection of cells and organs whose role is to protect the body from foreign invaders. Includes the thymus, spleen, lymph nodes, B and T cells, and antigen-presenting cells.

Immunity

Protection against or resistance to a disease.

Immunization

The process by which an individual is protected against infection by a disease-causing microorganism. In active immunization (vaccination), a person is exposed to a small amount of a killed or inactivated microorganism, or its proteins, in order to stimulate an immune response. In passive immunization, a person is given manufactured antibodies or antibodies transferred from another individual.

Immunocompetent

Able to mount a normal immune response.

Immunocompromised

Unable to mount a normal immune response because of an impaired immune system.

Immunodeficiency

Inability to produce normal amounts of antibodies, immune cells or both.

Immunogenicity

The ability of an antigen or vaccine to stimulate an immune response.

Immunologic failure

Occurs when an HIV-infected individual's CD4 count decreases below the baseline count or does not increase above the baseline count within the first year of anti-HIV treatment. People who experience virologic failure but do not switch to an effective drug regimen usually progress to immunologic failure within about 3 years. Immunologic failure may be followed by clinical failure. See also *clinical failure*.

Immunology

The medical specialty concerned with the immune system and its disorders.

Immunomodulator

A natural or man-made substance that can modify the functioning of the immune system.

Immunosuppression

The state in which the immune system cannot respond normally to foreign invaders. May be caused by drugs (e.g., chemotherapy) or result from certain diseases (e.g., HIV infection).

Immunotherapy

Treatment to stimulate or restore the body's immune system to fight disease.

Implementation research

The scientific study of methods to promote the systematic uptake of research findings into routine practice.

Incidence

The number of new cases of a disease in a population over a specific period of time (e.g., annual number of new HIV cases in a country). Often reported as the number of cases per 100,000 people. Compare with *prevalence*.

Inclusion/exclusion criteria

The medical or social standards determining whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate participants and keep them safe.

Incubation period

The period of time between HIV infection and the onset of symptoms.

Independent Data Monitoring Committee (IDMC)

Similar to a Data Safety Monitoring Board (DSMB), an independent committee of community representatives and clinical research experts that reviews blinded data while a trial is ongoing. See also *Data Safety Monitoring Board*.

Indication

The use for which a drug is intended and approved.

Infection

Establishment of an infectious micro-organism in a suitable host. The term is also used to refer to disease caused by an infectious micro-organism.

Infectious

Capable of being transmitted from person to person.

Inflammation

The body's response to tissue injury or infection, which typically includes redness, swelling, heat and pain.

Inflammatory mediators

Molecules that are released by immune cells during times when harmful agents invade our bodies.

Informed consent

The process through which study participants learn about the risks and benefits of study participation, so that they can decide whether to not to voluntarily participate.

Informed consent document

A document that describes the rights of study participants, and includes details about the study, such as its purpose, duration, required procedures and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

Inhibitor

An agent that inhibits or blocks an activity.

Innate antimicrobial factors

Components of innate or nonspecific immunity that aid in the body's natural defense against foreign invaders.

Innate immunity

See *nonspecific immunity*.

Institutional Review Board (IRB)

A committee of experts who review and monitor clinical trials to ensure that they are ethically conducted and that the rights of study participants are protected. Federal regulations dictate that any institution that conducts or supports clinical trials must have an IRB.

Integrase

An HIV protein that plays an important role in the virus's life cycle. Integrase inserts HIV's genetic information into the infected cell's own DNA.

Integrase inhibitor

A class of anti-HIV drugs that prevents the HIV integrase protein from inserting HIV's genetic information into an infected cell's own DNA.

Integration

The process by which viral DNA is integrated into, or made part of, the genetic material of a host cell.

Intent-to-treat (ITT) analysis

A method of analyzing the results of a clinical trial in which all participant originally assigned to a study group are analyzed, including those who dropped out due to study product side effects, pregnancy or other reasons. ITT analysis differs from per-protocol analysis. Compare with *per-protocol analysis*.

Intercellular

Occurring between cells.

Interferon (IFN)

A cytokine – a protein involved in regulating immune system activity – that the body produces to fight viruses. Laboratory-made versions of IFN are used in the treatment of some viral infections and cancers. There are three main types of interferon: alpha, beta and gamma.

Interim analysis

A planned analysis of blinded data while a trial is ongoing that is conducted by the study's Data Safety Monitoring Board or Independent Data Monitoring Committee.

Interleukin-2 (IL-2)

A cytokine – a protein involved in regulating immune system activity – that can increase the production of certain disease-fighting white blood cells. During HIV infection, IL-2 levels gradually decline. A laboratory made version of IL-2 is used to treat some cancers and has been studied as a way to increase the number of CD4 cells and other immune system cells in people with HIV.

Interleukin-7 (IL-7)

A cytokine – a protein involved in regulating immune system activity – produced in small amounts in bone marrow cells that increases the body’s production of certain disease-fighting white blood cells. Laboratory produced IL-7 is a drug product that appears to induce HIV replication in latent, or resting, infected cells. Activation of HIV in resting cells allows antiretroviral drugs to target HIV in those cells.

International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network

A National Institutes of Health-funded clinical trials network that evaluates treatments for HIV-infected children and adolescents and also develops new therapeutic approaches for preventing mother-to-child transmission (MTCT) of HIV.

International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)

A National Institutes of Health-funded clinical trials network that evaluates strategies for optimizing treatment by doing large sample trials in HIV-infected individuals.

International Partnership for Microbicides (IPM)

A non-profit product development partnership established to accelerate the development and accessibility of microbicides to prevent HIV transmission in women.

International Rectal Microbicide Advocates (IRMA)

An advocacy organization working to advance rectal microbicide research and development.

Intervention

In medicine, a treatment or action taken to prevent or treat a disease or to improve health in other ways.

Intracellular

Within a cell.

Intravaginal

Within the vagina.

Intravaginal ring

A doughnut-shaped polymeric drug delivery device designed to provide controlled release of drugs to the vagina over extended periods of time.

Intravenous (IV)

Inside a vein. Intravenous also refers to an injection made directly into a vein.

In situ

Occurring in place or at a specific site.

In utero

Before birth. The time period when a fetus or embryo develops in the uterus.

Investigational Drug

Also known as an experimental drug. A drug that has not been approved by the Food and Drug Administration (FDA) to treat a particular disease or condition. The safety and effectiveness of an investigational drug must be tested in clinical trials before the manufacturer can request FDA approval for a specific use of the drug.

Investigational New Drug (IND)

An FDA classification applied to experimental drugs undergoing clinical trials to assess their safety and efficacy prior to marketing approval.

Investigational New Drug (IND) Application

The process through which data about an experimental drug is submitted to and reviewed by the Food and Drug Administration (FDA) before the drug is allowed to be tested in clinical trials.

In vitro

Latin for “in glass.” Indicates that a research study was conducted in an artificial environment created outside a living organism (for example, in a test tube or petri dish).

