



ALLIANCE FOR MICROBICIDE DEVELOPMENT

29 June 2007, Volume 8, Number 25

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!

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1. MEDIA COVERAGE OF MICROBICIDES

"Don advocates clinical trials for breakthroughs"

Date: 26 June 2007

Source: *This Day (Lagos)*

Author(s): Deji Elumoye

<http://allafrica.com/stories/200706270377.html>

A university don and Chairman, University of Nigeria Teaching Hospital Resource Foundation (UNTHRF), Dr. (Mrs.) Ifeoma Okoye has advocated the use of clinical trials in Nigeria as a way of having break through in medical researches, saying, 'benefits of ethically conducted trials, in the vast majority of studies, far outweigh the risks'.

Speaking with newsmen in Ikeja, Lagos, Okoye, who doubles as the African Coordinator of Collaborative for Institutional Training Initiative (CITI) explained that clinical trials is dedicated to 'saving the lives through the encouragement of public-private partnerships'.

While denying that all clinical trials use human beings as guinea pigs, Okoye noted that clinical trials that are well-designed and ethically-executed are the best approach for the society. She explained that trials are based on human research subjects, good clinical practice, health information privacy and security, responsible conduct of research, and lab animal welfare.

"Though human being may be used in extreme cases, we can not shy away from the fact that clinical trials are the best for our research system", she said. She highlighted some of the benefits to include; new research treatments before they are widely available for life threatening conditions such as HIV and cancer; obtain expert medical care and additional diagnostic testing that would otherwise be unaffordable at leading health care facilities during the trial; provide opportunity for patients to make a contribution to the health of other people; and improving the health of future generations among others. She further explained that well developed and ethically conducted clinical trials can also benefit a developing nation like Nigeria in many ways, among which are provision of collateral social health services and data that will benefit entire society in health planning; determining disease prevalence and drug resistance patterns.

Others include enhanced economic activity for the general populace not participating in the trial; enhancing health-care research facilities and training of individuals in research ethics; as well as; long-term collaboration that embodies engagement with and a commitment to the population.

According to her, "the CITI initiative has expanded its training to include modules not only for medical sciences, but for social studies and humanities, for vet medicine, war veterans, and most recently is in the process of developing one for engineering disciplines".

She said clinical trials in Nigeria "would have impact on the ongoing clinical research activities, that would ultimately help in health programmes such as, roll back malaria', AIDS vaccine trials, **microbicide** trials, onchocerciasis trials, schistosomiasis trials, diabetes and breast cancer research. The potential political action to stop or limit clinical trials in Nigeria as a consequence of the outcry over the Pfizer / Kano trial would undoubtedly be very detrimental to the Nigerian people. So far, south Africa is the only African nation that has been involved in considerable pre-marketing clinical trials. Their experience so far has shown that funds allocated for clinical research has upgraded and improved the provision of health services by hospitals, and has also maintained doctors and paramedical personnel up-to-date with the development in health care, as well as provided better care to South African patients", Okoye emphasised.

To her, "Africa has a heavy burden of disease which are unique to our poor environment and which had been hitherto neglected by the global pharmaceutical industry. Due to the poverty status of the African nations, populations are mostly vulnerable and would need to be protected, thus the need to embark on massive sensitisation of the population alongside training of potential investigators in the region. By participating in clinical studies, the citizens of developing countries will gain greater knowledge about the process, have more frequent medical attention, and discuss more openly about any adverse event they may have experienced that could be related to the investigational product or other concomitant medications," she said.

"H.I.V. and AIDS: keep an eye on prevention"

Date: 25 June 2007

Source: *The New York Times*

Author(s): Adrienne Germain

http://www.nytimes.com/2007/06/25/opinion/l25aids.html?_r=1&oref=slogin

To the Editor:

Re "Two Cheers on Global AIDS" (editorial, June 18):

The G-8's 2005 commitment to universal access is not only about H.I.V.-AIDS treatment. The G-8 also committed to scaling up H.I.V. prevention, because we will never reach treatment goals unless we also prevent new infections.

Experts estimate that for every person in sub-Saharan Africa newly treated for AIDS last year, five more were newly infected. In sub-Saharan Africa, women shoulder a disproportionate number of these new infections, and their share is increasing in many other places around the world.

Effective prevention policies will require increased investment in sexual and reproductive health services that women use; comprehensive sexuality education that teaches young people to respect and protect each other; and **microbicides** and female condoms, which put the power of prevention in women's hands.

Adrienne Germain

President, International Women's Health Coalition

New York, June 19, 2007

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2. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

"AIDS in the third world: how to stop the HIV infection?"

Author(s): De Clercq E

Reference: N/A 69(2):65-80.

<http://lib.bioinfo.pl/pmid:17550059>

Published Abstract: Of the 38.6 million people living with HIV/AIDS globally, almost 25 million (65%) live in sub-Saharan Africa. Preventive strategies and measures fall short, often simply because they are not available or are largely male-controlled. A preventive HIV vaccine is still far away; hence the drive to develop alternative prevention technologies, such as **microbicides** and oral pre-exposure prophylaxis, that could be female controlled. There are, at present, twenty-two anti-HIV drugs which have been formally licensed for clinical use in the treatment of HIV infections (AIDS): zidovudine, didanosine, zalcitabine, stavudine, lamivudine, abacavir, emtricitabine, tenofovir, nevirapine, delavirdine, efavirenz, saquinavir, ritonavir, indinavir, nelfinavir, amprenavir, lopinavir, atazanavir, fosamprenavir, tipranavir, darunavir and enfuvirtide. These compounds, in combination, form the basis of HAART (highly active antiretroviral therapy), which has led to the development of a single daily pill existing of the combination of tenofovir disoproxil fumarate, emtricitabine and efavirenz, which has to be taken orally once daily for the treatment of AIDS. Beyond development of new drugs and clinical evaluation of existing medications, several companies within the pharmaceutical industry have established innovative policies that provide HIV medications at affordable prices in the least-developed countries. Reduced pricing is not alone a solution, and thus companies are actively working in partnership with the World Health Organization and other multinational groups to address roadblocks such as complex registration and procurement systems. Even in this period of successful anti-HIV therapy via HAART, a growing number of patients is cycling through the various remaining therapeutic options and are increasingly becoming dependent of the availability of newly developed anti-HIV agents. It is of concern that existing and future therapies will have to be effective against newly evolving (including drug-resistant) HIV variants in patients who currently face many years, if not decades, of chronic anti-HIV drug treatment. In spite of continuous long-term interventions to promote safer sexual behaviour, HIV prevalence is high and still rising in many parts of the world. The face of the epidemic is now black, female, young and poor..., and female controlled methods are urgently needed. Female controlled methods such as **microbicides** and cervical barrier methods provide hopeful perspectives when condom use is low due to social, cultural and/or economic factors, but, after all, the oral administration of a single daily pill would seem the most convenient way to prevent HIV infection, as its protective activity may be independent of the route of viral transmission.

