



ALLIANCE FOR MICROBICIDE DEVELOPMENT

30 May 2008, Volume 9, Number 21

The Alliance for Microbicide Development *News Digest* is an **unedited** compilation of:

- Media coverage of microbicides;
- Abstracts of articles on microbicides and relevant science in peer-reviewed journals;
- Material on other reproductive health and HIV prevention technologies, including HIV vaccines; and
- Matters of policy and politics with importance for microbicide research, development, and advocacy.

Its purpose is to:

- Raise awareness around the range of opinions and information about microbicides disseminated in the press and scientific journals; and
- Provide a neutral, objective basis for decision-making and evidence-based advocacy.

The *News Digest* is produced in a web-based format. Readers can view complete issues of the Digest or search by keyword for individual articles at http://www.microbicide.org/cs/weekly_news_digest. If you would like to be removed from the *Digest* distribution list, please send an email to digest@microbicide.org. We welcome comments, questions, and ideas about other microbicide-relevant topics we might cover, services we might provide, and better ways of providing them!

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1. ALLIANCE UPDATES AND COMMUNITY NEWS

Congressional Briefing: New Options for HIV Prevention

On Thursday, May 22nd, the AIDS Vaccine Advocacy Coalition (AVAC) and the Caucus for Evidence-Based Prevention sponsored a Congressional briefing entitled, "New Options for HIV Prevention: The Continuing Need for Research Investment." The briefing was chaired by Gene Copello, Executive Director of the AIDS Institute, and featured several speakers to discuss the current HIV prevention research field, followed by a panel of discussants. The speakers included Mitchell Warren, Executive Director of the AIDS Vaccine Advocacy Coalition (AVAC), and Carl Dieffenbach, Director of the Division of AIDS at the National Institutes of Health (NIH). Panel discussants included: Susan Buchbinder, Associate Clinical Professor, Department of Medicine, Epidemiology, and Biostatistics, University of California, San Francisco; Paula Frew; Director of Health Communications and Applied Community Research at the

Hope Clinic of the Emory Vaccine Research Center; Glenda Gray, Co-Director of the Perinatal HIV Research Unit of South Africa; Polly Harrison, Director of the Alliance for **Microbicide** Development; and Peter Kilmarx, Chief of the Epidemiology Branch at the Division of HIV/AIDS Prevention at the Centers for Disease Control and Prevention (CDC).

Mitchell Warren first discussed HIV vaccine research and why it is so important for the search for a vaccine to continue, despite the recent setback of the halted STEP clinical trial in September of 2007. He announced the release of AVAC's 2008 Annual Report: The Search Must Continue, which can be read at this website http://www.avac.org/pdf/reports/2008_Report/full.pdf. This year's report found there are fewer candidates in the vaccine research pipeline than ever before and therefore advocacy efforts around the need for new scientific concepts and discovery must increase. He referenced the discontinuation of the STEP study as a changing point in the field, not a failure. He took the time to define what success and failure are in clinical research trials to rectify the misleading messages surrounding STEP. He said that a successful clinical trial is one that gives a scientifically accurate result. In a clinical trial a product can fail, a concept can fail, and communication can fail. In the case of STEP, the vaccine product failed to produce the desired effect. But, the trial itself was a success because it brought forth a clear result, although it was not the result we had been hoping for.

Next, Dr. Dieffenbach shared scientific perspectives on HIV prevention and vaccine research. He first explained the immense biological challenge with discovering an HIV vaccine; for the first time in history scientists are attempting to develop a vaccine for which no one has ever been cured and no natural immune response has been adequate. While it is an extreme challenge, he feels it can and must be done. He told the audience that HIV prevention research is NIH's Division of AIDS's top research priority. Developing a vaccine is their number one HIV prevention priority. Dr. Dieffenbach said that a safe and effective vaccine is critical to effective control of the epidemic, but he also touched on other prevention science research such as male circumcision, pre-exposure prophylaxis, and **microbicides**. He said that biomedical research for all prevention interventions must be integrated with behavioral research, for several reasons. After male circumcision, there is a time when the male may be at increased risk for HIV and therefore behavioral counseling is important. Behavioral aspects such as adherence are critical to the research and future success of pre-exposure prophylaxis and non-adherence is also a key issue that is critical for **microbicide** research. In closing he emphasized the importance of community education and engagement in HIV prevention research and thanked the numerous volunteers in HIV prevention research studies.

During the panel discussion, Dr. Paula Frew stressed that there is not enough funding in research budgets for community education and involvement, which is key. She feels that the need for community engagement and the cost associated with it is another reason why NIH's research budget must be increased.

Dr. Glenda Gray, a pediatrician and researcher in South Africa, spoke to the audience about the damaging United States media coverage of the STEP trial. She said that what the US says about HIV vaccine research reverberates throughout the world. Therefore, the inaccurate headlines and calls to abandon the field of vaccine research are potentially very dangerous since the search for a vaccine requires the support of the global community.

Next, Dr. Polly Harrison, Director of the Alliance for **Microbicide** Development, gave an update on the **microbicide** development pipeline. There are currently 55 **microbicide** candidates in pre-clinical trials and 11 in human clinical trials in 13 countries throughout the world. She reiterated Dr. Dieffenbach's point that behavioral research to assess adherence and acceptance is absolutely critical to **microbicide** development.

Dr. Peter Kilmarx, Chief of the Epidemiology Branch, Division of HIV/AIDS Prevention at CDC, explained that CDC is studying the implementation and behavioral aspects of several clinical trials for HIV prevention technologies. He spoke about the coordination improvements between CDC and NIH and the need for that coordination to continue during this dynamic time in HIV prevention research.

EDITOR'S NOTE: Thanks to AIDS Action and IRMA for providing this summary.

Microbicide Panel Session at the Global Health Council Conference

<http://www.globalhealth.org/conference/>

The 35th Annual International Conference on Global Health took place on 27-31 May 2008 in Washington, DC. A panel session that includes **microbicides**, entitled "Community Feedback on Emerging Techniques for HIV Prevention," was held on Wednesday, 28 May 2008 from 9:45am-11:45am. Presenters included Lori Heise, Serra Sippel, and Cynthia Woodson. See below for further information. Additional details about the conference are available at <http://www.globalhealth.org/conference/>.

