



ALLIANCE FOR MICROBICIDE DEVELOPMENT

16 November 2007, Volume 8, Number 45

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. ALLIANCE UPDATES AND COMMUNITY NEWS

Difficulty accessing Digest and Alliance website

The Alliance has received reports of difficulties in accessing the Digest at the Alliance website, via the email message, or through online search, and some have noted recent difficulties with the website overall. Please send an email to digest@microbicide.org to report malfunctions with any Alliance resources, and we will address this issues promptly.

Thanksgiving holiday schedule for the News Digest

The Alliance will be taking a break for the Thanksgiving holiday and will not publish the News Digest on Friday, 23 November 2007. The next issue of the Digest will be published on Friday, 30 November 2007. That said, Alliance Alerts will continue to be sent as those become necessary in the periods 19-20 and 26-30 November. To all those who will be observing this holiday, we send best wishes, and to all of us, wishes for best outcomes in the important work we are all trying so hard to do.

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2. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

"The value of site preparedness studies for future implementation of phase 2/IIb/III HIV prevention trials: experience from the HPTN 055 study"

Author(s): Ramjee G, Kapiga S, Weiss S, et al

Reference: N/A Epub ahead of print.

http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=17984760&dopt=AbstractPlus

Published Abstract: OBJECTIVES:: To evaluate the preparedness for phase 2/IIb/III **microbicide** trials at 4 clinical trial sites: Durban and Hlabisa (South Africa), Lusaka (Zambia), and Moshi (Tanzania). DESIGN:: A prospective cohort study was undertaken to assess site suitability for **microbicide** efficacy studies. Study objectives included assessing sites' ability to recruit and retain high-risk women with the appropriate HIV incidence rates needed to conduct **microbicide** efficacy studies. METHODS:: Nine hundred fifty-eight consenting women were enrolled and followed for up to 1 year. Demographic, behavioral, laboratory, and clinical data were collected to determine the incidence rates of HIV, sexually transmitted infections, and pregnancy. RESULTS:: Accrual was completed in 6.3, 6.7, 7.1, and 8.3 months in Durban, Hlabisa, Moshi, and Lusaka, respectively. The highest month 12 participant retention rate was recorded in Durban (97%), followed by Hlabisa (94%), Moshi (86%), and Lusaka (93%). Mean overall age of enrolled participants was 28.6 years (ranging from 27.0 to 32.2 years) across sites. Despite condom counseling, rates of condom use were slightly lower at study end. Pregnancy incidence in the study as a whole was 20.2 per 100 women-years (wy). Overall HIV prevalence was 32.5%, and overall HIV incidence was 3.8 per 100 wy (95%

confidence interval [CI]: 2.6 to 5.2). HIV incidence per site was 5.3 per 100 wy in Durban (95% CI: 2.7 to 9.2), 6.2 per 100 wy in Hlabisa (95% CI: 3.4 to 10.5); 2.6 per 100 wy in Lusaka (95% CI: 1.0 to 5.8), and 1.4 per 100 wy in Moshi (95% CI: 0.3 to 4.0). CONCLUSIONS:: Preparatory studies provide accurate local estimates of HIV incidence, recruitment and retention rates, and behavioral characteristics of targeted populations for large-scale clinical trials. Determining these factors allows for better preparation for design, sample size, and appropriate population for future selection of trial sites. Because of the lower than expected HIV incidence observed at the Moshi site, only the South African and Zambian sites were selected for the phase 2/IIb trial.

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3. PUBLISHED RESEARCH: RELEVANT BASIC AND TRANSLATIONAL SCIENCE

"Inclusion of adolescents in preventive HIV vaccine trials: public health policy and research design at a crossroads"

Author(s): Jaspan HB, Cunningham CK, Tucker TJ, et al

Reference: N/A Epub ahead of print.

http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=17984759&dopt=AbstractPlus

Published Abstract: The search for a safe effective HIV vaccine has been a centerpiece of HIV research for almost 2 decades. More than 60 clinical HIV vaccine trials have been conducted to date. Several promising candidate HIV vaccines are in advanced clinical development. To date, however, no trial has included adolescents, one of the most important target groups for any preventive HIV vaccine. To license a vaccine for use in this age group, efficacy data or, at a minimum, bridging safety and immunogenicity data in this population are needed. To accomplish this, several critical issues and special challenges in the development and implementation of HIV vaccine trials in adolescents must be addressed, including regulatory considerations, potential differentials in safety and immunogenicity, alternative trial design strategies, recruitment and retention challenges, community involvement models, and approaches to informed consent/ assent. This article examines these issues and proposes specific next steps to facilitate the routine inclusion of this high-priority population in preventive HIV vaccine trials as early and seamlessly as possible.

"Induction of potent local cellular immunity with low dose X4 SHIV(SF33A) vaginal exposure"

Author(s): Tasca S, Tsai L, Trunova N, et al

Reference: N/A 367(1):196-211.

http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=17574643&dopt=AbstractPlus

Published Abstract: Intravaginal inoculation of rhesus macaques with varying doses of the CXCR4 (X4)-tropic SHIV(SF33A) isolate revealed a threshold inoculum for establishment of systemic virus infection and a dose dependency in overall viral burden and CD4+ T cell depletion. While exposure to inoculum size of 1000 or greater 50% tissue infectious dose (TCID₅₀) resulted in high viremia and precipitous CD4+ T cell loss, occult infection was observed in seven of eight macaques exposed to 500 TCID₅₀ of the same virus. The latter was characterized by intermittent detection of low level virus with no evidence of seroconversion or CD4+ T cell decline, but with signs of an ongoing antiviral T cell immune response. Upon vaginal re-challenge with the same limiting dose 11-12 weeks after the first, classic pathogenic X4 SHIV(SF33A) infection was established in four of the seven previously exposed seronegative macaques, implying enhanced susceptibility to systemic infection with prior exposure. Pre-existing peripheral SIV gag-specific CD4+ T cells were more readily demonstrable in macaques that became systemically infected following re-exposure than those that were not. In contrast, early presence of circulating polyfunctional cytokine secreting CD8+ T cells or strong virus-specific proliferative responses in draining lymph nodes and in the gut associated lymphoid tissue (GALT) following the first exposure was associated with protection from systemic re-infection. These studies identify the gut and lymphoid tissues proximal to the genital tract as sites of robust CD8 T lymphocyte responses that contribute to containment of virus spread following vaginal transmission.