"Determining the feasibility of utilizing the microbicide applicator compliance assay for use in clinical trials"

Author(s): Wallace AR, Teitelbaum A, Wan L, et al

Reference: N/A 76(1):53-56.

http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T5P-4NPHMT3-1&_user=10&_coverDate=07%2F31%2F2007&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C00050221&_version=1&_urlVersion=0&_userid=10&md5=e94b14a64d9de4e6e27c1d57fddc99c6

Published Abstract: *Introduction:* Participant's adherence to use of study product is a major concern in **microbicide** clinical trials, which can impact on proving product efficacy. In a previously described assay, single-use **microbicide** applicators exposed to the vagina were tested by spraying the applicator with trypan blue dye, resulting

in vaginal mucus staining on inserted applicators. As subjects in our Phase 3 trials return applicators only at quarterly visits, often mixing inserted and not-inserted applicators together in the same bag, cross-contamination could confound results. In addition, trypan blue is carcinogenic and thus potentially hazardous to technicians spraying daily. *Methods:* Applicators that were exposed to the vagina were placed in the same bag as unexposed applicators and shaken daily for up to 4 months. Validation was carried out in three clinical sites in South Africa. *Results:* Trypan blue was replaced with FD and C Blue #1 granular food dye. Cross-contamination did not occur, nor did the length of time affect reaction to dye. In South Africa, the assay was validated with an accuracy of over 95%. *Conclusion:* Applicator assay modifications render the test safe and suitable for use in clinical trials.

"Safety trial of the vaginal microbicide cellulose sulfate gel in HIV-positive men"

Author(s): Jespers V, Buve A, Van Damme L

Reference: N/A 34(7):519-22.

<http://www.stdjourn.com/pt/re/std/abstract.00007435-200707000-00018.htm;jsessionid=GFSVMpQW9KcJyKYDLGYjJ7w5wMsnhwWQKgpHG73ZLTpVrb9ymN2m!434772722!181195629!8091!-1>

Published Abstract: *Objective:* Cellulose sulfate (CS) is a promising vaginal **microbicide**. Because men will be exposed to the **microbicide** when engaging in vaginal intercourse, safety and acceptability need to be assessed in men. *Design:* This randomized double-blind phase I study assessed the safety and acceptability of seven consecutive daily doses of CS versus KY Jelly in 36 HIV-positive men. *Results:* No new or worsening of existing genital findings were observed during the follow-up examination. Mild genital symptoms were reported in 42% of CS users (itching, burning, tingling, testicular pain, dysuria, and warm or cold feeling) and 8% of KY Jelly users. *Conclusion:* CS gel applied to the penis was well tolerated in this HIV-positive male population. The itching and burning symptoms were not severe and can be explained by the preservative benzyl alcohol present in the CS gel.

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3. PUBLISHED RESEARCH: RELEVANT BASIC AND TRANSLATIONAL SCIENCE

"Effect of tenofovir on renal glomerular and tubular function"

Author(s): Christoph FA, Christen A, Zraggen S

Reference: N/A 21(11):1483-85.

<http://www.aidsonline.com/pt/re/aids/abstract.00002030-200707110-00014.htm;jsessionid=G13Yqvn3CFYhz1qRQxbx3vJZY0L0JqDXs35GCF70gGzgJmYNRLWJ!-1477679916!181195629!8091!-1>

Published Abstract: To evaluate tenofovir-related nephropathy, we quantified calculated glomerular filtration rates (GFR) and renal tubular function in 46 tenofovir-treated patients and 25 without tenofovir. We also analysed patients who stopped tenofovir for drug-related nephrotoxicity at our clinic. Tenofovir use combined with non-nucleoside reverse transcriptase inhibitors, but not with protease inhibitors, resulted in a significant increase in calculated GFR. Tenofovir use was associated with significantly lower phosphatemia and a marginally increased fractional excretion of uric acid, but no other signs of tubulopathy.

"Expression and function of bactericidal/permeability-increasing protein in human genital tract epithelial cells"

Author(s): Canny GO, Trifonova RT, Kindelberger DW, et al

Reference: N/A 194

<http://www.journals.uchicago.edu/JID/journal/issues/v194n4/36088/36088.html>

Published Abstract: Genital tract epithelia regularly encounter and adapt to the existence of bacterial pathogens. This study provides evidence that the endocervical and ectocervical epithelia of the human female genital tract express bactericidal/permeability-increasing protein (BPI). The constitutive expression of BPI was restricted to cell-bound protein and unaffected by human papillomavirus type 16/E6E7 immortalization and proinflammatory cytokine stimulation. Epithelial BPI was, in part, responsible for killing a commensal strain of *Escherichia coli*. The results of the present study suggest that BPI is tightly regulated and functionally expressed by epithelial cells in the female reproductive tract and may play a role in regulating bacterial colonization in the genital mucosa.

EDITOR'S NOTE: *The full text of this article can be found at the above website.*

"Maturation of blood-derived dendritic cells enhances Human Immunodeficiency Virus type 1 capture and transmission"

Author(s): Izquierdo-Useros N, Blanco J, Erkizia I, et al

Reference: N/A 81(14):7559-7570. Editorial commentary.

<http://jvi.asm.org/cgi/content/abstract/81/14/7559?etoc>

Published Abstract: Dendritic cells (DCs) are specialized antigen-presenting cells. However, DCs exposed to human immunodeficiency virus type 1 (HIV-1) are also able to transmit a vigorous cytopathic infection to CD4+ T cells, a process that has been frequently related to the ability of DC-SIGN to bind HIV-1 envelope glycoproteins. The maturation of DCs can increase the efficiency of HIV-1 transmission through trans infection. We aimed to comparatively study the effect of maturation in monocyte-derived DCs (MDDCs) and blood-derived myeloid DCs during the HIV-1 capture process. In vitro capture and transmission of envelope-pseudotyped HIV-1 and its homologous replication-competent virus to susceptible target cells were assessed by p24gag detection, luciferase activity, and both confocal and electron microscopy. Maturation of MDDCs or myeloid DCs enhanced the active

capture of HIV-1 in a DC-SIGN- and viral envelope glycoprotein-independent manner, increasing the life span of trapped virus. Moreover, higher viral transmission of mature DCs to CD4+ T cells was highly dependent on active viral capture, a process mediated through cholesterol-enriched domains. Mature DCs concentrated captured virus in a single large vesicle staining for CD81 and CD63 tetraspanins, while immature DCs lacked these structures, suggesting different intracellular trafficking processes. These observations help to explain the greater ability of mature DCs to transfer HIV-1 to T lymphocytes, a process that can potentially contribute to the viral dissemination at lymph nodes in vivo, where viral replication takes place and there is a continuous interaction between susceptible T cells and mature DCs.

