



ALLIANCE FOR MICROBICIDE DEVELOPMENT

21 September 2007, Volume 8, Number 37

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/publications/>. 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!

Areas covered in this News Digest:

1. MEDIA COVERAGE OF MICROBICIDES

- HIV - science in action
- New HIV prevention drug for women being tested
- Cellulose sulfate: two times more HIV, or not
- Diaphragms: a strangely permeable wall

2. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

- Microbicide research in developing countries: have we given the ethical concerns due consideration?
- Vaginal microbicides for preventing mother-to-child transmission of HIV infection--no evidence of an effect or evidence of no effect?

3. PUBLISHED RESEARCH: RELEVANT BASIC AND TRANSLATIONAL SCIENCE

- A randomized trial of the intrauterine contraceptive device vs hormonal contraception in women who are infected with the human immunodeficiency virus
- At what price? Differential pricing could make global medicines affordable in developing countries. But drugs for diseases that have no market in the developed world will require additional subsidies
- Patent sense: Protecting intellectual property saves lives in the developing world
- Potential impact of antiretroviral chemoprophylaxis on HIV-1 transmission in resource-limited settings
- Susceptibility of human female primary genital epithelial cells to herpes simplex virus, type 2 and effect of TLR3 ligand and sex hormones on infection
- The dynamics of intergenerational sexual relationships: the experience of schoolgirls in Botswana
- The role of a regular sex partner in sexually transmitted infections and reinfections: results from the study of female entertainment establishment workers in the Philippines

4. EPIDEMIOLOGY

- Researchers say Africa's declining AIDS prevalence dangerous

5. OTHER PREVENTION APPROACHES

- Medical mystery's unravelling will aid research
- 4 winners of Lasker Medical Prize

6. ANNOUNCEMENTS

- 1ST ANNUAL AIDS RESEARCH CONGRESS OF IRAN: CALL FOR ABSTRACTS
- AIDS VACCINE 2007: AN ADVOCATES' (OPINIONATED AND SELECTIVE) MEETING REPORT
- CONFERENCE ON RETROVIRUS AND OPPORTUNISTIC INFECTIONS (CROI): CALL FOR ABSTRACTS
- ELTON JOHN AIDS FOUNDATION GRANT AWARD TO IRMWG
- M2008 ABSTRACT DEADLINE - 30 SEPTEMBER 2007
- POPULATION COUNCIL'S SANDRA G. GARCIA IS RECOGNIZED FOR EXCELLENCE IN SEXUAL AND REPRODUCTIVE HEALTH RESEARCH
- SOCIETY FOR AIDS IN AFRICA: CALL FOR MEMBERS

1. MEDIA COVERAGE OF MICROBICIDES

"HIV - science in action"

Date: 20 September 2007

Source: *BBC News*

http://www.bbc.co.uk/insideout/content/articles/2007/09/14/london_aids_12_1_feature.shtml

For the first time a group of London community workers is helping scientists from St George's University of London develop a new gel that will act as a barrier against the HIV virus. It is now 25 years since the discovery of HIV. In 2006 about 40 million people in the world were living with the disease.

Whilst scientists around the world have struggled to find a vaccine for HIV, here in London they are dedicating their time to finding a product that women can apply to block the virus from entering the body. The gel called **Microbicides** would provide a female initiated prevention option.

Angelina Namiba, who is a member of the UK African **Microbicides** Working Group, told us that women need to be able to take control of their own sexual health: "We need a healthy future and if we can have another option of protecting ourselves that can only be a good thing - developing better products will empower women to do so."

After more than 15 years of lab testing and three phases of clinical trials on humans, they are just over a year away from knowing whether this product is safe and effective. If so, it could be available in African countries within the next three years. The success of this product depends not only on whether it is a scientific break-through but whether it is agreeable to those who will use it.

Therefore, the UK African **Microbicides** Working Group are working with the research scientists at St. George's University of London to advise them about what they want from this product and exactly how it should feel, smell and be used when it hits the market.

Although 95% of HIV infections occur in developing countries, there were 7,450 newly diagnosed cases in the UK in 2006 and 4,049 of these acquired their infection heterosexually. As women accounted for 63% of these cases, the need for the **Microbicide** gel has never been greater (source:Health Protection Agency).

Battle against disease

Since Winnie Ssanyu Sseruma was diagnosed with HIV in 1988, she has dedicated her life to volunteering, researching and speaking about issues affecting HIV positive people: "It is so important that this product comes out as quickly as possible and that women work in partnership with their men in this fight against HIV. "If men are left out, what we are fighting for in terms of reducing the number of infections will take much longer." She told Inside Out how finding a support group changed her life - instead of constantly thinking about dying, she met other HIV positive women who were not only living with the disease but were living well. Together they courageously campaign for greater HIV awareness and education for the sake of future generations.

Making a difference

Anya Sitaram joined the community workers as they toured the science labs to get a better understanding of what the Microbicide research involved and why it was taking 15 years to develop. Trish Fletcher, who has spent over 10 years researching **Microbicides**, explained the slow and tedious process of the research where many failures were encountered along the way. "What helps keep me going is that ultimately what I'm doing one day could make a big difference."

Martha Stefanidou, who is researching **Microbicides** for her PHD, said: "I think for us its easy to be stuck in the lab all day, its fantastic to be here with the community."

After the tour Winnie Ssanyu Sseruma said: "I think these meetings are really important for **Microbicide** advocates - for us to really get the knowledge we need in terms of what the process is like, what the end product is going to look like, so that we can give this information to the communities. "Therefore, when the product is ready we are already aware of what it is going to be like and all we have to do is point people in the direction of where they need to access it."

Tireless efforts

The next day it was the scientists turn to ask the questions when they went to the community centre where the UK African **Microbicides** Working Group gather. Trish asked the women whether they would actually want to use the **Microbicide** gel. The women said that a product that could prevent the spread of HIV was much in demand and they appreciated the tireless efforts of the scientific research. But they all agreed that some serious market research was needed to come up with a more appealing name than **Microbicides!**

Professor Robin Shattock from St George's University of London has been leading the research into HIV prevention and treatment since the discovery of the disease. He emphasised the importance of the bridging the gap between science and the community: "It benefits the advocates because it keeps them informed about the type of work the scientists are doing and it benefits the scientists because it keeps them in touch with the needs of the people so they can develop a product that these people will want to use. It doesn't matter how good it is at blocking the virus, if those it is meant for aren't going to use it."

Professor Shattock is keen point out that the first generation of **Microbicides** need not be 100% effective to be rolled out in HIV high risk areas. "As the scientific research advances so will the efficacy of the product. However, a **Microbicide** that is efficient 60% of the time, introduced into 73 low income countries would avert 2.5 million HIV infections over three years."

Yvonne Feare from the UK African **Microbicides** Working Group said: "To actually come here and see first hand your work and to imagine that in the laboratory there could actually be a miracle, a product that really empowers women, is amazing, so we are very grateful for the work you are doing and it keeps us going and gives us motivation to go for it, so let's go for it!"

