# IAVI VACCINE LITERACY LIBRARY

2022

iavi

Translating **science** into **global** health impact

## About IAVI

IAVI is a non-profit scientific research organization dedicated to addressing urgent, unmet global health challenges including HIV, tuberculosis, and emerging infectious diseases. Its mission is to translate scientific discoveries into affordable, globally accessible public health solutions.


## Acknowledgements

IAVI would like to acknowledge the contribution of Doreen Asio, Monica Bagaya, Vincent Basajja, Kundai Chinyenze, William Dekker, Evanson Gichuru, Nyokabi Jacinta, Sarah Joseph, Dagna Laufer, Sharon Lipesa, Shelly Malhotra, Miliswa Magongo, Blossom Makhubalo, Roselyn Malogo, John Mdluli, Ireen Mosweu, Juliet Mpendo, Gaudensia Mutua, Vincent Muturi-Kioi, Conwell Mwakoi, Jauhara Nanyondo, Gertrude Nanyonjo, Jacinta Nyakobi, Faith Ochieng, Fred Otieno, Daisy Ouya, Gayle Patenaude, Hilda Phiri, Lewis Schrager, Nicole Sender, Elana Van Brakel, Anja Van der Westhuizen, Kelvin Vollenhoven, Jeffery Walimbwa, Mathias Wambuzi for reviewing the content of the **IAVI Vaccine Literacy Library**.

Lead Consultants: Roger Tatoud and Rebekah Webb.

Design and Illustration: Anthea Duce.





Requests for permission and inquiries should be directed to:

IAVI
Email: info@iavi.org
Website: iavi.org
Tel: +1.212.847.1111
125 Broad Street, 9th floor
New York, NY 10004


The text of the **IAVI Vaccine Literacy Library** may be found online at *www.iavi.org/news-resources/iavi-vaccine-literacy-library*


IAVI gratefully acknowledges the generous support provided by the following major funders

Biomedical Advanced Research and Development Authority (BARDA) | Foundation for the National Institutes of Health | National Institute of Allergy and Infectious Diseases | amfAR, The Foundation for AIDS Research | Broadway Cares/Equity Fights AIDS | Cancer Research UK | The City of New York, Economic Development Corporation | Congressionally Directed Medical Research Program (DoD) | GSK | The Hearst Foundations | Keith Haring Foundation | Merck & Co., Inc., Kenilworth, NJ, USA (known as MSD outside the USA and Canada)

And many other generous individuals and partners around the world

As of April 2022

# Abbreviations

| | |
|---|---|
| **AE** | Adverse event |
| **AIDS** | Acquired immunodeficiency syndrome |
| **APC** | Antigen-presenting cell |
| **BCG** | Bacillus of Calmette and Guerin |
| **CAB** | Community advisory board |
| **CBO** | Community-based organisation |
| **CD** | Cluster of differentiation |
| **CDC** | Centers for Disease Control and Prevention |
| **CEPI** | Coalition for Epidemic Preparedness Innovations |
| **COVID-19** | Coronavirus Disease 2019 |
| **CRF** | Circulating recombinant forms |
| **CTL** | Cytotoxic T lymphocyte |
| **DNA** | Deoxyribonucleic acid |
| **DOT** | Directly observed therapy |
| **EMA** | European Medicines Agency |
| **ERC** | Ethics Review Committee |
| **FDA** | U.S. Food and Drug Administration |
| **GCLP** | Good Clinical Laboratory Practice |
| **GCP** | Good Clinical Practice |
| **HIV** | Human immunodeficiency virus |
| **ICH** | International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use |
| **IEC** | Independent Ethics Committee |
| **IGRA** | Interferon-gamma release assays |
| **IRB** | Institutional Review Board |
| **LASV** | Lassa virus |
| **LMIC** | Low- to middle-income countries |
| **LTBI** | Latent tuberculosis infecton |
| **MDR-TB** | Multidrug-resistant tuberculosis |
| **M.tb** | Mycobacterium tuberculosis |
| **NAT** | Nucleic acid test |
| **NGO** | Non-governmental organisation |
| **NK** | Natural killer cells |
| **NP** | Nucleoprotein |
| **NRA** | National Regulatory Authority |
| **POD** | Prevention of disease |
| **POI** | Prevention of infection |
| **POR** | Prevention of reinfection |
| **RNA** | Ribonucleic acid |
| **SAE** | Serious adverse event |
| **SAHPRA** | South African Health Products Regulatory Authority |
| **TB** | Tuberculosis |
| **TPP** | Target product profile |
| **TST** | Tuberculin skin test |
| **UNAIDS** | Joint United Nations Programme on HIV/AIDS |
| **VISP** | Vaccine-induced seropositivity |
| **VL** | Viral load |
| **VMMC** | Voluntary medical male circumcision |
| **WHO** | World Health Organization |
| **XDR-TB** | Extensively drug-resistant TB |

# Introduction


The **IAVI Vaccine Literacy Library** contains basic information about HIV, TB, and Lassa virus vaccines, explained in simple language and in a user-friendly format. The text is divided into eight modules covering a range of topics, from basic science and clinical trials to social and ethical issues related to vaccine development and testing, as well as future access to and use of vaccines. The resource also includes a list of abbreviations used and a glossary with definitions of key terms.