"The safety of tenofovir disoproxil fumarate for the treatment of HIV infection in adults: the first 4 years"

Author(s): Nelson MR, Katlama C, Montaner JS, et al

Reference: N/A 21(10):1273-81.

<http://www.aidsonline.com/pt/re/aids/abstract.00002030-200706190-00006.htm;jsessionid=G15Npl1RyNvQpn9BQTNG2h9ckvs5fyNxyw9kcJnmfTTJt1bfk15!1354923979!181195628!8091!-1?index=1&database=ppvovft&results=1&count=10&searchid=1&nav=search>

Published Abstract: *Objective:* To characterize the safety profile of tenofovir disoproxil fumarate (DF) for the treatment of HIV infection in adults over the first 4 years of use. *Methods:* A tenofovir DF expanded access program (EAP) was initiated in 2001; safety data were examined from this program and from the manufacturer's database, which contained reports of all postmarketing adverse drug reactions received up to 30 April 2005. Specific analyses were performed to characterize the renal safety of tenofovir DF. *Results:* The EAP enrolled 10 343 patients; serious adverse events (SAEs) were reported in 631 (6%). A renal SAE of any type was observed in 0.5% of patients, and graded elevations in serum creatinine occurred in 2.2% of the patients evaluated. In a multivariate analysis, baseline risk factors for the development of increased serum creatinine on-study were elevated serum creatinine, concomitant nephrotoxic medications, low body weight, advanced age, and lower CD4 cell count. For postmarketing safety data (455 392 person-years of exposure to tenofovir DF) the most commonly reported serious adverse drug reactions were renal events, with a distribution by type similar to that observed in the EAP. Bone abnormalities were infrequently reported in either the EAP or the postmarketing safety databases. No new unexpected toxicities were identified in postmarketing safety surveillance. *Conclusions:* The data demonstrate a favorable safety profile for tenofovir DF in the treatment of adults with HIV infection. Risk factors for development of nephrotoxicity can be identified and may be useful in managing those patients at greatest risk.

"Transmitted HIV-1 drug resistance: are we seeing just the tip of an epidemiological iceberg?"

Author(s): Stekler J, Coombs RW

Reference: N/A 196:336-338.

<http://www.journals.uchicago.edu/JID/journal/issues/v196n3/38688/38688.html>

Published Abstract: (None)

Because of increasing recognition of HIV-1 drug resistance among antiretroviral (ARV)-naive individuals, national guidelines now recommend HIV drug-susceptibility genotyping before the start of HIV treatment (a moderate-strength recommendation based on expert opinion) and consideration of genotyping at the time of HIV diagnosis (an optional-strength recommendation based on expert opinion) [1]. In this issue of the Journal, Smith et al. [2] present data that further support the persistence of ARV drug-resistant HIV in seminal plasma and provide evidence for the horizontal transmission of HIV drug resistance in the absence of ARV therapy. Captain Edward John Smith ignored several warning about icebergs and went down with the RMS Titanic; are Davey M. Smith and colleagues giving us a warning about a metaphorical HIV drug-resistance iceberg that we should heed to avoid a similar fate?

The authors describe 5 recently infected subjects who had HIV with nonnucleoside reverse-transcriptase inhibitor (NNRTI) mutations that were detectable in both blood and seminal plasma by a population-based sequencing assay. In 1 subject, the NNRTI mutation persisted in seminal plasma for at least 1179 days after HIV infection. Although the study size is too small to draw definitive conclusions about differences in the persistence of resistance mutations between blood and seminal plasma, this analysis provides further evidence that, at least in some individuals, transmitted drug-resistant virus can persist for less than 2 years after HIV infection [3-6]. Additional longitudinal studies are needed to determine differences in the detection and persistence of HIV drug-resistance mutations in different compartments over time.

The impact of drug resistance on "transmission fitness" (i.e., the relative ability of viruses to infect susceptible hosts and to maintain a reproductive number less than 1, thus guaranteeing the continued transmission of drug-resistant virus) is another area in need of further study. In their study of partner pairs, Smith et al. found very similar drug-resistance patterns in the blood and seminal plasma of both the previously treated source and the ARV-naive recipient partner in transmission pair 1. This case is a counterexample to the supposition that different selection pressures exist between the blood and genital tract of individuals who receive ARV therapy [7, 8] and that HIV drug-resistance mutations may confer low transmission fitness, compared with wild-type virus, in individuals infected with a mixture of mutant and wild-type viruses [9-11]. Further study of transmission pairs is essential to assess whether the transmission of resistant virus is dependent on the quantity of virus in the genital tract, whether transmission fitness is correlated with the replication capacity of virus in the blood or genital tract, and what other factors may be associated with a relative advantage for the transmission of a drug-resistant virus.

On the population level, it is unclear whether ARV-experienced individuals represent the primary source of transmitted HIV drug resistance or whether secondary transmission occurs primarily from ARV-naive individuals (as is described for transmission pair 2) and which source contributes most to the forward transmission of drug-resistant virus [12]. Transmission of drug resistance from ARV-naive sources has been previously documented after mother-to-child [13] and heterosexual [14] transmission. It is intriguing to consider whether individuals with primary HIV infection (PHI) are not only more likely to transmit HIV infection [15] but also may contribute disproportionately to the transmission of HIV drug resistance [12]. HIV RNA levels in seminal plasma are highest during the first few months after HIV acquisition [16], and sexual transmission from source partners with PHI contributes to a significant proportion of overall HIV incident infections [15, 17-20]. If the risk of transmission of HIV drug resistance is associated with increasing HIV RNA levels in the genital tract, then perhaps this transmission risk provides an additional impetus for HIV prevention efforts

to identify individuals with acute HIV infection using pooled nucleic acid testing algorithms [21, 22]. Unfortunately, because the risk of HIV transmission likely affects the rate of transmitted HIV drug resistance and, conversely, HIV drug resistance likely affects the risk of HIV transmission, complex mathematical modeling will be required to more fully understand the population dynamics of HIV drug resistance [23, 24].