Anyone who wants further information on HIV Science In Action can email hiv.science.in.action@sgul.ac.uk

"New HIV prevention drug for women being tested"

Date: 18 September 2007

Source: *Antigua Sun*

Author(s): Afeefah Beharry

<http://www.antiguasun.com/paper/?as=view&sun=442747109309172007&an=142204096909172007&ac=Local>

Women will soon be able to access another method of protection against HIV and other Sexually Transmitted Infections (STIs) once all goes well with the testing of a new product called "**Microbicides.**"

This is according to Ann Marie Dobson, public education officer at Jamaica AIDS Support For Life who also said that the product is being tested among different populations in Africa. Dobson told journalists who gathered in Jamaica from several Caribbean countries for a workshop that HIV is rapidly becoming a "women's epidemic". She said that of every 10 people newly infected with HIV, six are women and even in the developed world, rates of new infections among women are rising.

The **microbicide** according to Dobsob, is a product that will prevent the sexual transmission of HIV and potentially, other STIs, and is likely to be applied topically to the vagina as a gel, cream, film, suppository, or vaginal ring.

Dobson further stated that some will also prevent pregnancy, while others will prevent HIV, but not pregnancy. The cream is likely to be inexpensive and available over the counter. "**Microbicides** offer an alternative to condoms, as the most feasible method for primary prevention of HIV." Dobson said.

Dobson went on to explain that unlike men or women condoms, **microbicides** are a potential preventive option that women can easily control and do not require the co-operation, consent or even knowledge of the partner. Dobson stated that **microbicides** should reduce the risk of re-infection with other HIV strains, help protect both partners, reduce the risk of other STDs, yeast and bladder infections and allow conception while protecting partner.

Among other reasons, this new product was invented to help women to feel a sense of empowerment and to protect themselves without feeling uncomfortable. Several women have raised complaints about women condoms. They said that the condoms were expensive, not widely available and very uncomfortable. According to the UNAIDS Fact sheet, the Caribbean is the second most-affected region in the world after Africa, with an HIV prevalence of 1.6 per cent. There were 330,000 people living with HIV in the Caribbean at the end of 2005. Around 22,000 were children under the age of 15. Adult women make up 50 per cent of the total number of people living with HIV in the region.

"Cellulose sulfate: two times more HIV, or not"

Date: 31 August 2007

Source: *Community HIV/AIDS Mobilization Project HHS Watch*

<http://champnetwork.org/media/HHSWatch0907.pdf>

EDITOR'S NOTE: *The September 2007 issue of CHAMP's HHS Watch features many great articles about the HIV and STI prevention field. The Alliance highlights two articles in this Digest that have particular relevance, however we suggest reading the newsletter in its entirety, as it is available for public download at the above website.*

The reason for searching out more focused anti-HIV **microbicides** is the failure of the cellulose sulfate (CS) **microbicide** testing effort (see HHSWatch March 2007). CS is a broadly active charged molecule that interferes with viral coatings and cellular membranes. Two major cellulose sulfate efficacy trials, taking place mainly in Africa, were closed down prematurely last January. One was sponsored by Family Health International (FHI) in North Carolina, the other by Virginia-based CONRAD. Preliminary results from the CONRAD trial appeared to show that cellulose sulfate was paradoxically linked to a higher rate of new HIV than placebo. Researchers presented both trials' complete results at the IAS conference, but they still do not have an explanation for what went wrong.

In the CONRAD trial, the HIV rate was 60% to 120% higher in the cellulose sulfate arm than in the placebo arm, depending on how you count the results. In contrast, the FHI cellulose sulfate trial observed no effect on HIV transmission from cellulose sulfate. HIV rates among the cellulose sulfate recipients were actually less than among those who used the placebo gel, although the trial stopped too early to tell whether this difference was statistically

significant.

The contrasting results might be related to differences in the two trial populations: the CONRAD enrollees were somewhat older (30 years versus 23 years for the FHI group) and had sex more often (11 times per week compared with 6 times per week in the FHI trial). If cellulose sulfate causes minor vaginal disruption, it might have been aggravated by very frequent sex plus older age. This in turn would have led to more susceptibility to HIV.

Such possibilities are under investigation. Meanwhile, major trials of two similar-acting **microbicides** continue without reported difficulty.

"Diaphragms: a strangely permeable wall"

Date: 31 August 2007

Source: *Community HIV/AIDS Mobilization Project HHS Watch*

<http://champnetwork.org/media/HHSWatch0907.pdf>

One even larger trial yielded negative results that resonated through both conferences (Padian et al., Lancet July 2007 and IAS 2007 abstracts TUAC101 [Govender et al.], TUAC102 [van der Straten et al.], TUAC104 [Watadzaushe et al.], TUAC105 [Montgomery et al.], WEPEC046 [Milford et al.], WESS304 [Padian], and WEPL103 [Padian]). That trial enrolled 5,000 southern African HIV negative women to test the protective effect of a standard contraceptive barrier device, cervical diaphragms. The relatively thin cervical lining is considered a potentially sensitive area for HIV infection in women.

Half the trial participants received the diaphragms plus a neutral lubricating gel to ease insertion. Everyone received randomized repeated safe sex counseling with free condoms. They also were treated at study entry for curable (i.e. bacterial) STDs. Notably, 59% of enrollees tested positive for HSV-2 at enrollment.

After 24 months, the rate of HIV acquisition was virtually the same, about 4%, in the diaphragm and control groups. The incidence rates were also the same in each arm for women with baseline positive tests for bacterial STDs or herpes. (But the HSV-2-positive women as a whole acquired HIV at a rate of almost 5%, compared with 3% for the HSV-2-negative women.) Reproductive tract infections were also equal in the diaphragm and non-diaphragm arms, as was the pregnancy rate.

Diaphragm use left something to be desired: Over the course of the study, women in the diaphragm arm reported using diaphragms at 73% of their most recent sexual activity. In any case, the high-adherence population did not show a reduced risk for HIV. One important difference between the diaphragm and control groups was condom use: After entry into the trial, women in both groups greatly increased their use of condoms during sex, but the non-diaphragm arm increased its rate still more. Yet, the groups' HIV rates were equal. There might be some protective effect after all.

But one suspects that participants' reports of their condom use were inaccurate: in the regular clinical surveys, 85% of the control group members reported that they had used condoms during their most recent sexual act, yet 6% of them

acquired HIV. It doesn't add up. And here's another aspect that doesn't make sense: The yearly pregnancy rate in both arms was 13%. You might well conclude from this trial that diaphragms are not protective against pregnancy as well as HIV.

This trial wasn't designed to compare diaphragms to no condoms, and didn't have the size and statistical power to look only at high condom adherers, either. A trial that focuses on the sizable number of women who are unable to use condoms due to lack of partner cooperation might provide some valuable insights.

When diaphragms are used for contraception, a spermicidal cream or gel is added. The cream was not used in this study for fear that it would prove irritating and, hence, promote HIV transmission. For HIV protection, it might be necessary to add an antiretroviral **microbicide**. An initial safety and acceptability trial of that combination recently took place in Madagascar with 192 women (Behets et al. ISSTD 2007 abstract O-021 and Norris Turner et al. abstract P 493). That trial used the AcidForm **microbicide**, which keeps the cervicovaginal environment mildly acidic and hostile to HIV. An agent that directly kills HIV might be used instead. One example is tenofovir gel, now the subject of a 1,000-woman South African trial testing its value as a standalone **microbicide**.

[Return to Table of Contents](#)

2. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

"Microbicide research in developing countries: have we given the ethical concerns due consideration?"

