

GLOSSARY OF TERMS

Microbicides and HIV
Prevention Research





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This glossary and other resources are available at www.mtnstopshiv.org

A

ABC

An HIV prevention approach focused on behavioral changes:

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

In the context of HIV infection and AIDS, refers to complete avoidance of sexual intercourse to prevent passing an HIV infection from one sexual partner to another.

Abstract

A concise summary of a research study's objectives, methods, results and conclusions. Typically may not exceed a certain number of words (e.g. 150-250 words).

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, from a needle stick injury, for example.

Accrual

The process of recruiting participants into a trial in order to reach its target number of enrolled participants.

Acquired immunity

Also referred to as adaptive immunity, the body's ability to fight or prevent a specific infection due to the existence of antibodies from previous exposure to the antigen, either from previous illness, vaccination or through breast milk or blood. See also *antibody* and/or *antigen*.

Compare with *innate immunity*.

Acquired Immunodeficiency Syndrome (AIDS)

A chronic, potentially life-threatening condition 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), making the body vulnerable to a range of very serious illnesses, infections and cancers.

ACTG

See *AIDS Clinical Trials Group*

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)*.

Adaptive Immunity

See *acquired immunity*.

Adherence

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

Adverse event

An unwanted reaction or side effect to a pharmaceutical product or intervention. 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 to assess the safety of study products. See also *side effect*.

Agonist

A chemical substance, such as a drug, that binds to a receptor on a cell's surface and promotes a specific cellular activity. Compare with *antagonist*.

AIDS Clinical Trials Group (ACTG)

An HIV/AIDS clinical trials network funded by the U.S. National Institute of Allergy and Infectious Diseases (NIAID) focused on investigating the viral and immune pathogenesis of HIV-1 infection and its complications; evaluating novel drugs and strategies for treating HIV-1 infection and evaluating interventions and strategies to treat and prevent HIV-related co-infections and co-morbidity.

AIDS-defining illness

A variety of conditions that occur in the late stages of HIV infection and signal progression to AIDS.

Allele

A variation of a gene on a specific place on a chromosome; individual organisms have 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 (a thin membrane inside the uterus) during pregnancy.

Anal intercourse

Intercourse involving the insertion of the penis into the anus of a sexual partner (male or female). See also *receptive anal intercourse*.

Antagonist

A chemical substance, such as a drug, that binds to a cell's receptor and blocks the action of another substance or drug. Compare with *agonist*.

Antenatal

Occurring before birth, as in HIV exposure or transmission from mother to fetus 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 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. Tests typically used to detect HIV antibodies are ELISA (enzyme-linked immunosorbent assay) and Western blot.

Antigen

Any substance considered foreign to the body that can stimulate the body's immune system 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 them 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 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 antiretroviral (ARV) drugs. Some of these employ the same mechanism of action as ARV drugs used in HIV treatment. Examples include tenofovir gel and the dapivirine vaginal ring.

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 harming other parts of the body. Apoptosis plays a crucial role in developing and maintaining health by eliminating cells that are old, unnecessary or unhealthy.

Approved drug

A drug that has undergone rigorous study, including in human clinical trials, and based on a comprehensive review of all data, is subsequently given authorization by a national drug authority (such as the U.S. Food and Drug Administration) to be licensed for use within that country for a specific indication or condition. See also *off-label use*, *New Drug Application*.

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

A group or subgroup of participants in a clinical trial who are assigned to receive the same intervention, e.g., an active drug or a placebo. Most randomized trials have two arms, but some have three arms, or even more.

Article 58

Refers to a section within a regulation of the European Medicines Agency (EMA) that allows the EMA to express scientific opinion on the safety and effectiveness of products for use outside the European Union, e.g., in developing countries. The opinion helps guide decisions of in-country national drug authorities (NRAs) and the development of guidance by the World Health Organization. See also *European Medicines Agency* and *WHO guidance*.

ASPIRE

Stands for A Study to Prevent Infection with a Ring for Extended use. A Phase III clinical trial designed to evaluate the safety and effectiveness of the dapivirine vaginal ring for preventing HIV when used by women for a month at a time. Being conducted by the Microbicide Trials Network (MTN). See also *The Ring Study* and *dapivirine ring*.

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

Showing no signs or symptoms of a disease. Also refers to the second stage of HIV disease progression. Although a person is asymptomatic, 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 answer questions about sexual behaviors and product use privately via a laptop computer.

Autoimmune

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

AVAC

A non-profit organization dedicated to the prevention of HIV. First reference may be AVAC: Global Advocacy for HIV Prevention. Formerly called the AIDS Vaccine Advocacy Coalition

Aviremia

Lack of virus in the blood plasma.

B

B cell

Also known as a B lymphocyte, an infection-fighting white blood cell that produces antibodies against foreign substances (antigens), such as bacteria, viruses and allergens.

Bacteria

Simple single-celled microorganisms, many of which can cause disease but are essential to health. Bacteria are classified by their shape (rod, spirochete, etc.), staining properties (Gram positive or Gram negative), and habitat (aerobic – needing oxygen, or anaerobic – not needing oxygen).

