

FACTSHEET



Glossary of terms used in microbicides research

Arms – the groups in a clinical trial, usually known as the **control group** and **intervention group**. Comparing results from the different groups enables researchers to determine whether and how well a new intervention (treatment, vaccine, prevention method, or whatever is being tested) works. Some studies are designed to test more than one treatment; these would have more than two arms/groups.

Cellulose Sulfate (CS) – a gel that was tested as a possible topical microbicide but in 2007 was found to be NOT effective. Researchers thought that CS could potentially block HIV infection (and possibly other STI infections) by creating a barrier between the virus and the woman's cells in the vagina which the virus targets for infection. This would make it more difficult for the virus to enter the woman's cells.

Cohort – a defined group of people who are followed over a period of time during a trial to see if anything changes in their situation (e.g. a group of HIV negative women would be treated as a cohort).

Coital act – sex involving the penetration of a penis into a vagina.

Control group – the comparison group in a clinical trial. This is the group of trial participants who do NOT receive the intervention that is being tested. Depending on the intervention being tested, they usually either receive no treatment at all, a **placebo**, or the current treatment in use.

Diaphragm – a small latex or silicone dome/cup that covers the cervix (the lower part of the uterus, or womb, that connects to the vagina). A diaphragm prevents pregnancy by covering the cervix and blocking sperm from entering the uterus. It also blocks viruses and bacteria from entering. Trials have shown that diaphragms DO NOT protect women from HIV infection.

Double-blind – in a double-blind trial, neither the participants nor the researchers know which participants are in the **control group** and which are in the **intervention group**. This is done to reduce bias from both researchers and participants. An independent group of experts who are not researchers in the trial, the **Data Safety Monitoring Board**, look at the data at different points in the trial.

DSMB (Data Safety Monitoring Board) – an independent panel of experts who are not researchers associated with the clinical trial, but who have a responsibility to look at the

results at different points during a trial to make sure that it is not ethically necessary to stop the trial either because the intervention causes greater risk or is overwhelmingly successful.

Efficacy versus Effectiveness – **Efficacy** refers to how well an intervention works under controlled situations (such as in a trial). **Effectiveness** refers to how well an intervention works in real-life settings.

Epithelium – layer of cells lining the vagina, the cervix, uterus (and other body cavities).

Fusion inhibitor – a microbicide that would work by preventing HIV from attaching to a woman's cells.

Interim data analysis – conducted by the **DSMB**. Data from the **control and intervention groups** of a trial are examined and analysed during the trial at different points, not just at the end when all the data is completely collected and the trial is finished. These interim data analyses are used to make sure that the trial does not need to be stopped early for safety reasons, or because the intervention being tested is either causing harm or is shown to be effective.

Intervention group – the group of participants receiving the intervention (e.g. new treatment, vaccine, prevention method) in a clinical trial.

Microbicide – any compound or substance that can be used to reduce the ability of a virus or bacteria to infect cells. The microbicide candidates being developed and tested now for HIV prevention are all topical gels or creams that are inserted into the vagina (or anus), and that coat the cells lining the reproductive tract.

Second and third generation microbicides – first generation candidates were the first possible microbicides that were tested but proven not effective. Second and third generation candidates are those more recently developed that use and build on the results obtained from the candidates that didn't work, as well as new information and knowledge about HIV. Some of these more recent microbicide candidates are ARV-based.

Mode of action – how a treatment works. There are several possible modes of action for microbicides. Some microbicides act as physical barriers, blocking the virus from

entering a woman's cells, others prevent HIV from entering and infecting the woman's cells, while others preventing the virus from making more copies of itself.

N-9 (Nonoxynol-9) – a spermicide (kills sperm to prevent pregnancy) that was tested as a microbicide to prevent HIV infection. It was NOT effective, and its regular use increased women's risk of HIV infection. N-9 works as a surfactant, by breaking up the membrane (outer layer) of the virus, but its regular use also caused irritation and lesions in the vagina, which made it easier for HIV to enter the woman's cells.

Oral prophylaxis – taking anti-retroviral pills, either before sexual exposure (**pre-exposure prophylaxis**) or after sexual exposure (**post-exposure prophylaxis**) to HIV.

Pap test (also known as a **Pap smear**) – a medical screening test, where cells are taken from the cervix and looked at under a microscope to see if there are any cells that look abnormal. The Pap smear is a way to screen women for early signs of cervical cancer.

Phase III clinical trials – randomised clinical/controlled trials on large groups of participants to look at the **efficacy** of a new intervention. Phase III trials are begun only after Phase I and Phase II trials (which are smaller studies that look at safety, at doses, and at efficacy) are successfully completed.

Placebo – in a blind or double-blind clinical trial, the **control group** receives a placebo. This is not the treatment being tested, but looks exactly like the treatment. For topical microbicide trials, the control group received a gel that looked and was used the same as the gel given to the **intervention group**, except that it did not contain the microbicide. Placebos are used in blinded clinical trials so that participants and researchers do not know which participants are in the **control group** and which are in the **intervention group**.

Post-exposure Prophylaxis (PEP) – taking oral anti-retroviral medication for a short period of time after exposure (such as an accidental needlestick for a health care worker), or possible exposure to HIV (as in the case of rape). PEP should begin 2-24 hours after the exposure to HIV,

and no later than 72 hours. There is evidence that PEP can lower the risk of HIV infection after exposure.

Pre-Exposure Prophylaxis (PrEP) – taking oral anti-retroviral medication before HIV exposure. Currently, clinical trials are being done to determine the efficacy and effectiveness of PrEP for HIV prevention.

Randomised clinical/controlled trial – a study to determine whether and how well a medical intervention (e.g a drug treatment, a vaccine, a prevention method, etc.) works. Usually, there are two groups (also called **arms**), the **control group** and the **intervention group**. The control group either gets no treatment, the current standard treatment, or a placebo. The intervention group gets the new intervention. Results from both groups are compared to see whether and how well the intervention works. Participants are placed into the groups randomly (by chance, without knowing which groups they are placed in). There are stages of trials. The first stages test with small numbers of participants to make sure the intervention is safe. Later stages enroll more people and test the intervention's **efficacy**.

Seroconversion – becoming infected with HIV. In clinical trials, this term is used to refer to people who were HIV negative when they enrolled in the trial, and who became infected during the trial.

STI – sexually transmitted infection.

Surfactant microbicide – a microbicide that works by disrupting or breaking up the membrane (outer surface) of the HIV virus.

Target cell – type of cell that HIV, or another virus or bacteria, infects.

Tenofovir – an antiretroviral (ARV) that is currently being tested in gel format as a possible topical microbicide to prevent HIV infection.

HIV Vaccine – a vaccine that would prevent HIV infection. There is no effective HIV vaccine at present, but there are several possible vaccines being developed and tested.

Vaginal lesions – small scrapes or tears in the vagina, which may be cellular entry points for HIV.



1101-1106 Sangro House • 417 Smith Street • Durban • South Africa
Tel: +27 31 307 1253 • Fax: +27 31 307 1254 • Email: genderaids@gaf.org.za • Website: www.gaf.org.za