In vivo

Latin for “in life.” Indicates that a research study was conducted in a living organism (animal or human). Compare with *ex vivo*.

iPrEx

A phase III clinical trial that evaluated the daily use of the antiretroviral Truvada in gay men, male to female transgendered women and other men who have sex with men.

iPrEx OLE

An open-label extension trial for participants in iPrEx.

Isomolar

Pertaining to the concentration of solutes (made up of salts and sugars) normally found in cells.

K**Killer T Cell**

See *CD8 cell* and *cytotoxic T lymphocyte*

L**Lactobacillus**

A bacterium normally found in the mouth, intestinal tract and vagina.

Langerhans cell

A specialized dendritic cell in the skin and mucous membranes that transports antigens to the lymph nodes.

Latency

The time period when an infectious organism is in the body but is not producing any noticeable symptoms. In HIV disease, latency usually occurs in the early years of infection. Also refers to the period when HIV has integrated its genetic information into a cell's DNA but has not yet begun to replicate.

Latent HIV reservoir

A collection of resting cells (such as T cells) in the body that are infected with HIV. The virus is spread within the body when these host cells become active. See also *latency*.

Late-stage disease

Advanced progression of a disease; late-stage HIV disease occurs years or decades after initial HIV infection and is characterized by a low CD4 cell count (under 200 cells/mm³), high viral load, wasting syndrome and possibly opportunistic infections.

Lentivirus

A virus characterized by a long incubation period. HIV is a lentivirus.

Lesion

Small scrapes, sores or tears in tissue. Lesions in the vagina or rectum can be cellular entry points for HIV.

Leukocyte

See *white blood cell*.

Life cycle

A sequence of developmental phases that cells or organisms undergo. For example, a cell's life cycle ends with division; a virus's life cycle includes replication within a host cell.

Ligand

A molecule that binds to a specific receptor on a cell's surface.

Live-attenuated virus

A weakened live virus used in vaccines to provoke an immune response.

Localized

Affecting a specific body site, organ or system.

Log

A measure based on the logarithmic scale that refers to quantities in factors of 10. A log change is an exponential or 10-fold increase or decrease (e.g., a change from 10 to 100 is a 1 log, or 10-fold, increase; 1,000,000 to 10,000 is a 2 log, or 100-fold, decrease). Changes in viral load are often expressed in logs.

Logistic regression

See *regression analysis*.

Longitudinal

Refers to a study that follows participants over an extended period.

Long-term nonprogressor

An individual who has been infected with HIV for several years but maintains a high CD4 cell count, does not exhibit symptoms of immune system decline, and has not developed opportunistic illnesses despite lack of treatment.

Lymphokine

A cytokine (chemical messenger that affects the immune response) secreted by white blood cells.

M**Macrophage**

A type of disease-fighting white blood cell that engulfs and destroys foreign invaders and stimulates other immune system cells to fight infection.

Magnetic Resonance Imaging (MRI)

A noninvasive technique that uses magnetic fields and radio waves instead of x-rays to produce three-dimensional computerized images of the body's internal tissues and organs.

Maintenance therapy

Also known as secondary prophylaxis. A treatment to prevent an infection from coming back after it has been brought under control.

Maraviroc

A type of drug called an entry inhibitor that prevents HIV from entering a healthy cell. It is prescribed for the treatment of HIV as part of antiretroviral therapy, and is being developed as a microbicide and intravaginal ring for HIV prevention.

Mean

A statistical measurement of the central tendency, or average, of a set of values. For example, in the series "1, 1, 1, 2, 2, 10, 32," the mean is 7 (determined by adding all the values and dividing by the number of values). Compare with *median*.

Mechanism of action

Refers to the specific biochemical interaction through which a drug substance produces its pharmacological effect. A mechanism of action usually includes mention of the specific molecular targets to which the drug binds, such as an enzyme or receptor.

Median

The middle value in a distribution; the number within a series that is preceded and followed by an equal number of values. For example, in the series "1, 1, 1, 2, 2, 10, 32," the median is 2 (there are three values lower and three values higher). Compare with *mean*.

Memory cell

A long-lived B cell or T cell that is specialized to recognize and respond to a specific pathogen; memory cells remain in the body after an initial immune response, and are primed to respond to a subsequent attack by the same invader. Compare with *näive T cell*.

Men who have sex with men (MSM)

A term used to refer to men who engage in anal intercourse with other men.

Messenger RNA (mRNA)

A molecule that carries genetic instructions for building a particular protein from the cell's DNA to the place in a cell where proteins are assembled. There, the mRNA serves as a blueprint for the construction of a specific protein.

Meta-analysis

A type of analysis that combines data from a number of different trials (e.g., several clinical trials looking at the same drug).

Metabolism

The physical and chemical reactions that produce energy for the body. Metabolism also refers to the breakdown of drugs or other substances within the body, which may occur during digestion or elimination.

Microbe

A living organism (e.g., a bacterium) that can be seen only through a microscope.

Microbicide Trials Network (MTN)

A clinical trials network funded by the U.S National Institutes of Health that evaluates topical and oral products to prevent the sexual transmission of HIV.

Microbicides

Currently under development and testing, products designed to prevent or reduce the sexual transmission of HIV or other sexually transmitted infections (STIs) when applied topically on the inside of the vagina or rectum.

Microbicides Development Programme (MDP)

A public-private partnership funded by the UK Department of International Development with support from the UK Medical Research Council (MRC).

Monotherapy

The use of only one drug to treat a disease. For HIV, combination therapy with three or more active anti-HIV drugs has proven to be more effective than monotherapy. Combination therapy, also known as highly active antiretroviral therapy or HAART, is now the gold standard for HIV treatment. Compare with *combination therapy*.

Morbidity

The rate of sickness or disease within a certain population.

Mortality

Death; the mortality rate is the rate of death in a given population.

Mother-to-child transmission (MTCT)

The passage of HIV from an HIV-infected mother to her infant. The infant may become infected while in the womb, during labor and delivery, or through breastfeeding. See also *vertical transmission*.

Mucosa

Also referred to as mucus membrane. Moist tissue layers that line particular organs and body cavities such as the vagina and rectum.

Mutation

A change in genetic material that may occur during a cell's replication. With HIV, mutations arise because it is prone to making mistakes during its replication. Some mutations can make HIV resistant to a particular drug. See also *drug resistance*.

N**Naïve**

Inexperienced; the term is used to refer to an individual who has never taken a certain drug or class of drugs.

Natal

Refers to birth.

National Institute of Allergy and Infectious Diseases (NIAID)

An institute of the U.S National Institutes of Health (NIH) that conducts and funds research to better understand, treat, and prevent infectious, immunologic, and allergic diseases.

National Institutes of Health (NIH)

A multi-institute agency of the U.S. Department of Health and Human Services (HHS). NIH conducts research in its own laboratories and funds research in universities, medical schools, hospitals, and other research institutions throughout the United States and abroad.