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 *lactobacillus*.

Baseline characteristics

Data collected from all participants at the beginning of a clinical study for the purposes of comparison at a later time, such as at the end of the study. This can include demographic information (e.g., age, marital status), behavioral measures (e.g., use of condoms) or results of laboratory tests (e.g., liver function or CD4 count).

Bias

In a clinical trial, a flaw in the study design, method of collecting information, or in interpretation of the data. Bias can lead to incorrect conclusions such that the true effect of the intervention being studied is either underestimated or overestimated. One way to help reduce the potential for bias in a clinical trial is to employ a double-blind design, whereby neither the researchers nor the participants know the treatment being received. See also *double-blind study*

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 biomarker of disease progression and as a measure of response to antiretroviral treatment.

Biomedical Prevention

Refers generally to microbicides, vaccines, pre-exposure prophylaxis, treatment as prevention and voluntary medical male circumcision.

Biopsy

The surgical removal and laboratory examination of a small sample of an organ or tissue to aid in the diagnosis and treatment of a health condition.

Blinded

When either the researcher or the participants – or both – do not know the group to which participants are assigned. See also *double-blind study*.

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. Compare with *unblinding*.

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 that a biomedical prevention approach, such as a vaccine or a microbicide, 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

Infection in the gastrointestinal tract, vagina or elsewhere in the body arising when overgrowth of the *C. albicans* yeast disrupts the normal balance of different bacteria (flora). 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 tuberculosis (TB), and microbicides and vaccines for the prevention HIV.

Care, treatment and support

Refers to the range of interventions for people living with HIV/AIDS, including antiretroviral therapy, treatment and prevention of opportunistic infections, nutritional support, and support focused on mental health and meeting the needs of daily living. 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

A type of protein called a receptor that sits on the surface of some immune system cells. To enter a host cell, HIV must bind to two different receptors: the CD4 receptor and either the CCR5 receptor or the CXCR4 receptor. CCR5 and CXCR4 are often referred to as co-receptors. See also *CXCR4* and *CD4*.

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. See also *CCR5*.

CD4

A type of protein called a receptor found on the surface of certain cells of the immune system that HIV binds to, along with another receptor (CCR5 or CXCR4) to enter host cells. See also *CCR5* and *CXCR4*.

CD4 cell

Also known as a helper T cell or CD4 lymphocyte. A type of white blood cell for fighting infections that has the CD4 receptor on its surface. CD4 cells coordinate the immune response, signaling other cells 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. Compare with *viral load*.

CD8 cell

Also called a cytotoxic T lymphocyte, 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 found inside the body that has not yet infected (entered) a host cell.

Cell-mediated immunity

Also referred to as cellular immunity, the immune protection provided by direct action of T-cells of the immune system. This type of immune protection differs from that involving primarily B cells and antibodies, called humoral immunity. Compare with *humoral immunity*.

Centers for Disease Control and Prevention (CDC)

An agency of the U.S. Department of Health and Human Services (HHS) responsible for protecting people's health and safety. Its activities emphasize disease prevention and control, environmental health, and health promotion. The CDC also conducts international prevention activities for HIV, tuberculosis (TB), malaria and other diseases. First reference is usually 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 a research animal to an infectious pathogen in order to test the safety and effectiveness of potential treatments and/or prevention approaches and determine whether evaluation of the intervention should proceed to clinical trials in humans.

Chemokines

Small proteins that serve as chemical messengers to control the activities of the immune system. See also *cytokines*.

Chemoprevention

Also known as chemoprophylaxis, 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 HIV or cancer.

Chlamydia

A sexually transmitted infection (STI) caused by a bacterium called *Chlamydia trachomatis*. Left untreated, can cause damage to the female and male reproductive systems and infertility. See also *sexually transmitted infection (STI)*.

Chromosome

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

Chronic

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

Circumcision

See *voluntary medical male circumcision*

Cisgender

A person who identifies as the sex they were assigned at birth. See also *Transgender*.

Clade

A group of organisms that are genetically similar and descended from a single parent organism. With HIV, the term 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. May be prescribed to save certain classes of drugs for later use or to avoid side effects specific to a class.

Clearance

Refers to the state in which a drug or microorganism is no longer present in 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.

Clinical Research Site (CRS)

In general, the center, clinic or other location where a research study is conducted. Also refers to a component of a Clinical Trials Unit (CTU) where trials are conducted through the HIV/AIDS clinical trials networks of the U.S. National Institute of Allergy and Infectious Disease (NIAID). See also *Clinical Trials Unit*.

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. The clinical trial process includes Phase I, II, IIb, II, IIIb and IV post-marketing evaluation.

Clinical Trials Agreement (CTA)

A contract for services agreed to by the sponsor of a clinical trial and product developer or pharmaceutical collaborator.

Clinical Trials Unit (CTU)

An organization/institution funded by the U.S. National Institute of Allergy and Infectious Diseases (NIAID) that coordinates and executes clinical trials and other research studies for NIAID-funded HIV/AIDS clinical trials networks (e.g., the Microbicides Trials Network). CTUs comprise clinical research sites (CRSs) where the trials are conducted. See also *Clinical Research Site* and *HIV/AIDS clinical trials network*.