"Mucosal HIV-binding antibody and neutralizing activity in high-risk HIV-uninfected female participants in a trial of HIV-vaccine efficacy"

Author(s): Schneider JA, Alam SA, Ackers M, et al

Reference: N/A 196:1637-44.

<http://www.journals.uchicago.edu/JID/journal/issues/v196n11/38535/brief/38535.abstract.html>

Published Abstract: *Background.* This study investigated gp120-binding antibody and neutralizing activity, at the gingival- and cervical-mucosal levels, in response to a bivalent gp120 candidate vaccine. *Methods.* Women who met the study's inclusion criteria for documented high-risk behaviors participated in a nested substudy of the multicenter phase 3 trial of human immunodeficiency virus (HIV)-vaccine efficacy, VAX004. Gingival, cervicovaginal lavage, and plasma specimens were collected at 6-month intervals for 3 years. Binding-antibody and neutralizing-activity assays quantified the presence of anti-HIV activity in mucosal specimens. *Results.* Vaccine recipients were more likely than placebo recipients to have IgG binding antibodies in all 3 compartments tested and to have only IgA binding antibody in plasma (P (less than) .0001). The relationship between vaccine and cervicovaginal IgG achieved significance (odds ratio [OR], 6.6 [P = .01]) but was weakened by the presence of cervicovaginal leukocytes. There was no relationship between immunization and the presence of neutralizing activity, in either bivariate or multivariate modeling (OR, 6.0 [P = .29]). *Conclusions.* Vaccination is associated with the presence of both gp120-binding IgG in all compartments and plasma IgA but not with neutralizing activity. There is a role for the measurement of mucosal immunity in response to candidate vaccines and, in particular, for a determination of HIV-specific neutralizing antibodies.

"Single-dose tenofovir and emtricitabine for reduction of viral resistance to NNRTIs in women given intrapartum nevirapine for perinatal HIV prevention: an open-label randomised trial"

Author(s): Chi BH, Sinkala M, Mbewe F, et al

Reference: N/A Epub ahead of print.

http://www.natap.org/2007/HIV/110707_02.htm

Published Abstract: *Background* Intrapartum and neonatal single-dose nevirapine are essential components of perinatal HIV prevention in resource-constrained settings, but can induce resistance to other non-nucleoside reverse transcriptase inhibitor drugs. We aimed to investigate whether this complication would be reduced with a single peripartum intervention of tenofovir and emtricitabine. *Methods* We randomly assigned 400 HIV-infected pregnant women who sought care at two public-sector primary health facilities in Lusaka, Zambia. One was excluded, 200 were assigned to receive a single oral dose of 300 mg tenofovir disoproxil fumarate with 200 mg emtricitabine under direct observation, and 199 to receive no study drug. Short-course zidovudine and intrapartum nevirapine were offered to all HIV-infected women, according to the local standard of care. Women who met national criteria for antiretroviral therapy were referred for care and not enrolled. Our primary study outcome was resistance to non-nucleoside reverse transcriptase inhibitors at 6 weeks after delivery. We used standard population sequencing to determine HIV genotypes. Analysis was per protocol. This study is registered with ClinicalTrials.gov, number NCT00204308. *Findings* Of the 200 women who were randomly assigned to the intervention, 14 were lost to follow-up or withdrew from the study, two did not take study drug according to protocol, and one specimen was lost; 23 of 199 controls were lost to follow-up or withdrew from the study, and three specimens were lost. Women given the intervention were 53% less likely than controls to have a mutation that conferred resistance to non-nucleoside reverse transcriptase inhibitors at 6 weeks after delivery (20/173 [12%] vs 41/166 [25%]; risk ratio [RR] 0.47, 95% CI 0.29-0.76). We noted postpartum anaemia, the most common serious adverse event in mothers, in four women in each group. 20 of 198 (10%) infants in the intervention group and 23 of 199 (12%) controls had a serious adverse event, mostly due to septicaemia (n=22) or pneumonia (n=8); these events did not differ between groups, and none were judged to be caused by the study intervention. *Interpretation* A single dose of tenofovir and emtricitabine at delivery reduced resistance to non-nucleoside reverse transcriptase inhibitors at 6 weeks after delivery by half; therefore this treatment should be considered as an adjuvant to intrapartum nevirapine.

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

"The costs associated with adverse event procedures for an international HIV clinical trial determined by activity-based costing"

Author(s): Chou VB, Omer SB, Hussain H, et al

Reference: N/A 46(4):426-32.

<http://www.jaids.org/pt/re/jaids/abstract.00126334-200712010-00008.htm;jsessionid=H7yc1vn03HTvYZ9v5QwWXPh71BYrJCyVZcT8lv5nhg243W7jLRCQ!->

Published Abstract: *Objective:* To determine costs for adverse event (AE) procedures for a large HIV perinatal trial by analyzing actual resource consumption using activity-based costing (ABC) in an international research setting. *Methods:* The AE system for an ongoing clinical trial in Uganda was evaluated using ABC techniques to determine costs from the perspective of the study. Resources were organized into cost categories (eg, personnel, patient care expenses, laboratory testing, equipment). Cost drivers were quantified, and unit cost per AE was calculated. A subset of time and motion studies was performed prospectively to observe clinic personnel time required for AE identification. *Results:* In 18 months, there were 9028 AEs, with 970 (11%) reported as serious adverse events. Unit cost per AE was \$101.97. Overall, AE-related costs represented 32% (\$920,581 of \$2,834,692) of all study expenses. Personnel (\$79.30) and patient care (\$11.96) contributed the greatest proportion of component costs. Reported AEs were predominantly nonserious (mild or moderate severity) and unrelated to study drug(s) delivery. *Conclusions:* Intensive identification and management of AEs to conduct clinical trials ethically and protect human subjects require expenditure of substantial human and financial resources. Better understanding of these resource requirements should improve planning and funding of international HIV-related clinical trials.