ARV resistance is an emerging issue in both resource-poor countries with limited ARV experience and industrialized nations in which ARVs have been used for less than 2 decades [25]. In countries with limited ARV experience, ARV rollout programs ideally should be coupled with HIV drug-resistance surveillance programs [26]. In industrialized countries, incomplete public health surveillance has left uncertainty about whether secular trends exist in transmitted HIV drug resistance (as reviewed in [27]). It is clear, however, that the number of persons infected with multidrug-resistant (MDR) HIV is increasing [27], and cases of extremely drug-resistant (XDR) HIV have been described in New York City [28] and, recently, in Seattle, Washington [29]. It is very likely that many cases of XDR HIV remain undiagnosed because of limited use of drug-resistance genotyping and that some diagnosed cases remain unreported outside of epidemiological surveillance studies. Given that population-based genotyping can only identify HIV drug-resistance mutations that occur in less than 10%-50% of the viral subpopulation [30-35], it is also likely that the prevalence of HIV drug resistance, MDR HIV, and XDR HIV would be significantly greater if more-sensitive assays were used for the detection of drug resistance [36, 37].

The clinical implication of transmitted HIV drug resistance detected by standard genotyping is not clear [27, 38-43]. However, the potential impact of primary drug resistance on disease progression and blunting of the response to initial ARV therapy suggest that hitherto-unseen hazards may be lurking below the therapeutic surface. If sensitive resistance assays become more widely available and are used without appropriate clinical validation, there could be some unanticipated consequences. For example, HIV care providers might avoid convenient first-line agents that require fewer pills and less-frequent dosing. This might lead to a decrease in adherence because of the greater complexity of initial ARV regimens. As a consequence, the best intentions could lead to a paradoxical increase in the prevalence of HIV drug resistance. Given the potential risks and lack of clear benefits, we should confirm that the use of highly sensitive resistance testing improves immunological and virological outcomes before a new standard of care is implemented. If there is in fact true equipoise about whether transmitted drug resistance affects clinical outcome, then it behooves investigators to design and support randomized clinical trials to validate the utility of highly sensitive resistance testing.

Ultimately, our therapeutic task is to stop HIV transmission as early as possible, to mitigate the transmission of drug-resistant HIV, and to avoid the epidemiological drug-resistance iceberg. Should we screen patients for high levels of genital HIV RNA and for viral resistance in genital secretions, to counsel patients about the potential risk for transmission of drug-resistant HIV? Should we be more diligent about prescribing ARVs with good penetration into genital fluids? Will the use of ARVs to prevent HIV transmission in serodiscordant couples decrease HIV transmission but eventually increase the risk of transmission of resistant virus? These and many other important questions remain unanswered but warrant further discussion and study.

EDITOR'S NOTE: The references for this article were quite numerous, so we refer the reader to the article, available at the above website, for the complete list.

4. EPIDEMIOLOGY

"Kenya says HIV/AIDS rate drops to 5.9 percent"

Date: 25 June 2007

Source: *Reuters*

<http://www.alertnet.org/thenews/newsdesk/L25725707.htm>

Kenya's AIDS rate has dropped to 5.9 percent and should fall further in coming years, but hundreds a day still die from it, authorities said on Monday.

"Although we have made impressive progress in fighting AIDS, we still face a big challenge ahead of us," minister of state for special programmes John Munyes told a news conference.

According to latest statistics from the state-run National Aids Control Council (NACC), Kenya's AIDS rate fell from 6.1 percent in 2004 to 5.9 percent of the east African nation's 35 million people the following year. Kenya aims to reduce AIDS to 5.5 percent by 2010. Officials cite better prevention, more widespread use of anti-retroviral drugs (ARVs), greater use of condoms and more responsible sex habits for the fall in infection rates.

"Of notable significance is the decline in new infections from 85,000 in 2004 to 60,000 in 2005 as well as the drop in HIV prevalence from 6.1 percent to 5.9 percent in the same period," NACC chairwoman Miriam Were added at the news conference.

Munyes, whose ministry works on health projects, said 315 Kenyans were dying a day from AIDS and AIDS-related illnesses. Kenya was home to about 1.2 million AIDS orphans, he added.

"Report examines trends in HIV prevalence in South Africa"

Date: 25 June 2007

Source: *Kaiser Daily HIV/AIDS Report*

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=45786

"National HIV and Syphilis Prevalence Survey, South Africa, 2006," Department of Health, South Africa: This new report, based on antenatal surveys conducted in all nine provinces in South Africa, finds national HIV prevalence among pregnant women was 29.1% in 2006, down from 30.2% in 2005. The report shows statistically significant declines in HIV prevalence among those under 20 years old, 15.9% to 13.7%, as well as ages 20-24, 30.6% to 28.0%. The report found no statistically significant changes among older age groups. The decline in prevalence among those under age 20 "implies a reduction in new infections (incidence) in the population," according to the report. "For the first time, the findings of this survey show evidence of a decline in HIV prevalence in South Africa after several years of relative stability," the report notes (South African Department of Health, Summary Report).

EDITOR'S NOTE: The full report can be found at <http://www.doh.gov.za/docs/hivsummary-f.html>

"Declining HIV infection rates among recently married Primigravid women in Pune, India"

Author(s): Gupte N, Sastry J, Brookmeyer R, et al

Reference: N/A Epub ahead of print.

http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=17577126&dopt=Abstract

Published Abstract: BACKGROUND:: A single recent study has suggested a decrease in HIV risk for women attending antenatal clinics (ANCs) in southern India. Yet, some have questioned the validity of the Indian national surveillance data and analyses. Previous studies suggest that the only major HIV risk factor for married Indian women is the risk behavior of their husbands. Therefore, to address concerns about potential selection bias in the analysis of sentinel surveillance data from multiple sites, we estimated the trajectory of HIV transmission rates among recently married, monogamous, primigravid women attending a single large ANC in Pune, India. METHODS:: Participants were self-referred, young, primigravid women from 18 to 27 years of age consenting to HIV screening. Time trends in HIV prevalence over 3.5 years were evaluated by logistic regression adjusted for age. HIV incidence was estimated by dividing the number of HIV-infected mothers by an estimate of exposure person-time, which was an estimate of the average age-specific duration of marriage. RESULTS:: Between August 16, 2002 and February 28, 2006, 30,085 (79.5%) of 37,858 pregnant women consented to HIV screening; 10,982 (36.5%) were primigravid and their age range was from 18 to 27 years. HIV infection risk declined over 3.5 years among primigravid women. An estimated 19,739 person-years (PYs) of exposure yielded an overall HIV incidence rate 1.25/100 PYs (95% confidence interval [CI]: 1.10 to 1.42). Estimated HIV incidence decreased from 2.2/100 PYs (95% CI: 1.6 to 3.0) in 2002 to 2003 to 0.73/100 PYs (95% CI: 0.5 to 1.0) in 2006. DISCUSSION:: HIV infection risk among young primigravid women in Pune seems to have decreased over the past 3.5 years. A decreasing HIV risk among pregnant women in Pune would also decrease the number of HIV-exposed infants. We hypothesize that decreased high-risk sexual behavior among young recently married men is most likely contributing to a decreasing risk to their wives and children in Pune.