Author(s): Moodley K

Reference: N/A 8(10)Provisional Abstract.

<http://www.biomedcentral.com/1472-6939/8/10>

Published Abstract: *Background* HIV prevention research has been fraught with ethical concerns since its inception. These concerns were highlighted during HIV vaccine research and have been elaborated in **microbicide** research. A host of unique ethical concerns pervade the **microbicide** research process from trial design to post-trial **microbicide** availability. Given the urgency of research and development in the face of a devastating HIV pandemic, these ethical concerns represent an enormous challenge for investigators, sponsors and Research Ethics Committees (RECs) both locally and internationally. *Discussion* Ethical concerns relating to safety in **microbicide** research are a major international concern. However, in the urgency to develop a medically efficacious **microbicide**, some of these concerns may not have been anticipated. In the risk-benefit assessment of research protocols, both medical and psycho-social risk must be considered. In this paper four main areas that have a potential for medical and/or psycho-social harm are examined. Male partner involvement is controversial in the setting of covert use of **microbicides**. However, given the long-term exposure of men to experimental products, this may be methodologically, ethically and legally important. Covert use of **microbicides** may impact negatively on relationship dynamics leading to psychosocial harm to varying extents. The unexpectedly high rates of pregnancy during clinical trials raise important methodological and ethical concerns. Enrollment of adolescents without parental consent generates ethical and legal concerns that must be carefully considered by RECs and trial sites. Finally, paradoxical outcomes in recent trials internationally have

advanced the debate on the nature of informed consent and responsibility of researchers to participants who become HIV positive during or after trials. *Summary* Phase 3 **microbicide** trials are an undisputed research and ethical priority in developing countries. However, such trials must be conducted with attention to both methodological and ethical detail. It is imperative that guidelines are formulated to ensure that high ethical standards are maintained despite the scientific urgency of **microbicide** development. Given the controversy raised by emergent ethical issues during the course of **microbicide** development, it is important that international consensus is reached amongst the various ethics and regulatory agencies in developing and developed countries alike.

"Vaginal microbicides for preventing mother-to-child transmission of HIV infection--no evidence of an effect or evidence of no effect?"

Author(s): Wiysonge CS, Shey MS, Shang J, et al

Reference: N/A 97(7):530-3.

<http://highwire.stanford.edu/cgi/medline/pmid;17805456>

Published Abstract: BACKGROUND: Vaginal disinfection is a simple, potentially effective strategy for reducing mother-to-child transmission (MTCT) of HIV that can be implemented in combination with antiretroviral therapy or even in the absence of prenatal HIV testing. We systematically reviewed currently available randomised controlled trials to estimate the benefits and risks of this intervention. METHODS: We conducted an exhaustive search for published and unpublished trials assessing the effect of vaginal **microbicides** on MTCT of HIV, extracted data in triplicate, assessed statistical heterogeneity between trial results, and conducted meta-analysis using Mantel-Haenszel's method. FINDINGS: Five potentially eligible studies were identified, two of which met eligibility criteria. Pooling the data shows that the effect of vaginal disinfection on the risk of MTCT of HIV (relative risk (RR) 0.94, 95% confidence interval (CI) 0.71 - 1.25) and neonatal death (RR 1.36, 95% CI 0.32 - 5.79) is uncertain. The combined data (two trials with 708 participants) had less than 80% power to detect a 30% reduction in the risk of MTCT of HIV from a baseline risk of 30%, and are compatible with a wide range of effects; from a 29% reduction to a 25% increase in risk. One trial, with 108 participants, showed no evidence that adverse effects increased in mothers (RR 1.02, 95% CI 0.87 - 1.20) and found that adverse effects decreased in neonates (RR 0.45, 95% CI 0.32 - 0.64). INTERPRETATION: At present there is insufficient and inconclusive evidence on the effect of vaginal **microbicides** on the risk of MTCT of HIV. This review identifies the need and provides the impetus for an adequately powered randomised controlled trial to assess the effect(s) of this inexpensive intervention.

[Return to Table of Contents](#)

3. PUBLISHED RESEARCH: RELEVANT BASIC AND TRANSLATIONAL SCIENCE

"A randomized trial of the intrauterine contraceptive device vs hormonal contraception in women who are infected with the human immunodeficiency virus"

Author(s): Stringer EM, Kaseba C, Levy J, et al

Reference: N/A 197(2):144.e1-8.

http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=pubmed&dopt=AbstractPlus&list_uids=17689627&tool=MedlinePlus

Published Abstract: OBJECTIVE: The purpose of this study was to determine whether the intrauterine contraceptive device (IUD) is effective and safe among women who are infected with the human immunodeficiency virus (HIV). STUDY DESIGN: We randomly assigned 599 postpartum, HIV-infected women in Zambia to receive either a copper IUD or hormonal contraception and followed them for at least 2 years. RESULTS: Women who were assigned randomly to hormonal contraception were more likely to become pregnant than those who were assigned randomly to receive an IUD (rate, 4.6/100 vs 2.0/100 woman-years; hazards ratio, 2.4; 95% CI, 1.3-4.7). One woman who was assigned to the IUD experienced pelvic inflammatory disease (crude rate, 0.16/100 woman-years; 95% CI, 0.004-868); there was no pelvic inflammatory disease among those women who were assigned to hormonal contraception. Clinical disease progression (death or CD4+ lymphocyte count dropping below 200 cells/microL) was more common in women who were allocated to hormonal contraception (13.2/100 woman-years) than in women who were allocated to the IUD (8.6/100 woman-years; hazard ratio, 1.5; 95% CI, 1.04-2.1). CONCLUSION: The IUD is effective and safe in HIV-infected women. The unexpected observation that hormonal contraception was associated with more rapid HIV disease progression requires urgent further study.

"At what price? Differential pricing could make global medicines affordable in developing countries. But drugs for diseases that have no market in the developed world will require additional subsidies"

Author(s): Danzon PM

Reference: N/A 449:176-79.

<http://www.nature.com/nature/journal/v449/n7159/full/449176a.html>

Published Abstract: For the general population in developing nations to have appropriate access to medicines, existing drugs must be affordable, and innovation is needed to develop new medicines. But this presents a potential conundrum: prices that are high enough to pay for research and development (R and D) may make medicines unaffordable in developing regions. Differential pricing¹ (also known as price discrimination) can offer a solution to this dilemma, at least for drugs with considerable sales in the developed world. Prices in affluent countries - and to a lesser extent in middle-income countries - could generate sufficient revenue to pay for R and D, whereas prices in developing nations need only cover their marginal costs. But differential pricing will be possible only if market separation can be sustained, preventing the low prices in developing countries from spilling over to higher-income nations. However, for drugs that treat diseases endemic only in the developing world, sales are insignificant in the developed world, and additional subsidies are essential to attract R and D for these diseases.