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4. HIV/AIDS VACCINES

"New strategy for attacking AIDS focuses on cell's distress signal"

Date: 09 November 2007

Source: *San Francisco Chronicle*

Author(s): Sabin Russell

<http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2007/11/09/BAQCT7E9P.DTL&hw=HIV+vaccine&sn=001&sc=1000>

San Francisco researchers have come up with a new strategy for a potential AIDS vaccine: creating one that attacks a newly discovered distress signal displayed by cells infected with HIV.

Efforts to design vaccines that identify and kill HIV itself have been repeatedly stymied by the ability of the AIDS virus to mutate quickly. As soon as the vaccine-assisted immune system learns to attack the virus or cells infected with it, new forms of the microbe emerge that the body's defenses do not recognize.

But the distress signal - actually small proteins churned up to the surface of cells infected with HIV - is unchanging.

In theory, a vaccine might be crafted to destroy cells that display this signal - killing at the same time the hidden HIV quietly duplicating itself inside them.

"For a vaccine against an infectious agent, this is a completely new strategy," said Dr. Douglas Nixon, a UCSF immunologist.

The distress signal itself is created when HIV infects a cell and disturbs the remnants of ancient viruses that have been slumbering inside human genes. About 8 percent of the DNA in the human genome - the blueprint for making all the cells in the body - consists of viral genes inserted millions of years ago.

For reasons that have yet to be understood, some of these fossil genes are activated when a cell is attacked by a modern virus. They produce tiny proteins that float to the surface of the cell, where they present a distinctive signal - like waving a distress flag.

In experiments described in the journal PLoS Pathogens on Thursday, Nixon and colleagues describe how the signals from these ancient viruses are found consistently on cells infected with HIV.

The signals - called HERVs, for Human Endogenous Retroviruses - were found in 15 of 16 volunteers who were infected with HIV but had not yet taken antiviral drugs. Similarly, four uninfected volunteers showed little to no evidence of the signals.

More intriguingly, the HIV-infected volunteers who had the lowest amount of virus in their blood were those who had the highest level of the signals - suggesting that their immune systems may be exerting some control over their HIV infections.

This is where the potential of a vaccine that attacks Human Endogenous Retroviruses comes in. If scientists could develop a vaccine that provokes a strong response against these ancient viral signals, they might be able to kill cells infected by HIV.

There are some indications that a small subset of people who are able to control HIV naturally - the "elite controllers" - produce high levels of Human Endogenous Retrovirus proteins. "We are actively looking at elite controllers," Nixon said.

The idea of attacking diseased cells by targeting a distress signal first came up in cancer research. Nixon has previously researched HERV production in patients with testicular cancer. Independently, researchers at the University of Toronto also were studying them, and after meeting with Nixon the two teams decided to collaborate.

Nixon said there is an enormous amount of research to be done before a potential vaccine of this nature will be available for testing in humans. He acknowledged that, because 8 percent of the human genome is made up of these ancient viral fossils, any vaccine that attacked them has the potential to attack friendly cells - an autoimmune response that could be dangerous.

But during a week marked by disappointing news about a field trial of an experimental AIDS vaccine developed by Merck & Co., the latest research continues to hold out hope.

UCSF research fellow Keith Garrison, who is the lead author of the study, noted that the distress signals may not be limited to infections with viruses such as HIV - and hence vaccines might be crafted to prevent or treat other diseases. "It may be that stimulating immunity against HERVs is a good way of containing all kinds of negative conditions in cells," he said.

Media coverage of discontinuation of Phambili and STEP HIV vaccine trials

Due to the wealth of media coverage and statements from the field in response to the discontinuation of the Phambili and STEP HIV Vaccine trials, the Alliance compiled summaries of this coverage through *Alerts* sent on 8 November and 15 November 2007. If you missed these and/or would like to have them re-sent to you individually, please email alliance@microbicide.org.

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5. OTHER PREVENTION APPROACHES

"Redesigning a condom so women will use it"

Date: 13 November 2007

Source: *The New York Times*

Author(s): Donald G McNeil

http://www.nytimes.com/2007/11/13/health/13cond.html?_r=2&adxnnl=1&oref=slogin&adxnnlx=1195092041-1YtMbCVvj0aYxzlKWb4Jbw

The female condom has never caught on in the United States. But in the third world, where it was introduced in the late 1990s, public health workers hoped it would overthrow the politics of the bedroom, empower women and stop the AIDS epidemic in its tracks.

It did not. Female condoms never really caught on there, either.

Only about 12 million female condoms are delivered each year in poor countries, compared with about 6 billion male condoms. Couples complained that the female version was awkward, unsightly, noisy and slippery - or, as Mitchell Warren, who was one of its earliest champions, now says, "the yuck factor was a problem." Many women tried it, but in the end, it was adopted mainly by prostitutes.

Now scientists are trying again. A new design - much the same at one end, different at the other - has been developed, and its makers hope it will succeed where its predecessor failed.

"Over 15 years, there's been no real competition, no second-generation product," said Michael J. Free, head of technology at PATH, a nonprofit group based in Seattle that did the redesign. "There's no lack of interest, but we've been stalled."

However, the new design does not overcome the glaring drawback that doomed the first to be a niche product: it cannot be used secretly. For that reason, married women, now one of the highest risk groups for AIDS in poor countries, rarely use it.

"I don't want my husband to know that I am wearing a condom," said Lois B. Chingandu, the director of SAfaids, an anti-AIDS organization in Zimbabwe.

"Condoms are almost undiscussable within a marriage" in Africa, she added. "It is something associated with casual sex. If a wife uses a condom, the message is that you have been unfaithful. If she even initiates the discussion, it tips the power scale. Men resist quite a lot, and it can result in violence."

But for couples who have agreed on condoms, and for sex workers whose clients cooperate, the new design has several advantages.

The redesigned female condom is made of softer, thinner polyurethane to better transmit warmth. It is easier to insert; one end is bunched up as small as a tampon, an improvement on the old design, which resembled the stiff rubber ring of a diaphragm and had to be folded into a figure 8 for insertion.

