



ALLIANCE FOR MICROBICIDE DEVELOPMENT

04 January 2008, Volume 9, Number 1

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

"Sex work, border society and stigma: questions for Steffanie Strathdee"

Date: 29 December 2007

Source: *Voice of San Diego*

Author(s): Sam Hodgson

http://www.voiceofsandiego.org/articles/2008/01/02/government/featured_stories/80strathdee122907.txt

Earlier this year, UCSD researcher Stephanie Strathdee released a study chronicling various characteristics of female sex workers in Tijuana and other border cities.

The results were shocking. Twenty-seven percent of the women Strathdee studied tested positive for at least one sexually transmitted infection; 14 percent almost always use drugs before sex; 73 percent have clients who use drugs. When examining sex workers with U.S. clients, she found the median price per sex act with a condom was \$20. The price for a sex act without a condom: \$30.

Strathdee and her colleagues' study was interventionist in nature. The researchers aimed to encourage safe-sex practices, such as wearing condoms and receiving regular tests for STIs. But Strathdee says that more intervention is needed, and it's needed now.

"What we're seeing in Tijuana is the edge of an emerging HIV epidemic," Strathdee says. "And, if we don't do something about it -- not just as individuals, but as a society, as a border community on both sides -- then we're going to be paying the price."

Strathdee sat down with [voiceofsandiego.org](http://www.voiceofsandiego.org) to talk about her research.

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One of the most alarming things that came out of this study is that for 10 extra dollars, many sex workers would have sex without a condom. Is that an issue of not thinking much about their health or is it an issue of education?

I think that's an important point, that for just a little bit of extra money, some sex workers in Tijuana would be having sex without condoms. I think what's important for people in San Diego and in the armchairs of middle America to understand is that some people who are involved in sex work are involved in the trade because they are economically deprived and socially disadvantaged. And the only way that they can make ends meet is to try to sell their body. And, if somebody's offering them a little bit of extra money for unprotected sex, they may not realize that not only are they compromising their health and possible they health of their lovers or children, but they're putting a community at risk. So, what's important for everybody to realize is that nobody should have to put a price on their health. And, nobody should be putting sex workers in the position where they should have to ask themselves "is it worth it." And, I think that, nobody really likes condoms, but they are the reality that we have to face in this world until we have a vaccine or we have a **microbicide** that women can use without men knowing about it that would eradicate the virus. Until that day happens, condoms are going to be a reality and we're just going to have to deal with that.

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EDITOR'S NOTE: The above is an excerpt of the full interview, which is available for public access at the above website.

"Circumcision to prevent HIV: a promising strategy raises provocative questions"

Date: 28 December 2007

Source: *Journal Watch General Medicine*

Author(s): Bruce Soloway

<http://general-medicine.jwatch.org/cgi/content/full/2007/1228/9?ct=ct>

As access to antiretroviral therapy for HIV-infected people slowly penetrates the developing world, preventing new HIV infections remains a high priority. Unfortunately, efforts to lower transmission rates through behavior change and use of vaginal **microbicides** generally have been disappointing, and an HIV vaccine remains only a distant hope.

In December 2006, the NIH announced the early termination of two randomized controlled studies of adult male circumcision in Kenya and Uganda after interim analyses showed that, in each trial, HIV incidence was halved among men who had been circumcised compared with those who had not. In both trials, researchers randomized uncircumcised, HIV-negative men to surgical circumcision either immediately or after a delay of 24 months; all participants were given risk-reduction counseling and condoms. No differences in risk behaviors were observed between groups in either study nor were severe complications of surgery seen (*Journal Watch* Mar 13 2007).

Based on these studies, an editorialist called male circumcision "the most compelling evidence-based [HIV] prevention strategy to emerge since the results from mother-to-child transmission clinical trials." Epidemiologic modeling suggested that, in southern Africa alone, widespread male circumcision could prevent 2 million new HIV infections and 300,000 deaths in the next decade. The huge potential benefits of this strategy immediately brought forth new questions: What might be the direct and indirect effects on male-to-female transmission? What is the optimal age for circumcision? How can resources be deployed to maximize benefits and minimize risks? Will circumcision be accepted in different cultures? How can circumcision be promoted without undermining education about condom use and campaigns against female genital mutilation?

Finally, what are the implications of these findings for advice on newborn circumcision in developed countries? In a study published in 2006, uncircumcised men in a New Zealand birth cohort were more than three times as likely as circumcised men to have sexually transmitted infections between age 18 and age 25 (*Journal Watch* Dec 7 2006). Other evidence suggests that circumcision lowers risk for urinary tract infections, genital ulcer disease, penile cancer, and, perhaps, transmission of human papillomavirus. The perceived benefits of newborn circumcision in any setting will depend on the perceived risks for these negative outcomes. The new data on HIV and sexually transmitted diseases could shift the discussion perceptibly toward advocacy for circumcision in the developed world, particularly among groups perceived to be at greatest risk for HIV infection.

"N-9 contraceptives must carry warning label"

Date: 27 December 2007

Source: *Bay Area Reporter*

Author(s): Ed Walsh

<http://www.ebar.com/news/article.php?sec=news&article=2556>

The federal Food and Drug Administration is adopting a new rule that will require warning labels on contraceptive products that contain the spermicide nonoxynol-9 but the federal agency is delaying the establishment of a similar rule on condoms containing N-9.

"It's still not sufficient," said Judy Auerbach, the deputy executive director of science and public policy for the San Francisco AIDS Foundation.

Echoed Anna Forbes, the deputy director for Global Campaign for **Microbicides**, "It seems to me that they are completely stalling about this."

The FDA is considering labeling requirements for N-9 condoms separately because it classifies condoms as "medical devices." The two major manufacturers of N-9 condoms, Church and Dwight, the makers of the Trojan brand, and Ansell, the maker of the LifeStyles brand, wrote to the FDA suggesting that warning consumers about N-9 condoms could be confusing and could cause fewer consumers to use condoms at all.

That objection was the major factor in causing the FDA to delay N-9 labeling rules.

Citing that objection, the FDA opted to study the issue further. The first phase of the study will be completed by February and the second phase, which will take about 17 weeks, will begin after the FDA analyzes the first study, according to FDA spokeswoman Peper Long.

A number of organizations, including the Global Campaign for **Microbicides** and SFAF, have called for the removal of N-9 from condoms.

In an advisory letter to the FDA last year, Fred Dillon, who was then SFAF's public policy and communications director, wrote: "... the San Francisco AIDS Foundation has joined with a broad coalition of women's health groups, HIV/AIDS organizations, state and local public health officials, and research scientists calling on manufacturers to remove N-9 from condoms and lubricants, because the small amount of N-9 they contain is dangerous if used rectally and offers no documented contraceptive benefit. While there has been progress on this front, we are disappointed that some companies continue to produce N-9 condoms. The San Francisco AIDS Foundation strongly encourages the FDA to take immediate steps to end the manufacturing or sale."