Session: Community Feedback on Emerging Techniques for HIV Prevention

The process of convening groups representing sex workers and women living with HIV and engaging in dialogue with them, the specific concerns expressed by the stakeholders about **microbicides** development and access, and the ongoing process of addressing their concerns in global **microbicides** efforts (global); the current status of **microbicide** research and the potential role and limitations that a new prevention tool could play in expanding women's HIV protection strategies (global); and community concerns about **microbicides**, and recommendations for the process of a successful introduction rollout program (Zimbabwe, Malawi).

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2. MEDIA COVERAGE OF MICROBICIDES

"Africa: Women and scientific experiments - is informed consent enough?"

Date: 29 May 2008

Source: *Fahamu* (Oxford)

Author(s): Jegede Ademola Oluborode

<http://allafrica.com/stories/200805290720.html>

This article is a reflection on the provision of article 4(2)(h) of the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa (Protocol on the Rights of Women) which seeks to prohibit all medical and scientific experiments on women without their informed consent. The article argues that the prohibition of all medical or scientific experiments on women without their informed consent, without more, falls short of other ethical

requirements for safety in scientific and medical experimentation. This in itself is an expression of the regrettable gap which over the years has existed in major international human rights instruments, to which most African States are signatory. To this end therefore, the article suggests that along with the requirement of consent, there is a need to legally prescribe appropriate human rights standard on the performance of medical and scientific experiments. The article concludes that a re-draft of article 4 (2)(h) of the Protocol on the Rights of Women is imperative to ensure maximum legal protection for women, who by virtue of their role in the society are most vulnerable to medical and scientific exploitation.

INJUSTICES IN MEDICAL OR SCIENTIFIC EXPERIMENTS AND WOMEN [1]

Examples of where women have been victims to medical and scientific exploitation under the pretext of research are not new. Grave atrocities were committed in the process of medical experiments carried out during the Second World War on non-consenting women and children prisoners of Nazi concentration camps [2]. During the same period in history, African women from the German South West Africa, now Namibia, were part of sterilization programmes instituted by Germany without their consent [3]. In more recent times, evidence from Nigeria implicated Pfizer International Incorporated (PII) of fraud and criminal breach of trust of its controversial drug test, popularly known as Trovan Clinical Trials, which it carried out on Nigerian citizens in Kano in 1996, which had fatal results [4].

The burden of disease, generally, including malaria, sickle cell anaemia, tuberculosis and HIV/AIDS, weighs heavily on Africa, where these illnesses are most prevalent. In more ways than one, the impact of these diseases has been disproportionately borne by women. While medical and scientific trials and research involving women, holds great prospects for the solution of these problems, researches and pharmaceutical companies who engage in trials can not always be trusted to function with due consideration for ethical requirements, when such requirements are not well specified and projected in the African human rights system.

It is noteworthy that due to low level of literacy in Africa, very few women who are research participants are sufficiently educated to really understand the details of studies and trials in which they are engaged [5]. The poverty and powerlessness of women often lead to their participation in clinical and scientific researches merely for inexpensive inducements, and largely due to less understanding of study risks, or for the pregnant women, under the mistaken belief that such studies will result in care for their unborn children. There are for instance, controversies which have surrounded **microbicide** trials carried out on women in South Africa which revealed that women in the study developed higher risk of HIV infection [6]. In 2007, the US-based reproductive health research organisation, CONRAD, also announced the premature end of trials of a cellulose sulphate-based **microbicide** in Nigeria, Benin and Uganda after the data safety and monitoring committee found a higher number of infections in the active group compared to the placebo group [7].

The New England Journal of Medicine carried a comment on 15 on-going clinical trials testing cheaper drug regimens to prevent maternal-foetal transmission of HIV in Africa. Some 16,000 pregnant, HIV-positive women were enrolled in the placebo-controlled trials. The problem with these trials was that it began after Zidovudine (AZT) had been found to prevent such transmission by 50% or more, and is recommended to all HIV-positive pregnant women in western countries. In other words, it was reported that, thousands of women in the trials were getting sugar pills to test the efficacy of the new regimens whereas if they had been enrolled in trials in Europe, they would have received a standard course of AZT [8]. This further underscores the point that the truth in Africa, is that very few women do enjoy the benefits of the research in which they participate.

The survival of women therefore raises the question as to whether international human rights have done enough to protect women in terms of medical and scientific experimentation and if not, whether there is the need for the African human right system to review existing legal framework with the view of addressing such gap.

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EDITOR'S NOTE: The full text of this article, including references, is available for public access at the above website.

"AIDS vaccine research and clinical trials must continue"

Date: 28 May 2008

Source: *Health-e*

Author(s): Mitchell Warren, Lynn Morris

<http://www.health-e.org.za/news/article.php?uid=20031971>

This month, here in South Africa and around the world, researchers, community leaders, and thousands of men and women who have volunteered for AIDS vaccine trials commemorated HIV Vaccine Awareness Day.

Following the failure last year of a vaccine candidate developed by the pharmaceutical company Merck, and tested here in South Africa in the Phambili trial and in other countries around the world in the STEP trial, we observe the date this year with disappointment, but also with resolve.

There is simple, clear message that must be heard on this day - and every day - that an AIDS vaccine is possible. And it is critically needed!

Eleven years ago, when US President Clinton called for an accelerated effort to develop an AIDS vaccine, the field was reeling from the failure of early vaccine candidates and grappling with the complexities of the task of developing an effective vaccine. At that time no AIDS vaccine trials had been conducted here in South Africa, and few trials had been conducted outside of the U.S.

Today, there is a robust global AIDS vaccine research and development agenda and researchers here in South Africa and elsewhere on the continent are a major part of the research effort. Thousands of men and women in South Africa and around the world have volunteered for AIDS vaccine trials that have provided critical information for researchers to help move the field forward. And, despite the recent setbacks, most scientists still believe that a vaccine is possible and many volunteers remain committed to testing candidate AIDS vaccines.

Discovering and developing an AIDS vaccine will be especially difficult. It must be a global effort with dedicated work from hundreds, or even thousands, of researchers and the participation of tens of thousands of men and women volunteering for clinical trials in South Africa and around the world, and it will require the cooperation of governments and policymakers, funders, and community leaders.