During sex, the new female condom also moves more like a vagina than the old design did, according to couples in Seattle, Thailand, Mexico and South Africa who tested a series of prototypes, said Joanie Robertson, project manager for the condom at PATH. The old design hung passively from the rubber ring, which could shift around and sometimes hurt; the new design has dots of adhesive foam that adhere to the vaginal walls, expanding with them during arousal.

According to PATH, more than 90 percent of the couples were satisfied with the ease of use and comfort of the new condom, and 98 percent found the sensation of sex to be "O.K. to very satisfactory."

Nonetheless, progress is now stalled.

PATH is seeking approval from the Food and Drug Administration so the condom can be sold in the United States. And with the drug agency's approval, it would be much easier to license the condom in poor countries or get a World Health Organization endorsement.

While the F.D.A. designates male condoms as Class 2 medical devices - meaning that a new maker has to pass tests only for leakage and bursting - it puts female condoms in Class 3, the same category as pacemakers, heart valves and silicone breast implants.

That decision was made in 1999 - after much debate, and well after the condom was in use overseas - because there was no clinical data on the effectiveness of female condoms, and failure could be life-threatening if the woman's partner had AIDS. An advisory panel suggested not even calling it a "condom" and instead labeled it an "intravaginal pouch," but the agency rejected that advice.

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

"Museveni cautions youth on circumcision"

Date: 07 November 2007

Source: *New Vision*

Author(s): Fortunate Ahimbisibwe

<http://www.newvision.co.ug/D/8/13/596096>

President Yoweri Museveni has said circumcision should not be promoted in the fight against HIV/AIDS, as it will encourage recklessness among the youth.

Addressing over 500 youth delegates who attended the Youth Activist Forum on Tuesday at Hotel Africana in Kampala, Museveni said he would continue advocating for the ABC strategy (Abstinence, Faithfulness and Condoms.)

"Some NGO's have been saying rubbish about circumcision but I will continue encouraging the youth to abstain, and use condoms only if they must. How many Bagisu have died of AIDS and yet all of them are circumcised?" he asked. "You would rather use a condom as a fall-back position but not rely on circumcision."

Museveni warned the youth against contracting HIV/AIDS and encouraged them to get married immediately after school.

"By the time you get your first degree when you are 24, you should find a responsible partner and enjoy the rest of your lives together. Getting a partner should be a process but not meeting in the bus park and getting married." He added that Uganda's population growth rate was not a problem.

"At 30 million, we should not be worried. Japan, which is about the same age as Uganda, has over 120m but it's a fast-developing country. Population is not the problem here, the problem is underdevelopment and this is what we are trying to address."

On the controversial land give-aways to investors, Museveni said this was part of an effort to create employment for the youth.

"Your enemies are the people who are delaying these industries and fighting for small pieces of land, therefore delaying employment for you." He warned that the Government would attach the property of people who get money through SACCOs and fail to pay it back.

"This is not going to be like the Entandikwa. If you fail to pay back, your property will be attached."

The forum, a precursor to the Commonwealth Youth Forum to take place in Kampala later this month, was organised by the Global Forum for International Cooperation.

"Nepal village women mail condoms for husbands working abroad"

Date: 06 November 2007

Source: *Associated Press*

<http://www.iht.com/articles/ap/2007/11/06/asia/AS-GEN-Nepal-Condoms-for-Husbands.php>

Women in a rural village in Nepal have been mailing condoms to their husbands working abroad to protect them from sexually transmitted diseases, a news report said Tuesday.

The women in Pang village, in the midwestern mountains of Nepal, have been writing to their husbands urging them not to have sex with other women, but also mailing them condoms so that if they are unfaithful, at least they will have safe sex.

The Kantipur newspaper said that social workers have been counseling women in this remote village about sexually transmitted diseases over the past two years.

"As I learned that unsafe relations make a person vulnerable to HIV, I sent a condom along with the letters to my husband," the newspaper quoted local resident Laxmi Sunar as saying.

An estimated 3 million Nepalese work in foreign countries to support their families back in Nepal, mostly manual work in the construction industry.

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6. NON-HIV STIS AND REPRODUCTIVE HEALTH

"More than 1 million chlamydia cases sets record for U.S. sexually transmitted diseases"

Date: 13 November 2007

Source: *Associated Press*

<http://www.iht.com/articles/ap/2007/11/13/america/NA-MED-US-Sexual-Disease-Rates.php>

More than 1 million cases of chlamydia were reported in the United States last year - the most ever reported for a sexually transmitted disease, federal health officials said Tuesday.

"A new U.S. record," said Dr. John M. Douglas Jr. of the federal Centers for Disease Control and Prevention.

More bad news: Gonorrhea rates are jumping again after hitting a record low, and an increasing number of cases are caused by a "superbug" version resistant to common antibiotics, federal officials said Tuesday.

Syphilis is rising, too. The rate of congenital syphilis - which can deform or kill babies - rose for the first time in 15 years.

"Hopefully we will not see this turn into a trend," said Dr. Khalil Ghanem, an infectious diseases specialist at Johns Hopkins University's School of medicine.

The CDC releases a report each year on chlamydia, gonorrhea and syphilis, three diseases caused by sexually transmitted bacteria.

Chlamydia is the most common. Nearly 1,031,000 cases were reported last year, up from 976,000 the year before.

The count broke the single-year record for reported cases of a sexually transmitted disease, which was 1,013,436 cases of gonorrhea, set in 1978.

Putting those numbers into rates, there were about 348 cases of chlamydia per 100,000 people in 2006, up 5.6 percent from the 329 per 100,000 rate in 2005.

CDC officials say the chlamydia record may not be all bad news: They think the higher number is largely a result of better and more intensive screening.

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EDITOR'S NOTE: The full text of this article is available at the above website. The CDC 2006 STD Surveillance Report referred to in this article is available at <http://www.cdc.gov/std/stats/>.