Natural history study

A study designed to investigate the natural development of a disease or condition over time.

Natural killer (NK) cell

A type of white blood cell that is able to kill tumor cells and cells infected with viruses or other foreign invaders.

Nef

An HIV gene that influences viral replication and may help the virus evade host defenses.

Neonate

A newborn, especially within the first month of birth.

Nephrotoxic

Toxic or destructive to the kidneys.

Neutralizing antibody

An antibody that neutralizes (renders harmless) an infectious microorganism.

Nevirapine

Brand name Viramune. A non-nucleoside reverse transcriptase inhibitor drug approved for use as part of combination antiretroviral therapy for HIV. Often used to prevent the transmission of HIV from mother to child.

New Drug Application (NDA)

An application submitted by a drug manufacturer to the Food and Drug Administration (FDA) for a license to market and sell a particular drug in the United States. The drug manufacturer files an NDA after information from clinical trials is available for FDA review.

NK cell

See *natural killer cell*.

NNRTI

See *non-nucleoside reverse transcriptase inhibitor*.

NNRTI-sparing regimen

Drug combination that omits the use of any NNRTIs so that the drug class can be saved for use in future treatment. See also *non-nucleoside reverse transcriptase inhibitor*.

Noncoitally dependent

In HIV prevention, means that products or regimens are used or followed in a manner that is independent of sexual intercourse. Compare with *coitally dependent*.

Noninferiority trial

A study that seeks to demonstrate that the experimental statement is not worse than the control treatment. May be necessary with a placebo, or control, group cannot be ethically included in a study.

Non-nucleoside reverse transcriptase inhibitor (NNRTI)

A class of anti-HIV drugs that bind to and disable HIV's reverse transcriptase enzyme, a protein that HIV needs to make more copies of itself. Without functional reverse transcriptase, HIV replication is halted. Current NNRTI drugs are only effective against HIV-1 and not against HIV-2. Compare with *nucleoside reverse transcriptase inhibitor*.

Nonoxynol-9 (N-9)

A contraceptive spermicide found in many products and sold over the counter. N-9 can cause vaginal and rectal tissue damage and is not effective for HIV prevention or recommended as a lubricant for receptive anal intercourse.

Nonresponder

An individual who does not show improvement (e.g., decreased viral load) while undergoing treatment.

Nonspecific immunity

Also called innate immunity; the immune system's immediate first line of defense.

NPT

New prevention technology.

NRTI

See *nucleoside reverse transcriptase inhibitor*.

NRTI-sparing regimen

Drug combination that omits the use of any NRTIs so that the drug class can be saved for use in future treatment. See also *nucleoside reverse transcriptase inhibitor*.

Nucleic acid

Chemical structure that stores genetic information. There are two types of nucleic acid, DNA and RNA. Human genetic information is stored as DNA, whereas HIV's genetic information can be stored as both DNA and RNA.

Nucleoside

A precursor to a building block of DNA or RNA. Nucleosides must be chemically changed into nucleotides before they can be used to make DNA or RNA. See also *nucleotide*.

Nucleoside analog

See *nucleoside reverse transcriptase inhibitor*.

Nucleoside reverse transcriptase inhibitor (NRTI)

A class of anti-HIV drugs that block the replication of HIV by interfering with reverse transcriptase (RT) a protein that HIV needs in order to make more copies of itself. NRTIs work in a slightly different way than NNRTIs. Compare with *non-nucleoside reverse transcriptase inhibitor*.

Nucleotide

A building block of DNA or RNA, the chemical structures that store genetic information. See also *nucleoside*.

Nucleotide analog

See *nucleotide reverse transcriptase inhibitor*.

Nucleotide reverse transcriptase inhibitor (NtRTI)

A class of anti-HIV drugs that block the replication of HIV by interfering with reverse transcriptase (RT) a protein that HIV needs in order to make more copies of itself. NtRTIs work in a slightly different way than NRTIs.

Nucleus

The part of a cell that contains the organism's genetic information.

Q**Observational study**

A clinical trial in which no experimental drug is administered, but symptoms, laboratory values and response to therapy and/or the course of disease are observed during the study.

Odds ratio (OR)

A statistical measure of the likelihood of developing a disease or condition if a certain factor (e.g., a pathogen or drug) is present.

Office of AIDS Research (OAR)

The office within the U.S. National Institutes of Health (NIH) Office of the Director responsible for the scientific, budgetary, legislative and policy elements of the NIH HIV/AIDS research program.

Off-label

Use of a drug for a condition other than that for which it was FDA-approved.

Open-label trial

A clinical trial in which both the researchers and the participants know who is getting which drug or vaccine.

Opportunistic infection (OI)

An illness caused by any one of various organisms that occur in people with weakened immune systems, including people with HIV/AIDS. OIs that are common in people with AIDS include *Pneumocystis jiroveci* pneumonia (PCP); cryptosporidiosis; histoplasmosis; toxoplasmosis; other parasitic, viral, and fungal infections; and some types of cancers.

Oral

Refers to the mouth; taken by mouth.

Osteoporosis

Severe loss of bone mass, density, and strength. Although usually an age-related disorder, osteoporosis may also occur as a result of HIV infection or as a side effect of anti-HIV drugs.

Over-the-counter (OTC)

Refers to drugs that are available without a prescription.

P**p24**

A core protein of HIV produced by the *gag* gene; the presence of p24 in the blood indicates that HIV is actively replicating.

Package insert

Also known as prescribing information or product label. A document prepared by the manufacturer of a drug and approved by the Food and Drug Administration (FDA) to describe a drug's approved uses, dosages, contraindications, potential side effects and other relevant information. This information is inserted inside each manufactured drug bottle and attached to any promotional or labeling materials.

Pandemic

A worldwide epidemic; occurring over a wide geographic area and affecting an exceptionally high proportion of the population.

Pap smear

A method for the early detection of cervical cancer. A Pap smear is done by placing a speculum in the vagina, locating the cervix, and then scraping a thin layer of cells from the cervix. The cells are placed on a slide, sent to a laboratory and analyzed for abnormalities. HIV-infected women often have abnormal Pap smear results, usually as a result of human papillomavirus (HPV) infection.

Parenteral

Any route of administration, such as for a drug, into the body other than through the digestive system. For example, through the veins (intravenous), into the muscles (intramuscular), or through the skin (subcutaneous).

Partners PrEP

A Phase III clinical trial evaluating the use of the antiretroviral Truvada and tenofovir for preventing HIV among HIV-negative partners in serodiscordant relationships.

Passive immunity

The body's ability to prevent or fight a specific infection after receiving antibodies from another person. The most common example of passive immunity is when an infant receives the mother's antibodies by consuming her breast milk.

Pathogen

General term for any disease-causing organism.

Pathogenesis

General term for the origin and development of disease.

Pathology

The study of disease, focusing on causes, development and progression.

Pathophysiology

The functional changes that accompany a disease.

PCR

See *polymerase chain reaction (PCR) assay*.