All of this is made more urgent following the disappointing results of the vaccine being tested in the Phambili and STEP trials and by the news that the vaccine may have caused some volunteers to be more susceptible to HIV

infection, for reasons researchers are continuing to investigate.

But we cannot give up. The lives of millions of people here and around the world depend on our finding more options for preventing HIV infection.

Some have called for vaccine research to retreat to the lab and go back to basics. But this is not the answer. The AIDS vaccine effort has always included basic science, preclinical work and human trials and must continue to integrate all of these components going forward. The results of the STEP trial could not have been predicted from studies in the laboratory or in animals and that is why it is important that research in all areas continues.

The outcome of clinical trials of one candidate vaccine, no matter how disappointing, cannot form the basis for abandoning human testing of AIDS vaccine candidates. Human clinical trials are absolutely critical for gathering much-needed information to move research forward. If researchers gave up on developing drugs or vaccines because of unsuccessful attempts, we would have far fewer treatment and prevention options for many diseases. For instance, we would not have a polio vaccine or drugs to treat TB.

There is no doubt that we are closer to finding an AIDS vaccine now than we were a decade ago, and we must continue to go forward, building on sound science - including what we have learned from the Phambili and STEP trials.

Fortunately, the last decade has also brought new treatments for HIV infection and an unprecedented global effort to ensure that more people have access to HIV treatment and existing prevention options, including male and female condoms.

And there are now more research efforts underway to find new biomedical prevention interventions, including **microbicides** and other interventions that could be controlled by women. A clinical trial here in South Africa showed that male circumcision reduces HIV infection rates and work is underway to make this intervention available to men in many communities.

We are adamant that that the search for an AIDS vaccine must emphasize perseverance, but must also simultaneously redouble efforts to implement proven prevention and treatment efforts and to identify other new biomedical prevention strategies.

The AIDS vaccine field has been disappointed, discouraged and - in all honesty - uncertain what the next ten or twenty years will hold for AIDS vaccine research. But that is the nature of the scientific process. Every field that has had breakthroughs has also had setbacks. And we need to anticipate more setbacks in our search for an AIDS vaccine.

To acknowledge failure of a single vaccine candidate is in no way to concede overall defeat. We all now have a tremendous opportunity to learn from these disappointments and to be better for them - better, even, than we might have been without them.

Mitchell Warren is the executive director of the AIDS Vaccine Advocacy Coalition (AVAC) based in New York. Lynn Morris is the Head of the AIDS Unit at the National Institute for Communicable Diseases (NICD) based in Johannesburg, and the Chair of the AIDS Vaccine 2008 Conference that will be held in Cape Town in October.

3. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

"Amphipathic DNA Polymers Exhibit Anti-herpetic Activity In vitro and In vivo"

Author(s): Bernstein DI, Goyette N, Cardin R, et al

Reference: N/A Epub ahead of print.

<http://aac.asm.org/cgi/content/abstract/AAC.00279-08v1?maxtoshow=&HITS=2&hits=2&RESULTFORMAT=&andorexacttitle=and&andorexacttitleabs=and&fulltext=microbicide%2C+microbicides&andorexactfulltext=or&searchid=1&usestrictdates=yes&resourcetype=HWCIT&ct>

Published Abstract: Phosphorothioated oligonucleotides have a sequence-independent antiviral activity as amphipathic polymers (APs). The activity of these agents against herpes virus infections in vitro and in vivo was investigated. The previously established sequence-independent, phosphorothioation dependent antiviral activity of APs was confirmed in vitro by showing that a variety of equivalently sized homo and heteropolymeric AP sequences were similarly active against herpes simplex virus type 1 (HSV-1) infection in vitro compared to the 40 mer degenerate parent compound (REP 9) while the absence of phosphorothioation resulted in loss of antiviral activity. Additionally, REP 9 demonstrated in vitro activity against a broad spectrum of other herpes viruses: HSV-2 (EC₅₀, 0.02-0.06 μM), human cytomegalovirus (EC₅₀, 0.02-0.13 μM), varicella zoster virus (EC₅₀ <0.02 μM), Epstein-Barr virus (EC₅₀, 14.7 μM) and human herpesvirus types 6A/B (EC₅₀, 2.9-10.2 μM). The murine **microbicide** model of genital HSV-2 was then used to evaluate in vivo activity. REP 9 (275 mg/ml) protected 75% of animals from disease and infection when provided 5 or 30 minutes prior to vaginal challenge. When an acid stable analog (REP 9C) was used, 75% of mice were protected when treated with 240 mg/ml 5 minutes prior to infection (P<0.001) while a lower dose (100 mg/ml) protected 100% of the mice (P<0.001). The acid stable REP 9C formulation also provided protection at 30 minutes (83%, P<0.001) and 60 minutes (50%, P=0.07) against disease. These observations suggest that APs may have **microbicidal** activity and potential as broad spectrum anti-herpetic agents and represent a novel class of agents that should be studied further.

EDITOR'S NOTE: *Symbols in this abstract may not display correctly in the PDF version of the Digest. Please view the web version of the Digest or the abstract in its original location to view the correct symbols.*

"Male partners of young women: assessing their attitudes toward topical microbicides"

Author(s): Auslander BA, Rupp RE, Short MB, et al

Reference: N/A 42(6):626-28.

<http://highwire.stanford.edu/cgi/medline/pmid;18486872>

Published Abstract: Male partners' attitudes toward **microbicide** use are important to understand; however, there are challenges in conducting research with adolescent couples. We describe the experience of recruiting male

partners of adolescent females enrolled in a **microbicide** acceptability study. Creative solutions to enrolling partners of young women in studies need to be explored.

"Perceptions of acceptability and utility of microbicides in Ghana, West Africa: A qualitative, exploratory study"

Author(s): Tanner AE

Reference: N/A 5(1):11-18.