"Trends in prevalence of HIV, Syphilis, Hepatitis C, Hepatitis B, and sexual risk behavior among men who have sex with men: results of 3 consecutive respondent-driven sampling surveys in Beijing, 2004 through 2006"

Author(s): Ma X, Zhang Q, He X, et al

Reference: N/A Epub ahead of print.

http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=17577125&dopt=Abstract

Published Abstract: BACKGROUND:: Studies tracking trends in HIV prevalence and risk behavior among men who have sex with men (MSM) in China are rare. We report on 3 consecutive cross-sectional surveys measuring the prevalence of HIV, other infectious diseases, and related risk behavior among MSM in Beijing in 2004, 2005, and 2006. METHODS:: We applied respondent-driven sampling (RDS) to recruit MSM for a structured face-to-face interview on demographic characteristics and HIV risk-related behavior. Blood specimens were drawn for HIV,

syphilis, hepatitis B virus, and hepatitis C virus (HCV) testing. RESULTS: A total of 325 MSM participated in 2004, 427 in 2005, and 540 in 2006. HIV prevalence increased from was 0.4% (95% confidence interval [CI]: 0.1 to 0.8) in 2004, 4.6% (95% CI: 2.2 to 7.6) in 2005, and 5.8% (95% CI: 3.4 to 8.5) in 2006. This rise apparent rise was accompanied by an increase in syphilis and self-reported history of sexually transmitted diseases (STDs), high prevalence of multiple sex partners, and low consistent condom use. HCV prevalence also increased, from 0.4% (95% CI: 0.1 to 0.8) in 2004 to 5.2% (95% CI: 2.3 to 8.2) in 2006. CONCLUSIONS: We detected a possible rising prevalence of HIV and related risk behavior among MSM in Beijing using RDS in each of 3 consecutive years. Practical measures, including MSM-friendly HIV testing, STD services, and health provider education, are urgently needed to stop the further spread of HIV in this population.

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5. NON-HIV STIS AND REPRODUCTIVE HEALTH

"Trichomoniasis and bacterial vaginosis in pregnancy: inadequately managed with the syndromic approach"

Author(s): Romoren M, Velauthapillai M, Rahman M, et al

Reference: N/A 85(4):297-304.

http://www.ncbi.nlm.nih.gov/sites/entrez?tmpl=NoSidebarfile&db=PubMed&cmd=Retrieve&list_uids=17546311&dopt=Abstract

Published Abstract: OBJECTIVE: To measure the prevalence of *Trichomonas vaginalis* (TV) infection and bacterial vaginosis (BV) among pregnant women in Botswana, and to evaluate the syndromic approach and alternative management strategies for these conditions in pregnancy. METHODS: In a cross-sectional study, 703 antenatal care attendees were interviewed and examined, and specimens were collected to identify TV, BV, *Candida* species, *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. Information on reproductive tract infections earlier in pregnancy was obtained from a structured interview and the antenatal record. FINDINGS: TV was found in 19% and BV in 38% of the attendees. Three-fourths of women with TV or BV were asymptomatic. Syndromic management according to the vaginal discharge algorithm would lead to substantial under-diagnosis and over-treatment of TV and BV. Signs of vaginal discharge were more predictive of the presence of these conditions than were symptoms. Among the 546 attendees on a repeat antenatal visit, 142 (26%) had been diagnosed with vaginal discharge earlier in their pregnancy--14 of them twice. In 143 cases, an attendee was diagnosed with vaginal discharge in the second or third trimester; however, metronidazole had been prescribed only 17 times (12%). CONCLUSION: Diagnosis and treatment of TV and BV among pregnant women in sub-Saharan Africa presents major challenges. Half the pregnant women in this study were diagnosed with TV or BV, but these conditions were not detected and treated during antenatal care with syndromic management. Also, health workers did not adhere to treatment guidelines. These results indicate that management guidelines for TV and BV in antenatal care should be revised.

EDITOR'S NOTE: *The full text of this article can be found at*

http://www.scielo.org/scielo.php?script=sci_arttext&pid=S0042-

6. POLITICS AND POLICY

"SIECUS releases report on state sex education, abstinence programs"

Date: 28 June 2007

Source: *Kaiser Daily Womens Health Policy Report*

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=45893

"SIECUS State Profile: A Portrait of Sexuality Education and Abstinence-Only-Until-Marriage Programs in the States," Sexuality Information and Education Council of the United States: The fourth edition of the resource includes profiles of the status of each state's sex education programs in fiscal year 2006, as well as the amount of money state-based organizations receive for abstinence-only-until-marriage programs and how the funds are used. The report also includes information on state laws, proposed legislation and recent events related to sex education in each state (SIECUS release, 6/27).

EDITOR'S NOTE: *The full SIECUS report by state can be found at*

<http://www.siecus.org/policy/states/index.html>

"HHS counters with its own sex-ed critique"

Date: 21 June 2007

Source: *The Washington Post*

Author(s): Christopher Lee

<http://www.washingtonpost.com/wp-dyn/content/article/2007/06/20/AR2007062002235.html>

Liberal critics periodically complain that federally funded "abstinence only" sex-education materials are full of false or misleading statements about the effectiveness of condoms and other issues. Now the Bush administration is firing back, charging that programs that endorse condom use also are marred by imbalance and inaccuracies.

The latest round in the sex-ed culture war comes in a 40-page report by the Department of Health and Human Services that critiqued "comprehensive sex-education curricula" -- materials that teach about both abstinence and the use of condoms and other protective methods. The analysis -- requested two years ago by Sen. Tom Coburn (Okla.) and former senator Rick Santorum (Pa.), both conservative Republicans -- concluded that nine widely used curricula contained misleading statements about condom failure, focused too little on abstinence and were only marginally successful in persuading young people to use condoms or, better yet, to delay having sex.

"This study shows that very little of the message is around abstinence," said Harry Wilson, an associate commissioner in HHS's Administration on Children, Youth and Families. "When it comes to what they actually do in their curricula, this shows that it is kind of given the short end of the stick."

One curriculum, Safer Choices Level 1, mentioned condoms 383 times and abstinence only five, the report said. But Douglas Kirby, a senior research scientist at ETR Associates, the California-based nonprofit organization that developed the curriculum, said the materials make the same point with different language, using phrases such as "choosing not to have sex" or "saying no to sex."