Peak concentration

The highest concentration of a drug in the blood after dosing. Contrast with *trough concentration*.

Peer review

The process of subjecting an author's scholarly work, research or ideas to the scrutiny of others who are experts in the same field. Peer review requires a community of experts in a given (and often narrowly defined) field, who are qualified and able to perform impartial review.

Pelvic exam

Examination of the organs of the female reproductive system, including the vagina, cervix and uterus.

Pelvic Inflammatory Disease (PID)

An infection of the upper female genital tract affecting the uterus, fallopian tubes and ovaries, commonly caused by the bacteria responsible for two sexually transmitted infections (STIs), gonorrhea and chlamydia. If left untreated, PID can cause pain, tubal pregnancy and infertility. Severe cases may even spread to the liver and kidneys, causing internal bleeding and death.

PEPFAR

The President's Emergency Plan for AIDS Relief (PEPFAR), is a multi-billion dollar initiative, launched in 2003 by U.S. President George W. Bush to address HIV/AIDS, TB and malaria in developing countries.

Peptide

A short chain of amino acids that are chemically linked to one another. Longer chains of amino acids are referred to as polypeptides.

Perianal

Around the anus.

Perinatal

The time period spanning shortly before and after birth.

Perinatal transmission

See *mother-to-child transmission*.

Peripheral blood mononuclear cells (PBMCs)

Any blood cell having a round nucleus (e.g. a lymphocyte, a monocyte or a macrophage).

These blood cells are a critical component in the immune system to fight infection and adapt to intruders.

Per-protocol analysis

A method of analyzing results of a clinical trial in which only those participants who completed the study are included in analysis. This excludes participants who may have dropped out of the study due to study product side effects, pregnancy or other reasons. Contrast with *intent-to-treat analysis*.

Person-year

A shorthand term used by epidemiologists and statisticians to make comparisons; its value is determined by multiplying the number of individuals by the number of years. For example, one person followed for 10 years or 10 people followed for one year both equal 10 person-years.

p-glycoprotein

A plasma membrane protein that pumps drugs and other substances out of cells.

pH

A measure of the acidity or alkalinity of a solution. Solutions with a pH less than 7.0 (the pH of water) are considered acidic. Solutions with a pH greater than 7.0 are considered alkaline. A normal pH for a healthy vagina usually ranges between 3.5 and 4.5.

Pharmacodynamics (PD)

The biochemical and physiological effects of drugs and their mechanisms of action in the body.

Pharmacokinetics (PK)

How drugs are processed and used in the body, including how they are absorbed, metabolized, distributed and eliminated.

Pharmacology

The branch of medical science that studies the chemistry, effects and uses of drugs.

Phase I trial

The first stage of human testing of a new drug or intervention, typically evaluating drug pharmacokinetics, safety and acceptance, in a small number (10 to 100) of healthy volunteers. Also written as Phase 1 trial.

Phase II trial

The second stage of the evaluation of a new drug or intervention in humans. These trials evaluate drug safety and preliminary efficacy (effectiveness) in a larger number of participants. Phase II trials may be divided into Phase IIa (pilot trials in individuals with the disease to be treated) and Phase IIb, which are sometimes called proof-of-concept trials. Also written as Phase 2 trial.

Phase IIb trial

A study designed to determine efficacy and safety of a product, drug or intervention in a large number of participants. See also *proof-of-concept study*.

Phase III trial

A study designed to determine the effectiveness of a treatment, often by comparing it to an existing standard therapy or a placebo, in large numbers of participants (typically hundreds or thousands). Trial results are used to evaluate the overall risks and benefits of the drug and provide the information needed for regulatory approval. Also written as a Phase 3 trial.

Phase IIIb trial

A study that is conducted after regulatory submission, but before approval of a product or drug. Often conducted to obtain additional safety data or to support marketing claims made about the drug.

Phase IV Trial

Post marketing studies conducted after a new treatment is approved and made available. These trials provide additional information about safety and efficacy in large numbers of individuals under “real world” conditions.

Phenotype

Visible characteristics or behavior that results from the interaction of an organism’s genetic “blueprint” (genotype) and the environment; phenotypic resistance testing determines whether an organism is susceptible to a specific drug in a test tube. Compare with *genotype*.

Phosphorylation

A chemical process involving the addition of one or more molecules called phosphate groups. For drugs like tenofovir to have anti-HIV activity inside targeted cells, they must first undergo this chemical change.

Physiological

Of or relating to the normal, healthy functioning of a living organism.

Placebo

A placebo is an inactive tablet or gel that contains no active drug. In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness.

Placebo-controlled study

A study that identifies the true effect of a treatment by comparing results in participants taking the actual treatment to those in participants taking an inactive look-alike, or placebo, treatment.

Placenta

The vascular organ that connects the fetus to the mother's uterus, allowing the exchange of oxygen and nutrients, and the removal of waste products.

Placental transfer

The transfer of drugs, for example, from mother to fetus by way of the placenta.

Plasma

The clear, liquid part of the blood in which red blood cells, white blood cells, and platelets are suspended. Plasma contains nutrients, wastes, salts, gases and proteins.

Plasma cell

A type of immune cell that develops from B cells and produces large amounts of antibodies.

PLHIV

Person or people living with HIV.

Point Estimate

What is often referred to as the result of a clinical trial is the point estimate. The point estimate should always be considered in the context of confidence interval. See also *confidence interval*.

Pol

The HIV gene that encodes the virus' enzymes for replication (protease, integrase, reverse transcriptase); also refers to the protein (Pol) produced by this gene.

Polymerase Chain Reaction (PCR)

A laboratory technique that replicates tiny amounts of DNA so that it can be detected and measured.

Population Council

An international, nonprofit, nongovernmental organization that conducts biomedical, social science, and public health research on global issues, focusing on reproductive health, HIV and AIDS, and poverty, gender and youth.

Post-exposure prophylaxis (PEP)

Administration of anti-HIV drugs within 72 hours of a high-risk exposure, including unprotected sex, needle sharing, or occupational needle stick injury, to help prevent development of HIV infection. Compare with *pre-exposure prophylaxis (PrEP)*.

Post-marketing study

See *Phase IV trial*.

Postnatal

The time period following birth (may refer to the newborn).

Postpartum

The time period after childbirth (usually refers to the mother).

Preclinical

Refers to the preliminary testing of investigational drugs in test tubes or laboratory animals that occurs before human testing may begin.

Pre-existing condition

A medical problem that existed before a specific date.

Pre-exposure prophylaxis (PrEP)

The use of antiretroviral drugs as a preventive measure to potentially decrease the risk of HIV transmission. Similar to providing antimalarial drugs to travelers in countries with high rates of malaria as a preventive measure. Compare with *post-exposure prophylaxis (PEP)*.

Prenatal

Period of time spanning from conception to the beginning of labor.

Prevalence

The number of people in a population with a particular disease or condition at a given time. The prevalence rate is determined by dividing the number of people with the condition by the total population. Compare with *incidence*.