Barring manufacturers choosing to voluntarily remove N-9 from condoms, SFAF is recommending that the FDA require warning labels for condoms containing N-9.

N-9 was once promoted as a way to reduce the risk of HIV transmission after it was shown to kill the AIDS virus in laboratory studies. But subsequent studies on humans showed it had just the opposite effect because it stripped the protective cells lining the rectum and vagina, leaving the user at a greater risk of HIV transmission.

The FDA says that the rule governing contraceptive products other than condoms is being finalized following a public comment period. The agency expects the rule will take effect on June 19, 2008.

Although condoms containing N-9 will not be affected by the new rule, the N-9 contraceptive products will include the following warning: "Use a latex condom without nonoxynol-9 if you or your sex partner has HIV/AIDS, multiple sex partners, or other HIV risk factors."

In its exhaustive 2001 report on N-9, the World Health Organization found that N-9 condoms do not provide users with any additional contraceptive benefit and "should not be promoted."

N-9 was once included in lubricants that were marketed to gay men. After a series of articles appeared in the Bay Area Reporter in 2002, all three major manufacturers who were producing N-9 lube agreed to stop. Most manufacturers of N-9 condoms including the Berkeley-based Mayer Laboratories, which produces Kimono condoms, as well as the corporate giants, Durex and Johnson and Johnson, voluntarily stopped producing N-9 condoms.

Contrary to the WHO report, the manufacturers who still make N-9 condoms, Church and Dwight and Ansell, have maintained that N-9 condoms provide an additional contraceptive benefit.

In letters to the FDA last year, Church and Dwight and Ansell maintained that N-9 condoms provide an additional contraceptive benefit.

Forbes said that those corporations are making an "intuitive leap." Forbes said there is no evidence that the small amount of N-9 in condoms provides any benefit to the consumer.

"Women's perceptions and experiences of HIV prevention trials in Soweto, South Africa"

Author(s): Stadler JJ, Delany S, Mntambo M

Reference: N/A 66(1):189-200.

<http://www.ncbi.nlm.nih.gov/pubmed/17904718?dopt=Abstract>

Published Abstract: Persistently high rates of HIV infection in sub-Saharan Africa have driven the exploration for additional methods of prevention, such as **microbicides**. Multi-site, field-based clinical trials of **microbicides** are conducted in diverse social and cultural contexts. Local social and cultural perceptions of HIV/AIDS and sexual risk can have profound implications in shaping community responses to the clinical trials, thereby affecting enrolment and retention. Moreover, clinical trials may have a significant impact on trial participants with regard to their views of AIDS, health and relationships. Following these issues, this paper explores the subjective experiences of women enrolled in a **microbicide** feasibility study. Qualitative data were collected in two phases. The first phase took place prior to the inception of the feasibility study. Men and women from Soweto participated in focus group discussions about their perceptions and experiences of the AIDS epidemic and sexual risk. The second phase started once enrolment into the feasibility study had begun. Twenty-one women who were enrolled in the **microbicide** feasibility study were interviewed and participated in focus groups, and were asked about their experiences of participating in the **microbicide** feasibility study. Special attention was placed on how they felt their participation had affected their everyday lives. Interviews and discussions were conducted in local languages, recorded, translated and transcribed. Data were analysed thematically. The central finding of this study is the sense of empowerment that feasibility study participants felt in spite of their being embedded in a culture that has come to fear, deny or ignore AIDS. We discuss the critical role of repeated, voluntary counselling and testing, knowledge of HIV status, and heightened awareness of sexual and reproductive health in reshaping study participants' approaches to sexual relationships and AIDS, as well as the benefits that participation entailed.

2. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

"Acceptability of hypothetical microbicides among women in sex establishments in rural areas in southern China"

Author(s): Wang Y, Liao S, Weeks MR, et al

Reference: N/A 35(1):102-110.

<http://www.stdjournals.com/pt/re/std/abstract.00007435-200801000-00021.htm;jsessionid=H7IKkThX6KT12JD3RxHTQhySxfcJ1XgkLTT561MPm5VGGwCYV8yR!901085598!181195628!8091!-1>

Published Abstract: *Objectives and Goal:* The objectives of this study were to measure the potential acceptability of a hypothetical **microbicide** among women in sex establishments in rural areas of Southern China and demographic, behavioral, and social context factors likely to affect **microbicide** acceptability. *Study Design:* This was a cross-sectional survey, using a quota sampling, among 300 women from sex establishments in 3 rural towns. An interviewer-administered standardized questionnaire was used to measure the acceptability score of hypothetical **microbicides'** characteristics, as well as sexual relationships and behaviors and other contextual factors. *Results:* Findings showed a generally positive response to **microbicides**, indicated by an acceptability index score of 2.89 (SD, 0.56, scale of 1-4) in the overall sample. Multivariate analysis shows that the acceptability score varied significantly by study sites, type of sex-work establishments, marital status, sex partner type, vaginal product experience, locus of control by partners, and locus of control by chance. *Conclusions:* **Microbicides** may be acceptable among sex workers in rural settings in China; however, contextual factors should be carefully considered in education and promotion of **microbicides** in the future.

"Adolescent girls' communication with partners about microbicide use"

Author(s): Short MB, Ramos S, Oakes JK, et al

Reference: N/A 4(4):243-48.

<http://highwire.stanford.edu/cgi/medline/pmid;18082067>

Published Abstract: *Background:* Topical **microbicides** could be a female-controlled method of preventing sexually transmissible infections. Despite the possibility of surreptitious use, most women report that they would tell partners, and **microbicides** may be detectable. The purpose of the present study was to examine communication between adolescent girls and their partners regarding **microbicides**. *Methods:* Girls (aged 14-21 years) participated in a 6-month study in which they were given vaginal moisturisers to use when they had intercourse. Data was collected about their demographics, sexual histories and conversations with mothers and partners. Both quantitative and qualitative analyses were conducted. *Results:* Girls (n = 171) were asked about conversations with their partners. Talking with mothers and using the product were significantly related to talking with partners. Reasons for not talking

were intrapersonal or interpersonal variables, the context of the relationship did not warrant an explanation and the lack of a decision to communicate. There seemed to be no difference in conversations for those who used or did not use. Girls had conversations with their partners when deciding to be in the study, when they were engaged in study activities or when deciding to use the product. Conversations about using the product focused on needing to use the product because of study demands, the lubricating properties or wanting to experience product use. *Conclusions:* Most of the girls talked to their partners and had positive conversations. Girls may need help initiating conversations and managing reluctant partners.

"Antimicrobial polypeptides are key anti-HIV-1 effector molecules of cervicovaginal host defense"

Author(s): Cole AM, Cole AL

Reference: N/A 59(1):27-34.