"It's all about abstinence; it's just different words," Kirby said. "There's twice as much material in this curriculum on abstinence than on condoms and contraception."

HHS spends about \$176 million a year on abstinence education, said Wilson, who did not know the comparable figure for comprehensive sex education. The new study, which cost \$77,000, was done by the nonprofit Sagamore Institute for Policy Research in Indianapolis and the Medical Institute for Sexual Health, an Austin-based nonprofit group that advocates that adolescents and adults remain abstinent "until committing to a life-long mutually monogamous relationship such as marriage."

It is the latest burst in a rhetorical exchange that has been raging for years. In 2004, Henry A. Waxman (D), a liberal California congressman, issued an analysis that found that 11 of 13 abstinence-only curricula contained medically inaccurate or misleading information, including assertions that touching a person's genitals can result in pregnancy and that condoms fail to prevent HIV transmission as often as 31 percent of the time in heterosexual intercourse.

The HHS report said that of the nine curricula it reviewed, six had medically inaccurate statements, most commonly that the spermicide nonoxynol-9 reduced the risk of contracting HIV and other sexually transmitted diseases. The Centers for Disease Control and Prevention has said that it does not protect against such infections.

The HHS report said that eight of the curricula contained no inaccuracies about statistics related to condom effectiveness, but that the numbers sometimes lacked context. For example, programs that say latex condoms prevent pregnancy 97 percent of the time when used correctly (the figure actually is 98 percent, experts said) should also note that studies show that the probability of pregnancy during the first year of "typical" use is 15 percent. Not everyone uses condoms properly every time.

The report also objected to statements such as, "Condoms made of latex provide good protection from HIV when used correctly and consistently during vaginal, anal or oral sex." It said such statements lacked "explicit details" about condom failure rates.

James Trussell, a demographer at Princeton University whose research on condom failures was cited frequently in the HHS report, said the authors got the data right but overstated the importance of the errors.

"These examples of medical inaccuracies pale in comparison to those in abstinence-only curricula," he said in an e-mail. "Many errors cited in the Waxman report are egregious, whereas many errors cited in the [HHS] report are not."

"Non-physician clinicians in 47 sub-Saharan African countries"

Author(s): Mullan F, Frehywot S

Reference: N/A Epub ahead of print.

http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=17574662&dopt=Abstract

Published Abstract: Many countries have health-care providers who are not trained as physicians but who take on many of the diagnostic and clinical functions of medical doctors. We identified non-physician clinicians (NPCs) in 25 of 47 countries in sub-Saharan Africa, although their roles varied widely between countries. In nine countries, numbers of NPCs equalled or exceeded numbers of physicians. In general NPCs were trained with less cost than were physicians, and for only 3-4 years after secondary school. All NPCs did basic diagnosis and medical treatment, but some were trained in specialty activities such as caesarean section, ophthalmology, and anaesthesia. Many NPCs were recruited from rural and poor areas, and worked in these same regions. Low training costs, reduced training duration, and success in rural placements suggest that NPCs could have substantial roles in the scale-up of health workforces in sub-Saharan African countries, including for the planned expansion of HIV/AIDS prevention and treatment programmes.

EDITOR'S NOTE: *The full text of this article is available for free at*

<http://www.thelancet.com/journals/lancet/article/PIIS0140673607607855/fulltext>

"Power, pleasure, pain, and shame: Assimilating gender and sexuality into community-centred reproductive health and HIV prevention programmes in India"

Author(s): Degnan Kambou S, Magar V, Hora G, et al

Reference: N/A 2(2):155-168.

<http://www.informaworld.com/smpp/content~content=a777207485~db=all~order=page>

Published Abstract: Inspired by the vision of the Millennium Declaration, CARE and ICRW (International Centre for Research on Women) partnered with the Inner Spaces, Outer Faces Initiative (ISOFI) to learn how to more effectively integrate gender and sexuality into CARE's sexual and reproductive health programmes. Drawing from lessons learned from gender mainstreaming, ISOFI focuses initially on fostering personal change among staff, helping them to explore their own gender and sexuality 'baggage' and supporting transformation of their 'inner space'. ISOFI then gradually integrates mechanisms to promote organizational change, and finally extends to community development practice, the 'outer face'. As a system promoting change in organizational culture and practice, ISOFI features structured iterative loops of reflection and learning, action and experimentation, and analysis and assimilation. This article describes the ISOFI Innovation System, and reports on ISOFI-generated learning and innovation in sex positive HIV prevention programming for truckers and reproductive health interventions for women in India.

7. PHARMACEUTICAL INDUSTRY

"A drug on the market"

Date: 25 June 2007

Source: *The New Yorker*

Author(s): James Surowiecki

http://www.newyorker.com/talk/financial/2007/06/25/070625ta_talk_surowiecki

Last month, a fierce and costly battle erupted over the diabetes drug Avandia after an article in *The New England Journal of Medicine* suggested that the drug raised the risk of a heart attack by forty-three per cent. In the publicity storm that ensued, the number of new Avandia prescriptions shrank by twenty-one per cent, and investors lopped more than twelve billion dollars off the market capitalization of the drug's maker, Glaxo-Smith-Kline. Then came a furious backlash. The article's lead author, Steven Nissen, was accused of being a publicity-seeking crusader with a conflict of interest (Nissen had previously received research support from the maker of one of Avandia's competitors). GlaxoSmithKline dismissed Nissen's work, which was a meta-analysis of forty-two other studies, and published interim results from its own long-term study of Avandia's safety, which it claimed proved the drug to be no more dangerous than its competitors. There were complaints about the "tabloid" hype that journals attach to their stories, and the British medical journal *The Lancet* said that "alarmist headlines and confident declarations help nobody."

This kind of brouhaha, with volleys of personal attacks and fights for the biggest headline, doesn't look much like science. But it's all too typical of the way we measure the safety and efficacy of drugs. The U.S. has no rational system for "post-market surveillance" - the evaluation of drugs after they've been approved. Instead, oversight is left to a motley collection of altruists, academics, lawyers, self-publicists, and drug companies, who make their own arbitrary decisions about which drugs to study, how to evaluate them, and what risks to look for. Somehow, the truth is expected to rise to the surface from among all these competing interests and random decisions.

One might expect the Food and Drug Administration to bring order and rationality to this system. But the way the F.D.A. is configured and run prevents it from doing so. Before a drug has been approved, the F.D.A. has tremendous leverage over pharmaceutical companies, and can require them to do the studies that it deems necessary. As soon as the agency actually approves a drug for sale, though, its authority is markedly diminished. The agency can recommend that the manufacturer of a drug already on the market conduct studies, but it can't, with a few exceptions, force the company to do so. Furthermore, it can't fine companies that don't follow its recommendations, and it can't limit their advertising or sanction them in any real way. As a result, most post-market studies promised by drug companies have never been started, and, of those which have, nearly three-quarters remain incomplete.