Prevention (primary, secondary)

In the context of HIV, prevention activities are designed to reduce the risk of becoming infected with HIV (primary prevention) and the risk of transmitting the disease to others (secondary prevention). Prevention services include voluntary counseling and testing, condom distribution, disease surveillance, outreach and education, and blood safety and harm reduction programs for injecting drug users.

Prevention of mother-to-child transmission (PMTCT)

Prevention of the passage of HIV from an HIV-infected mother to her infant, whether in the womb, during labor and delivery, or through breastfeeding. See also *vertical transmission*.

Prevention trials

Refers to trials designed to find better ways to prevent disease in people who have never had the disease or to prevent a disease from returning.

Primary care

Basic medical care; the first line of medical management of a condition.

Primary HIV Infection (PHI)

The first stage of HIV infection, which can last for several weeks. HIV multiplies very often and can easily be transmitted to others during this time. PHI is also known as acute HIV infection.

Primary infection

The initial introduction of an infectious organism into the body.

Primary resistance

When an individual is infected by a strain of HIV-1 that is already resistant to one or more antiretroviral drugs.

Prime-boost

A strategy of administering one vaccine dose (or one type of vaccine) to elicit certain immune responses, followed by or together with a booster, a second vaccine dose (or second type of vaccine). The prime-boost strategy may be used to strengthen the initial immune response or to elicit different types of immune response.

Probiotic

A microbe that protects its host and prevents disease.

Proctoscopy

Examination of the rectum and lower end of the colon with a lighted instrument. See also *sigmoidoscopy*.

Prognosis

A forecast of the probable course or outcome of a disease.

Progression

Advancement or worsening of a disease.

Proinflammatory cytokine

A chemical messenger (e.g., IL-6, tumor necrosis factor) that promotes an inflammatory immune response.

Proliferation

Rapid multiplication or replication.

Proof-of-concept study

Clinical studies, often referred to as Phase IIb studies, designed to be large enough to produce evidence of efficacy or effectiveness, but small enough to represent a measured step before going on to a Phase III efficacy trial. See also *Phase IIb trial*.

Prophylaxis

Therapy to prevent the onset of a particular disease or to prevent recurrence of symptoms of an existing infection that has been brought under control.

Prospective study

A study that looks forward in time; a prospective cohort study follows a specific group of people over a period of time. Compare with *retrospective study*.

Protease

An enzyme that breaks down long polypeptides into smaller protein units. HIV's protease enzyme cuts long chains of HIV polypeptide into the smaller, active proteins used in HIV replication.

Protease Inhibitor (PI)

A class of anti-HIV drug that prevents replication of HIV by disabling HIV protease. Without HIV protease, the virus cannot make more copies of itself. See also *protease*.

Protein

A highly complex biological molecule consisting of specific combinations of amino acids linked together by chemical bonds. Proteins are the building blocks required for the structure, function, and regulation of the body's cells, tissues, and organs. Examples of proteins are enzymes, cytokines and antibodies; and the major components of hair, skin and muscle.

Protocol

A study plan on which a clinical trial is based. The plan is designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes the hypothesis, characteristics of participants, schedule of tests, study medications, length of the study and how results will be analyzed.

Provirus

A DNA version of HIV's genetic material that has been integrated into the host cell's own DNA.

Pruritus

Itchiness

Psychosocial

Refers to mental health and social conditions, or factors affecting psychological or social wellbeing.

Purulent

Characterized by the accumulation of pus.

P-value

A probability value reported in experiments such as clinical trials. A p-value is calculated to assess whether trial results are likely to have occurred simply through chance. See *statistical significance*.

Q**Qualitative**

Relating to, or expressed in terms of, quality; qualitative research is based on individual, often subjective, analysis. Compare with *quantitative*.

Quantitative

Relating to, or expressed in terms of, quantity; quantitative research is based on numerical data. Compare with *qualitative*.

Quiescent

Refers to a state of resting, inactivity or latency.

R**Radioimmunoassay**

A procedure for detecting antigens or antibodies using radioactive-labeled proteins.

RAI

See *receptive anal intercourse*.

Randomized trial

A type of clinical trial in which participants are assigned by chance to one of two or more treatment or placebo groups. A randomized trial design helps researchers gather meaningful information and make valid statistical calculations.

RANTES

A chemokine that binds to CCR5, a co-receptor of HIV, and inhibits the entry of HIV into a host cell. RANTES is an acronym for regulated on activation, normal T expressed and secreted.

Rapid test

A type of HIV-1 enzyme-linked immunosorbent assay (ELISA) that can detect antibodies to HIV in the blood in less than 30 minutes with greater than 99% sensitivity and specificity. A positive rapid test result should be confirmed by an HIV Western blot test.

RCT

See *randomized controlled trial*.

Reagent

An agent used to promote a chemical reaction.

Receptive anal intercourse

Refers to the act of being penetrated during anal intercourse. Carries a higher risk of HIV transmission than receptive vaginal intercourse.

Receptor

A specific binding site on a cell's surface or interior. When chemical messengers bind to receptors, various cellular functions are activated or inhibited. Viruses enter host cells by fusing with receptors on the cell surface, and many drugs exert their effects by binding to receptors and altering cellular function.

Recombinant

Produced by genetic engineering. Also refers to a new organism or compound produced by inserting the genetic material of one organism into the genetic material of another organism.

Reconstitution

Rebuilding and restoring to functionality (e.g., immune reconstitution); restoration of a compound to its original state.

Recruiting

The period during which a trial is attempting to identify and enroll participants.

Rectal lavage

Washing out of the rectum to detect abnormal sloughing of epithelial cells of the rectum.

Rectum

The lower part of the large intestine where feces are stored.

Recurrent

Returning or occurring repeatedly.

Red blood cells (RBC)

Cells in the blood that carry oxygen from the lungs to the tissues and then carry carbon dioxide from the tissues to the lungs.

Refractory

Resistant to treatment.

Registry

A population-based record of statistics (including incidence, prevalence and mortality rates) that can be used to monitor the HIV/AIDS epidemic in different communities and regions around the world.

Regression

A return to a previous condition; shrinking (e.g., of a tumor).

Regression analysis

A statistical technique used to analyze the relationship between variables; a technique used to predict the probability of an outcome as a function of independent variables.

Relapse

The return of signs and symptoms of a disease after a patient has been free of those signs and symptoms.

Relative risk

A statistical measure of the comparative risk of developing a disease or condition. Relative risk is the chance that a person with a specific risk factor (e.g., older age, exposure to a drug) will develop a condition compared with the chance that a person without that risk factor will develop the same condition.

Remission

The period during which symptoms of a disease diminish or disappear. In people infected with HIV, effective treatment regimens may result in the remission of HIV-associated symptoms and conditions.

Renal

Pertaining to the kidneys.

Replication

Multiplication or reproduction.