<http://highwire.stanford.edu/cgi/medline/pmid;18154593>

Published Abstract: Mucosal surfaces of the cervix and vagina are portals for heterosexual transmission of human immunodeficiency virus type 1 (HIV-1) and, therefore, play a fundamental role in the pathogenesis of primary infection. Cationic antimicrobial polypeptides including defensins are the principal effector molecules of mucosal innate immunity against microbes and viruses such as HIV. In cervicovaginal secretions, antimicrobial polypeptides constitute the majority of the intrinsic anti-HIV-1 activity, synergism between cationic polypeptides is complex, and full anti-HIV-1 activity involves the complete complement of cationic polypeptides. Periods in which cationic antimicrobial polypeptide expression is reduced are likely associated with increased susceptibility to HIV-1 infection. This review provides an overview of the role of cationic antimicrobial polypeptides in innate cervicovaginal anti-HIV-1 host defense, and discusses how hormones and bacterial infections can regulate their expression. Emphasis is placed on the theta-defensin (retrocyclin) class of anti-HIV-1 peptides and their potential for development as topical **microbicides** to prevent HIV-1 transmission.

"Mucosal innate immunity as a determinant of HIV susceptibility"

Author(s): Iqbal SM, Kaul R

Reference: N/A 59(1):44-54.

<http://highwire.stanford.edu/cgi/medline/pmid;18154595>

Published Abstract: Most human immunodeficiency virus (HIV) is acquired during sex, across a mucosal membrane. Despite many advances in our understanding of HIV pathogenesis, the initial events during mucosal transmission have been poorly characterized, and a better understanding of these events will probably be a key to the development of successful **microbicide(s)** and/or a preventative HIV vaccine. While a vast majority of mucosal HIV exposures do not result in productive infection, implying that innate mucosal immune defenses are highly protective, failure of these mucosal defenses resulted in over 3 million new HIV infections in 2006. We review recent findings regarding HIV mucosal immunopathogenesis, emphasizing the importance of innate immunity in natural protection

from infection, and examine how natural or induced perturbations in the mucosal innate system may underpin HIV transmission. Given the great challenges to the development of HIV **microbicides** and vaccines, identification and enhancement of 'natural' innate immune defenses present attractive avenues for development of safe, non-toxic **microbicides**.

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3. PUBLISHED RESEARCH: RELEVANT BASIC AND TRANSLATIONAL SCIENCE

"Betulinic acid derivatives that target gp120 and inhibit multiple genetic subtypes of human immunodeficiency virus type 1"

Author(s): Weihong L, Huang L, Ho P, et al

Reference: N/A 52(1):128-36.

<http://aac.asm.org/cgi/content/abstract/52/1/128?ct=ct>

Published Abstract: Betulinic acid (BA) derivatives can inhibit human immunodeficiency virus type 1 (HIV-1) entry or maturation depending on side chain modifications. While BA derivatives with antimaturation activity have attracted considerable interest, the anti-HIV-1 profile and molecular mechanism of BA derivatives with anti-HIV-1 entry activity (termed BA entry inhibitors) have not been well defined. In this study, we have found that two BA entry inhibitors, IC9564 and A43D, exhibited a broad spectrum of anti-HIV-1 activity. Both compounds inhibited multiple strains of HIV-1 from clades A, B, and C at submicromolar concentrations. Clade C viruses were more sensitive to the compounds than clade A and B viruses. Interestingly, IC9564 at subinhibitory concentrations could alter the antifusion activities of other entry inhibitors. IC9564 was especially potent in increasing the sensitivity of HIV-1YU2 Env-mediated membrane fusion to the CCR5 inhibitor TAK-779. Results from this study suggest that the V3 loop of gp120 is a critical determinant for the anti-HIV-1 activity of IC9564. IC9564 escape viruses contained mutations near the tip of the V3 loop. Moreover, IC9564 could compete with the binding of V3 monoclonal antibodies 447-52D and 39F. IC9564 also competed with the binding of gp120/CD4 complexes to chemokine receptors. In summary, these results suggest that BA entry inhibitors can potently inhibit a broad spectrum of primary HIV-1 isolates by targeting the V3 loop of gp120.

"Comparative evaluation of the inhibitory activities of a series of pyrimidinedione congeners that inhibit human immunodeficiency virus types 1 and 2"

Author(s): Buckheit RW, Hartman TL, Watson KM, et al

Reference: N/A 52(1):225-36.

<http://aac.asm.org/cgi/content/abstract/52/1/225?ct=ct>

Published Abstract: Seventy-three analogs of SJ-3366 (1-(3-cyclopenten-1-ylmethyl)-5-ethyl-6-(3,5-dimethylbenzoyl)-2,4(1H,3H)-pyrimidinedione) were synthesized and comparatively evaluated for their ability to inhibit

the replication of human immunodeficiency virus type 1 (HIV-1) and HIV-2 and for their ability to suppress virus entry and reverse transcription. These studies were performed to identify inhibitors with activity greater than that of the current lead molecule (SJ-3366) and to utilize structure-activity relationships (SAR) to define the chemical features of the pyrimidinedione congeners responsible for their efficacy, toxicity, and dual mechanism of action against HIV. The results of our SAR evaluations have demonstrated that the addition of the homocyclic moiety at the N-1 of the pyrimidinedione results in acquisition of the ability to inhibit virus entry and extends the range of action of the compounds to include HIV-2. In addition, the results demonstrate that analogs with a methyl linker between the homocyclic substitution and the N-1 of the pyrimidinedione had a greater number of highly active molecules than those analogs possessing ethyl linkers. Six molecules were identified with activity equivalent to or greater than that of SJ-3366, and five additional molecules with highly potent inhibition of reverse transcriptase and virus entry and possessing high efficacy against both HIV-1 and HIV-2 were identified. Six molecules exhibited significant inhibition of viruses with the highly problematic nonnucleoside reverse transcriptase inhibitor (NNRTI) resistance engendering amino acid change K103N in the reverse transcriptase. These evaluations indicate that a new class of NNRTIs has been identified and that these NNRTIs possess highly potent inhibition of HIV-1 with an extended range of action, which now includes HIV-2.

"Genital herpes in Africa: time to rethink treatment"

Source: O`Farrell N, Moodley P, Sturm AW. *Lancet* 370(9605):2164-66, 22 Dec 2007;Viewpoint.