Instead of relying on drugmakers to test their own products, the agency could, in principle, run or commission its own trials. But it lacks both the money and the infrastructure to do so. While there is an office devoted to "surveillance and epidemiology," which is theoretically responsible for post-market monitoring, its budget is startlingly small, it does not function as an independent agency, and its recommendations are often overruled. The F.D.A. as a whole is far more focussed on what happens to drugs before they enter the market: for every seven employees who work on drug

approval, only one works on post-market safety.

The result of all this is that the F.D.A. can't identify problems quickly and systematically. When the agency does instigate a post-market study of a drug, for instance, it's generally because of "adverse-event" reports from doctors and patients, like the accounts of serious skin reactions caused by the anti-arthritis drug Bextra. But most such reports deal with surprising problems that seem to be directly caused by a drug. More common problems, like heart attacks, often fall through the cracks, because they can have so many causes. As a result, the agency's ability to catch problems early usually comes down to chance. Adverse-event reporting didn't, for instance, uncover the negative effects of Vioxx; its coronary risks were discovered only because Merck, hoping to gain approval for a new use of the drug, happened to run some new studies. And had Nissen chosen to study a different drug no one would be talking about Avandia today.

Drug companies may like this haphazard system of surveillance, even if it leaves them exposed to the kind of publicity that Glaxo is currently enduring. For the rest of us, though, it's a bizarrely inefficient and confusing process, one that almost all consumers (and many doctors) are ill-equipped to navigate. Small government has its virtues, but providing information about the risks and efficacy of drugs is a classic public good - precisely the kind of service that government can best provide. This doesn't have to be cumbersome or expensive. One approach, which is followed in Europe, would be to require drugs to be reviewed again after five years, thereby forcing drugmakers to do the necessary post-market studies. And simply giving the F.D.A. the money it needed to run its own studies would make a big difference. (Congress is at long last taking small steps in this direction. For decades, lobbyists have helped defeat attempts to toughen the F.D.A.'s post-market authority, but the Senate just passed, and the House is now considering, a bill that would enhance the F.D.A.'s power.) A newly strengthened F.D.A. would not be perfect in its judgment, and it wouldn't usher in a utopian era of pharmaceutical safety - risks and side effects are unavoidable when it comes to drugs. But it would keep Americans far safer than relying on the benevolence of drug companies or the random choices of crusaders does. In this case, what we don't know really can hurt us.

"Over 20 years, Gilead has acquired success"

Date: 22 June 2007

Source: *The San Francisco Chronicle*

Author(s): Bernadette Tansey

<http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2007/06/22/BUGOOQJ11B1.DTL>

In just two decades, Gilead Sciences Inc., the Bay Area's second-largest biotechnology company, has established itself as the nation's dominant seller of HIV drugs, with such products accounting for two-thirds of its \$3 billion in revenue in 2006. That's a tremendous success story in an industry where thousands of competitors fight for a place in the sun. But as Foster City's Gilead celebrates its 20th anniversary today, it's not resting on its laurels.

The biotechnology sector is in turmoil now as major pharmaceutical companies increasingly encroach on its turf -- using science to develop cutting-edge therapies based on how cells work at the molecular level. More and more, big pharma is looking to claim this territory by swallowing up biotech companies with promising products. But Gilead has a great chance to thrive and stay independent by extending its reach into whole new treatment areas. It's continuing

down the path it has long followed as a big fish that eats other creatures rather than getting consumed itself. That's a strategy industry leader Genentech is also following as it uses its commanding position in cancer drugs and the enormous revenue they produce to establish beachheads in new therapy lines, such as Alzheimer's disease and multiple sclerosis.

Gilead doesn't match Genentech in drug innovation, analysts say. Gilead has built most of its product portfolio by acquiring experimental drugs from other companies, rather than discovering therapies through research. The company is held up as a model of savvy management, meticulous planning and follow-through, something that can be seen in its approach to acquiring technology developed by others. Analysts describe Gilead as a genius of execution rather than a genius of innovation.

"They are extremely methodical," Rodman and Renshaw analyst Michael King said. One example was Gilead's purchase last year of the Denver-area company Myogen Inc. Gilead paid \$2.5 billion for a company in a field unrelated to its major product line. "Didn't they pay too much?" worried some investors who wondered how Myogen figured in Gilead's plans. Myogen was Gilead's second acquisition in 2006. It had paid \$365 million for Corus Pharma of Seattle, developer of a drug for lung infections in cystic fibrosis patients. These takeovers were calculated to position Gilead in new arenas.

"The idea is to build franchises that we hope will surpass HIV" in growth potential, said Chief Operating Officer John Milligan. That strategy paid off June 15, when the Food and Drug Administration approved one of the experimental therapeutic drugs that came with the Myogen deal, lung medication Letairis. The drug is designed to treat disabling pulmonary arterial hypertension, an elevated blood pressure in the lungs that can cause shortness of breath and heart failure. Analysts predict sales of as much as \$1 billion by 2010. Letairis is one of Gilead's steppingstones into markets that will make it a more diversified drug company. It is also trying to develop improved medicines for other cardiopulmonary disorders and forms of hepatitis.

But the company is not neglecting its core franchise. It aims to break new ground in HIV treatment through experimental compounds in its pipeline. Gilead scientists are trying to create next-generation HIV drugs called integrase inhibitors, designed to stop the virus from multiplying. In some new markets, Gilead is a late-comer taking on an entrenched competition. But the company wasn't the first to come to market with HIV drugs, either.

"They're fast followers," King said. "They followed behind GlaxoSmithKline and Bristol-Myers (in HIV drugs) and ate their lunch." Gilead's top-selling products are HIV drugs Viread and Emtriva, and combination pills with both drugs. The multi-drug tablets simplify the treatment regimens needed to suppress viral growth and keep HIV-positive people healthy. The combination pill Truvada contains Viread and Emtriva. Atripla, approved in mid-2006, combines both the Gilead drugs with Bristol-Myers Squibb's Sustiva. Atripla is the first product that contains all three medications used in a typical HIV regimen in a single pill taken once a day.

Analysts expect Gilead to challenge the market leadership of large pharmaceutical companies internationally as Atripla wins regulatory approval in Europe and elsewhere. JPMorgan analyst Geoffrey Meacham estimates that Gilead's HIV drug revenue will grow by 40 percent to about \$3 billion in 2007. Analysts expect HIV to be Gilead's primary source of growth for the foreseeable future. But Gilead needs to expand into other disease areas to maintain the growth rates Wall Street expects, BWS Financial analyst Hamed Khorsand said.