Resistance

Resistance refers to the ability of some microorganisms, including viruses such as HIV, to adapt so they can survive and multiply in the presence of drugs that would normally weaken or kill them. For HIV, drug resistance exists when the virus can multiply in the presence of one or more antiretroviral (ARV) drugs.

Resistance testing

Laboratory testing to determine if an individual's HIV strain is resistant to anti-HIV drugs.

Retrospective study

A study based on medical records, looking backward in time at events that happened in the past; a retrospective cohort study uses the records of a specific group of subjects. Compare with *prospective study*.

Retrovirus

A type of virus, such as HIV, that stores its genetic information in a single-stranded RNA molecule and constructs a double-stranded DNA version of its genes using a special enzyme called reverse transcriptase. The DNA copy is then integrated into the host cell's own genetic material.

Rev

An HIV gene necessary for the construction of new virus particles; also refers to the protein (Rev) produced by this gene.

Reverse Transcriptase (RT)

An enzyme found in HIV and other retroviruses. RT converts single stranded HIV RNA into double-stranded HIV DNA. Some anti-HIV drugs interfere with this stage of HIV's life cycle.

Ribonucleic Acid (RNA)

Chemical structure that carries genetic instructions for protein synthesis. Although DNA is the primary genetic material of cells, RNA is the genetic material for some viruses like HIV.

Ribonucleotide

A structural component or building block of RNA. See also *nucleotide*.

Risk/benefit ratio

A measurement used to evaluate whether potential benefits outweigh potential risks.

Risky behavior

In HIV, refers to any behavior or action that increases an individual's probability of acquiring or transmitting the infection. Some examples of risky behaviors are having unprotected sex, having unprotected sex with multiple partners and injecting drugs with contaminated needles. Alcohol use has also been linked to risky behavior because of its effect on an individual's ability to make decisions and negotiate safer sex.

S**Safer sex**

Ways to reduce the risk of spreading or acquiring HIV or other sexually transmitted infections during sexual activity by preventing the exchange of body fluids that can transmit HIV. The most common practice barriers include latex condoms, gloves and dental dams.

Safety

Potential short- and long-term effects, both bad and good, of drugs or treatments.

Sample size

The number of participants in a clinical trial.

Scale up

Refers to the concept of achieving a sufficient level of coverage uptake, intensity and duration of an intervention to enable the intended effect.

Second-line treatment

The second preferred therapy for a particular condition, used after first-line treatment fails or if a person cannot tolerate first-line drugs.

Semen

A whitish, viscid fluid ejaculated from the penis containing spermatozoa and secretions from the prostate gland.

Semen-Derived Enhancer of Virus Infection (SEVI)

A collection of the enzyme prostatic acidic phosphatase (PAP) that is found in semen and that can increase the likelihood of HIV infection.

Sensitivity

The ability of an organism to respond to a drug or other agent.

Sequelae

Conditions resulting from a disease or injury.

Seroconversion

The process by which a newly infected person develops antibodies to HIV. These antibodies are then detectable by an HIV test. Seroconversion may occur anywhere from days to weeks or months following HIV infection. See also *window period*.

Serodiscordant couple

A relationship in which one partner is HIV-positive and the other is HIV-negative.

Serologic test

A laboratory test to determine if an individual has antibodies to a particular foreign invader, such as a virus. A positive serologic test indicates that an individual is infected or has had an infection in the past.

Serology

The study or analysis of blood, in particular the clear fluid portion of blood; tests that measure components (e.g., microorganisms, antibodies, chemicals) in the blood.

Seronegative

See *serostatus*.

Seropositive

See *serostatus*.

Seroprevalence

The number or proportion of people in a given population who have positive serologic tests for a particular infection.

Serostatus

The presence or absence of detectable antibodies against an infective agent, such as HIV, in the blood. Seronegativity, or seronegative status, means that the person has no detectable antibodies and is not infected with the agent or has not had the chance to develop antibodies to an early infection. Seropositivity or seropositive status means that the person has detectable antibodies and is infected with the agent or had previously been infected with the agent.

Serum

The clear, thin and sticky fluid that separates from blood when it clots.

Serum level

Test to measure the amount of a substance (e.g., a drug) in the blood's serum.

Set point

The viral load established a few weeks to months following infection, after the initial burst of virus replication has subsided. The viral set point is thought to remain steady for an indefinite period of time if the infection is not treated with anti-HIV drugs. An individual's viral set point may determine how quickly HIV infection will progress without treatment. Higher set points suggest that disease will progress faster than lower set points.

Sexually transmitted disease/infection (STD/STI)

Any disease or infection that is spread through sexual contact.

Shedding

Release of infectious particles (e.g., bacteria, viruses) into the environment, for example, by sneezing, fecal excretion or from an open lesion. In HIV, viral shedding occurs via semen, vaginal secretions and other bodily fluids.

SHIV

A genetically engineered hybrid virus having an HIV envelope and a SIV core that developed as an animal model for testing potential HIV treatment and prevention approaches. See also *Simian Immunodeficiency Virus*.

Side effect

An action or effect of a drug (or vaccine) other than desired therapeutic effects.

Sigmoidoscopy

Examination of the sigmoid colon (the lower transverse part of the colon) with a lighted, flexible viewing instrument. See also *proctoscopy*.

Simian

Refers to monkeys.

Simian Immunodeficiency Virus (SIV)

A virus similar to HIV that can infect monkeys, chimpanzees, and macaques and can cause a disease similar to AIDS in some of these animals. Because the two viruses are closely related, researchers study SIV as a way to learn more about HIV.

Sloughing

Dead tissue separating from living tissue.

Social harm

In HIV prevention research, refers to unintentional harmful impact that participations in a study or use of a product may have on the participant or those who are close to him or her.

Soluble

Capable of being dissolved.

Specific immunity

Also called adaptive immunity. Antigen-specific immune defense carried out by lymphocytes (e.g., B cells and T cells), which respond to specific pathogens.

Speculum

An instrument used to widen an opening to look within a passage or a cavity. For example, a speculum may be used to widen the opening of the vagina so that the cervix is more easily visible.

Standard deviation

A statistical measure of how widely the values in a group of values are spread around the mean, or midpoint.

Standard of care

A treatment plan that experts agree is appropriate, accepted and should be widely used for a given disease or condition.

Standards of prevention

The ethical framework for the conduct of HIV prevention trials stipulating that all trial participants be provided proven HIV prevention methods that are widely available and considered standard in their localities.

Statistical significance

The probability that the outcome of an experiment or clinical trial is not due to chance; typically, a clinical trial result is considered statistically significant if there is a less than a 5% probability (designated by a p-value of less than .05) that the observed outcome could have occurred by chance alone if the treatments being compared were equally effective. See also *P-value*.

Stopping Rules

Statistical parameters defined before a trial begins that determine whether a study should continue, or stopped or modified (for efficacy, safety reasons or futility), before its scheduled end. Data Safety Monitoring Boards use these rules as guides when they conduct interim reviews of blinded data while a study is in progress.

Strain

A specific genetic variant of a particular organism. See also *subtype* and *wild-type virus*.