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 of sex. 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. May be used to obtain small samples of tissue (biopsy) for laboratory analysis.

Combination therapy

Two or more drugs used together to achieve optimal results. Controlling HIV infection requires multiple drugs in different classes, referred to as highly active antiretroviral therapy, or HAART. Compare with *monotherapy*. See also *highly active antiretroviral therapy (HAART)*.

Community Advisory Board (CAB)

A group of community members and individuals impacted by HIV/AIDS who provide recommendations regarding clinical research being conducted at a particular research site.

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.

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 (CT) 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.

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 approach that may not be as effective. Also called condom substitution. Most biomedical approaches being evaluated are intended to be used in tandem with condoms.

Confidentiality

Within a clinical trial, refers to the protection of a trial participant’s personal identity and all personal medical information collected as part of the study.

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.

Conjoint analysis

A statistical technique used in market research to determine how people value different features that make up an individual product or service.

CONRAD

A non-profit organization based in the United States 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 group of participants in a clinical trial who do not receive an experimental drug or treatment so that comparisons can be made with the group that does.

Controlled trial

A type of clinical trial in which observations are made between one group of participants given an experimental drug or intervention and another group (i.e., the control group) that is given either a standard intervention for the disease or a placebo.

Core

The inner protective coat of protein surrounding the genetic material of most viruses. In HIV, the core is mostly made up of the p24 protein.

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. See also *receptor*

Cross-immunity

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

Crossover trial

A trial in which the participants receive each of the interventions under study (and/or a placebo) but in different order. For example participants in group 1 may use product A for the first part of the study, while group 2 participants will use product B. The two groups then switch, or crossover, so that they each use the other product for the second part of the study. See also *washout period*.

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

A protein called a receptor on the surface of some immune system cells. In order to enter a host cell, HIV must bind to two different receptors: CD4 and either the CXCR4 or CCR5 receptor. CXCR4 and CCR5 are often referred to as co-receptors. See also *CCR5* and *CD4*.

Cytokines

Small proteins that act as chemical messengers between cells to help regulate an immune response. See also *chemokines*.

Cytology

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

Cytopathology

Disease, disorders or the destruction of cells.

Cytopenia

An abnormal reduction in the number of cells, in particular, blood cells.

Cytoplasm

The gel-like substance that surrounds 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 for preventing HIV by the International Partnership for Microbicides (IPM).

Dapivirine ring

An intravaginal ring containing the antiretroviral drug dapivirine that is being tested in two Phase III trials for preventing HIV in women when worn for a month at a time. See also *ASPIRE* and *The Ring Study*.

Data Safety Monitoring Board (DSMB)

An independent committee of clinical research experts that reviews data not available to the study team while a clinical trial is in progress to ensure that participants are not exposed to undue risks. A DSMB can recommend that the study be stopped if the intervention is not effective, is causing harm to participants or the study is not likely to serve its scientific purpose. See also *Independent Data Monitoring Committee*.

Demonstration project

A project that tests and measures the effect of a treatment or prevention approach in a real-world setting.

Dendritic cell

A type of antigen-presenting cell that picks up foreign substances from the bloodstream and presents them to other cells 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.

Department of Health and Human Services (HHS)

A department of the U.S. federal government that administers the nation's programs for public health, welfare and income security. The U.S. National Institutes of Health and the U.S. Centers for Disease Control and Prevention are both part of HHS.

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 through evaluation of an individual's medical history, clinical symptoms and/or laboratory test results.

Diaphragm

A type of contraceptive, which is a small latex or silicone dome/cup that covers the cervix (the lower part of the uterus that connects to the vagina) thereby blocking sperm from entering the uterus.

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, that supports a global research portfolio on HIV/AIDS, its related co-infections, and co-morbidities. 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 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 in which neither the participants nor the researchers know who is receiving a particular treatment. This design is used to prevent bias in research results. See also *bias*.

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, and is associated with increased risk of pelvic inflammatory disease (PID). See also *pelvic inflammatory disease*.

Drug absorption

The passage of a drug through mucous membranes or skin.

Drug activity

The immediate effect that a drug has to certain cells and chemical structures inside the body.

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 Regulatory Authority (DRA)

A national agency responsible for ensuring that medicines and biological products (e.g., microbicides or vaccines) are evaluated properly and meet international standards of quality and safety before approving their use in-country.

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.

Drug-sparing regimen

A drug combination that omits the use of a particular class of antiretrovirals (ARVs) so they can be saved for use in later treatment.

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.

Dual-protection technology (DPT)

A product or technology that is designed to address two different health indications at the same time. For example, a vaginal product that protects against both unwanted pregnancy and HIV infection. See also *multipurpose prevention technology (MPT)*.

E

Effectiveness

Refers to how well treatment or intervention may work under real life conditions. Compare with *efficacy*.

Efficacy

Refers to how well an intervention works under ideal situations, such as in a trial where it is assumed participants are using the intervention consistently and correctly (e.g., taking a daily tablet without ever missing a dose). Compare with *effectiveness*.