<http://www.thelancet.com/journals/lancet/article/PIIS0140673607619102/fulltext>

That genital ulcer disease increases the risk of HIV infection was first identified in Africa in the mid-1980s,¹ and several studies have since confirmed this association. Bacterial genital ulcer diseases such as chancroid, syphilis, or donovanosis were initially thought to be responsible for the link with HIV. As the incidence of these bacterial diseases has diminished, genital herpes has been identified as having an increasing role in HIV transmission at the population level because of its growing prevalence.²⁻⁴ In a meta-analysis, the population-attributable risk percentage of HIV transmissions due to herpes simplex virus type 2 (HSV2) infection (that causes genital herpes) was estimated to be 19% in populations which had a 22% HSV2 antibody positive prevalence;⁵ this risk rose to 47% in populations with 80% HSV2 antibody positive prevalence. The importance of HSV2 in Africa has been reinforced by evidence that both men and women have high HSV2 antibody levels.⁵

Despite the strength of this epidemiological evidence, only minimal treatment is available for genital herpes throughout most of the African continent despite treatment for other STIs (sexually transmitted infections) being readily available. The reasons for this lack of attention are many (panel); herpes is often referred to as an incurable STI and although this is also the case for HIV, the availability of highly active antiretroviral therapy (HAART) has reduced mortality and now made HIV a manageable condition in most cases. This progress in HIV treatment suggests that the perceived logistical difficulties with drug management of HSV2 infections could be resolved in a similar way.

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

"In the era of systematic reviews, does the size of an individual trial still matter"

Author(s): Guyatt GH, Mills EJ, Elbourne D

Reference: N/A 5(1):e4. The PLOS Medicine Debate.

<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0050004>

Published Abstract: Background to the debate: Systematic reviews that combine high-quality evidence from several trials are now widely considered to be at the top of the hierarchy of clinical evidence. Given the primacy of systematic reviews - and the fact that individual clinical trials rarely provide definitive answers to a clinical research question - some commentators question whether the sample size calculation for an individual trial still matters. Others point out that small trials can still be potentially misleading.

"Telephone support to improve antiretroviral medication adherence: a multisite, randomized controlled trial"

Author(s): Reynolds NR, Testa MA, Su M, et al

Reference: N/A 47(1):62-68.

<http://www.jaids.org/pt/re/jaids/abstract.00126334-200801010-00007.htm;jsessionid=H27WCfpdJwyT4kL4wvCR47MnFQVnJQJqv1mFr6m41CXKjJl0Tnqz!1390229169!181195629!8091!-1>

Published Abstract: *Objective:* To determine whether proactive telephone support improves adherence to antiretroviral therapy (ART) and clinical outcomes when compared to standard care. *Methods:* A multisite, randomized controlled trial (RCT) was conducted with 109 ART-naive subjects coenrolled in AIDS Clinical Trials Group (ACTG) 384. Subjects received standard clinic-based patient education (SC) or SC plus structured proactive telephone calls. The customized calls were conducted from a central site over 16 weeks by trained registered nurses. Outcome measures (collected over 64 weeks) included an ACTG adherence questionnaire and 384 study endpoints. *Results:* For the primary endpoint, self-reported adherence, a significantly better overall treatment effect was observed in the telephone group ($P = 0.023$). In a post hoc analysis, composite adherence scores, taken as the first 2 factor scores from a principal components analysis, also found significant intervention benefit ($P = 0.023$ and 0.019 respectively). For the 384 primary study endpoint, time to regimen failure, the Kaplan-Meier survival curve for the telephone group remained above the SC group at weeks 20 to 64; a Cox proportional hazard model that controlled for baseline RNA stratification, CD4, gender, age, race/ethnicity, and randomized ART treatment arm suggested the telephone group tended to have a lower risk for failure (hazard ratio = 0.68; 95% confidence interval: 0.38 to 1.23). *Conclusions:* Findings indicate that customized, proactive telephone calls have good potential to improve long-term adherence behavior and clinical outcomes.

4. EPIDEMIOLOGY

"Reduced rates of HIV acquisition during unprotected sex by Kenyan female sex workers predating population declines in HIV prevalence"

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

Reference: N/A 22(1):131-37.

<http://www.aidsonline.com/pt/re/aids/abstract.00002030-200801020-00016.htm;jsessionid=H7pZbYkVHkwbT4HrWBLFVw8vYV1yPNTvxY01JfgRpGdxQhNd340v!1390229169!181195629!8091!-1>

Published Abstract: *Objectives:* Female sex workers (FSWs) form a core group at high risk of both sexual HIV acquisition and secondary transmission. The magnitude of these risks may vary by sexual risk taking, partner HIV prevalence, host immune factors and genital co-infections. We examined temporal trends in HIV prevalence and per-act incidence, adjusted for behavioral and other variables, in FSWs from Nairobi, Kenya. *Methods:* An open cohort of FSWs followed since 1985. Behavioral and clinical data were collected six monthly from 1985 to 2005, and sexually transmitted infection (STI) diagnostics and HIV serology performed. A Cox proportional hazards model with time-dependent covariables was used to estimate infection risk as a function of calendar time. *Results:* HIV prevalence in new FSW enrollees peaked at 81% in 1986, and was consistently below 50% after 1997. Initially uninfected FSWs remained at high risk of acquiring HIV throughout the study period, but the rate of HIV acquisition during unprotected sex with a casual client declined by over four-fold. This reduction correlated closely with decreases in gonorrhoea prevalence, and predated reductions in the Kenyan HIV population prevalence by over a decade. *Conclusions:* The per-act rate of HIV acquisition in high-risk Nairobi FSWs fell dramatically between 1985 and 2005. This decline may represent the impact of improved STI prevention/therapy, immunogenetic shifts in at-risk women, or changes in the proportion of HIV exposures occurring with clients who had acute HIV infection. Declining HIV incidence in high-risk cohorts may predict and/or be causally related to future reductions in population prevalence.

5. HIV/AIDS VACCINES

"Why a market-driven vaccine plan faces big obstacles"

Date: 31 December 2007

Source: *The Wall Street Journal*

Author(s): Nick Timiraos

http://online.wsj.com/article_email/SB119906129300958545-IMyQjAxMDE4OTA5MzAwNjMxWj.html

Nearly 2.5 million children die every year from diseases for which vaccine development or distribution is faltering. Drug makers have shown little interest in vaccines that could stem this tide of childhood deaths because they aren't profitable.

Now, a handful of Western nations and international bodies is moving ahead with a market-based experiment aimed at tackling two big problems: the lack of research on vaccines needed primarily by poor countries -- only 10% of disease-related drug research focuses on maladies that affect 90% of the world's population -- and the long distribution time. Hepatitis B vaccine was developed in 1981, but two decades passed before it was introduced in the world's poorest nations.

The new approach, called the advance market commitment, works like this: Donors commit to buying yet-to-be-developed vaccines in bulk for poor nations, if drug makers are able to deliver a product that meets specifications and a price can be settled on in advance. The idea is that everyone involved wins: Drug companies get an incentive to innovate, while donors avoid bankrolling dead-end research.

Supporters of the plan range from Bill Gates to Pope Benedict XVI and include public-health officials, nongovernmental organizations, wealthy nations and some drug makers. Backers say the beauty of the idea is that it lets the market -- not governments -- determine which vaccine will be produced and which company will produce it.