"Negative mucosal synergy between Herpes simplex type 2 and HIV in the female genital tract"

Author(s): Rebbapragada A, Wachihi C, Pettengell C, et al

Reference: N/A 21(5):589-98.

http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=17314521&dopt=AbstractPlus

Published Abstract: OBJECTIVE: There is substantial epidemiological evidence that infection by Herpes simplex virus type 2 (HSV2) enhances both HIV susceptibility and subsequent sexual transmission. Both infections are extremely common in female sex workers (FSWs) in sub-Saharan Africa, and up to 80% of new HIV infections in urban men in the region are acquired via transactional sex. The present study aimed to elucidate the mucosal immune interactions between HIV and HSV2 in the genital tract. METHODS: Endocervical immune cell populations, cytokine/chemokine protein levels in cervico-vaginal secretions and cervical immune gene expression profiles were measured in a well-defined cohort of HIV-infected and uninfected Kenyan FSWs. Associations between the genital immune milieu and infection by and/or shedding of common genital co-pathogens were examined. RESULTS: HIV-infected FSWs were much more likely to be infected by HSV2, and to shed HSV2 DNA in the genital tract. There was also a profound negative 'mucosal synergy' between these viruses. In HIV uninfected FSWs, HSV2 infection was associated with a ten-fold increase in cervical immature dendritic cells (iDC) expressing DC-SIGN, and a three-fold increase in cervical CD4+ T cells expressing CCR5. HIV infection was associated with iDC depletion in the cervix, and with increased HSV2 genital reactivation, which in turn was associated with HIV shedding levels. CONCLUSIONS: The findings suggest a mucosal vicious circle in which HSV2 infection increases HIV target cells in the genital mucosa, subsequent HIV infection impairs HSV2 mucosal immune control, and local HSV2 reactivation enhances both HSV2 and HIV transmission.

"Prevalent herpes simplex virus type 2 infection is associated with altered vaginal flora and an increased susceptibility to multiple sexually transmitted infections"

Author(s): Kaul R, Nagelkerke NJ, Kimani J, et al

Reference: N/A 196:1692-97.

<http://www.journals.uchicago.edu/JID/journal/issues/v196n11/38343/brief/38343.abstract.html>

Published Abstract: *Background.* Prevalent herpes simplex virus type 2 (HSV-2) infection increases human immunodeficiency virus acquisition. We hypothesized that HSV-2 infection might also predispose individuals to acquire other common sexually transmitted infections (STIs). *Methods.* We studied the association between prevalent HSV-2 infection and STI incidence in a prospective, randomized trial of periodic STI therapy among Kenyan female sex workers. Participants were screened monthly for infection with *Neisseria gonorrhoeae* and *Chlamydia trachomatis*, and at least every 6 months for bacterial vaginosis (BV) and infection with *Treponema pallidum*, *Trichomonas vaginalis*, and/or HSV-2. *Results.* Increased prevalence of HSV-2 infection and increased prevalence of BV were each associated with the other; the direction of causality could not be determined. After stratifying for sexual risk-taking, BV

status, and antibiotic use, prevalent HSV-2 infection remained associated with an increased incidence of infection with *N. gonorrhoeae* (incidence rate ratio [IRR], 4.3 [95% confidence interval {CI}, 1.5-12.2]), *T. vaginalis* (IRR, 2.3 [95% CI, 1.3-4.2]), and syphilis (IRR, 4.7 [95% CI, 1.1-19.9]). BV was associated with increased rates of infection with *C. trachomatis* (IRR, 2.1 [95% CI, 1.1-3.8]) and *T. vaginalis* (IRR, 8.0 [95% CI, 3.2-19.8]). *Conclusion.* Increased prevalences of HSV-2 infection and BV were associated with each other and also associated with enhanced susceptibility to an overlapping spectrum of other STIs. Demonstration of causality will require clinical trials that suppress HSV-2 infection, BV, or both.

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7. POLITICS AND POLICY

"The poorest bear the brunt of the HIV/AIDS epidemic"

Date: 13 November 2007

Source: *The Vancouver Sun*

Author(s): Alexis Palmer

<http://www.canada.com/vancouversun/news/editorial/story.html?id=0106b207-b062-4c5f-8e18-4682ab2053d1>

The average 34-year-old Canadian woman is contemplating having her first child.

In Zambia, 34 is the average age that a woman dies. It seems extreme, but it is not so different from neighbouring sub-Saharan countries in Africa.

There are many reasons for this, from the colonial legacy to structural inequities to geographic vulnerabilities, but the main culprit for the drop in life expectancy is the HIV/AIDS pandemic.

An estimated 28 million people in sub-Saharan Africa are living with HIV/AIDS. In Canada, HIV/AIDS is still a major concern with 2,300 to 4,500 new infections each year, but the advantage for Canadians is that we have access to treatment in the form of antiretroviral therapy (ART). For those able to access the main health channels, HIV has evolved from being a death sentence to being a manageable chronic disease. No doubt this is due to the tireless work of medical personnel, public health agencies and human rights advocates.

It is certainly important to recognize the successes in our communities; it is equally important not to forget those who are still struggling in resource-poor parts of the world.

Globally, 40 million people are living with HIV/AIDS, six million of whom need life-saving antiretroviral drugs (ARVs) right now. Six million people who are sure to die without them.

Worldwide, in 2005, 384,000 people were receiving drugs through the Global Fund, with the vast majority of the recipients living in sub-Saharan Africa; 384,000 people out of the six million in need translates as only 6.4 per cent of the people in need being reached. Surely we can do better than that.

Millions of people die each year because of AIDS, malaria and tuberculosis, all of which are treatable and preventable. These diseases always affect the impoverished and vulnerable more severely.

In the case of HIV, there is no disputing the fact that it affects the poor, marginalized and resource-poor more acutely than any other population. Providing treatment in the form of ARVs can improve prevention, reduce stigmas, enhance dignity and instil hope in people for whom there is none.

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

"WHO talks on research strategy for developing world diseases stall"

Date: 12 November 2007

Source: *Drug Researcher.com*

Author(s): Staff reporter

<http://drugresearcher.com/news/ng.asp?id=81282>

Talks between World Health Organization (WHO) member states and the drug industry over how to narrow the health gap between rich and poor countries have stalled.