Economics of differential pricing

This prescription of differential pricing and separate markets for on-patent pharmaceuticals is at odds with the free-trade and global-pricing maxims generally favoured by economists. The reason is that R and D costs roughly US\$1

billion for each new drug approved in 2007, including the cost of failures and the necessary return on capital invested over the 8-12 years required for R&D². Pharmaceutical R and D can benefit patients globally, raising the question of how this joint cost should be allocated among consumers to generate the greatest benefit. Counting all consumers equally, the answer is that prices should vary inversely with the consumers' price sensitivity - a theory of optimal differential pricing known as Ramsey pricing³. Prices must exceed marginal production cost for at least some users in order to pay for R and D. But if all consumers are charged the same price, then the most price sensitive will reduce their use and lose more benefit than would the less price-sensitive consumers. In practice, such sensitivity to drug prices is hard to measure, but a reasonable assumption is that it varies inversely with income. Ideally then, countries with lower per-capita income should be charged less than countries with higher per-capita income

More generally, economic theory shows that differential pricing promotes greater social welfare than uniform pricing if consumers in aggregate buy more under differential pricing⁴ - which seems plausible for pharmaceuticals. A simulation⁵ comparing worldwide pharmaceutical prices, revenues and number of consumers served under a single global price with differential pricing between national markets (that is, one price per country) found that differential pricing increases consumer access to drugs by a factor of roughly 4-7 compared with uniform pricing. In addition, differential pricing within, as well as between, countries could significantly increase affordability for poor populations in countries that have a skewed income distribution and no national health insurance. Differential pricing would not only increase the use of existing drugs (static efficiency) but should also increase R and D and the flow of new drugs as a result of increased sales revenue (dynamic efficiency)⁶.

A common objection to differential pricing is that it 'shifts costs' between low- and high-priced markets (see ref. 7, for example). But this argument implicitly assumes that the joint costs of R and D should be allocated equally to all users and/or that manufacturers engage in cost-plus pricing, such that if some consumers pay less, others automatically pay more. But, if markets are separate, manufacturers set the price for each market based on local conditions, irrespective of prices elsewhere. Thus prices would not automatically fall in high-priced markets such as the United States if low-priced markets were to pay more. It is true that if manufacturers were required to charge a uniform price worldwide, prices might drop in the United States because the single price would be based on a weighted average of price elasticities in all the major markets. However, this could be viewed as 'free riding' of high-income, price-insensitive countries on price-sensitive, lower-income countries, and not as the elimination of cost-shifting.

Implementing differential pricing

Although there is widespread support for differential pricing of medicines used to treat HIV/AIDS, tuberculosis and malaria in the lowest-income countries, there is no consensus on applying differential pricing more generally to other drugs and to middle-income countries, or on appropriate benchmark prices and differentials for different countries. Setting benchmark prices based on costs is unworkable because accounting costs do not capture all relevant R and D costs - including failures and the necessary return on funds invested. Moreover, setting prices based on costs creates perverse incentives for producers to inflate costs. More generally, achieving differential pricing through regulation would be vulnerable to political pressures, because underpricing immediately benefits current consumers, but its negative effect on the flow of new drugs is not evident for 8-12 years and will be hard to attribute to specific policies or politicians.

Fortunately, a regulatory structure is not needed to achieve appropriate price differentials. If markets are separate and reasonably competitive, the price differentials that manufacturers would voluntarily charge to maximize profits are similar to the Ramsey optimal price (ROP) differentials required to maximize welfare. Absolute prices may differ,

however, because ROP prices are intended to cover costs with a normal return on capital, whereas actual prices can yield positive profits or fail to cover costs, depending on market conditions, competition, regulation and other factors.

...

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

"Patent sense: Protecting intellectual property saves lives in the developing world"

Author(s): Herrling P

Reference: N/A 449:174-75.

<http://www.nature.com/nature/journal/v449/n7159/full/449174a.html>

Published Abstract: Many diseases are endemic in the developing world, yet for a number of these there are few safe and effective treatments. This lack of medicines results from an industrial model that has been in place for more than 50 years. Basic scientific research carried out in the public sector is translated into life-saving medicines mainly by pharmaceutical companies. This is a lengthy, onerous and expensive process - taking about 15 years and costing hundreds of millions of dollars per drug - and comes with a high risk of failure. Nevertheless, more than 90% of new molecular entities discovered and developed as medicines between 1990 and 1999 originated from pharmaceutical companies^{1, 2}.

Drug firms may be the main source of new therapies, but they remain commercial entities that can invest the considerable resources required to translate basic science into an effective medication only when there is a reasonable chance of financial return.

There is little opportunity to get an adequate return on investment for infectious diseases such as tuberculosis (TB), dengue fever, malaria, leishmaniasis and African trypanosomiasis (sleeping sickness), which mainly affect people living in resource-poor regions. In other words, market mechanisms fail in these cases, and there is insufficient drug-discovery research and development (R and D) for these common infectious diseases.

No secrets

Some organizations interested in improving access to medicines in the developing world, such as Medecins Sans Frontieres and Oxfam, think that a major impediment to affordable medicines is the patent system. But this is not the case. This system protects intellectual property in countries whose economies are based, to a large extent, on innovation. A patent is defined as a grant by the state of exclusive rights for a limited time in respect of a new and useful invention. These rights usually imply that, for a limited time, only the innovator, or a person or entity licensed by the innovator, can sell products based on the invention. This offers the innovator an opportunity to recover the investment needed to develop the invention into a practical product. Without this incentive, important discoveries would never be developed into useful products. Modern patent law provides protection for 20-25 years, which should be compared with the 15 years, on average, needed for the discovery and development of a new drug. In return for these rights, the innovator discloses a description of the invention that allows other experts to reproduce the key

findings. This process is firmly based on the premise that knowledge is gained only through a full understanding and appreciation of previously published advances.

In the absence of a patent, the only way inventors can protect their inventions is through total secrecy, which is counter to furthering innovation, a fact often ignored by those who consider that patents prevent research. It is only when patents are used excessively to protect information - to the extent that researchers cannot use a patent-protected invention in their studies - that the system is a considerable barrier to further innovation. To prevent such abuse of patents, several countries have implemented the 'research exemption', which allows scientists to use patent-protected technology freely for their research provided they do not exploit it commercially. In light of these issues, the protection of intellectual property with patents is crucial for pharmaceutical companies to discover and develop new drugs for the developing world.

...

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

"Potential impact of antiretroviral chemoprophylaxis on HIV-1 transmission in resource-limited settings"

Author(s): Abbas UL, Anderson RM, Mellors JW

Reference: N/A 2(9):e875.

<http://www.plosone.org/article/fetchArticle.action?articleURI=info%3Adoi%2F10.1371%2Fjournal.pone.0000875>

Published Abstract: *Background* The potential impact of pre-exposure chemoprophylaxis (PrEP) on heterosexual transmission of HIV-1 infection in resource-limited settings is uncertain. *Methodology/Principle Findings* A deterministic mathematical model was used to simulate the effects of antiretroviral PrEP on an HIV-1 epidemic in sub-Saharan Africa under different scenarios (optimistic, neutral and pessimistic) both with and without sexual disinhibition. Sensitivity analyses were used to evaluate the effect of uncertainty in input parameters on model output and included calculation of partial rank correlations and standardized rank regressions. In the scenario without sexual disinhibition after PrEP initiation, key parameters influencing infections prevented were effectiveness of PrEP (partial rank correlation coefficient (PRCC) = 0.94), PrEP discontinuation rate (PRCC = -0.94), level of coverage (PRCC = 0.92), and time to achieve target coverage (PRCC = -0.82). In the scenario with sexual disinhibition, PrEP effectiveness and the extent of sexual disinhibition had the greatest impact on prevention. An optimistic scenario of PrEP with 90% effectiveness and 75% coverage of the general population predicted a 74% decline in cumulative HIV-1 infections after 10 years, and a 28.8% decline with PrEP targeted to the highest risk groups (16% of the population). Even with a 100% increase in at-risk behavior from sexual disinhibition, a beneficial effect (23.4%-62.7% decrease in infections) was seen with 90% effective PrEP across a broad range of coverage (25%-75%). Similar disinhibition led to a rise in infections with lower effectiveness of PrEP (50%). *Conclusions/Significance* Mathematical modeling supports the potential public health benefit of PrEP. Approximately 2.7 to 3.2 million new HIV-1 infections could be averted in southern sub-Saharan Africa over 10 years by targeting PrEP (having 90% effectiveness) to those

at highest behavioral risk and by preventing sexual disinhibition. This benefit could be lost, however, by sexual disinhibition and by high PrEP discontinuation, especially with lower PrEP effectiveness (≈50%).