## Audience

The **IAVI Vaccine Literacy Library** is targeted to a broad range of stakeholders involved in HIV, TB, and Lassa virus vaccine-related work. While all the modules can be adapted for use at the local community level, they are generally written for individuals who provide education and information related to HIV, TB and Lassa virus.

## Use of the IAVI Vaccine Literacy Library

The **IAVI Vaccine Literacy Library** is meant for use by individuals and organisations that are providing education and information related to HIV, TB and Lassa virus vaccine research and development.

Groups that may use this material include, but are not limited to:

- Clinical vaccine trial site staff.
- Non-Governmental Organisation (NGO) staff, to incorporate vaccine messages into their existing work.
- Medical professionals or institutions, to provide vaccine information to patients or to incorporate into advocacy efforts.
- Health Centres, to provide clients with vaccine information.
- Academic or religious leaders, to provide information and/or informed advice.
- Community Advisory Boards.

The **IAVI Vaccine Literacy Library** is designed for multiple uses to serve a variety of needs. For certain audiences, it may be used as reference information, such as background reading for training workshops. It can also be used as a reference document to develop educational materials or tools, or to incorporate vaccine information into existing tools, such as:

- Fact sheets on specific vaccine topics.
- Brochures to be given to potential vaccine trial participants.
- Informational videos to be shown in community settings.
- Street plays to be performed in community settings.
- Radio programmes.

The **IAVI Vaccine Literacy Library** can also be used directly for recruitment of trial participants or may be used to engage communities or national-level stakeholders to build understanding of and support for clinical trials and an eventual vaccine.

## Using and Navigating the Core Content

The **IAVI Vaccine Literacy Library** is divided into eight modules covering a range of topics, from basic science and clinical trials to social and ethical issues related to vaccine development and testing, as well as future access and use.

Each module can be read and used as a standalone document.

Certain issues or concepts are covered in more than one module. These "cross-cutting issues" are cross referenced to other modules in capitalised text. All scientific and technical terms are defined in a comprehensive glossary that provides definitions for technical and scientific terms and expressions.

## Acknowledgement of IAVI and Materials Review

As described, the **IAVI Vaccine Literacy Library** is designed primarily as a reference on HIV, TB, and Lassa virus vaccines that can be used to develop or adapt materials or messages.

If IAVI has not been involved in production of materials or tools based on the **IAVI Vaccine Literacy Library**, no review by IAVI is required. IAVI does request that appropriate acknowledgement of the **IAVI Vaccine Literacy Library** be given, but the IAVI logo should not be used.

IAVI requests that it be notified of any tools or materials produced, in order that they be added to the **IAVI Vaccine Resource Library**, which is a public resource serving the entire HIV, TB, and Lassa virus-vaccine field. Proper credit will be given for all resources included in the **IAVI Vaccine Literacy Library**.

## Disclaimer

IAVI assumes no responsibility or liability for any errors or omissions in the content of the **IAVI Vaccine Literacy Library**. The information contained in this Resource Library is provided on an 'as is' basis with no guarantees of completeness, accuracy, usefulness, or timeliness.

## How to Cite the IAVI Vaccine Literacy Library

IAVI Vaccine Literacy Library, IAVI, New York, USA, 2022.

# MODULE 8:
## GUIDANCE FOR TRAINERS

# MODULE 8

# GUIDANCE FOR TRAINERS

## CONTENTS 113



# 1. Introduction

This **IAVI Vaccine Literacy Library** is a core reference text that provides simple explanations about key aspects of vaccine development and clinical trials. It has been designed to help members of the vaccine research field fill any gaps in their knowledge, and to conduct training workshops for relevant audiences about a range of issues related to vaccine development.

The aim of this manual is to:

- Build vaccine clinical trial literacy among communities where research is conducted.
- Support literacy and understanding among NGO partners and communities.
- Serve as a reference tool for training various stakeholders, including the media, policymakers and new staff working in clinical trial settings.

# 2. Target Audience

The target audience for the manual includes:

- Community liaison officers and community engagement staff who deliver trainings and presentations to the community.
- Clinical trial staff as needed, for example as part of their induction training.