<http://highwire.stanford.edu/cgi/medline/pmid;18496615>

Published Abstract: Vaginal **microbicides**, substances that may substantially decrease transmission of sexually transmitted infections (STI) including human immunodeficiency virus (HIV), are currently in clinical trials. They are being presented as woman-initiated prevention methods that have the potential to be used without partners' knowledge. However, it is recognised that covert use may be challenging, due to the accompanying increase in vaginal lubrication. This study explored factors that may influence acceptability and utilisation of vaginal **microbicides** in Ghana, a sub-Saharan West African country with relatively low rates of HIV. Qualitative research methods were employed in Accra, Ghana in 2005. Individual interviews were conducted with 10 staff working in reproductive health settings, and two focus groups were conducted with young women aged 24-28. Three main topics emerged during the interviews and focus groups, including issues related to available contraceptive and prevention methods, perceptions of **microbicide** interest and acceptability, and cultural influences on **microbicide** acceptability and use. Participants discussed issues associated with available contraceptive options that may influence **microbicide** uptake. All respondents suggested that Ghanaian women would have a high level of interest in **microbicides**, with varying interest in formulas with different contraceptive and disease prevention properties. Cultural factors that may impact on **microbicide** use, often related to gender and power issues, were also discussed. Thus, as **microbicides** are being developed, cultural issues and behavioral correlates will need to be assessed to help ensure acceptability and use. In addition, gendered negotiation power and the implications of covert use need to be addressed in **microbicide** education and social marketing.

"Savvy vaginal gel (C31G) for prevention of HIV infection: A randomized controlled trial in Nigeria"

Author(s): Feldblum PJ, Adeiga A, Bakare R, et al

Reference: N/A 3(1):e1474.

<http://www.plosone.org/article/info:doi%2F10.1371%2Fjournal.pone.0001474>

Published Abstract: *Background* The objective of this trial was to determine the effectiveness of 1.0% C31G (SAVVY) in preventing male-to-female vaginal transmission of HIV infection among women at high risk.

Methodology/Principal Findings This was a Phase 3, double-blind, randomized, placebo-controlled trial. Participants made up to 12 monthly follow-up visits for HIV testing, adverse event reporting, and study product supply. The study was conducted between September 2004 and December 2006 in Lagos and Ibadan, Nigeria, where we enrolled 2153

HIV-negative women at high risk of HIV infection. Participants were randomized 1:1 to SAVVY or placebo. The effectiveness endpoint was incidence of HIV infection as indicated by detection of HIV antibodies in oral mucosal transudate (rapid test) or blood (ELISA), and confirmed by Western blot or PCR testing. We observed 33 seroconversions (21 in the SAVVY group, 12 in the placebo group). The Kaplan-Meier estimates of the cumulative probability of HIV infection at 12 months were 0.028 in the SAVVY group and 0.015 in the placebo group (2-sided p-value for the log-rank test of treatment effect 0.121). The point estimate of the hazard ratio was 1.7 for SAVVY versus placebo (95% confidence interval 0.9, 3.5). Because of lower-than-expected HIV incidence, we did not observe the required number of HIV infections (66) for adequate power to detect an effect of SAVVY. Follow-up frequencies of adverse events, reproductive tract adverse events, abnormal pelvic examination findings, chlamydial infections and vaginal infections were similar in the study arms. No serious adverse event was attributable to SAVVY use.

Conclusions/Significance SAVVY did not reduce the incidence of HIV infection. Although the hazard ratio was higher in the SAVVY than the placebo group, we cannot conclude that there was a harmful treatment effect of SAVVY.

"Savvy(R) (C31G) gel for prevention of HIV infection in women: A Phase 3, double-blind, randomized, placebo-controlled trial in Ghana"

Author(s): Peterson L, Nanda K, Kofi Opoku B, et al

Reference: N/A 2(12):e1312.

<http://www.plosone.org/article/info:doi%2F10.1371%2Fjournal.pone.0001312>

Published Abstract: *Objective* The objective of this trial was to determine the effectiveness of 1.0% C31G (SAVVY) in preventing male-to-female vaginal transmission of HIV infection among women at high risk.

Methodology/Principal Findings This was a Phase 3, double-blind, randomized, placebo-controlled trial. Participants made up to 12 monthly visits for HIV testing, adverse event reporting, and study product supply. The study was conducted between March 2004 and February 2006 in Accra and Kumasi, Ghana. We enrolled 2142 HIV-negative women at high risk of HIV infection, and randomized them to SAVVY or placebo gel. Main outcome measures were the incidence of HIV-1 and HIV-2 infection as determined by detection of HIV antibodies from oral mucosal transudate specimens and adverse events. We accrued 790 person-years of follow-up in the SAVVY group and 772 person-years in the placebo group. No clinically significant differences in the overall frequency of adverse events, abnormal pelvic examination findings, or abnormal laboratory results were seen between treatment groups. However, more participants in the SAVVY group reported reproductive tract adverse events than in the placebo group (13.0% versus 9.4%). Seventeen HIV seroconversions occurred; eight in participants randomized to SAVVY and nine in participants receiving placebo. The Kaplan-Meier estimates of the cumulative probability of HIV infection through 12 months were 0.010 in the SAVVY group and 0.011 in the placebo group ($p = 0.731$), with a hazard ratio (SAVVY versus placebo) of 0.88 (95% confidence interval 0.33, 2.27). Because of a lower-than-expected HIV incidence, we were unable to achieve the required number of HIV infections (66) to obtain the desired study power. *Conclusions/Significance* SAVVY was not associated with increased adverse events overall, but was associated with higher reporting of reproductive adverse events. Our data are insufficient to conclude whether SAVVY is effective at preventing HIV infection relative to placebo.

"Setting the stage: host invasion by HIV"

Source: *Nat Rev Immunol.* 2008 Jun;(8)447-57. Review.

Author(s): Florian Hladik, M. Juliana McElrath

<http://www.nature.com/nri/journal/v8/n6/full/nri2302.html>

For more than two decades, HIV has infected millions of people worldwide each year through mucosal transmission. Our knowledge of how HIV secures a foothold at both the molecular and cellular levels has been expanded by recent investigations that have applied new technologies and used improved techniques to isolate ex vivo human tissue and generate in vitro cellular models, as well as more relevant in vivo animal challenge systems. Here, we review the current concepts of the immediate events that follow viral exposure at genital mucosal sites where most documented transmissions occur. Furthermore, we discuss the gaps in our knowledge that are relevant to future studies, which will shape strategies for effective HIV prevention.