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

"Susceptibility of human female primary genital epithelial cells to herpes simplex virus, type 2 and effect of TLR3 ligand and sex hormones on infection"

Author(s): MacDonald EM, Savoy A, Gillgrass A, et al

Reference: N/A Epub ahead of print.

<http://www.bioreprod.org/cgi/content/abstract/bioreprod.107.063933v1?ct=ct>

Published Abstract: Genital epithelial cells are the first line of defense that sexually transmitted viruses encounter. The mechanism of viral pathogenesis in these cells is not well understood. Here, we show that a primary cell culture model from human reproductive tract tissues can be used as a novel ex-vivo model to examine the interaction of Herpes simplex virus, type 2 (HSV-2) with female genital mucosa. Confluent, polarized primary cultures of human endometrial and cervical epithelial cells (ECs) were established and shown to be free from any significant contamination of any other cell type. Both endometrial and cervical ECs were found to be highly susceptible to HSV-2 infection. The kinetic of infection was similar to in vivo infection, with earliest viral shedding seen at 18 hours post-infection. Primary EC monolayers could be infected both apically and basolaterally, but preferential viral shedding was seen on the apical side of cells. Following treatment of the monolayers with Poly (I:C), an innate immune activator that acts via TLR3, viral shedding was reduced significantly, comparable to levels seen when anti-viral formulation, acyclovir, was used. Treatment of epithelial and stromal co-cultures with estradiol increased HSV-2 infection in endometrial epithelial cells, but viral shedding decreased following treatment with progesterone. To the best of our knowledge, this is the first study that examines the interaction of primary human female genital epithelial cells with HSV-2, using an ex-vivo culture model. The results provide valuable information regarding the susceptibility of women's genital epithelial cells to HSV-2 and the ability of innate immunity and hormones to modify this susceptibility.

"The dynamics of intergenerational sexual relationships: the experience of schoolgirls in Botswana"

Author(s): Nkosana J, Rosenthal D

Reference: N/A 4(3):181-7.

<http://publish.csiro.au/?paper=SH06070>

Published Abstract: *Background:* Studies conducted in several sub-Saharan African countries have revealed that women and girls engage in intergenerational sexual relationships without the protection of condoms, giving cause for concern about HIV transmission. These relationships often occur against the girls' will and for many reasons, including reasons associated with subsistence. However, some young women do act as active social agents who rationally

engage in intergenerational sexual exchanges oriented towards consumption. The present study examines the dynamics of intergenerational sexual relationships among schoolgirls in Botswana. *Methods:* In-depth interviews were conducted with 15 schoolgirls who were currently in an intergenerational sexual relationship. The social, cultural and economic factors that cause young girls to engage in these relationships and how intergenerational sex contributes to unsafe sexual practices were examined. *Results:* The findings revealed that not all girls were passive and controlled by their older sexual partners. Some derived pleasure, enjoyment, love and equal partnership in these sexual relationships. They displayed a capacity to take charge of their own sexual lives by insisting on and engaging in safe-sex behaviours. Another set of girls had little or no decision-making power. Their relationships with older boyfriends were characterised by coercion and manipulation. Negotiation for condom use was difficult for this group. *Conclusions:* Effective policy and practice can be informed by the findings, leading to a reduction in HIV transmission as a result of intergenerational sex. In particular, the study has drawn attention to girls who are able to assert themselves within intergenerational sexual relationships and successfully negotiate safe sex. These strategies can be incorporated in programs to assist girls who face challenges and difficulties in negotiating safe sex with older men.

"The role of a regular sex partner in sexually transmitted infections and reinfections: results from the study of female entertainment establishment workers in the Philippines"

Author(s): Chiao C, Morisky DE

Reference: N/A 34(8):534-40.

http://www.ncbi.nlm.nih.gov/sites/entrez?orig_db=PubMed&db=PubMed&cmd=Search&term=Sexually%20Transmitted%20Diseases%5BJour%5D%20AND%2034%5Bvolume%5D%20AND%208%5Bissue%5D%20AND%20534%5Bpage%5D%20AND%202007%5Bpdat%5D

Published Abstract: OBJECTIVE: The main objective of this study is to understand the association between living with a regular sex partner, risk-taking behaviors, and one's history of sexually transmitted infections (STIs). METHODS: Data on sexual behavior and STI histories were obtained from 876 Filipina entertainment establishment workers (FEEWs) through a large-scale participatory research survey. RESULTS: About one-third of FEEWs live with a regular sex partner. Single FEEWs are significantly more likely than partnered FEEWs to engage in commercial sex. Being single, engaging in commercial sex, and using condoms inconsistently, in turn, are significantly associated with a positive STI history. CONCLUSION: These results suggest that living with a regular sex partner is an independent and protective factor against having an initial STI and subsequent reinfection. Programmatic strategies aimed at reducing STIs among entertainment establishment workers through promoting safer sex behaviors could potentially benefit by including a component that addresses sexual networks.

[Return to Table of Contents](#)

4. EPIDEMIOLOGY

"Researchers say Africa's declining AIDS prevalence dangerous"

Date: 18 September 2007

Source: *Xinhua News Agency*

<http://in.news.yahoo.com/070918/43/6kvt7.html>

Researchers have expressed fears that reducing HIV/AIDS incidences in Africa is an indication that more people are succumbing to the disease and may not be a result of effective campaigns to reduce the number of new infections. The marked reduction in HIV/AIDS prevalence can only be a result of many deaths from the disease because there is no indication that many more people have been treated while new incidences of infections have continued to soar.

According to Joachim Osur, senior reproductive health expert with IPAS, an international organisation specialising on women's health issues, the reductions of HIV/AIDS prevalence reported in Kenya, Uganda and Rwanda is not good news.

In August, Kenya reported that HIV/AIDS prevalence rate dropped from 6.1 percent in 2006 to 5.1 percent in 2007 while new infections declined from 60,000 to 55,000 in that period. The figures show that at least 151 Kenyans get infected with the virus every day. The number of those who died of the disease doubled the number of new infections while 53,000 more were saved from death due to their access to treatment.

At a reproductive health conference convened by an alliance of east African journalists over the weekend, Osur said, 'The reducing HIV/AIDS prevalence means many infected people are dying from the disease. It does not mean the situation is getting better.' Unity Media for Social Change (MESUC), an association of east African journalists, convened the conference with the support of the Commonwealth Secretariat in London, to encourage regional policy debates around reproductive health issues.