The target audience for the slides for each module is the community in which the research is being conducted, including:

- Communities and civil society groups and networks in countries and regions where trials are being conducted.
- Non-Governmental Organisation (NGO) staff that advocate and support clinical trials particularly in settings where access to information may be limited.
- Community Advisory Board (CAB) members, and other community members who conduct outreach around clinical trials, (e.g., peer leader network members).
- Clinical trial centre staff, particularly those who are not directly involved in vaccine work.
- Health care professionals or institutions that conduct clinical trials or provide information to potential study participants.
- Key media representatives in relevant countries who may cover stories on vaccine development.
- Other community leaders such as religious or academic leaders.

## 3. How to Use this Manual

The manual consists of seven content modules. Each module has a table of contents at the beginning, with a set of summary points.

The glossary contains definitions of all the scientific and technical terms used in the manual.

At the end of each module is a key references section.

**TIP!** It is important to read and understand the content of each module, perhaps with a member of your clinical trial staff, before delivering a training session.

## 4. Using the Slides

Each module has an accompanying set of slides that can be used in presentations with community audiences. These slides incorporate the summary points, diagrams, and illustrations from each module.

## 5. How to Plan a Training or Presentation

The most important thing to do when planning a training session is to think about your audience and the key information that they need to take home with them.

1. Who is being trained? Consider what level of knowledge your audience already has about the subject. Are they potential trial participants or already working in the field? Have they received any other training on vaccines or clinical trials?

2. Who should co-facilitate the session? Is it important to have someone from the community co-present or co-host? Will the audience be more receptive to a medical professional? It is often useful to have an expert to serve as a resource for any questions that may be asked, such as a trial coordinator, nurse from the trial site staff, or a local expert from an ethics review board.

3. How long is the training? In some contexts, a multi-day training is not feasible. Community audiences usually have limited time and will need shorter sessions, perhaps scheduled over a number of weeks. Consider carefully the amount of information that your audience can take in over the time you have.

4. What equipment will be needed? Will you use a laptop and projector, or work from handouts only? Do you need flipcharts and markers?

**TIP!** Remember to allow plenty of time for questions from the audience. Be clear whether you want people to ask questions as they arise, or to save them for a Q&A part of the training.

# 6. Selecting the Content

The manual has been structured to allow modules to be presented individually or grouped together to suit the needs of the audience. The content of some modules overlaps so that you can deliver modules separately if you wish. This flexible format allows trainers to design their own tailored sessions based on the specific needs of the audience.

Trainers should also consider adapting sessions based on the cultural context of trainees. Sessions have been developed with generic content, and where possible, trainers may choose to include culturally-relevant examples, metaphors, or stories as a way to make the subject matter more relevant to trainees.

### Introduction to HIV, TB, and Lassa Fever Vaccine Research

This training would include all seven content modules (97 slides) and follow the order of the modules as set out in the manual. The session could be delivered in half a day with a coffee break and time for questions or extended into a whole day if time allows.

### Introduction to Vaccines (HIV, TB, and Lassa)

For audiences outside of clinical trial settings, this shorter training would include Modules 1-4 and Module 6 (70 slides).

### Disease-Specific Trainings

In contexts where research only focuses on one disease, this training would draw only the specific content from all seven modules and could be delivered in 2 hours including time for questions.

### Introduction to Vaccine Clinical Trials

For audiences that already know about how vaccines work, you can exclude Modules 2, 3, and 4 and focus on Modules 5 and 6. This training would take 1.5–2 hours including time for questions.

### Adapting Training Materials for Different Audiences

The slides have been designed so that you can print them out as handouts. Ideally, you would print one slide per page so that any diagrams and illustrations can be clearly read. Depending on your audience you may also want to use the resources listed at the end of each module to supplement your handout materials.

**TIP!**

When drawing up your training agenda, remember to build in time for introductions and setting ground rules, coffee/tea breaks, wrapping up, and evaluation. Ground rules may include things such as returning from breaks on time, not interrupting others, and turning mobile phones off while the workshop is in session.

# 7. Answering Difficult Questions

There are a number of questions that are frequently asked by the community at any presentation on vaccine research. These include questions about vaccine safety, the ethics of clinical trials and how human rights are protected, for example:

- Can vaccines cause illness?
- How do we know vaccines are safe?
- Do the vaccines used in clinical trials protect you?
- Why are vaccines tested on people in developing countries?
- Why are vaccines tested on babies and young children?
- Will our community have access to the vaccine if it is effective?

With vaccine hesitancy growing around the world, it is important to take these questions seriously and prepare how to answer them. You may be challenged by people in the community who feel their rights have been neglected in the past, or who are tired of being the subject of research. It is recommended to always begin presentations to the community with a focus on how collaboration between communities and researchers can solve long-standing problems caused by disease and ill-health.