ELISA

See *Enzyme-linked immunosorbent assay*.

EMA

See *European Medicines Agency*.

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 caused by factors in the body. Compare with *exogenous*.

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 and 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

A specific outcome that a trial is designed to evaluate to determine the safety and effectiveness of the intervention under study. A common endpoint for an HIV prevention trial is HIV infection. Each trial participant who acquires HIV during the study represents an endpoint.

Enrollment

The act of signing up volunteers into a study based on eligibility criteria and informed consent. Also refers to the number of participants in a clinical study.

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. See also *inclusion/exclusion criteria*.

Entry inhibitor

A class of antiretrovirals designed to combat infections 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 specific proteins (gp120 or gp141) 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. See also *viral envelope*.

Envelope

The outer protective membrane of HIV 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. Acts as a catalyst for specific chemical reactions, converting specific 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 and 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. Compare with *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 absorbs and secretes 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).

Ethics committee (EC)

A committee of experts who review and monitor clinical trials to ensure their ethical conduct and that the rights of study participants are protected. Ethics committees are similar to Institutional Review Boards (IRB). EC and/or IRB approval is required before any trial can be conducted, and researchers are under obligation to report on the study's progress and outcomes to the EC and/or IRB as well. See also *Institutional Review Board (IRB)*.

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.

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

An institute of the U.S. National Institutes of Health (NIH).

European Medicines Agency (EMA)

A decentralized agency of the European Union (EU) located in London, responsible for scientific evaluation of medicines developed by pharmaceutical companies for use in the EU. Through Article 58, the EMA provides scientific opinion on the safety and effectiveness of products for use in developing countries. See also *Article 58*.

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.

Exogenous

Introduced from or carried by factors outside the body. Compare with *endogenous*.

Experimental drug

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

Explant

A technique used to isolate cells by taking a tissue sample from a living organism and transferring it into a culture medium to study.

Exploratory objective

Refers to a question being asked in a trial that is of interest to the researchers but not as important as the primary and secondary questions being asked. See also *primary objective*, *secondary objective*.

Ex vivo

Outside of or removed from the body of a living organism. Compare with *in vivo*.

F

False negative

A test or procedure result that incorrectly indicates a negative or normal result when an abnormal condition is actually present. Compare with *false positive*.

False positive

A test or procedure result that incorrectly indicates a positive or abnormal result when no abnormal condition is actually present. Compare with *false negative*

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. Can also be used in the rectum to protect against HIV during anal sex. See also *condom*.

FemPrEP

A Phase III clinical trial that evaluated 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 different parts of the body, such as the intestines or vagina.

Flow cytometry

A method for identifying and sorting cells and their components by staining with a fluorescent dye and examining them under a beam of light.

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 in the United States. First reference is usually 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 *voluntary male medical 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, ointments, injectable solutions and vaginal rings. A single drug may be available in multiple formulations.

FTC

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

Futility

When efforts to achieve a result are likely to fail. In the context of a clinical trial, futility refers to the unlikelihood of the study being able to determine that a product is effective.

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. Often leaves women unable to negotiate sexual situations, including on the use of male condoms.

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. 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*. Compare with *phenotypic testing*.

Gestation

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

Glycoprotein (GP)

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)

Internationally agreed-upon standards for the conduct of clinical trials, including in handling data, protecting participant 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)

Guidance for trial funders, sponsors and implementers on how to effectively engage with all stakeholders in the design and conduct of biomedical prevention trials.

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.

Guidance

A generic term that refers to the provision of advice for making a decision or taking a course of action. Normative agencies, such as the World Health Organization (WHO), may issue guidance comprising evidence-based normative recommendations and operational, programmatic or complementary non-normative advice necessary to implement a strategy or process. See also *World Health Organization*.

Guidelines

Documents issued by normative agencies, such as the World Health Organization (WHO), that contain evidence-based recommendations about specific health interventions.

H

Half-life

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

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.

Hepatotoxicity

The capacity of a substance to have damaging effects on the liver. 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 can be transmitted to the genital region. The virus can become latent (inactive), when 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), and symptoms will 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 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/AIDS Clinical Trials Network

A large collaborative group of clinicians and researchers funded by the National Institute of Allergy and Infectious Diseases (NIAID) of the U.S. National Institutes of Health (NIH) that conduct clinical studies focused on NIAID's highest HIV/AIDS scientific priorities. Each HIV/AIDS clinical trials network comprises a leadership group (with a Leadership and Operations Center, Statistical Data and Management Center and Laboratory Center); and the network's associated Clinical Trials Units (CTUs) and clinical research sites (CRSs). There are five HIV/AIDS clinical trials networks: AIDS Clinical Trials Group (ACTG); HIV Prevention Trials Network (HPTN); HIV Vaccine Trials Network (HVTN); International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT); International Network for Strategic Initiatives in Global HIV Trials (INSIGHT); and Microbicide Trials Network (MTN).

HIV/AIDS Network Coordination (HANC)

An office that works with National Institutes of Allergy and Infectious Diseases (NIAID)-funded HIV/AIDS clinical trials networks to facilitate collaboration and communication for improved research efficiency.