HIV vaccines and **microbicides** hold promise for preventing the acquisition of HIV-1 and HIV-2, the two viruses that cause AIDS, but the success of designing such agents needs a clear understanding of where HIV first encounters its target cells - primarily T cells, macrophages and dendritic cells (DCs) - and how it gains entry at various sites to eventually establish infection. HIV infection has rapidly spread since the early 1980s to become an epidemic disease (see the UNAIDS/WHO AIDS epidemic update) that is largely maintained by sexual transmission through the lower genital and rectal mucosa (Fig. 1, Table 1). Here, we have endeavoured to assemble the current knowledge on the acquisition of HIV at mucosal sites, confining our discussion to the lower genital mucosa.

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EDITOR'S NOTE: *The full text of this article is available with a subscription at the above website.*

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4. PUBLISHED RESEARCH: RELEVANT BASIC AND TRANSLATIONAL SCIENCE

"Hormonal contraception and the risks of STI acquisition: results of a feasibility study to plan a future randomized trial"

Author(s): Hubacher D, Raymond ER, Beksinska M, et al

Reference: *N/A* 77(5):366-70.

<http://www.ncbi.nlm.nih.gov/pubmed/18402854>

Published Abstract: BACKGROUND: Because of limitations in observational studies, a randomized controlled trial (RCT) would help clarify whether hormonal contraception increases the risks of acquiring a sexually transmitted infection (STI). However, the feasibility of such a trial is uncertain. STUDY DESIGN: We conducted a study to assess the feasibility of conducting a RCT that would compare the acquisition risk for *Chlamydia trachomatis* and *Neisseria*

gonorrhoeae in women randomized to an intrauterine device (IUD) or depot medroxyprogesterone acetate (DMPA). In our cross-sectional survey conducted at three clinics, we gave information on a potential RCT to clients, asked them questions to assess comprehensibility and finally asked respondents whether they would consider enrolling in such a trial. In addition, the 190 participants provided urine or endocervical swab specimens so we could estimate the prevalence of STIs. RESULTS: Overall, 70% of participants stated that they would take part in a future trial and accept randomization to either the IUD or DMPA. Participant understanding of the trial requirements was high. Twenty-nine percent of the participants were infected with either *N. gonorrhoeae* or *C. trachomatis*. CONCLUSION: With a high prevalence of STI in this population and the apparent willingness of appropriate candidates to participate, an RCT to measure risks of incident STI infection from hormonal contraception appears feasible.

"Inhibition of HTLV-1 cell-to-cell transmission in vitro by carbohydrate-binding agents"

Author(s): Balestrieri E, Ascolani A, Igarashi Y, et al

Reference: N/A Epub ahead of print.

<http://aac.asm.org/cgi/content/abstract/AAC.01671-07v1?maxtoshow=&HITS=2&hits=2&RESULTFORMAT=&andorexacttitle=and&andorexacttitleabs=and&fulltext=microbicide%2C+microbicides&andorexactfulltext=or&searchid=1&usestrictdates=yes&resourcetype=HWCIT&ct>

Published Abstract: Peripheral blood mononuclear cells (PBMCs) from healthy individuals can be infected by HTLV-1 upon co-cultivation of the PBMCs with irradiated HTLV-1-transformed human MT-2 cells. This model system closely mimics HTLV-1 transmission through cell-to-cell contact. Carbohydrate-binding agents (CBAs) such as the (1,3)/(1,6)mannose-specific *Hippeastrum* hybrid agglutinin (HHA) and the GlcNAc-specific *Urtica dioica* agglutinin (UDA), but also the small-size, nonpeptidic (1,2)-mannose-specific antibiotic Pradimicin A (PRM-A) were able to efficiently prevent cell-to-cell HTLV-1 transmission at non-toxic concentrations as evidenced by the lack of appearance of virus-specific mRNA and of the viral protein Tax in the acceptor cells. Consistently, antivirally active doses of CBAs fully prevented HTLV-1-induced stimulation of PBMC growth. The inhibitory effect of CBAs on HTLV-1 transmission was evident also when HTLV-1-infected C5MJ cells were used in place of MT-2 as a virus-donor cell line. The anti-HTLV-1 properties of the CBAs highlight the importance of the envelope glycans in events underlying HTLV-1 passage from cell to cell and indicate that CBAs should be further investigated on their potential to prevent HTLV-1 infection, including mother-to-child virus transmission by cell-to-cell contact through breast milk feeding.

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5. EPIDEMIOLOGY

"Massive HIV/AIDS survey kicks off"

Date: 27 May 2008

Source: *Health-e*

<http://www.health-e.org.za/news/article.php?uid=20031970>

The 3rd South African National HIV, Behaviour and Health Survey has kicked off in Pretoria, Cape Town and Durban aiming to reach 28 000 people in 15 000 randomly selected households across the country in the next five months.

The survey will be undertaken by a consortium of research institutions led by the Human Sciences Research Council (HSRC) and seeks to find out the levels of HIV infection in South Africa, and to learn what South Africans know, believe and feel about HIV/AIDS.

"This survey is a key instrument in our understanding the reach of HIV in our country. If we cannot reliably ascertain the extent of the disease in the country, we cannot plan accordingly. We need reliable figures so that a host of health and social interventions in response to HIV in the public, private and NGO sectors, can be targeted and implemented accurately," said Dr Olive Shisana, CEO of the HSRC:

Fieldworkers are already in the field in the Western Cape, Gauteng, North-West, and the Free State.

The survey involves asking participants to be pricked on a fingertip or heel (in the case of babies using a small pin known as a lancet), which will yield a few drops of blood that will be collected on special paper.

Those aged 12 years and older will also answer questions about their health and sexual behaviour. Participation is voluntary and all participants will remain completely anonymous. The point is not to furnish participants with their results, but rather to gain a clearer understanding of the reach of HIV/AIDS in South Africa and people's responses to the epidemic.

Many high profile individuals in South Africa have given their support to this important study and have agreed to promote participation in the survey. These calls for participation are aimed at all South Africans - old and young, of all races, able-bodied and disabled, and people from many different backgrounds.