Each module has been written with the frequently asked questions on vaccines and clinical trials in mind, and Module 6 addresses many of these in detail. The summary points from Modules 1 and 5 are also useful in this context.

**TIP!**

If you are not sure how to answer a question, make a note of it and tell your audience you will find out and feed back to them after the training session.

# 8. How to Conduct a Refresher Training

In contexts where research is ongoing over a number of years, for example at a Phase III trial site, it will be useful to hold refresher training for key stakeholders each year. To do this you can use the summary points slides and a few illustrations, rather than the complete set of slides. Rather than going through the script line by line, you can ask the audience what they remember from the previous training. A refresher training can be shorter and conducted in a two-hour session if needed.

# 9. Acknowledgement of IAVI and Materials Review

As described, the **IAVI Vaccine Literacy Library** is designed primarily as a reference on HIV, TB, and Lassa virus vaccines that can be used to develop or adapt educational and advocacy materials or messages.

If IAVI has not been involved in production of materials or tools based on the **IAVI Vaccine Literacy Library**, no review by IAVI is required. IAVI does request that appropriate acknowledgment of the **IAVI Vaccine Literacy Library** be given, but the IAVI logo should not be used.

IAVI requests that it be notified of any tools or materials produced, in order that they be added to the **IAVI Vaccine Literacy Library**, which is a public resource serving the entire HIV, TB, and Lassa virus vaccine field. Proper credit will be given for all resources included in the **IAVI Vaccine Literacy Library**.

# Glossary

A

**Acquired immunity:** immunity that develops during a person's lifetime.

**Adjuvant:** a substance added to its formulation to enhance or modify the immune response to the components of the vaccine.

**Adverse event:** an unexpected medical problem experienced by an individual in a clinical trial. The term is used whether the effect can be attributed to the vaccine under study or something else happening during the study.

**Adverse reaction (also known as adverse event or side effect):** in a clinical trial, an unwanted effect detected in participants and attributed to the study vaccine.

**AIDS (acquired immunodeficiency syndrome):** the most advanced stage of HIV infection, characterised by a deterioration of the immune system and a susceptibility to a range of opportunistic infections and cancers.

**Antibody:** a protein found in the blood or bodily fluids that binds, neutralises, and helps destroy pathogens (e.g., bacteria, viruses) or toxins. Antibodies are also known as immunoglobulins. Each antibody binds specifically to the antigen that stimulated its production.

**Antibody-mediated immunity:** immunity that results from the activity of antibodies. Also called humoral immunity.

**Antigen**: any substance that stimulates the immune system to trigger an immune response.

**Antigen-presenting cell (APC):** B cell, macrophage, dendritic cell or other cells that ingest and process pathogens such as bacteria and viruses. An APC displays fragments of the pathogen on its surface to attract and activate the cells of the immune system that respond specifically to that antigen (see also dendritic cell; macrophage).

**Antiretrovirals:** drugs that reduce the ability of HIV or other types of viruses to multiply in the body.

**Apoptosis:** cellular suicide. A possible mechanism used by HIV to destroy cells of the immune system. HIV may cause apoptosis in both HIV-infected and HIV-uninfected immune system cells. Also known as programmed cell death.

**Arm:** a group of participants in a clinical trial, all of whom receive the same treatment, intervention, or placebo.

**Attenuated:** weakened. Attenuated viruses are often used as vaccines because they can no longer produce disease but still stimulate a strong immune response, similar to that caused by the natural virus.

B

**B lymphocyte (B cell):** one of the two major classes of lymphocytes, B lymphocytes are white blood cells of the immune system that are derived from the bone marrow and spleen. B cells develop into plasma cells, which produce antibodies.

**Baseline:** the time point in a study just before initiation of an intervention (for example vaccination). Measurements taken at later time points may be compared with those taken at baseline to determine if the intervention makes a difference.

## B

**Binding antibody:** an antibody that attaches to part of a pathogen. Binding antibodies may or may not lead to the killing of the pathogen.

**Blinded study:** a clinical trial in which participants are unaware as to whether they are in the experimental or control arm of the study. See also double-blind study.

**Booster:** a vaccine dose given after the first dose to increase the immune response to the vaccine antigen(s). A booster may be given shortly after the first dose or much later. The vaccine given as the booster dose may or may not be the same as the primary vaccine. See also prime-boost.

**Breakthrough infection:** an infection that occurs during a vaccine trial conducted to prevent that infection. Such an infection is caused by exposure to the infectious agent and may occur before or after the vaccine has taken effect or all doses have been given.