HIV Prevention Trials Network (HPTN)

A U.S. National Institutes of Allergy and Infectious Diseases (NIAID)-funded HIV/AIDS clinical trials network focused on developing and evaluating integrated HIV prevention strategies.

HIV RNA

See *viral load (VL)*.

HIV shedding

See *shedding*.

HIV test

A test, usually of a sample of blood, that determines whether someone has HIV through detection of antibodies that the body produces in reaction to the infection or detection of the virus itself.

HIV Vaccine Trials Network (HVTN)

A U.S. National Institute of Allergy and Infectious Diseases (NIAID)-funded HIV/AIDS clinical trials network focused on finding a safe and effective preventive HIV vaccine.

HLA

See *Human Leukocyte Antigen (HLA)*.

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.

HHS

See *Department of Health and Human Services*.

HPV

See *human papillomavirus*.

HSV

See *herpes simplex virus 1* and *herpes simplex virus 2*

Human Immunodeficiency Virus (HIV)

The virus that causes Acquired Immunodeficiency Syndrome (AIDS). HIV is a lentivirus, in the retrovirus family. Two types have been identified. 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. Compare with *cell-mediated immunity*.

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.

Hypo-osmolar

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.

**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

See *Injecting drug user*.

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 that 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 baseline within the first year of treatment. People who experience virologic failure and do not receive an effective drug regimen can progress to immunologic failure. Immunologic failure may be followed by clinical failure. See also *clinical failure*.

Immunology

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

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.

IMPAACT

See *International Maternal Pediatric Adolescent AIDS Clinical Trials*

Implementation

Process of applying a set of activities or interventions designed to put guidance into practice.

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, or in a clinical trial, as the number of new infections for every 100 participants in a given year. Compare with *prevalence*.

Inclusion/exclusion criteria

The medical or social standards determining whether a person may or may not be eligible to enter a clinical trial, often based on age, gender, type and stage of a disease, previous treatment history, and other medical conditions.

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 clinical research experts that reviews data not available to the study team while a trial is ongoing to ensure that participants are not being exposed to undue risk. An IDMC can recommend that the study be stopped if the intervention is not effective, is causing harm to participants or the study is not likely to serve its scientific purpose. 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; signs are redness, swelling, heat and pain.

Inflammatory mediators

Molecules released by immune cells during times when harmful agents invade the body.

Informed consent

An ongoing process in which a study participant voluntarily confirms his or her willingness to participate or to continue participating in a study after all relevant aspects of the trial, including potential risks and benefits, have been explained.

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 the risks and potential benefits of participation. 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.

Injecting drug user (IDU)

Individuals who use needles/syringes to inject drugs; considered a high-risk population for acquiring HIV.

Innate antimicrobial factors

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

Innate immunity

Often referred to as the body's first line of defense, immunity that occurs naturally and is present at birth. (May also be called nonspecific immunity.) Compare with *acquired immunity*.

Institutional Review Board (IRB)

A committee of experts who review and monitor clinical trials to ensure they are ethically conducted and the rights of study participants are protected. In some countries, may be called an Ethics Committee (EC). IRB and/or EC approval is required before any trial is conducted, and researchers are under obligation to report on the study's progress and outcomes to the IRB and/or EC as well.

Integrase

An HIV protein that plays an important role in the virus's life cycle by inserting 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 participant data is examined according to study group at the time of enrollment. This would include participants who later discontinued product use due to pregnancy, HIV infection or other reasons, or who left or did not complete the study. ITT analysis differs from per-protocol analysis. Compare with *per-protocol analysis*.

Intercellular

Occurring between cells.

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.

International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network

A U.S. National Institute of Allergy and Infectious Diseases (NIAID)-funded HIV/AIDS clinical trials network that evaluates treatments for HIV-infected children and adolescents and 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 evaluating strategies for optimizing treatment through large sample trials in HIV-infected individuals, as well as studies of influenza.

International Partnership for Microbicides (IPM)

A non-profit product development partnership based in the United States established to accelerate the development and accessibility of microbicides to prevent HIV.

International Rectal Microbicide Advocates (IRMA)

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

Intervention

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 flexible doughnut-shaped drug delivery product designed to provide controlled release of a drug to cells within 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 a drug regulatory authority, such as the U.S. 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 developer can request regulatory approval for a specific use of the drug.

Investigational new drug (IND)

A U.S. Food and Drug Administration 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 U.S. Food and Drug Administration (FDA) before the drug is allowed to be tested in clinical trials.

In vitro

Latin for “in glass.” Refers to research conducted in an artificial environment created outside a living organism (for example, in a test tube or petri dish). Compare with *in vivo*.

In vivo

Latin for “in life.” Refers to that occurring within a living organisms natural state . Compare with *in vitro* and *ex vivo*.

iPrEx

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

iPrEx OLE

An open-label extension trial for participants in iPrEX.

Iso-osmolar

When there is no difference in the concentration of salt and sugar solutes in the body’s fluids compared to 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*.