In Pretoria, Hlubi Mboya, who plays HIV-positive Nandipha in the SABC soap *Isidingo*, gave a blood sample for the survey. "My dream", she said, "is to see an AIDS-free generation".

The 5fm morning show team, hosted by Gareth Cliff, who gave a blood sample on air this morning, called on listeners on air to participate in the study if they are selected for giving a blood sample and the accompanying questionnaire.

At the HSRC office in Cape Town, Olympic swimmer Natalie du Toit also joined in the call for participation of young, and especially white South Africans, in the survey. She also gave a blood sample to illustrate the anonymous nature of the survey.

Information from this survey will inform policy makers about the HIV/AIDS situation in South Africa and will also help to inform HIV prevention campaigns and contribute to the expansion of services for people and families infected and affected by AIDS and people living with HIV/AIDS.

"No HIV stage is dominant in driving the HIV epidemic in sub-Saharan Africa"

Author(s): Abu-Raddad LJ, Longini IM

Reference: N/A 22(9):1055-61.

<http://www.aidsonline.com/pt/re/aids/abstract.00002030-200805310-00007.htm;jsessionid=L8WLJnL2IHCdCC3Btpg1L8xfK35L7nPHhF2yDk7kTL9NKHbpQ2gv!195308708!181195628!8091!-1>

Published Abstract: Objective: To estimate the role of each of the HIV progression stages in fueling HIV transmission in sub-Saharan Africa by using the recent measurements of HIV transmission probability per coital per HIV stage in the Rakai study. Methods: A mathematical model, parameterized by empirical data from the Rakai, Masaka, and Four-City studies, was used to estimate the proportion of infections due to each of the HIV stages in two representative epidemics in sub-Saharan Africa. The first setting represents a hyperendemic HIV epidemic (Kisumu, Kenya) whereas the second setting represents a generalized but not hyperendemic HIV epidemic (Yaounde, Cameroon). Results: We estimate that 17, 51, and 32% of HIV transmissions in Kisumu were due to index cases in their acute, latent, and late stages, respectively. In Yaounde, the fractions were 25, 44, and 31%. We found that the relative contribution of each stage varied with the epidemic evolution with the acute stage prevailing early on when the infection is concentrated in the high-risk groups with the late stage playing a major role as the epidemic matured and stabilized. The latent stage contribution remained largely stable throughout the epidemic and contributed about half of all transmissions. Conclusion: No HIV stage dominated the epidemics though the latent stage provided the largest contribution. The role of each stage depends on the phase of the epidemic and on the prevailing levels of sexual risk behavior in the populations in which HIV is spreading. These findings may influence the design and implementation of different HIV interventions.

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6. OTHER PREVENTION APPROACHES

"Uganda: Circumcision alone can't tame HIV/AIDS"

Date: 27 May 2008

Source: *The Monitor*

Author(s): Vanessa J. Akello

<http://allafrica.com/stories/200805270730.html>

Recently, I was in a meeting where the question of whether "HIV Counseling and Testing (HCT or VCT) contributes to HIV reduction," was prominent. What was worrying was the fact that the zeal put into discrediting HCT was being put into the promotion of male circumcision by a development partner.

As we fight HIV/Aids, it is important to embrace all prevention strategies. This goes for male circumcision, which is said to prevent HIV transmission by about 60% if used with the ABC strategy (Abstinence, Being faithful to one partner, and Condom use for those with high risk behaviours). Thus, Uganda is embracing male circumcision and is in

the process of developing a policy guideline.

However, embracing new innovations does not mean we throw away existing methods. Undisputedly, HCT is still relevant today and as a prevention strategy. How can we protect our unborn children, in the midst of limited resources like drugs, if we do not know the HIV status of pregnant mothers so that we identify those with HIV and prevent transmission of the virus to their unborn children?

How can we prevent HIV in young people who intend to get married or become sexually active if we do not encourage them to take HIV tests and know their sero-status?

What of couples who are discordant- one partner is HIV negative while the other is HIV positive? Organisations or governments cannot lead HIV prevention and interventions without HCT. We can authoritatively speak today about Aids in Uganda and the world because there is HIV counselling and testing.

The HCT itself can lead to behavioural change. A multi-centre VCT efficacy trial in Kenya, Tanzania, and Trinidad found a number of changes due to VCT, according to "Voluntary HIV Counselling and Testing Efficacy Group, 2000." The trial had a randomised sample of 3,120 volunteers and 586 couples.

Results showed there was a significantly greater decline in the proportion of individuals who had unprotected sex with non-primary partners among the group that received VCT compared to the group that received a health education intervention only.

In addition, HIV-infected individuals were likely to reduce sexual risk behaviours with primary partners and HIV-infected men were likely to reduce risk behaviours with non-primary partners as well.

Couples who participated in VCT were significantly more likely to reduce unprotected sexual intercourse with their enrolled partner when compared to those who received health education only. The study concluded that VCT is efficacious in promoting behavioural change.

Another study, "HCT Practices at an Urban Hospital in Kampala, Uganda" notes that HCT has been prioritised as a key component of prevention and care and presents impacts like informing individuals about their sero-status, educating people on specific risk reduction, provision of strategies for disclosure and testing, helping in identifying and overcoming barriers to risk reduction, and linking HIV-infected individuals to care. The paper cites several other studies that have shown reduction in HIV risk behaviours following HCT.

Therefore, if HIV counselling and testing can significantly contribute to HIV prevention and is the entry point of any HIV intervention, then we must embrace it and expand it nationally to address the Aids pandemic. Resources should be put into HCT so that all individuals in Uganda know their status.

We welcome new strategies. However, policy formulation and guidelines need to be thoroughly exhausted before implementation can begin.

"Male circumcision gains ground as anti-AIDS weapon"

Date: 24 March 2008

Source: *Associated Press*

http://www.usatoday.com/news/world/2008-05-24-kenya-aids_N.htm

Sitting underneath the bright murals at a clinic, 22-year-old Elijah Ochanda gestures at his shorts and explains: "When they remove this thing, it makes you safer."

He is talking about the circumcision he is about to undergo at the urging of his older brother. He has watched several friends die of AIDS, and has come to believe the science that says circumcision can prevent men from being infected.