The acquisition model wasn't Gilead's original plan when it was founded in 1987 as a discovery company pursuing new scientific avenues. But Gilead shifted gears when it got an opportunity to license a family of anti-viral compounds, which it developed into Viread and the hepatitis B drug Hepsera. Gilead CEO John Martin maintains that it takes as much scientific expertise to develop an effective drug from a promising compound acquired from outside the company as it does to invent a product in-house. The trick is to pick compounds with the most potential, find the optimum dose and identify the patient types most likely to benefit, he said. "The innovation process is not just in discovering the molecule," Martin said. "Many products fail because the right questions were not asked."

But Gilead is no slouch at in-house drug discovery. It developed Tamiflu, approved to treat seasonal influenza. In 1996, the company teamed up with F. Hoffmann-LaRoche Ltd. to co-develop the drug, which is being stockpiled as a potential treatment in case of a bird flu pandemic.

Meacham, the JPMorgan analyst, doubts that Gilead's new products will match the company's HIV revenue. He projects \$6.7 billion in company sales by 2010, with 75 percent coming from HIV drugs. JPMorgan has an investment banking relationship with Gilead. Advocacy groups such as Doctors Without Borders have called on Gilead to help meet the huge demand for HIV drugs in the developing world. Gilead offers its drugs at reduced rates in 97 countries, with prices in the poorest nations at \$17 per month for Viread and \$26.25 per month for Truvada. In the United States, the wholesale price for a 30-day supply of Viread is \$482.39 and \$778.75 for Truvada.

Outside of the HIV business, analysts see Letairis as Gilead's largest potential growth driver. The drug will compete with Tracleer, made by the Swiss company Actelion, which reported sales of \$724 million in 2006. Analysts disagree on how fast Letairis revenue will grow, with estimates ranging from \$300 million to \$1 billion by 2010. Analysts don't expect Gilead to snap up any more companies until at least 2008, because it's busy absorbing Myogen and Corus. But Khorsand wouldn't rule it out. "The company's been good at surprising people," he said.

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8. ANNOUNCEMENTS

amfAR LAUNCHES MSM INITIATIVE

<http://www.amfar.org/cgi-bin/iowa/news/record.html?record=218>

As the HIV/AIDS pandemic enters its second quarter-century, HIV is spreading rapidly among men who have sex with men (MSM), particularly in resource-limited countries. After the terrible price paid by gay men in the 1980s and '90s, it seems unthinkable that such a scenario could be repeated today. Yet discrimination, denial, and criminalization of male-male sex are again fueling this major health crisis, just as they did at the dawn of the HIV/AIDS era. But there is hope. Grassroots organizations are forming in parts of Africa, India, Southeast Asia, and other developing regions where the epidemic is reaching crisis proportions. With sufficient funding and support, these organizations can shift community attitudes, drive policy changes, and mobilize the necessary resources to reverse the alarming spread of HIV among MSM.

In an effort to help these organizations grow and become more effective, and to reduce rates of HIV infection and transmission among MSM in resource-limited countries, amfAR has launched a new MSM initiative.

The amfAR MSM Initiative will enable the Foundation to award small, targeted grants to grass-roots groups in support of innovative HIV/AIDS services for MSM in resource-limited countries. Grants will also be used to improve communication and increase collaboration among organizations. These grants will have an immediate and significant impact on poorer communities with few available resources for MSM. In addition, grants such as these can have a "multiplier effect" with the power to catalyze funding from additional donors. Through the Initiative, amfAR will also support advocacy efforts aimed at increasing funding for HIV/AIDS prevention and treatment services for MSM from public and private sources and at ending the stigma, discrimination, and violence that threaten the lives of MSM and fuel the spread of HIV/AIDS.

The amfAR MSM Initiative is supported by initial grants from the Bill & Melinda Gates Foundation, Hon. James C. Hormel, Mathilde Krim, Ph.D., MAC AIDS Fund, and the Elizabeth Taylor AIDS Foundation. The Initiative will be formally announced at the International AIDS Society Conference on HIV Pathogenesis and Treatment in Sydney, Australia, in July.

NEW REPORT FROM THE GLOBAL HIV PREVENTION WORKING GROUP

http://www.globalhivprevention.org/pdfs/PWG-HIV_prevention_report_FINAL.pdf

The Global HIV Prevention Working Group (PWG) released its new report, "Bringing HIV Prevention to Scale: An Urgent Global Priority." The report discusses the importance of greatly expanding coverage of evidence-based HIV prevention interventions and provides examples of successful scale-up efforts. The report contains valuable graphics and figures on rates of coverage for existing prevention interventions worldwide. These figures are critical advocacy tools for all of our work. It also offers recommendations for national governments, donors, multilateral organizations, providers, the research field, and civil society.

THE BIOMARKERS CONSORTIUM WEB SITE LAUNCHED FOR CONCEPT SUBMISSIONS AND POSSIBLE FUNDING

www.biomarkersconsortium.org

The Biomarkers Consortium has launched a Web site to encourage researchers to submit biomarker project concepts. Financial support for concepts approved for development will be procured through fund-raising efforts by the Foundation for the National Institutes of Health.

Available at www.biomarkersconsortium.org, the site is geared to biomedical, clinical, and technology-oriented health researchers and others in the health field. Principal investigators, research managers, prospective grantees in government, non-profit, and industry sectors, and science and health policy organizations and advocacy groups will find it to be a useful source of support.

UPDATED CD-ROM PUBLICATION OF 'PHOTO ATLAS FOR MICROBICIDE EVALUATION'

An updated edition of the Photo Atlas: 'Updated Photo Atlas for **Microbicide** Evaluation 2007,' published by the Thailand MOPH - U.S. CDC Collaboration, has just been released. This CD-ROM is intended to provide a training tool and reference for clinical examination and documentation of genital findings in clinical trials of vaginal **microbicides**. It follows and expands on the guidelines of the CONRAD/WHO Manual for the standardization of colposcopy for the evaluation of vaginal products: update 2004 and includes a wide range of reference photographs. A new feature of this updated edition is two "self-test" slide sets which can be used to evaluate the consistency of description and documentation of epithelial findings by staff at **microbicide** trial sites.

To obtain a copy of the CD-ROM, please contact: Atlas@tuc.or.th.

Reference: Bollen LJM, Whitehead SJ, Kantipong P, Kilmarx PH. Updated Photo Atlas for **Microbicide** Evaluation, 2007. Bangkok: Thailand MOPH - U.S. CDC Collaboration; 2007 [CD-ROM].

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