## C

**CD:** abbreviation for 'cluster of differentiation,' referring to molecules at the surface of cells that are used to identify immune cells, for example, CD4+ T cells.

**CD4+ T lymphocyte:** cell of the immune system that carries a molecule on its surface known as 'cluster of differentiation 4' (CD4). These cells are the primary targets of HIV. Also known as helper T cells, CD4+ T cells help orchestrate the immune response, including antibody responses as well as CTL responses (see also T cell).

**CD8+ T lymphocyte:** cell of the immune system that carries a molecule on its surface known as 'cluster of differentiation 8' (CD8) (see also cytotoxic T lymphocyte (CTL); T cell).

**Cell-mediated immunity (cellular immune response):** the immune response coordinated by T cells. This branch of the immune system targets cells infected with microorganisms such as viruses, fungi, and certain bacteria.

**Challenge:** in vaccine research and development, the deliberate exposure of an immunised animal to the infectious agent. Challenge experiments are never done in human HIV vaccine research.

**Circulating recombinant forms (CRFs):** HIV made of different subtypes of the virus that have recombined.

**Clade:** a group of related viruses classified according to their degree of genetic similarity. Also called a subtype or strain.

**Cohort:** groups of individuals who share one or more characteristics in a research study and who are followed over time. For example, a vaccine trial might include two cohorts, a group at low risk for HIV and a group at higher risk for HIV.

**Complement proteins:** blood proteins that play an important role in the immune response. Generally, complement proteins amplify the effects of antibodies and inflammation.

**Control arm:** in vaccine clinical trials, the group of participants that is not given the experimental intervention. The control arm can be given an intervention that is considered effective (the standard of prevention), a placebo, or no intervention. The control group is compared with one or more groups of participants given experimental vaccines to measure any effects of the vaccines tested as well as to measure differences in safety.

C

**Core:** the section of a virus that contains the genetic information and other proteins needed for a virus to replicate.

**Correlates of immunity (correlates of protection):** the immune responses a vaccine or natural immunity need to trigger to protect an individual from a certain infection.

**Cytokine:** a hormone-like protein produced by white blood cells that acts as a messenger between cells. Cytokines can stimulate or inhibit the growth and activity of various immune cells. Cytokines are essential for a coordinated immune response and can also be used as immunologic adjuvants. HIV replication is regulated by a delicate balance among cytokines.

**Cytotoxic T lymphocyte (CTL):** a type of immune system cell that can destroy cancer cells and cells infected with viruses, fungi, or certain bacteria. Also known as killer T cells.

D

**Deletion (genetic):** elimination of a gene or portion of a gene. Genetic deletion can occur naturally or in the laboratory.

**Dendritic cell:** antigen-presenting cell with thread-like tentacles (called dendrites) used to surround antigen, which they present to T cells.

**DNA (deoxyribonucleic acid):** the double-stranded, helical molecular chain found within the nucleus of each cell. DNA carries the genetic information that encodes proteins and enables cells to reproduce and perform their functions.

**Dose-ranging study:** a clinical trial in which two or more doses (starting at a lower dose and proceeding to higher doses) of a vaccine are tested against each other to determine which dose works best and has acceptable side effects.

**Dose-response relationship:** the relationship between the dose of a vaccine and an immune or physiologic response. In vaccine research, a dose-response effect means that as the dose of the vaccine increases, so does the level of the immune response.

**Double-blind study:** a type of clinical trial in which neither the participants nor the research team know which intervention a specific participant is receiving. This helps prevent bias or expectations from influencing the results of the study.

**Data and Safety Monitoring Board (DSMB):** a committee of independent clinical research experts who review data while a clinical trial is in progress. The DSMB ensures that participants are not exposed to undue (unacceptable) risk and looks for any differences in effectiveness between the experimental and control groups. The DSMB may review the data in such a way that they know which group received the vaccine and which group did not. This group may also recommend that a trial be modified or stopped if there are safety concerns or if the trial objectives have been achieved or will not be achieved. See futility.

E

**Effectiveness:** the measurement of how well a vaccine works to reduce infection or disease in the overall population when used in the 'real world.'

**Efficacy:** the measurement of how well a vaccine works at producing a desired clinical effect in optimal conditions, that is, in clinical trials.

**ELISA (enzyme-linked immunoabsorbent assay):** a laboratory test to detect the presence of antibodies in the blood or other body fluid.

E

**Endpoint:** an outcome or event used to objectively measure the effect of a drug or other intervention being studied in a clinical trial. Common endpoints include infection, severe toxicity, relief of symptoms, and improvements in quality of life.