Long-acting injectable

A biomedical HIV prevention approach under study and a form of pre-exposure prophylaxis (PrEP) that involves giving an injection containing an antiretroviral (ARV) drug every three months, for example, as opposed to taking an ARV tablet daily.

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.

Lymphocyte

A small white blood cell essential to immune defense. B cells, T cells and NKT cells are lymphocytes.

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 (antigens) and stimulates other immune system cells to fight infection. See also *antigen presenting cell (APC)*.

Maintenance therapy

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

Major Histocompatibility Complex (MHC)

See *Human Leukocyte Antigen (HLA)*.

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 gel and intravaginal ring for HIV prevention.

MCC

See *Medicines Control Council*.

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*.

Medical male circumcision

Surgical removal of the foreskin of the penis (the retractable fold of tissue that covers the head of the penis) to reduce the risk of HIV infection in men. Often referred to as voluntary medical male circumcision (VMMC).

Medical Research Council (MRC)

A publicly funded government agency for coordinating and funding medical research in the United Kingdom (UK). Not to be confused with the South African Medical Research Council. See also *South African Medical Research Council*.

Medicines Control Council (MCC)

The statutory body in South Africa that regulates the performance of clinical trials and the registration of medicine and medical devices to treat disease.

Memory cell

A long-lived B cell or T cell that remains in the body after an initial immune response and is primed to respond to a subsequent attack by the same invader. Compare with *naïve 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.

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 U.S. National Institute of Allergy and Infectious Diseases (NIAID)-funded HIV/AIDS clinical trials network that develops and evaluates products applied inside the vagina or rectum 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 inside the vagina or rectum. See also *rectal microbicides* and *vaginal microbicides*.

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).

MK-2048

A second generation integrase inhibitor being investigated for use as combination pre-exposure prophylaxis (PrEP) and as a combination intravaginal ring.

Monotherapy

The use of only one drug to treat a disease. HIV can only be treated effectively with a combination of three or more antiretroviral drugs, an approach known as highly active antiretroviral therapy or HAART. Compare with *combination therapy*.

Morbidity

The rate of sickness or disease within a certain population.

Mortality

Death; also 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*.

MRC

See *Medical Research Council (UK)* and *South African Medical Research Council*.

Mucosa

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

Multipurpose prevention technology (MPT)

Products or technologies under development to simultaneously address multiple sexual and reproductive health needs, such as unintended pregnancy and sexually transmitted infections. See also *dual-protection technology*.

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, referring 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 Institute of Child Health and Human Development (NICHD)

An institute of the U.S. National Institutes of Health. Correct first reference is *Eunice Kennedy Shriver* National Institute of Child Health and Human Development.

National Institutes of Health (NIH)

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

National Institute of Mental Health (NIMH)

An institute of the U.S. National Institutes of Health (NIH).

National Regulatory Authority (NRA)

The national agency within a particular country that regulates and determines which drugs are available for use within country.

Natural history study

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

Natural killer (NK) cell

A white blood cell that kills 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.

Network

A cooperative of institutions conducting clinical trials under a common research agenda. See also *HIV/AIDS clinical trials network*.

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 or product developer to the U.S. Food and Drug Administration (FDA) for a license to market and sell a particular drug or product in the United States. Filed in conjunction with FDA review. See also *approved drug*.

NK cell

See *natural killer cell*.

NNRTI

See *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 clinical trial designed to show that a new treatment or intervention is at least as effective as a standard treatment or approach. Such trials are conducted when a placebo-controlled trial is unethical because a standard therapy already exists. Participants are randomized to use either the standard treatment or the new treatment under study. Compare with *superiority trial*.

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. Compare with *nucleoside reverse transcriptase inhibitor*.

Nonoxynol-9 (N-9)

A contraceptive spermicide found in many products and sold over the counter that can cause vaginal and rectal tissue damage and is not recommended as a lubricant for receptive anal sex.

Nonresponder

An individual who does not show improvement while undergoing treatment.

Nonspecific immunity

See *innate immunity*.

Normative

Relating to the ideal standard, model or framework.

NPT

New prevention technology.

NRTI

See *nucleoside reverse transcriptase inhibitor*.

Nucleic acid

Chemical structure that stores genetic information. Human genetic information is stored as DNA, HIV 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 to make 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, 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 to make copies of itself. NtRTIs work in a slightly different way than NRTIs. Compare with *nucleoside reverse transcriptase inhibitor*.

Nucleus

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

O

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 used in clinical trials of the likelihood of developing a disease or condition when 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 HIV/AIDS research programs across all NIH institutes.

Office of Human Research Protection (OHRP)

The office within the U.S. Department of Health and Human Services (HHS) focused on protecting the rights, welfare and wellbeing of subjects involved in research conducted or supported by HHS, including the U.S. National Institutes of Health.

Off-label use

Use of a drug for a condition other than that for which it received drug regulatory approval.

Open-label extension (OLE) trial

A type of study conducted after a Phase III trial finds a product safe and effective in which former participants are offered the opportunity to enroll and use the product. In addition to providing former participants access to the product (there is no placebo), OLEs are typically designed to collect additional information about its safety and use.