"If the government were to subsidize research and development, ultimately it would be bureaucrats choosing the right avenue to research, selecting the right lab, the right institution," says Carlo Monticelli, an economist in the Italian Finance Ministry, which has been a top financial backer of the initiative.

Advance market commitments are still untested. In February, donors agreed to the first one -- for a vaccine for pneumococcal disease, which kills 700,000 children annually in developing countries. The Gates Foundation, the United Kingdom, Italy, Canada, Norway and Russia have committed \$1.5 billion for the project. Backers hope to complete the legal framework by April and to deliver a vaccine to participating countries by 2010.

But while such commitments are more promising than some alternatives -- trying to bully drug makers into cooperating with global-aid agendas, for example, or paying them millions of dollars to chase long-shot solutions -- the theory behind them has some serious holes in it.

For one thing, drug companies may not be willing to bet their development budgets on these commitments. Before a deal can be reached, drug makers, donors and recipient countries have to agree on a price and specifications for the vaccine. "Pharmaceutical companies will always be concerned about how reliable those [advance market commitments] really are, whether the plug could be pulled out at the 11th hour," says Peter J. Hotez, a tropical-disease specialist at George Washington University.

Moreover, though advance market commitments were first conceived as a way to spur research and development of vaccines still at an early stage -- those for HIV, tuberculosis and malaria, for example, which remain years or even decades away from completion -- they may not be well suited for that. Science, not money, presents the biggest hurdles for those diseases, says Adel Mahmoud, the former head of vaccines at Merck. That suggests advance commitments may be better suited to vaccines in the late stages of development, where funding is the biggest obstacle.

At least two companies, GlaxoSmithKline PLC and Wyeth, have late-stage vaccines in development that could help control pneumococcal disease in the developing world. (Wyeth's existing pneumococcal vaccine, Prevnar, isn't effective against strains of the disease found there.) The goal of the project is twofold: Spur final completion of the vaccines and offer financial insurance to drug makers that a market exists for them.

Skeptics contend that the pilot project won't prove that advance market commitments can deliver big scientific breakthroughs because the initiative is targeting a mostly developed vaccine. Such commitments aim for low-hanging fruit, they say, rather than delivering true scientific innovation.

Oxford economist Andrew Farlow argues that the opportunity costs of an advance market commitment are too high. Even if such arrangements save some lives, he says, they will peel away money and energy that could instead go to less-costly treatments for people already afflicted: "You may get your success story, but it's what you'll lose in the process that you might have had." He and others say that more people would be helped by paying for things like measles immunizations, improved water quality and sanitation or mosquito nets in malarial regions.

And while the "pull" funding of the commitments isn't meant to replace research grants and other "push" funding, some politicians have hailed commitments as a silver bullet. That has critics worrying that other policy approaches could be shortchanged.

Another test: Can advance market commitments encourage competition among drug makers by spurring more than one firm to develop a vaccine? The power of the commitments to draw in vaccine makers from developing countries could be crucial, given that those companies often best understand how to price and distribute vaccines in those markets.

These questions don't mean the experiment is without merit. If it works, it could produce huge societal and economic benefits. The World Health Organization estimates that malaria, for example, accounts for as much as 40% of public-health spending and 50% of outpatient visits in the hardest-hit countries. And a study by Harvard University economists suggests that malaria slows economic growth in the badly hit countries by as much as 1.3% a year. Those countries that reduced their disease burden by 10% boosted growth by 0.3% annually.

At the heart of an advanced market commitment, says Michael Kremer, the Harvard economist who came up with the idea in the 1990s, is an effort to make markets work for the world's poor.

The shortcomings, though, are a reminder that multiple approaches and some creative thinking will be needed to overcome the world's most daunting health problems.

"Immunization with adenovirus at the large intestinal mucosa as an effective vaccination strategy against sexually transmitted viral infection"

Author(s): Zhu Q, Thomson CW, Rosenthal KL, et al

Reference: N/A 1(1):23-30.

<http://www.nature.com/mi/journal/v1/n1/abs/mi20073a.html>

Published Abstract: The large intestinal mucosa contains immunological structures that may potentially serve as a site for induction of mucosal immunity against infections. Adenovirus (Ad), which is effective in gene transfer to epithelia, may be an ideal antigen delivery system for vaccination at the large intestinal mucosa. To investigate this potential, we immunized mice with recombinant replication-deficient Ad through a single intracolorectal (ICR) administration. Effective transfer of encoded genes was found in both the epithelial layer and lamina propria of the colorectal mucosa. Dendritic cells were able to transfer antigen to the draining lymph nodes, where antigen-specific CD8⁺ T cells were primed. Functional antigen-specific CD8⁺ T cells and IgA-specific antibodies were detected during the effector phase in the large intestine. Compared to other immunization routes (intranasal, subcutaneous), ICR immunization induced stronger colorectal immune responses and more potent protection against rectal challenge with pathogenic viruses. Further, this immunization strategy provided vaginal protection, more potent than that induced by vaccination in the nose or skin. Therefore, large intestine mucosal immunization using Ad represents an effective vaccination strategy against virus infection at both rectal and vaginal mucosal tissue sites.

EDITOR'S NOTE: *Mucosal Immunology is the official publication of the Society of Mucosal Immunology (SMI). It aims to provide a forum for both basic and clinical scientists to discuss all aspects of immunity and inflammation involving mucosal tissues. The journal reflects the interests of scientists studying gastrointestinal, pulmonary, nasopharyngeal, oral, ocular, and genitourinary immunology through the publication of original research articles, scholarly reviews, and timely commentaries, editorials and letters. Publication of basic, translational, and clinical studies will all be given equal consideration. Mucosal Immunology is now accepting submissions of papers discussing all aspects of immunity and inflammation involving mucosal tissues. Consult the guide to authors and submit your paper at <http://www.nature.com/mi/index.html>*

"One step forward, two steps back - will there ever be an AIDS vaccine?"

Source: Steinbrook R. *N Engl J Med* 357(26):2653-55, 27 Dec 2007; Perspective.

<http://content.nejm.org/cgi/content/full/357/26/2653>

In April 1984, when the human immunodeficiency virus (HIV) and AIDS were just beginning to be understood, a senior official in the Department of Health and Human Services stated at a press conference that there would be a marketable vaccine within "a minimum of two years, probably more like three years."¹ This prediction has haunted the search for an AIDS vaccine, whose most recent setback was the announcement that a promising vaccine candidate, Merck's V520, was not effective and may actually have increased some subjects' risk of acquiring HIV. Unfortunately, about a quarter-century after the discovery of HIV, there is neither a marketable vaccine nor a credible expectation about when there will be one.