Subclinical

Low-grade symptoms or without symptoms.

Subgroup analysis

Additional analysis of a smaller group of participants selected from a larger study population.

Subject

A volunteer participant in a clinical trial.

Sub-therapeutic

Refers to a dose or blood concentration of a drug that is too low to be effective.

Subtype

HIV is classified into two types, HIV-1 and HIV-2. Within HIV-1 are groups of similar viral strains. These are the major (M) subtype and non-M subtypes – new (N) and outlier (O). The majority of HIV-1 infections are by M-subtype viral strains. Subtype M HIV-1 is further broken down into nine genetically distinct strains known as clades. See also *strain* and *wild-type virus*.

Superinfection

Acquisition of a second or subsequent infection within a particular organism while an initial infection is still present; superinfection with HIV appears to worsen disease progression.

Superiority trial

A trial in which the objective is to determine whether one intervention is superior to another.

Surfactants

A class of candidate microbicides that disrupt microbial cell membranes, thereby inactivating or killing the virus. Examples include Nonoxynol-9 and Savvy.

Surrogate endpoint

A short-term outcome, such as a change in viral load or CD4 count that may be used as a substitute to reflect a clinical target outcome, such as mortality or disease progression. For example, a change in viral load (HIV RNA level) may be a surrogate endpoint for the progression of HIV to AIDS as a clinical endpoint.

Surrogate marker

See *biomarker*.

Survival rate

The percentage of a population or study group that remains alive after a given period.

Susceptible

Vulnerable to or able to contract a disease; vulnerable to the effects of a drug.

Sustained virologic response

The continued, long-term suppression of HIV RNA as a result of successful treatment with highly active antiretroviral therapy regimens.

Symptom

A subjectively perceptible sensation or change that signals the presence of a disease or condition.

Systemic

A term used to describe a disease or treatment that affects the body as a whole.

T

Target cell

Type of cell that HIV or another virus or bacteria infects.

T cell

A type of lymphocyte (disease-fighting white blood cell). The T stands for the thymus, the organ in which T cells mature. T cells include CD4 cells and CD8 cells, which are both critical components of the body's immune system.

TDF2

A Phase III clinical trial conducted by the U.S. Centers for Disease Control and Prevention that evaluated daily use of the antiretroviral Truvada in heterosexual men and women in Botswana.

Tenofovir

An antiretroviral (ARV) with the full name tenofovir disoproxil fumarate (TDF) and known by the brand name Viread. Tenofovir is a nucleoside/nucleotide reverse transcriptase inhibitor widely used as part of antiretroviral therapy. It is currently being tested for its ability to prevent HIV as pre-exposure prophylaxis (PrEP) and in gel formulations as a vaginal and rectal microbicide.

Teratogenic

Capable of causing birth defects, or malformations of a fetus.

Test and treat

An approach to HIV prevention by which HIV testing is followed by immediate treatment for those testing positive. See also *TLC+*.

T helper cell

See *CD4 cell*.

Therapeutic drug monitoring (TDM)

The measurement of plasma drug concentrations in an effort to provide the most effective dosage with the least possible toxicity; TDM can help guide decisions regarding changes in drug dosing.

Titer

A laboratory measurement of the amount of a given compound in a solution. For example, an antibody titer is the measurement of the amount of a particular antibody in a sample of blood.

TLC+

An HIV prevention approach being evaluated in the United States. TLC+ stands for Testing & Linkage to Care Plus. It aims to increase the percentage of HIV-positive Americans who know their HIV status, improve the health outcomes of individuals who are HIV-positive, and reduce HIV incidence (new cases of HIV infection). See also *test and treat*.

TMC-120

Also known as dapivirine, a nonnucleoside reverse transcriptase inhibitor being developed as a microbicide formulated as both a vaginal gel and intravaginal ring for the prevention of HIV.

Tolerability

Term used to indicate how well a particular drug is tolerated when taken by people at the usual dosage. Good tolerability means that drug side effects do not cause people to stop using the drug.

Topical

A substance, such as a cream or lotion, applied to body surfaces such as the skin or mucous membranes of the vagina or rectum.

Toxicity

An adverse effect produced by a drug or product that is detrimental to cells, tissues or a person's health.

Transcription

One of the steps in the HIV life cycle. Transcription is the process by which the HIV DNA provirus is used as a template to create copies of HIV's RNA genetic material as well as shorter strands of HIV RNA called messenger RNA (mRNA). HIV mRNA is then used in a process called translation to create HIV proteins and continue the virus's life cycle. See also *translation*.

Transepithelial

Existing or taking place across the epithelium.

Transient

Short-lived; not permanent.

Translation

The step in the HIV life cycle that follows transcription. Translation is the process by which the genetic information contained in HIV mRNA is used to build HIV proteins using the host cell's protein making machinery. Once these HIV proteins are produced, they can combine with copies of HIV's RNA genetic material to form new, complete copies of HIV. See also *transcription*.

Transmission

Spread of an infectious organism from one individual to another.

Transmitted/founder virus

The first of the mutagenic viruses, and the original basis for all of the viruses that follow.

Treatment-experienced

A term used to describe HIV-infected individuals who are currently being treated with anti-HIV drugs or who have taken anti-HIV drugs in the past.

Treatment failure

A broad term that describes failure of an anti-HIV treatment to adequately control HIV infection. The three types of HIV treatment failure are virologic, immunologic, and clinical failure. Factors that contribute to treatment failure include poor adherence, drug resistance and drug toxicity. See also *clinical failure*, *immunologic failure* and *virologic failure*.

Treatment-naïve

A term used to describe HIV-infected individuals who have never taken anti-HIV drugs.

Treatment regimen

A structured plan of treatment, usually with drugs, implemented to improve or maintain health.

Trial

An experiment involving the collection, analysis and interpretation of data. See also *clinical trial*.

Trial design

The structure of a clinical study or trial, e.g., open-label or double-blind, comparative or observational.

Trichomonas

A single-celled protozoan parasite that causes vaginitis (vaginal inflammation). Infection with trichomonas (trichomoniasis) is the most common curable sexually transmitted disease (STD) in young sexually active women. The parasite is sexually transmitted through penis-to-vagina intercourse or vulva-to-vulva (the genital area outside the vagina) contact with an infected partner.

Trough concentration

The plasma level of a drug measured just prior to the next dose. Contrast with *peak concentration*.

Truvada

The brand name for a combination drug that contains tenofovir and another active ingredient called emtricitabine (FTC). Truvada may also be referred to as TDF+FTC. Truvada is a nucleoside/nucleotide reverse transcriptase inhibitor widely used as part of antiretroviral therapy. It is currently being tested for its ability to prevent HIV as pre-exposure prophylaxis (PrEP).

U**Unblinding**

The process by which trial participants and, in the case of a double-blind study, researchers learn who received the study intervention and who received the placebo. Data Safety Monitoring Boards are the only groups that have access to this information until after the study has ended.