**Envelope:** outer surface of a virus, also called the coat. Not all viruses have an envelope.

**Enzyme:** a protein produced by cells to trigger a specific chemical reaction. Enzymes are generally named by adding the ending '-ase' to the name of the substance on which the enzyme acts (for example, the HIV reverse transcriptase converts HIV RNA into viral DNA)

**Epidemic:** a widespread outbreak of a disease in a large number of individuals over a particular period of time either in a given area or among a specific group of people.

**Epidemiology:** the study of the characteristics, frequency, and distribution of diseases in human populations.

**Epitope:** a specific part of an antigen that stimulates specific immune responses.

**Experimental arm:** in a clinical trial, the group of participants given the intervention being studied. Outcomes in the experimental arm are compared with those in the control arm to determine any differences, for example, in safety and effectiveness.

F

**Functional antibody:** an antibody that binds to an antigen and has an effect that can be demonstrated in laboratory tests. For example, neutralising antibodies are functional antibodies that inactivate HIV or prevent it from infecting other cells.

**Futility:** the inability of a clinical trial to achieve its objectives. A clinical trial can be stopped when an interim analysis of the results by the DSMB suggests that it is unlikely to achieve its objective and stopping it can save resources and time that could be used on more promising research.

G

**Genetic engineering**: the laboratory technique of recombining genes to produce proteins used for drugs and vaccines.

**Genome:** the complete genetic material of an organism, including all its genes. The genomes of viruses can exist as DNA or RNA.

**Glycoprotein (gp):** A protein that is coated with carbohydrates (sugars).

H

**Healthy participant:** someone with no known significant health conditions who participates in research to test a new drug, device, or intervention. Also known as 'Clinical Research Participant.'

**Helper T cell:** T-cell lymphocyte bearing the CD4 marker. Helper T cells regulate the functions of other cells of the immune response.

**Herd immunity:** protection from an infectious disease happening when a significant percentage of a population is immune to the infection either through vaccination or immunity developed through previous infection.

**Host:** a plant or animal harbouring another organism.

**Humoral immunity:** see antibody-mediated immunity.

**Hypothesis:** a proposed explanation made based on limited evidence as a starting point for further investigation.

I

**Immune complex**: an antigen bound to its specific antibody.

**Immune deficiency:** a breakdown or inability of certain parts of the immune system to function, thus making a person susceptible to diseases that they would not ordinarily develop.

**Immunisation:** the process of inducing immunity by administering a vaccine.

**Immunity:** protection provided by the immune system to a specific disease. Immunity may be innate or acquired, partial or complete, specific or nonspecific, long-lasting, or temporary.

**Immunocompetent:** capable of developing an immune response; possessing a normal immune system.

**Immunogen:** a substance capable of provoking an immune response. Also called an antigen.

**Immunogenicity:** the ability of an antigen or vaccine to stimulate immune responses.

**Immunoglobulin:** a general term for antibody immunotherapy: a treatment that stimulates or modifies the body's immune response.

**in vitro:** an artificial environment outside a living organism (e.g., in a laboratory) used for the conduct of experimental research.

**in vivo:** research performed with a living organism, e.g., human or animal studies.

**Incidence:** the number of individuals who develop a specific disease or experience a specific health-related event during a particular period of time (such as a month or year).

**Inclusion/exclusion criteria:** factors used to determine whether a person is eligible (inclusion criteria) or not eligible (exclusion criteria) to participate in a clinical trial. Eligibility criteria may include disease type and stage, other medical conditions, previous treatment history, age, and gender.

**Informed consent:** a process between a person and a researcher to ensure that the person understands all relevant facts associated with their participation in a clinical trial. Participants into a clinical trial are required to sign an informed consent form before joining a clinical trial to show that they understand the risks and benefits of participating in the research. Informed consent includes the right to leave a clinical trial at any point during the study.

**Innate immunity**: immunity that is present at birth and lasts a person's entire life. Innate immunity is the first response of the body's immune system to a harmful foreign substance or pathogen.

**Institutional Review Board (IRB):** a committee of medical professionals, statisticians, community advocates, and others that reviews clinical trial protocols before they can be initiated. IRBs ensure that the trial is scientifically sound, ethical, and that the rights and safety of participants are adequately protected.

K

**Key populations:** groups of people such as sex workers, people who use drugs, prisoners, transgender people, and men who have sex with men that are at higher risk of HIV or TB, in part due to discrimination and social exclusion.

L

**Latent TB infection (LTBI):** a state of persistent immune response to stimulation by *Mycobacterium tuberculosis* antigens without evidence of active TB.

**Live-vector vaccine:** a vaccine in which a live pathogen is weakened (attenuated) through chemical or physical processes to produce an immune response without causing the severe effects of the disease.

**Lymphadenopathy:** enlargement of the lymph nodes in response to regional infection or inflammation.

**Lymphocyte:** a type of white blood cell primarily responsible for immune responses. Present in the blood, lymph, and lymphoid tissues. See also B cell and T cell.