A successful HIV vaccine would either prevent infection or reduce the viral load in persons who became infected, helping them to remain healthy and perhaps reducing their likelihood of transmitting the virus to others. But vaccine developers face many scientific challenges, including those posed by the genetic diversity and rapid changes of the viral envelope proteins and other features that allow HIV to elude immune control.² Critical immunologic responses

that would prevent infection or control the virus are incompletely understood. Nonetheless, there has been considerable interest in vaccines, such as V520, that induce primarily T-cell responses, because numerous studies have provided evidence of the role of T-cell immunity in controlling HIV infection.

The V520 vaccine consists of three injections of a recombinant, replication-defective adenovirus type 5 vector that carries three HIV genes and was designed to elicit HIV-specific T-cell immune responses (see diagram). Adenovirus type 5 is a common cold virus and is generally considered harmless. The vaccine was evaluated in two trials involving volunteers who were HIV-negative but at high risk for infection. The HIV Vaccine Trials Network, which is funded by the National Institute for Allergy and Infectious Diseases (NIAID), in conjunction with the vaccine developer, Merck, conducted the STEP trial in the United States and abroad; the Phambili trial was conducted in South Africa. In September 2007, the STEP trial, which had enrolled 3000 subjects, was stopped after the data and safety monitoring board, at its first interim analysis, concluded that the vaccine neither prevented HIV infection nor reduced the amount of virus in those who became infected. In October, the Phambili trial, which had enrolled only 801 subjects, was also stopped; the trial's monitoring board concluded that there was no reason to anticipate more favorable results. Participants in both studies were told whether they received vaccine or placebo.

For the Merck vaccine candidate, a replication-deficient adenovirus type 5 was engineered to contain the gag, pol, or nef genes of HIV. This vaccine was given to volunteers at 0, 1, and 6 months. For the Vaccine Research Center (VRC) vaccine, a mixture of six DNA plasmids containing the gag, pol, nef, env A, env B, or env C genes is given to volunteers at 0, 1, and 2 months. At month 6, one injection of a different replication-deficient adenovirus type 5 is given; this was engineered to contain the gag/pol, env A, env B, or env C genes.

Since there was only one HIV case in a female STEP subject (though there were more than 1100 women enrolled), post hoc analyses of the data have focused on men. As of October 17, 2007, there had been 49 HIV infections in men who were HIV-seronegative when they underwent randomization and who had received at least one dose of the vaccine, as compared with 33 infections in comparable men who received placebo. The men at greatest risk for HIV infection appeared to be those who both received the vaccine and had higher levels of immunity to adenovirus type 5 before enrollment. Despite the sobering preliminary analyses, it is unclear whether administration of the vaccine actually increased the risk of acquiring HIV. This will not be known at least until ongoing studies and data analyses are completed - and might remain uncertain indefinitely.

Even the preliminary findings, however, have immediate implications for future vaccine trials, particularly a study involving 8500 patients that had been scheduled to start in the fall of 2007 but is now on hold until at least the summer of 2008. That trial, known as Partnership for AIDS Vaccine Evaluation (PAVE) 100, will test a vaccine strategy developed at the National Institutes of Health (NIH) that has four components: three injections of an HIV DNA vaccine, followed by a single boost with an HIV-adenoviral-vector vaccine (see diagram). The multiclade vaccine primarily elicits T-cell immunity and is another important test of the T-cell vaccine concept.

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

6. OTHER PREVENTION APPROACHES

"Rape cases likely to increase rate of HIV infection"

Date: 03 January 2008

Source: *The Nation*

<http://allafrica.com/stories/200801030006.html>

HIV infection is likely to increase following an upsurge of gang-rapes during the ongoing post-election violence, a government agency has warned. National Aids Control Council chairperson Miriam Were yesterday said gains made by Kenya in the war against Aids are likely to be reversed by the orgy of violence going on in parts of the country. On Tuesday, 19 women and girls were admitted to Nairobi Women's Hospital after they were gang-raped in various city estates. Men and boys who were sexually assaulted were also admitted to hospital.

Anti-retroviral drugs

Experts have praised Kenya for implementing a successful multi-sectoral response to HIV and Aids, which has reduced the national HIV prevalence rate to 5.1 per cent from 6.1 per cent. At the same time, new HIV infections have dropped to 55,000 from the previous 120,000 annually. On Wednesday, Prof Were urged victims of rape and sodomy to ensure they received anti-retroviral drugs in the nearest public health facility within 24 hours and not later than 72 hours.

"Uganda: country needs more HIV solutions"

Date: 31 December 2007

Source: *New Vision*

Author(s): Freddie Ssengooba

<http://allafrica.com/stories/200801020546.html>

As we exhaust the simple solutions to control the spread of HIV/AIDS, we are left with the task of tackling the complex ones. Despite Uganda's leading role in reducing the spread of the HIV infection from about 25% to 6% of the population, the recent estimates show that there are over 110,000 new infections each year. Already, over 150,000 persons are on HIV treatment and about 600,000 are yet to start the treatment.

There is, therefore, a big buildup of HIV infected persons that will need life-long treatment and palliative care services. Currently, most of these services are provided by donors such as US government Ireland, the UK, the World Bank and countries contributing to the Global Fund. Without this support, Uganda cannot shoulder the burden. As the simple solutions to prevent new HIV infections are exhausted, Uganda is faced with more complex causes of HIV transmission.

A major source of new infections is unsafe sex among the discordant couples and the youth. Discordant couples refer to marital relationships where one partner has HIV and the other does not. This contributes to about 60% of the new infections among adults. About a-quarter of the new infections are emerging from persons aged 25 years and below. The increasing number in the population implies that more individuals have HIV at the current population of 35 million people. The new infections in 2002 were estimated at 70,000 compared to about 110,000 in 2006. The increase in population is mostly responsible for more cases of HIV among the population.

Although male circumcision is not 100 % effective, it is the most feasible solution to reduce HIV infection among young couples. The youth face several huddles as they transit into marriage and becoming parents. Simple solutions of abstinence from sex and using condoms soon become erratic, irrelevant or sustainable over a long time.

A young couple will need to have children and will at some stage abandon the condom. In the short-term, the couple can test for HIV before getting marriage but many married couples acquire the infection during their marriage. According to a 2005 survey by the Ministry of Health and the Uganda Bureau of Statistics, one couple in every five has an extra-marital sex problem. The survey shows that extra-marital sex is a window for HIV to invade erstwhile clean couples. To prevent HIV infection arising from extra-marital sex, the current solution is that the practice must be stopped or condoms must be used.

The use of condoms in extra-marital sex was found to be only 34% during the Demographic and Health Survey of 2006. The implication is that 64% of all the extra-marital sex every day is prone to HIV infection. As we advocate for abstinence, faithfulness and the use of condoms, we need to provide contingency plans for those that fail on all these solutions.

With circumcision of boys and men, we will be providing a contingency method to the persons that are reckless in their sexual behaviour. Male circumcision can provide a safety-net that is 50% effective in preventing new infections. There is no doubt that male circumcision is more complex than radio and drama messages to promote abstinence or the use of condoms.