Dr. Robert Bailey, an epidemiology professor from the University of Illinois, is helping to roll out Kenya's first free circumcision project, which offers operations at public health facilities. Such projects are already running in Swaziland, Rwanda and Zambia, other countries where a large percentage of the population traditionally do not circumcise.

Bailey's study in Kisumu, western Kenya found infection rates were cut by 60% among men who were circumcised. The study, funded by the U.S. Institutes of Health and the Canadian Institutes of Health Research, was one of several that led the World Health Organization to include circumcision in its prevention policies a year ago.

It prompted the Kenyan government to form a task force to promote voluntary, medically safe operations.

But it's not that simple. Circumcision has become entangled in the violence that followed the disputed presidential election last December.

Supporters of President Mwai Kibaki, whose Kikuyu tribe circumcises its men, clashed with supporters of opposition leader Raila Odinga, who is Luo, a tribe that does not circumcise. The rite took on political significance, with Odinga's rivals publicly saying he wasn't a complete man. Many Luo were forcibly circumcised in the violence.

The violence has subsided, but Bailey says it has made the new power-sharing government, with Odinga as prime minister, wary of taking a public stance on circumcision. The disruption initially delayed the launch of the task force's program.

Still, it's noteworthy that Ochanda has overcome the tradition issue in opting for circumcision. And the Luo tribe's council of elders doesn't forbid it outright although they do say it is contrary to their traditions and worry it will promote promiscuity.

"If you want to do that on your own, no one will question you, but it is not our custom," said elder Odungi Randa.

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7. POLITICS AND POLICY

"Global AIDS policy and women's health"

Date: 26 May 2008

Source: *The Boston Globe*

Author(s): Pat Daoust

http://www.boston.com/bostonglobe/editorial_opinion/oped/articles/2008/05/26/global_aids_policy_and_womens_health/

In spite of scientific and medical advances in recent years, the AIDS pandemic remains the greatest public health crisis of our time. Each day 6,000 people die of AIDS and there are 7,000 new infections. These statistics are difficult to comprehend until you see the faces of those most often affected - young women, between the ages of 15 and 24, living in sub-Saharan Africa.

The United States could do a better job saving their lives if our leaders would place the best public health practices over political compromise. Congress should stipulate in its funding of overseas AIDS assistance that prevention, testing, and treatment of this disease should be linked with family-planning services in Africa. In many cases, US AIDS assistance is not provided at clinics with family-planning services because of conservatives' concern that such services might provide or advise on abortions.

Research has repeatedly shown that integration of HIV services within the context of women's health could save the lives of hundreds of thousands of women and, if pregnant, their newborns. The entry point to the healthcare system for many African women is the family-planning clinic. Timely access to messages on HIV prevention and life-saving treatments can slow the AIDS pandemic.

Three weeks ago I walked through a women's ward in the national referral hospital in Uganda with a local physician. I held the hand of a beautiful 18-year-old woman diagnosed with end-stage AIDS. Through the look of hope in her eyes, she begged not to be yet another statistic lost to a preventable and treatable disease. The majority of the women we assessed were dying of AIDS. Seventy percent of those admitted to the hospital share this fate.

"If only we could identify these women earlier we could reverse this outcome. Anti-retroviral drugs are available but most are too far advanced in the progression of their disease to benefit," the physician stated. "When they first come seeking ante-natal care or family planning we could educate, treat, and prevent such dire results. Most of these young women fall through the cracks due to fragmented healthcare."

Translating these eyewitness accounts and the evidence-based research into life-saving policy has proven difficult for congressional leaders. The President's Emergency Plan for AIDS Relief is currently being reauthorized. This vital program, which has saved millions of lives over the last five years, has been heralded by many on both sides of the aisle as the most significant legislative achievement of this administration. The proposed new budget is \$50 billion for the next five years, a significant increase over the original program. As welcome as the new funding is, Congress should take this opportunity to apply lessons learned.

The bill coming before the Senate makes no mention of linking HIV and family-planning services. To avoid controversy with conservative policy makers, the bill's Democratic drafters left linkages out completely.

Those of us who have worked in Africa know that family planning and reproductive health services are in fact not code words for abortion, as some suggest. Women's healthcare means access to contraception, prenatal care, safe labor and delivery, postpartum and newborn care, as well as treatment for sexually transmitted illnesses. Linking women's healthcare with HIV services should be obvious. Any restriction in moving integration of care forward is a big step backward in the US program's prevention and treatment efforts.

There is still time to address this critical component of our global AIDS policy when the bill is debated in the Senate. Bold leadership calling for effective, evidence-based interventions and not ideology is necessary. Senators can help women a world away by pushing for inclusion of strong language in the final Senate bill to support the integration of HIV services and family-planning programs.

We have lost over 30 million people to AIDS in the last 25 years. Compromise at the expense of the most vulnerable and voiceless should no longer be acceptable.

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8. HIV/AIDS FUNDING

"Advocates call for increased funding, renewed efforts for HIV/AIDS vaccine research"

Date: 23 May 2008

Source: *Kaiser Daily HIV/AIDS Report*

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=52322

Advocates and researchers at a panel discussion on Thursday called for an increase in funding for and a renewal of efforts to develop an HIV/AIDS vaccine, CQ HealthBeat reports. Panelists at the forum, which was sponsored by the Caucus for Evidence-Based Prevention and the AIDS Vaccine Advocacy Coalition, said that continued declines in funding from public and private institutions would severely undermine HIV/AIDS vaccine research.

AVAC Executive Director Mitchell Warren cited a recent headline in a Kenyan newspaper that read, "HIV Research Hits a Dead-End," adding, "In many ways that headline isn't entirely wrong; we have hit some barriers." Warren also referenced AVAC's latest annual report on HIV vaccine research efforts, saying, "The reality is there's a lot to be looking at; there's a lot to be planning for."

Panelists also emphasized the importance of a comprehensive strategy to fight HIV/AIDS. They used the metaphor of a "basket" or a "toolbox" of mechanisms to point out that there is no one universal approach to eliminating the disease. "We need to continue to ... have the discussion that there is no such thing as a magic bullet," Carl Dieffenbach, director of the division of AIDS at NIH, said. However, the vaccine "is the main ingredient that we need to put in this toolbox," he added.