The WHO Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property comprises Member States but encourages contribution from "individuals, civil society groups, government institutions, academic and research institutions, the private sector and other interested parties".

Their second meeting is ending this week with no agreed strategy and plan of action.

Tasked with ensuring that poorer countries have better access to medicines and also with stimulating innovation in research and development (R and D) for diseases that disproportionately affect people in developing countries, the working group will reconvene next April, before presenting its plan to the World Health Assembly in May.

The pharmaceutical industry argues that without strong sales and profits, it cannot justify the huge expense of drug discovery and development, and should be given more financial incentives to conduct this type of research.

In a statement, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) said that adapted, innovative funding mechanisms could create a 'pull' mechanism by creating "adequate demand for future innovative medicines and vaccines to address unmet developing world health needs."

"While all of us are disappointed, the issue of addressing unmet developing world health requires precise, pragmatic and sustainable solutions," said Dr. Harvey Bale, director general of IFPMA.

"Delegates have to sift through a wide range of policy proposals. Some advocate sustainable, practical solutions, built on the concrete improvements achieved so far, while others are largely theoretical or ideological in nature."

He added that although existing practical approaches, such as the Special Program for Research and Training in Tropical Diseases (TDR), are effective, they need to be reinforced.

The IFPMA said that the pharma industry should be encouraged to increase its involvement in R and D for for diseases of the developing world through incentives, such as orphan drug legislation and transferable fast-track regulatory reviews of the sort introduced by the US Food and Drug Administration (FDA) earlier this year.

In six days of talks involving representatives from 140 Member States of the WHO, the group did however make progress on agreeing basic principles underlying the effort, as well as on some specific elements of the strategy, such as how to promote R and D and prioritise those needs.

"25 years of HIV/AIDS science: reaching the poor with research advances"

Source: *Fauci AS. Cell. 2007 Nov 02;131(3)429-32.*

http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=17981106&dopt=AbstractPlus

Last year marked the 25th anniversary of the recognition of what we now call AIDS. The AIDS pandemic has claimed more than 25 million lives, the majority of them in the developing world, and has exacerbated poverty and slowed human development. Although much has been accomplished in HIV/AIDS research, much remains to be done, especially regarding delivery of HIV/AIDS therapies and care and prevention interventions to the poorest countries that need them most.

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8. HIV/AIDS FUNDING

"Gates Foundation, China to partner in HIV prevention"

Date: 14 November 2007

Source: *The Seattle Times*

Author(s): Kristi Heim

http://seattletimes.nsource.com/html/health/2004012740_gateschina14m.html

The Bill and Melinda Gates Foundation is launching a major partnership with the Chinese government to fight the spread of AIDS in China, after years of groundwork. The foundation said Tuesday it will commit an initial \$50 million toward rapidly expanding HIV-prevention efforts in high-risk populations and work with both the central government and nongovernmental organizations.

Dr. Ray Yip, former China director of the U.S. Centers for Disease Control and Prevention, will head the program from Beijing, where a small team of Gates Foundation staff will administer the funding and provide technical support.

The Gates funding would equal one-third of China's total government spending on HIV/AIDS this year. Of the total, \$20 million will go to the Chinese Ministry of Health and \$30 million will go to local, national and international NGOs. The grants will target the groups most vulnerable to HIV infection, such as injection drug users, sex workers and men who have sex with men.

While the prevalence of HIV remains relatively low in China, with about 650,000 people infected, halting its further spread is key to preventing an epidemic, experts say. In some parts of the country, more than half of injection drug users are HIV-positive. In the 1990s, thousands of people became infected in rural Henan province after donating blood plasma at collection centers that used contaminated equipment. Infection rates are also growing among men who have sex with men.

The government has made some progress, including opening 350 methadone clinics to curb needle-sharing by heroin addicts. At the same time, social stigma and official mistrust of grass-roots AIDS groups remain powerful obstacles. The country's top AIDS activists are routinely put under house arrest, and the foundation cited a study in China that found nearly a third of doctors said they would refuse to treat an HIV-positive person.

The funding will go toward expanding HIV testing, ensuring care and support for HIV-positive people, training to reduce high-risk behavior and educating the public.

"It really is right on target," said Dr. King Holmes, professor of medicine and director of the University of Washington Center for AIDS and STDs. "When you have an HIV epidemic so concentrated in high-risk populations, it's much more efficient and effective to focus prevention efforts on those groups."

The approach is similar to the Gates Foundation's Avahan HIV prevention initiative in India.

While other organizations focus on treatment or a vaccine, "the Gates Foundation really almost stands alone in emphasizing prevention of HIV transmission," Holmes said.

"Global Fund grants over \$1 Bn to fight disease in developing countries"

Date: 13 November 2007

Source: *Agence France Presse*

<http://www.medindia.net/news/Global-Fund-Grants-Over-1-Bn-to-Fight-Disease-in-Developing-Countries-29300-1.htm>

The Global Fund to fight AIDS, Tuberculosis and Malaria on Monday said it has approved 73 new grants worth more than 1.1 billion dollars (757 million euros) in developing countries over the next two years. The Fund, a public-private partnership set up by the then United Nations secretary general Kofi Annan in 2002, approved the grants during a board meeting in Kunming, China, it said in a statement.

The new grants mean the Fund's budget is now 32 percent higher than the 846 million dollars initially forecast for 2007. AIDS projects make up 48 percent of the total, malaria 42 percent and TB 10 percent, the Fund said. Two thirds of the projects (66 percent) are in Africa, 13 percent in Asia, 13 percent in the Middle East and 5 percent in Latin America, it added.

"This is the largest funding round in the Global Fund's history. The board is pleased with the strength and high level of ambition of the new grants and is looking forward to scaling up in the fight against the three diseases," said board chair Rajat Gupta.

For malaria, some 62 percent of the proposals were approved and 19 countries will benefit from the new packages. The Global Fund has said it needs between 12 and 18 billion dollars to fund its existing programmes and initiate new ones between 2008 and 2010.

