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Global Advocacy for HIV Prevention

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Biomedical HIV Prevention Research: The Basics

Basic Overview

We will introduce the range of biomedical HIV prevention options currently being studied and/or implemented:

- AIDS vaccines
- Microbicides
- Pre-exposure prophylaxis (PrEP)
- Treatment as prevention
- Medical male circumcision

For each option we will review:

- What is it?
- How might it work?
- Snapshot: What do we know?

HIV/AIDS Toolkit

Prior to exposure

- Education and behavior change
- Needle exchange
- Adult medical male circumcision
- Pre-exposure prophylaxis (PrEP)
- Preventive vaccines
- Treat other STDs (e.g., HSV-2)

Point of transmission

- Male and female condoms
- Use of clean needles
- Antiretroviral therapy (prevent vertical transmission)
- Post exposure prophylaxis (PEP)
- Microbicides (vaginal / rectal)

After infection

- Antiretroviral therapy
- Care
- Education and behavioral change
- Therapeutic HIV/AIDS vaccines

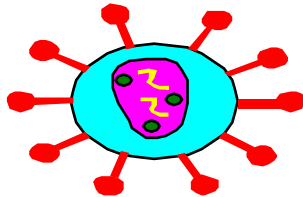
What is a vaccine?



- A substance that teaches the immune system how to **protect** itself against a **virus** or **bacteria**
- **No effective AIDS vaccine available today**
- **AIDS vaccines cannot cause HIV**
- No vaccine is 100% effective. Most licensed vaccines are 70%-95% effective.

How does a vaccine work?

- By teaching the body to recognize and fight invaders – vaccine presents a small amount of virus or copy of virus
 - AIDS vaccines **do not contain HIV**, only manufactured copies of one or more pieces of the virus
- Body reacts by creating antibodies or killer cells
- If someone who is vaccinated later “sees” the virus via sexual or needle exposure, the body calls on the vaccine-induced antibodies and killer cells to stave off infection or lessen disease progression if infection is established



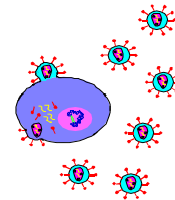
Body recognizes virus



Body sounds alarm



Fighter cells go into action



GOAL: HIV is controlled or killed

Types of experimental AIDS vaccines

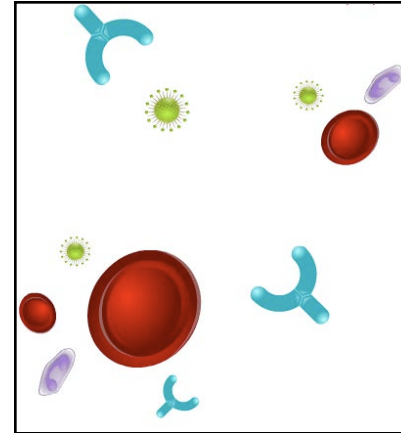
■ Preventive Vaccines

- Designed for people who are not infected with HIV
- Reduces risk of infection *or* viral load set point after infection

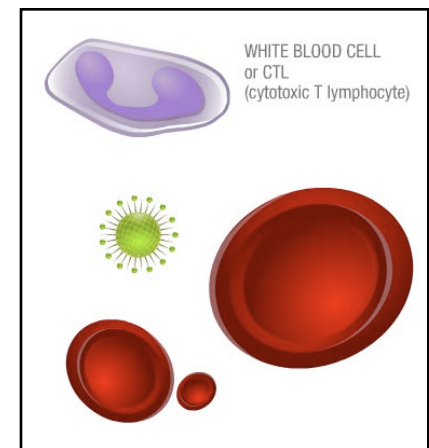
■ Therapeutic Vaccines

- Designed for people who are living with HIV
- Uses the body's immune system to control HIV in the body

Humoral Immunity



Cellular Immunity



What do we know?

- Proof of concept! The RV144 prime-boost AIDS vaccine trial showed a modest prevention effect (31% reduction in risk)--announced November 2009
- Researchers are trying to understand why the vaccine regimen in RV144 worked so that they might be able to create more effective vaccines