Patrick Orege, former director of Kenya's National Aids Control Council (NACC), told reporters at the conference new infections continue to spiral among adolescents and women but policies have failed to address issues of increasing treatment.

HIV/AIDS prevalence is measured by the number of people suffering from the disease within a particular locality. Uganda has reduced its prevalence rate by nearly 70 percent since the 1990s to the current 6.6 percent of the national population. UN Aids Agency (UNAIDS) has attributed the fall in HIV/AIDS prevalence to 'specific interventions' but warns that the failure to distribute life prolonging antiretroviral drugs remains a challenge in Africa. UNAIDS says in southern and eastern Africa, serious AIDS epidemics will most probably continue for some time.

Arthur Okwemba, a Kenyan media analyst, said that African governments should not rely on falling prevalence to measure successes in the war against HIV/AIDS. 'We should not rely on prevalence because of its volatility; we need to move to HIV/AIDS incidence studies to determine the number of new infections from every locality,' he said.

[Return to Table of Contents](#)

5. OTHER PREVENTION APPROACHES

"Medical mystery's unravelling will aid research"

Date: 20 September 2007

Source: *Globe and Mail (Canada)*

Author(s): Stephanie Nolen

<http://www.theglobeandmail.com/servlet/story/RTGAM.20070920.wblood20/BNStory/specialScienceandHealth/?page=rss&id=RTGAM.20070920.wblood20>

The volunteers were healthy - Pontiano Kaleebu knew they were healthy. The Ugandan microbiologist could tell that there was nothing wrong with the people who came to his clinic in Entebbe to volunteer to test an HIV vaccine. They felt and looked perfectly well.

But when he screened their blood for markers such as the number of white blood cells, dozens and dozens of would-be volunteers failed the tests. According to the results, they were "sick" and he had no choice but to turn them away - a professional loss, because it's never easy to recruit volunteers to test a product that sounds as scary as an AIDS vaccine. It was also a personal frustration, because Dr. Kaleebu, a widely respected researcher, was certain there was nothing wrong with them.

As it turns out, there wasn't, and unravelling that medical mystery may open the door to faster, more precise research into the treatment and prevention of the biggest killers in the hardest-hit regions.

Until now, researchers in Africa have used "reference ranges" - what are deemed "normal" levels of components of a person's blood - based on North Americans and Europeans. But healthy Africans, a new study shows, have different levels of white blood cells and other blood components. That shouldn't be a surprise, the doctor points out; the only shock is that it took this long for anyone to map out what's "normal" in Africa.

Dr. Kaleebu was part of a team that screened 5,500 clinically healthy, HIV-negative volunteers at a dozen sites across Africa, looking at blood chemistry and kidney and liver function, to develop the new reference ranges. The work was a partnership between the International AIDS Vaccine Initiative, for which Dr. Kaleebu is an investigator, the U.S. military's AIDS research program, and the U.S. Centers for Disease Control and Prevention.

While it is not possible to talk about values that are standard for the people in all 53 sub-Saharan African countries, the results of this two-year study do show that adults in Kenya, Zambia, Uganda and Rwanda have in common some differences from the Western values, including lower levels of lymphocytes, neutrophils - cells that "eat" anything they find that shouldn't be there - and red blood cells. They also had higher levels of eosinophils, which fight infection by parasites.

The findings are important for more than just recruiting volunteers to test AIDS vaccines - they will also be used in trials for treatments of a variety of infectious diseases, including malaria and tuberculosis. Using the results, researchers will now be able to monitor more accurately how volunteers in a trial are doing when they are taking a medication or vaccine. For example, a participant's red blood cell count might show up as "low" and cause worry, but compared against the new range, the cell count would not be deemed a concern. It will also give the researchers a better handle on how effective a treatment is.

Mark De Souza, international lab manager for the U.S. military HIV program, said that in one vaccine trial in Uganda, his staff screened out 58 per cent of potential participants because they had "abnormalities" based on the Western ranges. But when the volunteers were reassessed using values localized for the trial site, the screen-out rate was only 23 per cent, he said. "We were turning away heaps of healthy people," he said in a telephone interview from Bangkok.

There are genetic and environmental factors behind the differences. Compared with people in the West, Africans more commonly have parasites, or anemia, or some level of malaria exposure, which would cause them to test as unhealthy by the Western values even though they are well within the range of normal in their community, explained Pat Fast, the New York-based director of medical affairs for IAVI.

This does raise the question of whether the new reference ranges normalize conditions that are in fact the result of poor access to health care, a potential problem that all the researchers acknowledged, but they said the ranges are a first step toward improved care.

"Maybe if we completely revolutionized the health system, those values would be different," Dr. Fast said. "But it's not within our power to do that ... these people are living their lives and I bet most of them could out-work me."

The goal is to find a vaccine that is safe for people in this environment, and so it is crucial to test in their environment, she said. "It's important as much as possible to shift our locus to the countries we are trying to develop the vaccine for, to shift the way we think, the way we measure."

The new reference ranges may prove particularly relevant to AIDS treatment. Access to anti-retroviral drugs is increasing rapidly in Africa, which is home to 75 per cent of people with HIV. Drawing on Western experience, African patients are typically told to start AIDS treatment when their CD4 count level - a measure of the immune system - drops below 200. But if "normal" is already lower, treatment should perhaps be starting sooner. "A small shift in that curve could really change when you start treatment," Dr. Fast said. "You have to understand the normal before you start to understand disease."

"4 winners of Lasker Medical Prize"

Date: 16 September 2007

Source: *The New York Times*

Author(s): Lawrence K Altman

http://www.nytimes.com/2007/09/16/health/16lasker.html?_r=3&adxnnl=1&oref=slogin&adxnnlx=1190030774-R035c9uSEmS2biXT+GyHfg&oref=slogin&oref=slogin

Two surgeons who developed prosthetic heart valves that have prolonged the lives of millions of people are among the winners of this year's Lasker awards, widely considered the nation's most prestigious medical prizes. Drs. Alain Carpentier, 74, of the Georges Pompidou hospital in Paris, and Albert Starr, 81, of the Providence Health System in Portland, Ore., are among three American and one French scientists to win the awards, the Albert and Mary Lasker Foundation announced yesterday.

The third, Dr. Ralph M. Steinman, 64, of Rockefeller University in Manhattan, discovered a cell that starts a cascade of immune responses that defend the body against microbes. The cell is now the basis of experimental therapies for cancer and many other diseases. The fourth winner, Dr. Anthony S. Fauci, 66, is an internationally known immunologist who is being honored as the principal architect of two major Bush administration programs: the President's Emergency Plan for AIDS Relief, or PEPFAR, and Project Bioshield, which seeks to improve countermeasures against potential bioterror agents.

Dr. Fauci, who has directed the National Institute of Allergy and Infectious Diseases since 1984, marshaled scientific evidence to construct the United States' responses to these two global crises. The Lasker Foundation also cited Dr. Fauci for his role "in explaining issues of great concern like the science behind emerging biological hazards" to the public.

Mechanical heart valves did not exist 50 years ago. But the valves developed by Drs. Starr and Carpentier and then by others have made such replacements the second most common heart operation in this country, after coronary bypasses. An estimated four million valve operations have been performed worldwide on patients of all ages, and about 90,000 are performed in the United States each year. Valves control the flow of blood through the chambers of the heart. The valves can become damaged from long-term complications of infections, rheumatic fever and birth defects.