We have reached a time in the evolution of the HIV/AIDS epidemic where the simple ABCD (Abstinence, Being-faithful, Condoms and Drugs) approach is not sufficient to plug all the holes in HIV transmission. The public and our leaders need to seize the challenge and prepare for the tough solutions such as male-circumcision.

The writer is a lecturer at the Makerere Institute of Public Health

"West Bengal's sex workers' remarkable fight against HIV"

Date: 30 December 2007

Source: *Asian News International*

Author(s): Soma Mitra

<http://in.news.yahoo.com/071230/139/6p0gm.html>

Sex workers of Sonagchi, the single largest brothel in India, are doing a remarkable work in prevention of HIV infection and human trafficking by organizing camps for sex workers of West Bengal and asking them to fight for their

rights. Under the banner of Durbar Mahila Samannay Committee (DSMC), which organizes seminars, sex workers and others, who are directly or indirectly linked to the movement, discuss two major issues of HIV infection and human trafficking.

West Bengal is the state with highest number of HIV infected patients. The estimated figure is 150 thousand. At least 9000 sex workers including 3000 flying sex workers are considered as the most vulnerable to HIV infection. Rajeev Shukla, Project Director, West Bengal State AIDS Prevention and Control Society said that Bengal's open border with Bangladesh, Nepal and Bhutan, are the biggest challenge for HIV infection. Migrants from these countries carry the virus and as they are not traceable for treatment they further spread the disease.

Activists at DSMC think that the awareness could only be spread through movement. When 'Use Condom' campaign was launched there was hardly any taker for that. Sex workers were more vocal about violence against them, they said.

"Earlier police raids were so frequent that the numbers of clients were very poor. The fear of loosing them, used to stop us to ask for the use of condom. Police used to think sex workers encourage human trafficking which was an absolutely wrong notion," said Bharati Dey, who has been a sex worker for the last 30 years.

To stop human trafficking in sex trade, a self-regulatory board has been established by the sex workers. The board works as a filter and it checks whether the new girl joining the trade is an adult or a minor. This board also tries to find out if any new girl joining the profession is under any pressure to do so.

"This has been very successful way to check human trafficking, police raids have also reduced considerably," said Swapna Gayen, who too is a sex worker in Sonagachi for over two decades.

During the seminars, sex workers also discussed new amendments proposed in the existing laws, which they feel would criminalize sex work. There have already been protests against the new amendments, which criminalize clients of sex workers. Sex workers feel that such amendments would in return make the entire trade as a crime.

"It will criminalize the entire trade. The new amendments will force the trade to go underground," said a legal expert Tripti Tandon.

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7. POLITICS AND POLICY

"India: Prime destination for unethical clinical trials"

Date: 14 December 2007

Source: *Inter Press Service News Agency*

Author(s): Keya Acharya

<http://www.ipsnews.net/news.asp?idnews=40472>

Lack of regulation, accountability, low costs of operation and wide availability of target participants are reasons why multinational drug companies, researchers and institutions are increasingly basing their clinical trials in India. An estimated 40 percent of all clinical trials now take place in Asia, Eastern Europe, central and south America. "There is no compulsory registration system for clinical trials in these countries and many do not follow European directives in their operations", says Dr. Jacob Sijtsma of the Netherlands-based WEMOS, an advocacy health organisation tracking clinical trials in developing countries.

Sijtsma, who was in India for a bioethics conference, held earlier this month at the Bangalore-based National Institute of Mental Health Sciences, said there is a growing concern in India's medical and civil society on the lax regulation and ethicality over clinical trials conducted in this country. In 2006, WEMOS and the Centre for Research on Multinational Corporations prepared an overview of 22 known examples of unethical clinical trials, eight of which were operating in India.

The Indian examples of illegal and unethical trials involved Sun Pharmaceuticals and Novartis's Letrozole for inducing ovulation when approved only for breast cancer, Novo Nordisk's for diabetes treatment, Solvay Pharmaceuticals' for treating diarrhoea, Johnson and Johnson's for treating acute malaria, Pfizer's for cardiac events, Otsuka's for arterial disease, Indian companies Shantha Biotechnics and Biocon for diabetes and the John Hopkins' University's trials for treating oral cancer.

Other countries with documented illegal trials include Russia, Nepal, Uganda, Peru, China, Nigeria, Argentina and even places like London and New York involving well-known institutes like the U.S. National Institute of Health, Walter Reed Army Institute of Research, Centres for Disease Control and several international pharmaceutical firms.

Dr. Bernard Lo from the University of California at San Francisco, also here for the conference, said even more disturbing questions arise in the field of stem cell research in its newest method called Induced Pluripotent stem cell (iPs cells). In this system, embryonic stem cells are not used, but virtually any cell is taken to the laboratory, inserted with a human gene and grown into human cells.

"This makes for laboratory manipulation of basic science research, no consent is needed by anyone and the cells can be bought commercially, giving rise to all sorts of ethical questions that need to keep pace with the rapid research in this field," said Lo.

"I am extremely concerned about the conduct of stem cell research in India," said Dr. Pushp Bhargava, a highly respected former director of India's Centre for Molecular Biology at Hyderabad city. "We have no idea where these cells are coming from, whether they have been characterised," Bhargava told IPS. "There is no method of validation or checking," he complained.

WEMOS's Dr. Leontien Laterveer says a lack of transparency and secrecy shrouding all clinical trials, whether in India or other countries, makes it very difficult to obtain information about their operations. "We are appealing to Indian organisations looking at this issue to come forward and collaborate with us," say both Laterveer and Sijtsma.

More importantly, there are insufficient checks by the European Union in spite of the Helsinki Declaration on a code of ethics for clinical trials, making it easy for drugs to enter the European market, add the two.

"European pharmaceuticals are also not bothered about legal and regulatory aspects," said Laterveer. "They leave it to the countries themselves." The Helsinki Declaration is currently under review.

"We need the input of Southern experts to help process the review of the Helsinki Declaration," said Sijtsma.

Media exposes of exploitation in cases such as the U.S. John Hopkins' Hospital's collaboration with the Regional Cancer Treatment Centre in Kerala, in 2000, forced the Indian Council of Medical Research (ICMR) to inquire into the trials. The results however are still not public and no action has been taken against its then director, while the Johns Hopkins University barred the principal investigator from heading future research with human subjects.

In recent years, India has made some regulatory attempts, amending its drugs and cosmetics act to require compliance by trial conductors with a set of good clinical practices (GCP) guidelines along with the ethics committee that the ICMR formulated. But there is still no mandatory compensatory payment, or strong penalty against the defaulting company.

"We need to pin down direct responsibility for monitoring with the ethics committee and measures taken to permanently revoke the licence of the defaulting company," says Adarsh Gangadhar, a lawyer attached to the National Academy for Legal Studies and Research in Hyderabad.