Opportunistic infection (OI)

An illness caused by any one of various organisms in people with weakened immune systems, including people with HIV/AIDS.

Oral

Refers to the mouth; taken by mouth.

Osmolality

Pertaining to the concentration of solutes (made up of salts and sugars) normally found in cells. See also *hyperosmolar*, *hypo-osmolar* and *iso-osmolar*.

Osteoporosis

Severe loss of bone mass, density and strength. Although usually age-related in women, 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. See also *gag*.

Package insert

Also known as prescribing information or product label. A document prepared by the manufacturer of a drug and approved by the U.S. Food and Drug Administration (FDA) that describes a drug's approved uses, dosages, contraindications, potential side effects and other relevant information.

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 in which a thin layer of cells scraped from the cervix is 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 that evaluated daily use of the antiretroviral Truvada and of tenofovir for preventing infection 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 the sexually transmitted infections (STIs) including 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, tuberculosis (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.

Per-protocol analysis

A method of analyzing results of a clinical trial in which only those participants who completed the study on product are included in analysis. As such, this does not include participants who become pregnant or acquired HIV during the study or who left the study for any reason.

Compare 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.

Drug regulatory authorities, such as the U.S. Food and Drug Administration (FDA), often require a certain number of person-years of safety data on an investigational drug or product for it to be considered for possible approval.

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 involving a small number (10-100) of healthy volunteers, focused on evaluating safety, acceptance and how a drug is metabolized and excreted in the body. Also written as Phase 1 trial.

Phase II trial

The second stage in the clinical evaluation of a new drug or intervention, in which preliminary data on effectiveness and additional information about safety is collected among people with a certain disease or condition. Also written as Phase 2 trial.

Phase IIb trial

A study designed to be large enough to provide evidence of safety and effectiveness, or proof of concept. A positive result indicates the need for another trial – typically a Phase III trial, to confirm the results. 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. Open-label extension (OLE) studies are often Phase IIIb trials. See also *open-label extension study*.

Phase IV trial

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

Phenotype

Visible characteristics or behavior that result from the interaction of an organism’s genetic “blueprint” (genotype) and the environment. Compare with *genotype*.

Phenotype Resistance Testing

A laboratory test that determines whether an organism is susceptible to a specific drug. Compare with *genotypic assay*.

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 product (e.g., oral tablet or vaginal gel) that contains no active drug but looks the same as the active product under study.

Placebo-controlled study

A study that identifies the true effect of an investigational product (containing an active drug) by comparing results of participants taking the active product to those taking a placebo, an inactive look-alike product.

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 in a sample and is used to aid in the detection of sexually transmitted diseases, for example.

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*.

Post-trial access

Providing study participants (and sometimes trial site communities) access to a treatment or intervention found to be effective in the clinical 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 an antiretroviral (ARV) drug – typically, once a day – by someone who is not infected with HIV to decrease his or her risk of acquiring HIV. Compare with *post-exposure prophylaxis (PEP)*. See also *Truvada*.

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 during a specific point of 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, refers to activities designed to reduce the risk of becoming infected (primary prevention) and the risk of transmitting 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 infection from an HIV-infected mother to her infant, whether in the womb, during labor and delivery, or through breastfeeding. See also *vertical transmission*.

Primary care

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

Primary HIV infection (PHI)

The first stage of HIV infection, lasting several days or weeks. HIV can easily be transmitted to others during this time. Also called acute HIV infection. See also *acute HIV prevention*.

Primary infection

The initial introduction of an infectious organism into the body.

Primary objective

Refers to the main question being asked in a study, such as whether an intervention is effective. See also *secondary objective* and *exploratory objective*.

Primary resistance

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

Primary results

Refers to the results of a study that pertain to its primary objectives, i.e., the main questions it was designed to ask, such as whether a particular intervention is safe and effective.

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*.

Prodrug

A class of drugs, initially in inactive form, that are converted into active form in the body by normal metabolic processes.

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 provide evidence of effectiveness, but still limited in size and “power” so that results, if positive, indicate need for a larger Phase III trial to confirm the results. 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*.

Proteins

Highly complex biological molecules that are considered the building blocks of cells. Examples of proteins are enzymes, cytokines and antibodies; and the major components of hair, skin and muscle.

Protocol

A detailed study plan on which a clinical trial is based that is designed to answer specific research questions while safeguarding the health of the participants. 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.

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.

Receptive partner

The person who receives a partner's sexual organ into his or her body during vaginal or anal sex.

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.

Recruitment

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 in the rectum.

Rectal microbicide

Products being developed and tested as gels and lubricants to reduce a person's risk of HIV or other sexually transmitted infections from anal sex.

Rectum

The lower part of the large intestine.

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.

Reduced glycerin tenofovir gel

A formulation of tenofovir gel that contains less glycerin to make it more suitable for use in the rectum. Currently being tested as a rectal microbicide. See also *rectal microbicide* and *tenofovir*.

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 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

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. See also *phenotypic resistance testing* and *genotypic assay*.

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*.

Ring Study

See *The Ring Study*

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 infection, such as having unprotected sex, having multiple partners or 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.