In addition, Dieffenbach said that NIH should put more money toward reducing the risk of HIV vaccine research and development. He noted that drug makers generally are motivated to conduct vaccine research by the potential of a product's market success, but efforts often are hindered by the high risk involved. "There is so much unfunded opportunity," he said (Cooley, CQ HealthBeat, 5/22).

"U.S. medical research gets \$600 million from Institute"

Date: 27 May 2007

Source: *The Washington Post*

Author(s): Philip Rucker

<http://www.washingtonpost.com/wp-dyn/content/article/2008/05/26/AR2008052602370.html?hpid=topnews>

One of the world's largest private philanthropies will announce today a \$600 million initiative to fund risky but potentially lifesaving medical research by 56 of America's top scientists.

The Howard Hughes Medical Institute is expanding its flagship investigators program to nurture a new class of scientists. By endowing scientists' research over many years, the institute hopes they will make major discoveries in a variety of fields, including genetics and biology.

The scientists, chosen from more than 1,000 applicants, said they want to answer such ambitious questions as how global climate change affects the spread of cholera, malaria and other infectious diseases and whether doctors can apply the engineering behind the building of airplanes and computers to the human immune system.

The initiative comes as scientists are sounding alarms about a slump in federal research funding since 2003, saying it has starved potentially groundbreaking research projects of cash and could jeopardize the country's dominance in science against growing competition in Europe and China.

Private philanthropies -- led by the Chevy Chase-based nonprofit organization founded by Howard R. Hughes, the late aviator, engineer and film producer -- are helping fill this gap by lavishing money on research that many grantmakers would consider too risky but that could produce the greatest breakthroughs.

"We identify the best people and then free them up to do what they want to do and to be flexible and change directions and follow their noses into new fields," Hughes Institute President Thomas R. Cech said.

Just as the Bill and Melinda Gates Foundation is showering grants on programs to improve U.S. education and global health, the Hughes Institute is trying to foster long-term advances in medicine.

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EDITOR'S NOTE: The full text of this article is available for public access at the above website.

"Funding boost for B-cell-based HIV vaccine research"

Source: *Nature*. 2008 May 28;453(577). *News in Brief*.

<http://www.nature.com/news/2008/080528/full/453577b.html>

In an effort to speed up HIV vaccine research, the US National Institute of Allergy and Infectious Diseases (NIAID) last week awarded US\$15.6 million in grants for research on B-cell immunology.

The five-year awards will go to ten research teams. They come two months after NIAID director Anthony Fauci announced his institute's intention to "turn the knob" in the direction of basic research and discovery (see *Nature* 452,

503; 2008) after the highly public failure of a T-cell-based HIV vaccine candidate.

"This is the kind of thing we were talking about when we were talking about discovery," says Fauci, who says that planning for the awards began 14 months ago. B cells make antibodies that neutralize invading viruses, but humans seem unable to mount a response during HIV infection.

"The World Bank and HIV/AIDS in Africa"

Source: *Lancet*. 2008 May 24;371(9626):1724. Editorial.

<http://www.thelancet.com/journals/lancet/article/PIIS0140673608607357/fulltext>

Last week, the World Bank launched a new agenda for action on HIV/AIDS in Africa for the next 5 years, with four main objectives: to advise countries on the management of international financing, help countries to take a development response to HIV/AIDS, strengthen the monitoring capacity of countries to track the effectiveness of their response, and build stronger health systems.

The new agenda follows on from the Bank's Africa Multi-Country AIDS Program (MAP), which was launched in 2000. MAP was the first programme to offer African countries long-term funding for national HIV programmes. MAP supported multisectorial approaches to combat HIV/AIDS and was the strongest mechanism in funding to create the infrastructure for national AIDS councils. However, MAP's impact on HIV/AIDS is unclear. A few years after its launch other big funders, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, came onto the scene. Implicit in their creation was the fact that MAP was not working.

What about the new strategy? The Bank is continuing its unique multisectoral approach. It plans to disburse US\$250 million a year for HIV/AIDS initiatives in health, education, and transport. This investment is a welcome move. However, to be effective, the Bank's lending should be based on good performance and not left to the whimsy of individuals within the organisation. What is more, the Bank has lacked and continues to lack top-level political commitment to HIV/AIDS in Africa. The new strategy was not signed or launched by the Bank's new head, Robert Zoellick. It also speaks volumes that the agenda was not released at one of the many upcoming high-level HIV meetings.

The Bank must have a coherent, performance-based strategy with strong political support from its new leader if it is to make a real contribution to addressing HIV/AIDS. Its latest effort lacks that necessary commitment to a disease that remains an overwhelming threat to development in Africa.

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9. ANNOUNCEMENTS

Register for the Cervical Barrier Methods Forum

<http://my.ibpinitiative.org/public/cervicalbarriers/>

Please register for the next online forum in the Family Planning: A Global Handbook for Providers series on Cervical Barrier Methods, which will be held from June 2-6, 2008.

In this online discussion, health professionals around the world will share their experiences with diaphragms in diverse settings and their questions about potentially incorporating diaphragms into service delivery. This forum also is an opportunity to review the latest guidance on diaphragms featured in Family Planning: A Global Handbook for Providers and exchange information and experiences with colleagues who are working to provide high-quality family planning services.

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The discussion will be guided by the interest of the participants. The forum will focus on programmatic as well as technical issues and will include topics such as availability of and demand for diaphragms, women's perspectives, recent research on the diaphragm for HIV prevention and in combination with novel spermicides for contraception, incorporating and providing diaphragm services, and future research and programming opportunities. A variety of tools and resources on diaphragms will be available for easy access in the online Resource Library.

The Global Handbook was prepared through a unique collaboration between Johns Hopkins Bloomberg School of Public Health, the United States Agency for International Development (USAID), the World Health Organization (WHO), and over 30 organizations around the world.

This online discussion is sponsored by PATH, Ibis Reproductive Health and the INFO Project, based at the Johns Hopkins Bloomberg School of Public Health Center for Communication Programs in collaboration with the Implementing Best Practices (IBP) in Reproductive Health Initiative and WHO.

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