**Lymphoid tissue:** the part of the body that plays an important role in the immune response and helps protect it from infection and pathogens. Lymphoid tissue is present throughout the body and includes the lymph nodes, spleen, tonsils, adenoids, and other organs.

**Lymphomas:** types of cancer that begin in the lymphatic system.

M

**Macrophage:** a large cell of the immune system that can ingest pathogens. Macrophages stimulate other immune cells by presenting them with small pieces of the pathogen. Macrophages also can harbour large quantities of HIV without being killed, acting as reservoirs of the virus.

**Memory cell:** a subset of T cells and B cells that help the body defend itself against disease by remembering prior exposure to specific pathogens. They can proliferate (recognise the antigen and divide) more readily when the immune system re-encounters the same pathogen.

**Monoclonal antibody:** a custom-made, identical antibody that recognises only one epitope.

**Monocyte:** a type of immune cell that is made in the bone marrow and travels through the blood to tissues in the body where it becomes a macrophage or a dendritic cell.

**Monovalent vaccine:** a vaccine that contains only one antigen.

**Mucosal immunity:** immune response pertaining to mucous membranes. Mucosal immunity relies on immune cells and antibodies present in the linings of the reproductive tract, gastrointestinal tract, and other moist surfaces of the body exposed to the outside world.

N

**Natural killer cell (NK cell):** a type of immune cell that can kill tumour cells or cells infected with a virus or bacteria. An NK cell is a type of white blood cell. NK cells are 'natural' killers because they do not need to recognise a specific antigen to attack and kill their target.

**Neutralising antibody:** an antibody that prevents a virus from infecting a cell in the body, usually by blocking receptors on the cell or the virus itself.

**Nosocomial:** an infection acquired or occurring in a hospital.

**Nucleic acid:** an important class of macromolecules found in all cells and viruses. Nucleic acids play an important role in how genetic information is stored and used.

**Nucleic acid test (NAT):** a laboratory test to detect the genetic material of a microorganism. The viral load (HIV RNA) test is a type of nucleic acid test.

O

**Off-label use:** the legal use of a prescription drug to treat a disease or condition for which the drug has not already been approved by the regulatory authority.

**Open-label trial:** a type of clinical study in which both the researchers and the participants are aware of the drug or treatment being given.

**Opportunistic infection:** an illness caused by an organism that usually does not cause disease in a person with a healthy immune system.

P

**Pandemic:** An epidemic occurring over a very wide area (several countries or continents) and usually affecting a large proportion of the population.

**Parenteral:** administered into the bloodstream or by injection.

**Pathogen:** organisms (e.g., bacteria, viruses, parasites, and fungi) that cause disease in human beings.

**Pathogenesis:** the origin and development of a disease. More specifically, the way a microbe (bacteria, virus, etc.) causes a disease.

**Peptide:** a short compound formed by linking two or more amino acids. Peptides that contain many amino acids are called polypeptides or proteins.

**Phase I clinical trial:** The first step in testing a new vaccine in humans. A Phase I clinical trial tests the safety, side effects, best dose, and timing of a new vaccine.

**Phase II clinical trial:** These trials measure safety and immunogenicity in a larger group (50–3000) of participants. Here the goal is also to find the best dose and regimen. Phase II trials may last up to two years or longer.

**Phase III vaccine trial:** A large study that tests the safety and how well a new vaccine works compared with a standard treatment.

**Placebo:** An inactive substance or other intervention that looks the same as, and is given the same way as, the vaccine being tested.

**Plasma:** The clear, yellowish, fluid part of the blood that carries the blood cells.

**Preclinical:** research often using animals to find out if a drug, procedure, or treatment is likely to be useful. Preclinical studies take place before any testing in humans is done.

**Prevalence:** the total number of individuals in a population who have a disease or health condition at a specific point in time, usually expressed as a percentage of the population.

**Prime-boost:** in HIV vaccine research, administration of one type of vaccine, such as a live-vector vaccine, followed by or together with a second type of vaccine, such as a recombinant subunit vaccine. The intent of this combination regimen is to induce different types of immune responses and enhance the overall immune response, a result that may not occur if only one type of vaccine were to be given for all doses.

**Priming:** the first dose of a vaccine given to induce a particular immune response, followed by or together with a second dose of vaccine. The intent of priming is to induce certain immune responses that will be enhanced by the booster dose(s).

**Prophylaxis:** the prevention of disease.

**Protocol:** the detailed plan for a clinical trial that states the trial's rationale, purpose, vaccine dosage, routes of administration, length of study, eligibility criteria and other aspects of trial design.