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9. PHARMACEUTICAL INDUSTRY

"FDA damned if it does, damned if it doesn't"

Date: 09 November 2007

Source: *Fortune*

Author(s): John Simons

http://money.cnn.com/2007/11/08/magazines/fortune/simons_fda.fortune/?postversion=2007110905

The FDA just can't win. After years of public ridicule and congressional scrutiny, the Food and Drug Administration is taking a tougher stance against drugmakers in its review of new medicines. That new cautiousness, however, rankles its most powerful constituents: Big Pharma CEOs who charge that the agency is standing in the way of new medicines - and progress.

So is the FDA really to blame?

The agency's critics are vexed about recent reports that show FDA regulators have approved only 15 novel medicines so far this year - a pace that will likely match a 10-year low reached in 2002. Big Pharma CEOs contend that the FDA has become too anxious and hyper-vigilant about safety, requiring reams of additional data before it can make a decision.

"These developments have a negative impact on us," Novartis CEO Dan Vasella told *Fortune* recently. "Congress has been pressuring FDA reviewers - and it's extremely stressful for them. So, not making a decision becomes beneficial." Schering-Plough (Charts, *Fortune* 500) Chief Executive Fred Hassan echoed Vasella's sentiments in a recent interview with the *Wall Street Journal*. "When bureaucrats come under pressure, they tend to choose the path of

asking for more data, as opposed to approving the drug."

Wyeth CEO Bob Essner lodged a more scandalous charge. He told the Financial Times earlier this week that the FDA's new safety-first attitude is "essentially establishing monopolies" to companies that are first to get a drug approved in a particular therapeutic class. Essner believes the FDA is now using the efficacy of existing drugs as a benchmark for whether a new drug gets approved in the same class. "If you're the first company to get approved in a certain area and competitors can't get on the market, the FDA is now establishing monopolies. And that's certainly not its mandate," noted Essner.

Wyeth has had three drugs delayed or rejected this year: bifeprunox, a treatment for schizophrenia, Pristiq, for depression and menopausal symptoms, and Viviant for osteoporosis. For its part, Novartis recently had its potential blockbuster diabetes treatment, Galvus, delayed by FDA for more testing, too.

Even so, FDA officials deny that there are new criteria in place for assessing new medicines. Some of the shift may be institutional. Until recently, the agency has lacked clear leadership for most of the decade. The commissioner's post was empty for nearly the first two years of the Bush Administration. Mark McClellan ran the FDA for 16 months starting in late 2002. After McClellan left to run Medicare and Medicaid in 2004, the FDA's top slot remained unfilled again until 2005, when Lester Crawford took the helm - for just two months before resigning. Bush named Andrew Von Eschenbach acting commissioner in September 2005. Von Eschenbach didn't get the official title of commissioner until December 2006.

Ultimately, though, FDA Deputy Commissioner Janet Woodcock blames the industry for the dearth of new drugs coming through the agency. "I know the CEOs think we have become extremely conservative, but the standard for getting a drug approved has not changed," says Woodcock. "The number of new drug approvals is directly proportional to the number of applications we receive." The reason, then, for the downturn in new drugs approved in recent years? "It's because we're getting fewer submissions," says Woodcock.

The numbers support Woodcock's claim. It's no secret that Big Pharma has hit a research dry spell. Industry labs are churning out fewer novel discoveries and pipelines are virtually empty. The drop in new discoveries is reflected in the number of submissions sent to the FDA. Between 1996 and 2000, when the industry was still riding the wave of new lab finds, companies submitted an average of 38 new drug applications - technically "new molecular entity filings" - per year to the FDA. In turn, during the same period, the FDA granted an average of 36 approvals per year (see chart).

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

"CROs link arms to spread reach"

Date: 08 November 2007

Source: *Outsourcing-Pharma.com*

Author(s): Kirsty Barnes

<http://in-pharmatechnologist.com/news/ng.asp?id=81183>

This week two sets of contract research organisations (CROs) have announced plans to link arms in order to spread their reach further into this increasingly globalised marketplace.

India's Manipal AcuNova has this week announced a planned merger with German clinical research organisation (CRO) Ecron.

The new entity, named Ecron AcuNova, will be headquartered in Princeton, New Jersey - the current location of Acunova's US headquarters - and will provide Phase I-IV clinical trial services, including project management, biostatistics, clinical data management, medical writing, central laboratory and bioavailability/bioequivalence studies.

The European headquarters will be at Ecron's current location in Frankfurt and there will be an Asian base in Bangalore, India. There will be a staff of 265 employees and this is expected to grow, said the firms.

Ecron AcuNova said it would standardise its clinical operations using the current German practices of Ecron whilst streamlining its data management processes using the present methods employed in India by Acunova: "We foresee harmonisation of SOPs within the next six months."

Dr Wiedey, president of Ecron said: "This merger will benefit our European and US clients. The possibility of extending trials from Europe to India will make drug development faster".

"Trial data can be analysed with biostatisticians and data management professionals from India, speeding up submission to regulators like EMEA and FDA. We can take up bigger, complex projects with a broader range of services like central lab and PK/PD service."

"Indian CROs do not have a track record in seeing a drug through development and into market. Hence this merger will combine Acunova's access to investigators and patients with Ecron's quality reputation, making drugs available faster. Clients will be able to conduct trials at west and east European hospitals and enter regulated markets", added DA Prasanna, vice chairman of Acunova.

Meanwhile, two European CROs, Harrison Clinical Research and Cyncron have made a pact to collaborate together on their services offerings and broach new geographies.

Headquartered in Munich, Harrison provides clinical operations along with services in Regulatory affairs, medical writing, biometrics and pharmacovigilance, with offices throughout Central and Eastern Europe, as well as Russia and Ukraine.

From Munich the firm also runs a 35-bed clinical research unit for phase I and IIa clinical trials and a unit for outpatient studies.

Cyncron on the other hand, is based in Copenhagen and offers clinical operations in the Nordic countries from offices in Sweden and Finland, along with the same additional accompanying services.

The CRO also runs a 60-bed facility for phase I and IIa studies and ambulatory activities.