Uncontrolled trial

A research study in which there is no placebo group. Compare with *controlled trial*.

Undetectable viral load (UD VL)

The point at which levels of HIV RNA in the blood are too low to be detected with a viral load test. This does not mean that HIV has stopped replicating or has been removed from the body entirely, only that the small amount of virus remaining is below the test's ability to measure it. The level below which a test cannot detect virus depends on the brand of the test. See also *viral load (VL)*.

Universal precautions

Infection control measures used in health care settings aimed at preventing the transmission of HIV (and other blood-borne pathogens). These measures include the use of gloves and other protective gear, and the safe disposal of needles to prevent exposure to blood and other body fluids.

Upregulation

An increase in the rate at which a process occurs, a substance is released, etc. Compare with *down regulation*.

Uterus

The hollow organ within the female pelvis where fertilized eggs come to rest for development during pregnancy; the cervix leads to the uterus from the vagina and the fallopian tubes lead from the ovaries to the uterus.

V**Vaccine**

A substance that stimulates the body's immune response to prevent or control an infection. A vaccine is typically made up of some part of a bacteria or virus that cannot itself cause infection. Researchers are testing vaccines both to prevent (preventive HIV vaccine) and treat HIV/AIDS (therapeutic HIV vaccine); however, there is currently no HIV vaccine approved for use outside of clinical trials.

Vagina

The muscular canal extending from the cervix to the outside of a woman's body. It is usually six to seven inches in length, and its walls are lined with mucus membrane. The vagina also includes tiny glands that produce vaginal secretions.

Vaginal candidiasis

See *candidiasis*.

Vaginal defense enhancers

A class of topical microbicides that seek to make the vagina an environment hostile to STIs and HIV by maintaining or boosting the naturally protective acidity of the vagina or by increasing the colonization of protective microorganisms. Examples include BufferGel and ACIDFORM.

Vaginal flora

The bacteria that live inside the vagina, consisting primarily of lactobacilli, that aid in forming a natural defense against infections. An imbalance of vaginal flora can allow bad bacteria to take over and lead to infections and other conditions.

Vaginal yeast infection

Infection of the vagina caused by a fungus known as *Candida*. A vaginal yeast infection is characterized by itching, burning, soreness, pain during intercourse and/or urination.

Vaginitis

A term for any infection or inflammation of the vagina. In general, vaginitis may cause itching, irritation or abnormal vaginal discharge. There are several different kinds of vaginitis, each with their own causes and symptoms.

Vector

In vaccines, a harmless virus or bacteria used as a vaccine carrier to deliver pieces of a disease-causing organism (such as HIV) into the body's cells to stimulate a protective immune response. See also *vaccine*.

Vertical transmission

A term used to describe the transmission of a disease from parent to offspring. For example, HIV can be spread vertically from mother to child during pregnancy, at birth, or through breastfeeding. See also *horizontal transmission* and *mother-to-child transmission (MTCT)*.

Viral breakthrough

An increase in viral load while on antiretroviral treatment.

Viral load (VL)

The amount of HIV RNA in a blood sample, reported as number of HIV RNA copies per milliliter of blood plasma. The VL provides information about the number of cells infected with HIV and is an important indicator of HIV progression and of how well treatment is working. The VL can be measured by different techniques, including branched-chain DNA (bDNA) and reverse transcriptase-polymerase chain reaction (RT-PCR) assays. VL tests are usually done when an individual is diagnosed with HIV infection and at regular intervals after diagnosis.

Viral shedding

See *shedding*.

Viral suppression

Halting of the function or replication of a virus. In HIV, optimal viral suppression is measured as the reduction of viral load (HIV RNA) to undetectable levels and is the goal of highly active antiretroviral therapy (HAART).

Viremia

The presence of virus in the bloodstream.

Virion

A complete virus particle.

Virologic failure

Inability of anti-HIV drug treatment to reduce viral load or to maintain suppression of viral load. Virologic failure is the most common type of treatment failure and may lead to immunologic and clinical failure. See also *immunologic failure* and *clinical failure*.

Virological response

Reduction in viral replication in response to treatment, especially achievement of an undetectable viral load; sustained virological response (SVR) refers to continued lack of detectable virus after the completion of treatment.

Virology

The study of viruses and viral disease.

Virus

A microscopic organism that requires a host cell to make more copies of itself. Examples of illnesses caused by viral infections include AIDS, measles, mumps, rubella, polio, influenza and the common cold.

Viscosity

The property of resistance to flow in a fluid or semifluid.

VOICE

Vaginal and Oral Interventions to Control the Epidemic. A large-scale Phase IIb trial conducted by the Microbicide Trials Network (MTN) that is evaluating daily use of tenofovir gel and the antiretroviral drugs tenofovir and Truvada for preventing HIV in women.

Voluntary counseling and testing (VCT)

VCT is an internationally accepted intervention designed to enable people to learn their HIV status and receive counseling about risk reduction and referral to care if they are HIV-positive. VCT programs are a critical component of both HIV prevention and treatment activities.

Vulnerable populations

Populations that are at increased risk of exposure to HIV due to socioeconomic, cultural or behavioral factors. In some geographical regions of the world, vulnerable populations may include certain racial and ethnic minorities, men who have sex with men, injecting drug users, sex workers and women where gender inequality is pronounced.

Vulva

The external female genitalia, including the clitoris and the inner and outer labia surrounding the urethral and vaginal openings.

W**Washout period**

The time it takes for a drug to be completely cleared from the body after it is discontinued.

Water soluble

Capable of being dissolved in water; water-soluble compounds are easily excreted by the body. Compare with *fat soluble*.

Western blot

A laboratory technique used to detect a specific protein. A Western blot test to detect HIV proteins in the blood is used to confirm a positive HIV antibody test (ELISA). See also *enzyme-linked immunosorbent assay (ELISA)*.

White blood cell

Also known as a leukocyte. These cells make up the immune system and include lymphocytes, monocytes, neutrophils, eosinophils, macrophages and mast cells. White blood cells are made by bone marrow and help the body fight infection and other diseases.

Whole-killed virus

A type of vaccine in which inactivated virus is used to provoke an immune response.

Wild-type virus

A term to describe viral strains (including strains of HIV) that have not acquired any genetic mutations that create special characteristics, such as resistance to particular drugs.

Window period

The time period between a person's infection with HIV and appearance of detectable anti-HIV antibodies. Because antibodies to HIV take some time to form, an HIV antibody test will not be positive immediately after a person is infected. Most people develop detectable antibodies within 2 to 8 weeks (average 25 days). Ninety-seven percent will develop antibodies in the first 3 months following time of their infection, and in very rare cases, it can take up to 6 months.

Woman-year

See *person-year*.

World Health Organization (WHO)

The United Nations' health organization. Responsible for providing leadership on global health matters, shaping the health research agenda, setting standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends.

Z**Zinc**

An essential trace mineral that plays a role in cell maturation and wound healing.

Online References Include:

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