Dr. Prathap Tharyan, head of psychiatry at the respected Christian Medical College (CMC), Vellore, and South Asia coordinator of Cochrane, a network of specialists working to improve evidence-based healthcare, averred that "deception, fraud and structural problems in randomised clinical trials" are rampant in India. Tharyan has now helped set up an online Clinical Trials Registry through ICMR. Its implementation, however, remains dependent on wider awareness of the issues involved in India.

"Ethics awareness in India is evolving and the law intervening, but I find a deficiency in working out solutions for implementation," said Madhav Menon, one of India's leading legal experts.

The National Institute of AIDS Research (NIAR) at Pune is committed to setting up community advisory bodies (CABs) with participation from field workers, patients and others concerned to disseminate awareness and information on the rights of participants in clinical trials. However, the entire concept of CABs is still evolving, with insufficient information on rights or ethical principles and no mechanism for redressal of grievances, NIAR's Dr. Sanjay Mehendale told IPS.

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8. ANNOUNCEMENTS

BMC Research Notes

http://blogs.openaccesscentral.com/blogs/bmcblog/entry/bmc_research_notes_completing_the

BioMed Central is pleased to announce the forthcoming launch of the newest addition to the BMC series of journals, *BMC Research Notes*, which will begin to accept submissions in early 2008.

Journals are increasingly concerned with citations and impact factors, and it can be difficult for researchers and clinicians to publish valuable work that may not be highly cited. At the same time, science and medicine are becoming increasingly evidence-based and transparent.

The goal of *BMC Research Notes* is to provide a home for short publications, case series, incremental updates to previous work, results of individual experiments and similar material that currently lack a suitable outlet. The intention is to reduce the loss suffered by the research community when such results remain unpublished.

In clinical research, the prospective registration of randomized controlled trials has become a reality, whilst in the field of genomic research, scientists deposit large volumes of data into publicly accessible databases for the entire community to use.

A key objective of *BMC Research Notes* is to ensure that associated data files will, wherever possible, be published in standard, reusable formats and are exposed to ensure that they are searchable and easily harvested for reuse. We are working with researchers across the full spectrum of biomedical research to define appropriate recommendations for domain-specific data file standards, and we aim to provide detailed 'Additional data file' preparation guidelines, to complement our current detailed figure preparation guidelines.

BMC Research Notes will publish scientifically sound research across all fields of biology and medicine, enabling authors to publish updates to previous research, software tools and databases, data sets, small-scale clinical studies, and reports of confirmatory or 'negative' results. Additionally the journal will welcome descriptions of incremental improvements to methods that as well as short correspondence items and hypotheses. Submissions will be fully peer-reviewed, and will be handled by an international board of academic Associate Editors spanning all biological and medical disciplines.

Community-Based Family Planning Workshop - Feb 2008 in Mali

<http://www.childsurvival.com/features/Register/registration.cfm>

The USAID Flexible Fund, Child Survival Technical Support Plus (CSTS+) Project, and CORE Group are conducting a two-week workshop on the "Basics of Community-Based Family Planning" and "Program Design, Monitoring and Evaluation (PDME) of Family Planning Programs" in Bamako, Mali from February 4 to 15, 2008.

Workshop Objectives

The objectives of the Basics of Community-Based FP and PDME Workshop are to:

- 1) Explain key technical and programmatic concepts of FP service delivery; and
- 2) Explain a six-step process for developing a project design using a results framework and a monitoring and evaluation plan that is linked to the project design.

The workshop is geared towards program managers of community-based FP programs, and mid and senior level managers who are responsible for developing proposals, and designing, implementing, monitoring and evaluating programs. Attached is a detailed workshop description.

The training and materials will be free. Participants and their organizations will be responsible for airfare, local transportation, lodging, meals and incidentals. Lunch will be provided during workshop days.

EDITOR'S NOTE: Please visit the above website to register for this Workshop.

Excellence in Media Award for Global Health - Nominations Due 1 February 2008

http://www.globalhealth.org/conference/view_top.php3?id=744

The Excellence in Media Award for Global Health is given each year to a journalist (print, electronic, and/or visual) who has in the prior year most effectively captured the essence of a major issue in global health and conveyed it to a broad audience. The Global Health Council recognizes the vital role played by the media in informing the public, as well as decision-makers, and seeks through this award to highlight the important contributions to understanding and action made by the winner of the award.

Selection of the awardee is based on the quality of the reporting as well as its wide reach among readers and viewers. Nominations will be considered by an independent panel of noted journalists. See 2007 jury list. The award will be presented in Washington, D.C. at a special awards ceremony during the Global Health Council's annual international conference.

EDITOR'S NOTE: Please visit http://www.globalhealth.org/conference/view_top.php3?id=755 for further background information and criteria.

Fogarty International Center: Draft Strategic Plan: 2008-2012

http://www.fic.nih.gov/about/plan/strategicplan_08-12.htm

In July 2006, the Fogarty International Center (FIC) launched a transparent strategic planning process that included over 150 stakeholders in the U.S. and abroad. An initial Web comment period began in October 2006; stakeholder Strategic Planning Sessions were held in Cairo, Egypt in November 2006 and in Bethesda, Maryland in December 2006. In addition, discussions and retreats were held with the Fogarty Advisory Board and scientific staff respectively. Having garnered input from these diverse groups, FIC has now completed the draft Strategic Plan, and invites comments before the plan goes to press. The draft is available for public access at http://www.fic.nih.gov/about/plan/strategicplan_08-12.pdf, and comments can be sent to FICStratPlan@nih.gov.

Opportunity: Consultancy with AMAG in 2008

In 2007, the African **Microbicides** Advocacy Group (AMAG) embarked on an ambitious Strategic Planning and Organizational Development Process. We set up a special Task Force and brought in OD consultants to support us

through the process. At the end of 2007, we have a strategic plan to help AMAG transition to firmly establish itself, build up a secretariat and scale up its activities. The coming year will be significant for AMAG as we move into this next phase.

To this end, we are looking to bring on board a consultant to work closely with the AMAG Coordinator for up to 30 days over a 6-month period - to support AMAG in developing a fund-raising strategy, support transition activities and prepare specific proposals.

Specific Objectives will include:

1. Preparing specific documents towards the AMAG fund-raising and organisational development process (e.g. prototype proposal, costed workplan)
2. Mapping out and identifying strategic opportunities for fund-raising for AMAG
3. Approaching and/or planning initial meetings with potential funders for AMAG

If you are interested in working with AMAG: Please send us your recent CV/resume, your rates, three references, copy of a recent proposal you have prepared and a short letter stating why you would be interested and noting relevant experience that qualifies you for this. Please make sure to include all contact details.

Please send all documents by 15 January 2008 to amag_info@yahoo.com. Please note the subject of your email as: 2008 Consultancy with AMAG.

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