In 1960, Dr. Starr, working with the late Lowell Edwards, an engineer, implanted the first successful artificial heart valve. The patient died 10 years later after falling from a ladder. Earlier, Dr. Starr and other surgeons and engineers had tested valves designed to mimic the mitral valve's natural leaflets. (The mitral valve is situated between the upper and lower chambers of the left side of the heart.) But the devices failed because blood clots commonly formed, often leading to strokes.

Dr. Starr and Mr. Edwards chose a different design - a free-floating ball inside a cage that resembled a bottle stopper patented in 1858 - that hardly resembled a real heart valve. To help prevent strokes and other complications, they prescribed long-term anticoagulant drugs. The two scientists and other researchers also went on to develop newer valves with leaflets instead of a caged ball.

Mr. Edwards founded what is now Edwards Lifesciences of Irvine, Calif., to make the valves. It was a time when the Food and Drug Administration did not regulate devices. Because the inventors wanted accurate information about the safety and effectiveness of their valve, they created what the Lasker Foundation said was the first clinical-research tracking system for long-term follow-up of patients carrying implanted medical devices. The researchers restricted sale of the valve to medical centers specializing in heart surgery. The centers, in turn, reported any adverse reactions. A few among the initial recipients of the valves lived for at least 40 years with those valves, the foundation said.

In part to overcome the need for anticoagulant drugs, Dr. Carpentier began research on use of human cadaver valves and adapting pig valves for human use in 1964. He also earned a Ph.D. at the University of Paris to learn ways to strengthen animal valves to increase their durability. Dr. Carpentier found that a liquid chemical, glutaraldehyde, was better than other substances in sterilizing the tissue, reducing its propensity to cause adverse immunologic reactions and lengthening the valve's use. He also combined the animal tissue with a Teflon coating to create a device that could be produced in large amounts and kept on hospital shelves and that can avoid the need for anticoagulant drugs. Animal tissues account for an increasing percentage of valve replacements that almost equals mechanical ones, the

Lasker Foundation said. Dr. Carpentier went on to devise a ring that stabilizes and reshapes the area around the damaged valves so they can be repaired, not replaced.

In the 1970s, when most scientists were studying how the body reacted after an invasion by a microbe, Dr. Steinman began focusing on the initial steps of invasion. He discovered a rare cell in mouse spleens that moved in a distinctive way under laboratory conditions. The cell acted differently from other immune cells. For example, long projections emerged from the cells and floated before they retracted, creating a starlike pattern. He named them dendritic cells after the Greek word for tree. Although dendritic cells comprise only 1 percent of mouse spleen cells, Dr. Steinman found that they were the most powerful cell in priming the immune system. The dendritic cell can adjust the body's defenses by stimulating different T immune cells.

"No one had anticipated that any cell could so efficiently goad T cells into action," said Dr. Joseph L. Goldstein, the chairman of the Lasker jury and a Nobel laureate from the University of Texas Southwestern Medical Center in Dallas.

Dr. Steinman found that as dendritic cells mature, they migrate from the skin and other tissues to nearby lymph nodes. He and other scientists found that dendritic cells provide a safe haven for the AIDS virus and can transmit it to lymph nodes, helping to spread H.I.V. instead of killing it.

Scientists have found ways to produce large numbers of dendritic cells and are testing their use among cancer patients in 70 trials, Dr. Goldstein said. Scientists are also exploring use of dendritic cells for allergies, autoimmune diseases and in preventing rejection of transplanted organs and tissues.

Dr. Steinman and Dr. Fauci will each receive \$150,000 and Dr. Starr and Dr. Carpentier will each receive \$75,000.

[Return to Table of Contents](#)

6. ANNOUNCEMENTS

1ST ANNUAL AIDS RESEARCH CONGRESS OF IRAN: CALL FOR ABSTRACTS

<http://www.aarci.org/abstract-submissions-online.php>

The aim of the congress is to present new research and to discuss and exchange innovative topics in HIV/AIDS. We are confident that many valuable presentations, lectures and discussions will be beneficial to us all. The congress will cover all topics of major interest and the latest advances in the field.

1. Clinical Manifestation and Diagnosis of HIV/AIDS
2. HIV/AIDS Therapy
3. Information and Education about HIV/AIDS
4. HIV/AIDS Prophylaxis
5. HIV/AIDS and Society
6. HIV/AIDS and Addiction
7. HIV/AIDS and Family

8. HIV/AIDS and Other Related Aspects

Deadline for abstract submission: September 22, 2007(31 Shahrivar 1386).

AIDS VACCINE 2007: AN ADVOCATES' (OPINIONATED AND SELECTIVE) MEETING REPORT

http://aidsvaccineclearinghouse.org/conference/vaccine_seattle_2007.htm

This year's AIDS Vaccine Conference didn't get much attention from mainstream media. A handful of newspapers from Seattle, where the meeting was held, published broad articles peppered with familiar sound bites: an AIDS vaccine is, potentially, a critical tool for ending the epidemic; the first data from test-of-concept trials will provide important insights for the field; enduring scientific challenges mean that we are still many, many years from having a candidate that approaches sterilizing immunity.

Notably, some of these well-known themes were packaged under new headlines. One Seattle Times article ran with a headline which suggested that the focus for AIDS vaccines had shifted to "stopping transmission." This refers to the hope that a vaccine which lowered viral load could reduce the likelihood that someone who was immunized and later became HIV positive would pass the virus to his or her partner. Has the field really shifted its vaccine-related goals to reducing infectiousness? Not yet. (This was one of the topics on the agenda at a meeting on vaccine endpoints that AVAC attended in Paris this month). It is critical that we track, and work together to influence the ways that media outlets package and, inevitably, simplify complex messages about what we can and cannot expect from current generations of AIDS vaccines.

Turning away from the headlines, to the Seattle conference itself. AVAC, along with nearly a thousand other participants attended sessions which contained far more detail than any of the news coverage. For all the added specificity, the themes we heard were, by and large, familiar. The major sessions included reports on work on antibodies, variations on viral vector based candidates with no major breakthroughs to speak of. This isn't surprising-it's the reality of the slow and steady chipping away at major scientific challenges that the field has committed itself to over the past few years.

In this meeting report, we do a whirlwind tour through some of the major areas discussed at the meeting and then zero in on the two talks that we think defined the meeting by grappling, head on, with challenges that all of us in the field of AIDS vaccines are going to face in the coming months.

EDITOR'S NOTE: The full AVAC report is available at the above website.

CONFERENCE ON RETROVIRUS AND OPPORTUNISTIC INFECTIONS (CROI): CALL FOR ABSTRACTS

www.retroconference.org

The mission of the Retrovirus Conference is to provide a forum for basic scientists and clinicians to present, discuss, and critique their investigations into the biology and epidemiology of human retroviruses and the diseases they produce with the ultimate goal of translating laboratory and clinical research into progress against the AIDS epidemic.

CALL FOR ABSTRACTS

We are now accepting abstracts for CROI 2008 which will take place at the Hynes Convention Center, Boston, Massachusetts from February 3-6, 2008. The deadline for abstract submission is Wednesday, October 10 at 5:30 pm EDT.

Please visit the conference web site, given above, for the submission instructions and subject categories.