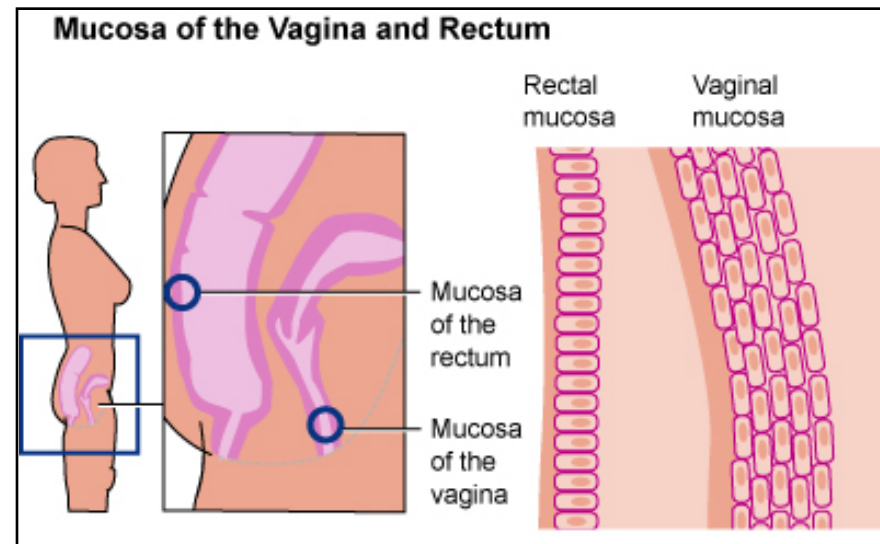
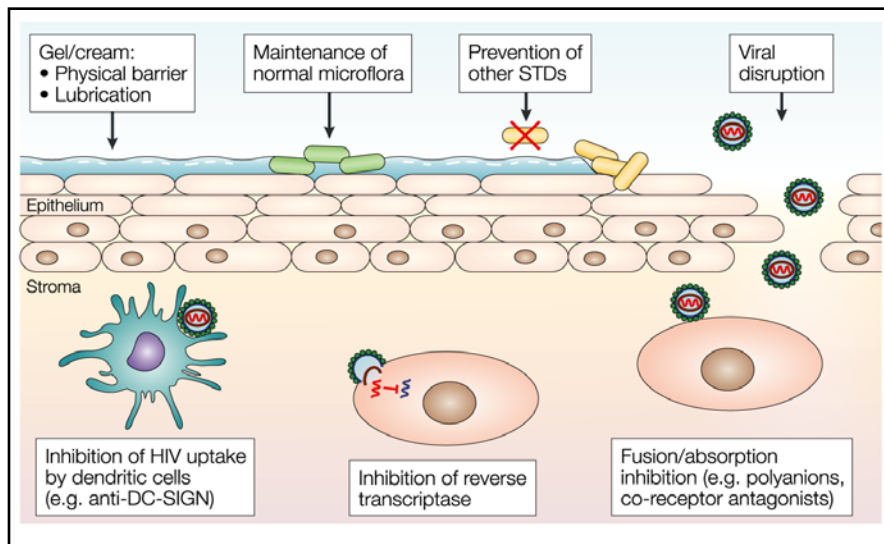
What is a microbicide?

- An effective microbicide could be used in the vagina or rectum to reduce the risk of HIV transmission during sex
- Microbicides are being tested in various forms--creams, foams, gels, slow release vaginal rings, films, enemas and suppositories



How might a microbicide work?

- Microbicides might provide protection through an active ingredient such as an ARV, which might block HIV activity directly or another approach may provide a physical barrier at the site of exposure (vagina and/or rectum)



What do we know?

- Proof of concept! CAPRISA 004 tested 1% tenofovir gel (an antiretroviral-based microbicide) in heterosexual women and showed that it reduced risk of HIV by approximately 39%
- 1% tenofovir gel is the only microbicide that has shown a protective effect in a large-scale trial; non-ARV-based candidates tested in earlier trials were safe but not effective (e.g., PRO 2000, Carraguard)
- Most data to-date is on vaginal microbicides; rectal microbicide research not as far along but making important advances

What is PrEP?

- Pre-exposure prophylaxis is a concept where people take medicine to *prevent* rather than to treat a disease or condition
- PrEP for HIV prevention involves HIV-negative individuals taking ARVs (drugs currently used to treat people with HIV/AIDS) to reduce risk of HIV infection



How might PrEP work?

- ARVs block HIV as it infects cells or copies itself once inside a cell; TDF and TDF/FTC are *reverse-transcriptase inhibitors*, drugs that are absorbed into cells and help block a critical step in viral replication
- In HIV-negative people, TDF and TDF/FTC appear to provide protection by stopping HIV from successfully copying itself
- Video available at <http://vimeo.com/24036739>

What do we know?

- Proof of concept! Three large-scale PrEP safety and effectiveness trials (in gay men and transgender women; serodiscordant couples; heterosexual men and women) have shown evidence of HIV risk reduction
- One large-scale trial in heterosexual women showed no effect
- Adherence matters—those who were able to follow the PrEP regimen as prescribed had lower risk

What is treatment as prevention?

- Use of antiretroviral treatment in HIV-positive people to reduce the risk passing HIV to others
- The strategy is a secondary benefit of ARV treatment of which the primary benefit is the individual's health
- The rationale is that ARVs reduce viral load, which has been shown to decrease infectiousness

What do we know?

- Treatment as prevention works! HPTN 052, a multinational trial in serodiscordant couples, showed that treatment initiation reduced risk of infection by 96% in the HIV-negative partner and reduced risk of extrapulmonary TB in HIV-positive partner
- Observational studies show a relationship between low viral loads and reduced risk of transmitting HIV to sexual partners
- Studies are ongoing to look at further benefit for HIV-positive individual and impact on HIV incidence

Medical Male Circumcision

- 4 ecological studies
- 35 cross-sectional studies
- 14 prospective studies
- 3 randomized controlled trials



- Recent data from South Africa show that MC has a direct effect on HIV prevalence with incidence rates 76% lower in circumcised men.

Confirm that medical male circumcision reduces risk of HIV infection in heterosexual men by approximately 60%

Global Recommendations

- Countries with high prevalence (>15%), generalized heterosexual HIV epidemics and low rates of MC should consider urgently scaling up access to MC services
- 13 countries identified: Botswana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe
- Consider ethics, communication, culture, health systems, funding, gender, comprehensive prevention strategies
- No conclusive evidence that MMC protects MSM
- For more on scale-up and other MMC resources, visit

 www.malecircumcision.org 20–80% prevalence >80% prevalence