"Biomarker market predicted to 'explode'"

Date: 07 November 2007

Source: *Drug Researcher.com*

Author(s): Matt Wilkinson

<http://www.drugresearcher.com/news/ng.asp?n=81169&m=2DRGN09&c=fcswojzbacwmbng>

The global market for biomarkers is expected to more than double over the next 5 years to reach an estimated \$12.8bn (8.7bn euros), according to a new market research report.

Biomarkers are biochemical features that either directly or indirectly provide information about the presence of a disease and its progression (or remission) and effects of a drug compound on the disease.

They can be used to evaluate drug therapies in clinical trials, acting as 'surrogate endpoints' during clinical trials where ultimately the condition would lead to the patients death if not treated effectively.

Biomarkers could also prove invaluable in determining the efficacy of drugs for neurological diseases such as Alzheimer's where currently the only way to conclusive tell whether a patient has the disease is to open up the brain after death and look for the build up of amyloid plaques.

Additionally they can be used to monitor a patients response to a drug to minimise the likelihood of them suffering an adverse event (AE).

These far-reaching benefits have led analysts from BCC Research to predict that the global market for biomarkers will grow from a predicted value of \$5.6bn in 2007 to \$12.8bn by 2012 at a compound average growth rate (CAGR) of 18 per cent.

The analyst's findings are discussed in a new report entitled: 'Biomarkers: The Expanding Global Market'.

BCC research segmented the biomarker market into three main sections: biomarker discovery, molecular diagnostics and clinical trials.

Of these, the biomarker discovery for applications in drug discovery, preclinical studies of drug development and diagnostics research applications was the largest and accounted for nearly 48 per cent of the total market in 2007.

This market is expected to grow to at a CAGR of 16.9 per cent to reach nearly \$6bn by 2012, somewhat vindicating companies such as Vermillion (formerly CIPHERGEN) turning their back on instrumentation sales to focus on biomarker discovery programmes.

The second biggest segment was found to be the use of biomarkers on molecular diagnostics applications which was estimated to be worth \$2.3bn in 2007. The report predicts this market will grow at a CAGR of 17.5 per cent to be worth \$5.2bn by 2012.

This market will provide the point-of-care and laboratory based diagnostic tools that enable a more informed ability to choose the right drug for a disease and patient.

While currently the smallest business segment, having been valued at around \$612m in 2007, the clinical trials market has been predicted to see the largest growth rate with a CAGR of 23.5 per cent.

This growth would see the market for biomarkers in clinical trials reach \$1.8bn by 2012, and has already been spotted by many CROs (contract research organisations), with Covance having launched a 'biomarker expert team' earlier this year.

The report suggests that the use of biomarkers to aid the discovery, testing and prescription of oncology therapeutics will be one of the biggest application areas. Applications in the cardiovascular and central nervous system areas are expected to grow during the next 7 years.

Advances in technology that enable faster metabolomic, proteomic and genomic data acquisition as well as its integration with clinical trial data using bioinformatics software will all be major driving forces behind the growth of this burgeoning area.

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10. ANNOUNCEMENTS

Call for Social Science and Cultural Studies Papers - HIV/AIDS in its third decade: renewed critique in social and cultural analysis

<http://www.iasociety.org/Default.aspx?pagelD=151>

The identification of HIV/AIDS nearly thirty years ago occasioned important developments in the social and cultural analysis of illness and disease. Critical analyses of science and its relationship to activism, research on illness

experience, stigma, sexuality and identity, and critiques of the limits of behavioural science were among the foci of a remarkable period of innovation in social thought and research.

As HIV/AIDS nears three decades of intervention, a series of new challenges are apparent. These include, for example, how to conceptualize and respond to transformations in the bodily experience of HIV, the pharmaceuticalization of life, the globalization of clinical scientific research on HIV/AIDS, the growing disparities in health and access to care for people living with HIV both within developed countries and between the global North and global South, a perceived crisis in the prevention of HIV, the growing trend toward the integration of HIV treatment and prevention, the nature and implication of shifts in the gendered and racialized representation of HIV/AIDS, and transformations in the relationship of science and activism.

Alongside these transformations, shifts have occurred in the social study of HIV infection. Most notably, HIV research from behavioural and health sciences perspectives has continued to develop and there are signs of a burgeoning interest in community-based research on HIV/AIDS. However, critical social and cultural approaches to the study of HIV/AIDS have not fared as well. Particularly missing have been the application of contemporary social theory to critical, social analyses of HIV and transformations of social theory itself to take into account emerging empirical research.

In this special issue of *Social Theory and Health* we invite papers written from a critical social science or cultural studies perspective on the issues facing the HIV/AIDS field nearly three decades since initial identification of the virus. In keeping with the journal's interdisciplinary perspective, contributions from a range and/or combination of disciplines including, for example, sociology, anthropology, cultural studies, history and critical psychology are encouraged. We particularly encourage papers that extend the scope of critical analyses of HIV by engaging with contemporary debates and issues in social theory. Both theory and theoretico-empirical papers are invited.

Contributors are welcome to approach the guest editors with initial inquiries about content or style. Please visit the journal website: <http://www.palgrave-journals.com/sth/index.html> and click on 'Instructions for authors' for guidelines on paper formatting and length.

Investing In Young People's Health and Development: Research That Improves Policies and Perspectives - An International Conference

http://www.jhsph.edu/gatesinstitute/policy_practice/adolhealth

The Bill and Melinda Gates Institute for Population and Reproductive Health at the Johns Hopkins Bloomberg School of Public Health, USA, will host an international conference - Investing in Young People's Health and Development: Research that Improves Policies and Programs - with its partners: Institute of Public Health, Obafemi Awolowo University; and Center for Population and Reproductive Health, University of Ibadan; and Nigeria's federal ministries of health, youth, and education, in partnership with a consortium of more than 40 international and national organizations.

This conference aims to provide an international forum for exchanging research and programmatically generated

evidence on how to meet the health and developmental needs of young people in low -resource settings. The conference offers an opportunity for researchers and practitioners - as consumers of research findings and implementers of youth programming - as well as youth themselves, to learn from research, share lessons and valuable experiences, and provide recommendations.

EDITOR'S NOTE: Further information on this conference, including Call for Abstracts, is available at the above website.

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