ELTON JOHN AIDS FOUNDATION GRANT AWARD TO IRMWG

<http://www.ejaf.org/pages/grants/2007.html>

Congratulations to the International Rectal **Microbicide** Working Group (IRMWG) for their grant award from the Elton John AIDS Foundation! Below is a description of the continual efforts of the IRMWG. To see a full list of the awards, please visit the above website.

AIDS Foundation of Chicago, Chicago, IL \$10,000

The AIDS Foundation of Chicago has convened the International Rectal **Microbicide** Working Group (IRMWG) to raise awareness and advocate for the development of safe and effective rectal **microbicides**. **Microbicides** are anti-HIV gels, foams and creams that are applied vaginally or rectally to reduce the risk of HIV transmission during intercourse. Rectal **microbicide** research has been underfunded because of its taboo nature, although it could be used to in conjunction with condoms or independently to reduce the risk of HIV transmission. The IRMWG currently has 400 members from 35 countries working to advance research and advocacy related to the development of rectal **microbicides**.

M2008 ABSTRACT DEADLINE - 30 SEPTEMBER 2007

<http://www.microbicides2008.com/main.asp>

Abstracts are invited under the following themes in the different tracks of M2008:

TRACK A Basic Sciences

- A.1 Sexual transmission of HIV: New findings
- A.2 Innate and adaptive immunity: Role in HIV mucosal acquisition and control
- A.3 Latest developments in biomarkers and in vitro models of efficacy and safety
- A.4 Animal models: Current status and latest data
- A.5 Emerging **microbicide** candidates

A.6 Biological role of STIs in HIV transmission

A.7 Formulation and delivery strategies

TRACK B Clinical

B.1 Empirical findings of Phase I and II clinical trials of new **microbicide** products including rectal microbicides

B.2 Adherence and compliance to trial procedures and product use: measurement, strategies, impact on retention and recruitment
B.3 Effectiveness trial status and presentation of baseline participant data

B.4 Alternative **microbicide** strategies and the role of STIs in HIV prevention

B.5 Barrier method strategies

B.6 Testing methods/ algorithm for measuring HIV end-points including HIV incidence

B.7 Alternative **microbicide** efficacy trials designs

TRACK C Socio-behavioural

C.1 Acceptability: initiation and use of various **microbicide** formulations and delivery mechanisms in different geographic settings and populations. Discussion of theoretical frameworks to examine acceptability encouraged

C.2 Adherence: including development of adherence-related measures, triangulation of data collection methods and/or analysis procedures, use of social science theory and/or research methods to boost adherence within trials - or in future service delivery settings

C.3 Rectal **Microbicides**: prevalence of anal sex in men and women; acceptability of **microbicide** gel for rectal use

C.4 Male Involvement in **Microbicide** Research: partner consent for trial participation; male acceptability of **microbicides**; influence of trial participation and **microbicide** use on sexual partnerships
C.5 Social Science research on Standards of Care: participant and/or community research on attitudes towards SOC levels, research on ethics and informed consent issues

C.6 Supporting Clinical trials: social science research on recruitment, informed consent, retention, assessing adherence, closing out trials

C.7 Access to **Microbicides** beyond Clinical Trials: focus on how providers, product costs and service delivery mechanisms may influence **microbicide** accessibility, acceptability and use in a post-marketing situation. Drawing lessons from other HIV prevention research studies

Track D Policy, Advocacy and Community

D.1 Policy

Policies that support **microbicide** development and research, and access. Involvement of positive people and their role in developing and implementing policy (and research) Standards of prevention, treatment and care for trial participants - policy issues

D.2 Advocacy:

Microbicides advocacy aimed at a variety of stakeholders-women, policy makers, trial communities, donors, people with HIV, etc. Preparing stakeholders for research results Ensuring rapid access to proven **microbicide** products Standards of prevention, treatment and care for trial participants - advocacy issues mobilising relevant partners (policy makers, donors, agencies, media etc) to support

D.3 Community:

Community mobilisation, preparedness and involvement - creating effective partnerships community Advisory Boards Defining, understanding and involving the community Mobilising communities for **microbicides** Working with the

media

POPULATION COUNCIL'S SANDRA G. GARCIA IS RECOGNIZED FOR EXCELLENCE IN SEXUAL AND REPRODUCTIVE HEALTH RESEARCH

Sandra G. Garcia, Sc.D., the Population Council's director of reproductive health for Latin America and the Caribbean (LAC), has been awarded the Guttmacher Institute's Darroch Award for Excellence in Sexual and Reproductive Health Research. Garcia is responsible for developing, coordinating, implementing, and supervising Council LAC research and projects in four priority areas: family planning/contraception, maternal health, reducing unsafe abortion, and sexually transmitted infections (STIs).

Garcia's research documenting abortion-related knowledge, attitudes, and practices in Mexico played an important role in the country's recent decision to legalize first-trimester abortion. Her collaboration with local nongovernmental organizations, universities, professional associations, and the Mexican government helped bring about this groundbreaking legislation. Her more than 30 peer-reviewed publications cover a wide range of topics, including applied research on new reproductive technologies, surveys of women's knowledge about emergency contraception, programs to prevent STIs among newborns, and innovative methods for measuring abortion incidence.

"Sandy is highly deserving of this award," said Sharon L. Camp, Guttmacher's president and CEO. "Her publication record and her ability to foster excellence among her research team make it clear that she has an absolute commitment to improving sexual and reproductive rights through sound research that can be easily applied to public policy."

Garcia, originally from Canutillo, Texas, received her master's and doctor of science degrees in population and international health from the Harvard School of Public Health. She has been with the Population Council since 1999.

The Darroch Award was established in 2005 to recognize excellence among sexual and reproductive health researchers who are in the early or middle years of their career. It is named for Jacqueline E. Darroch, Ph.D., former senior vice president for science at Guttmacher, whose three decades at the Institute exemplified rigorous and innovative work on sexual and reproductive health issues, and commitment to the practical application of research to policy and programs.

SOCIETY FOR AIDS IN AFRICA: CALL FOR MEMBERS

www.saafrica.org/registernow.php

The Society for AIDS in Africa (SAA), is currently calling for interested, dynamic, dedicated and proactive members of the larger society to join as members. It is doing this as part of a strategic reengineering process that the Society is undergoing. Membership is open to scientists, people living with HIV and AIDS, researchers, advocates, organizations and workers in HIV and AIDS, sexually transmitted infections, and other related areas. Membership is free till December 2007.

The Society for AIDS in Africa is a Civil Society Organization and has been in existence for over 15 years. Its goal is "to mitigate the impact of HIV and AIDS in Africa".

It has three major objectives:

- 1) Promotion of policy environment
- 2) Promotion of research
- 3) Knowledge and information sharing on HIV/AIDS and other STIs

The Society is the organizer of the International Conference on HIV/ AIDS and Sexually Transmitted Infections in Africa (ICASA).

For more information, please visit the society's website at www.saafrica.org/registernow.php to fill an online application form. Additional information is also available through the contact below.

SAA Secretariat Abuja Nigeria

Plot 823 Ralph Shodeinde Street

Central Business District

+ 234 96720215

+ 234 8055354791

+ 234 8034941221

lucbodea@saafrica.org

seun@saafrica.org

[Return to Table of Contents](#)