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

The process of achieving a sufficient level of coverage and uptake of an intervention by the intended population for whom it would benefit.

Secondary analysis

Involves the use of data to try to answer a different research question than the primary question the data was initially collected to answer.

Secondary objective

Refers to a question being asked in a trial that is not as important as the primary question. For instance, the primary objectives of a trial may be to determine the safety and effectiveness of a product, while the secondary objective may seek to determine if participants had any challenges in using the study product. See also *primary objective* and *secondary objective*.

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 an individual is infected or has had a past infection.

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 infectious 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 Simian immunodeficiency virus (SIV) core 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 the desired therapeutic effect. See also *adverse event*.

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 nonhuman primates.

Simian immunodeficiency virus (SIV)

A virus similar to HIV that can infect nonhuman primates (monkeys, chimpanzees and macaques) and 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 participating in a study or using a product may have on the study participant or those who are close to him or her.

Soluble

Capable of being dissolved.

South African Medical Research Council (SAMRC)

A national organization focused on research, development and technology transfer related to HIV/AIDS, tuberculosis, cancer and other conditions. Although often referred to as the MRC, it should not be confused with the U.K.'s Medical Research Council. See also *Medical Research Council*.

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.

Standard deviation

A statistical measure of how widely numbers 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.

Standard operating procedures

A set of written instructions or steps to be followed when carrying out a specific operation, such as a study protocol.

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 be stopped or modified (for efficacy, safety reasons or futility), before its scheduled end. Data Safety Monitoring Boards (DSMBs) and Independent Data Monitoring Committees (IDMCs) use these rules as guides in conducting interim reviews of blinded data while a study is in progress. See also *Data Safety Monitoring Board (DSMB)* and *Independent Data Monitoring Committee (IDMC)*.

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 called subtypes. 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*, *wild-type virus* and *clade*.

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 no longer under study that disrupt microbial cell membranes, thereby inactivating or killing the virus. Examples include Nonoxynol-9 and Savvy.

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.

TasP

See *treatment as prevention*.

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 a vaginal and rectal microbicide gel and in other formulations.

Tenofovir disoproxil fumarate (TDF)

See *tenofovir*.

Teratogenic

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

Test and treat

An approach to HIV prevention in 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.

The Ring Study

A Phase III clinical trial designed to evaluate the safety and efficacy of the dapivirine vaginal ring for preventing HIV when used by women for a month at a time. Being conducted by the International Partnership for Microbicides. See also *ASPIRE* and *dapivirine ring*.

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 and 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 inside 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 in 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.

Transgender

An umbrella term for people whose gender identity and/or gender expression differs from the sex they were assigned at birth.

Transient

Short-lived; not permanent.

Translation

The step in the HIV life cycle that follows transcription in which the genetic information contained in HIV mRNA is used to build HIV proteins with 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 (those that change their genetic blueprint every time they multiply), and the original basis for all of the viruses that follow.

Treatment as prevention (TasP)

The early provision of antiretroviral treatment in people with HIV in order to reduce their risk of transmitting the virus to others through sex.

Treatment-experienced

A term used to describe HIV-infected individuals who are 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

How a clinical study or trial is structured to answer the questions being asked, 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.

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 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, and also approved for use as prevention in the United States. See also *pre-exposure prophylaxis (PrEP)*.

U

Unblinding

The process by which trial participants and, in the case of a double-blind study, researchers, learn which participants received the study intervention and which received the placebo.

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 include the use of gloves and other protective gear, and the safe disposal of needles to prevent exposure to blood and other body fluids.

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.

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 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 microbicide

Products being developed and tested in many forms, including gels, films and rings, to reduce the risk of HIV or other sexually transmitted infections acquired through vaginal sex.

Vaginal yeast infection

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

Vector

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)*.

Vicriviroc

A CCR5 inhibitor being developed as a microbicide formulated as a combination intravaginal ring to prevent HIV. See also *CCR5*.

Viral breakthrough

An increase in viral load while on antiretroviral treatment.

Viral envelope

The outer coat of a virus, made up of two lipids (fatty molecules). HIV uses specific proteins embedded in its envelope to enter host cells.

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. Compare with *CD4 cell count*.

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

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

Voluntary counseling and testing (VCT)

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.

Voluntary medical male circumcision (VMMC)

Surgical removal of the foreskin of the penis (the retractable fold of tissue that covers the head of the penis) to reduce the risk of HIV infection in men.

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 its use is discontinued. In cross-over trials, participants typically have a washout period after they have completed a course of treatment with one study drug before beginning the course with a second study drug. See also *cross-over trial*.

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 an 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 from the time of 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.

Online References Include:

<http://www.clinicaltrials.gov/ct2/info/glossary>
<http://www.aidsinfo.nih.gov/ContentFiles/GlossaryHIVrelatedTerms.pdf>
<http://kff.org/glossary/global-health-glossary/>
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<http://www.aidsmap.com/Glossary>
<http://www.thebody.com/content/art12696.html>
<http://www.who.int/trade/glossary/en/>

Glossary of Terms

Microbicides and HIV Prevention Research

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 prevention research.



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