R

**Randomised trial:** a study in which participants are assigned by chance to one of two or more intervention arms or regimens. Randomisation minimises the differences among groups by equally distributing people with particular characteristics among all the trial arms.

**Reactogenicity:** physical reactions that occur soon after vaccination and are a physical manifestation of the inflammatory response to vaccination.

**Reagent:** any chemical used in a laboratory test or experiment.

**Receptor:** a molecule on the surface of a cell that can recognise and bind to other molecules such as antigens, antibodies.

**Recombinant DNA technology:** the technique by which genetic material from one organism is inserted into a cell to mass produce proteins.

**Regulatory gene:** genes that regulate the replication of pathogens.

**Reservoir:** HIV-infected cells that are not actively producing HIV.

**Retrovirus:** viruses that carry their genetic material in the form of RNA rather than DNA and have the enzyme reverse transcriptase that can transcribe it into DNA. In turn, this DNA will be used to create viral RNA in the infected cells.

**Reverse transcriptase:** the enzyme found in retroviruses that enables them to direct a cell to make DNA from their viral RNA.

**RNA (ribonucleic acid):** one of two types of nucleic acid made by cells. RNA contains information that has been copied from DNA (the other type of nucleic acid). Many forms of RNA have functions related to making proteins.

S

**Seroconversion:** the production of antibodies against a particular antigen in the blood of a person who did not have the antibodies before. When people develop antibodies, they 'seroconvert' from antibody-negative to antibody-positive (see also VISP).

**Serostatus:** the state of either having or not having detectable antibodies against a specific antigen, as measured by a blood test (serologic test).

**Serum:** the clear, yellowish liquid part of blood that remains after clotting. Serum is used for various laboratory tests.

**Simian-Human Immunodeficiency Virus (SHIV)**: a genetically engineered hybrid virus with a human virus envelope and a simian virus core.

**Side effect:** see adverse reaction.

**Simian Immunodeficiency Virus (SIV):** a diverse group of viruses that naturally infect a wide range of African monkeys. This infection generally does not result in immunodeficiency in African monkeys, but Asian or Indian rhesus macaques will develop simian AIDS (SAIDS).

**Statistical significance:** a mathematical measure of difference between groups in a clinical study. The difference is said to be statistically significant if it is greater than what might be expected to happen by chance alone.

**Sterilising immunity:** an immune response that completely prevents the establishment of an infection.

**Strain:** a specific version of virus of bacteria. Many diseases, including HIV and Lassa fever virus have multiple strains.

S

**Stratification:** separation of a study cohort into subgroups or strata according to specific characteristics.

**Subtype:** a subgroup of genetically related HIV-1 viruses. Also called a clade.

**Subunit vaccine:** a vaccine that contains only part of the virus or other pathogen which have been specially selected for their ability to stimulate immune cells.

**Surrogate marker:** substitute measure of a clinical or biological endpoint. For example, CD4 count is a surrogate marker of disease progression.

T

**T cell:** a type of white blood cell critical to the immune response. Among these are CD4 T cells and CD8 T cells.

**Therapeutic HIV vaccine:** a vaccine designed to boost the immune response against HIV in a person living with the virus to slow the progression of HIV infection or delay the onset of AIDS.

V

**Vaccine:** a substance administered to trigger an immune response against a particular disease to prevent an infection.

**Vector:** a bacteria or virus that does not cause disease in humans and is used in genetically engineered vaccines to transport genes coding for antigens into the body to induce an immune response.

**Viral Load (VL):** the amount of HIV in a sample of blood. Viral load is reported as the number of HIV RNA copies per millilitre of blood.

**Viremia:** the presence of virus in the bloodstream.

**Virion:** a mature infectious virus particle that exists outside of a cell.

**Virus**: a microorganism that infects cells and may cause disease. To reproduce, a virus must infect a cell and direct its cellular machinery to produce new viruses.

**Vaccine-Induced HIV Seropositivity (VISP):** antibody induced by vaccination and that can confound the interpretation of HIV diagnostics tests. VISP may have implications in the everyday life of clinical trial participants (for example access to insurance, employment, or immigration).

W

**Western blot:** a laboratory test to detect antibodies to specific components of a virus such as HIV in the blood.

**Window period:** the period of time from exposure to HIV to when the body produces enough HIV antibodies to be detected by standard HIV tests.

## RESOURCES

- NIH glossary of HIV/AIDS-related terms: *https://clinicalinfo.hiv.gov/en/glossary*
- CDC Vaccines and immunisation glossary: *https://www.cdc.gov/vaccines/terms/glossary.html*

iavi Translating **science** into **global** health impact

iavi.org
info@iavi.org

Go to iavi.org/subscribe
to receive our updates

Follow us