



ALLIANCE FOR MICROBICIDE DEVELOPMENT

01 February 2008, Volume 9, Number 5

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. MONTHLY MICROBICIDE PIPELINE UPDATE

February 2008

www.microbicide.org

The most recent summaries of Ongoing and Planned and Funded Clinical trials are now available on the Alliance homepage.

- **Microbicide** Candidates in Ongoing Clinical Trials: Summary as of February 2008 <http://www.microbicide.org/microbicideinfo/reference/Microbicide.Ongoing.Clinical.Trials.Summary1Feb08.pdf>
- **Microbicide** Candidates and Ancillary Devices in Planned and Funded Clinical Trials: Summary as of February 2008 <http://www.microbicide.org/microbicideinfo/reference/Microbicides.Planned.Funded.Clinical.Trials1Feb08.pdf>

Currently, there are 12 **microbicide** candidates in clinical development and over 40 confirmed products in preclinical development. As a continued effort to maintain the most up-to-date information, we urge you to visit the Alliance website at www.microbicide.org or contact Stephanie Tillman, Alliance Writer/Research Associate, by email (stillman@microbicide.org) or by phone (301-587-3302) with any updates, questions, or comments.

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2. ALLIANCE UPDATES AND COMMUNITY NEWS

Industrializing Microbicides Symposium at Microbicides 2008

http://www.microbicide.org/meetings/industrializing_microbicides.shtml

Registration and general information for the Alliance for **Microbicide** Development's symposium on Industrializing **Microbicides** are now available on the Alliance's website, http://www.microbicide.org/meetings/industrializing_microbicides.shtml. Updated information on the scientific program, faculty, location, and other event logistics is

provided.

To register, view the program, or learn more about this symposium, please visit: http://www.microbicide.org/meetings/industrializing_microbicides.shtml (the PDF with symposium information is available at <http://www.microbicide.org/microbicideinfo/reference/IndustrializingM2008.31Jan2008.pdf>). Registration is required to attend the symposium and can be completed (1) online, (2) by mail/fax, or (3) on-site. Early registration is strongly encouraged (seating is limited).

The Alliance for **Microbicide** Development organized the symposium in collaboration with the **Microbicides 2008** conference organizers and Scientific Advisory Council. Its objectives are to: 1) provide an overview of the **microbicide**-specific industrialization process so that the wider communities of relevance understand the components of that process and how each affects **microbicide** approval, commercialization, and access; and 2) among key players in the **microbicide** and allied fields, present and discuss core industrialization issues, challenges, and opportunities.

For more information, please contact Latifa Boyce, lboyce@microbicide.org, at the Alliance.

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3. MEDIA COVERAGE OF MICROBICIDES

"Pfizer seeks to prevent HIV"

Date: 30 January 2008

Source: *The Wall Street Journal*

Author(s): Avery Johnson

<http://online.wsj.com/article/SB120166682382128005.html>

A new Pfizer Inc. HIV drug will soon be reformulated in an effort to prevent the transmission of the virus, offering a faint ray of hope in an arena littered with disappointments.

The New York drug maker is expected to announce today that it will license its new medicine, Selzentry, to a nonprofit that investigates ways to turn HIV medicines for infected patients into vaginal substances to prevent transmission to women during sex. The partnership offers a low-risk way for Pfizer to find out if the medicine could become a frequently taken drug, while potentially offering an empowering concept to women in the developing world.

HIV preventives have proven elusive, with researchers and advocates still recovering from last year's collapse of Merck and Co.'s once-promising vaccine trial. And Pfizer's new venture with the International Partnership for **Microbicides** is a long shot that relies on an unproven theory. But with some 33 million people infected with HIV, the virus that causes AIDS, the enormous health and financial stakes continue to drive the hunt for treatments.

Pfizer's drug was approved last year for patients who have undergone other HIV treatment. Pfizer is now giving the IPM a license to try to turn the medicine into a **vaginal gel**, ring or film that might prevent transmission.

The Pfizer drug already has a safety portfolio approved by the Food and Drug Administration, potentially making it easier to get through testing in a new form. And the way Selzentry works, by blocking the virus from infecting healthy cells, could make it more appropriate for prevention than medicines that prevent already-diseased cells from replicating.

Jack Watters, Pfizer's vice president for external medical affairs, is hopeful about Selzentry's prospects as a preventive therapy, but he says "we're a long way from proving that."

Some drugs are used to both prevent and treat diseases such as malaria and tuberculosis, and there has been hope that existing HIV medicines can somehow do the same. The topical use is preferred to daily pills, because less medicine gets into the bloodstream, potentially making it safer for long-term use, and it can be concentrated where the disease enters the body, says Zeda Rosenberg, IPM's chief executive.

Selzentry could be particularly well-suited for HIV prevention. Because the drug interrupts the virus's ability to penetrate a healthy cell at an entry point called CCR5, it is only approved for patients who have one strain of the disease. But that receptor is the primary one responsible for HIV transmission, says John Mellors, chief of infectious diseases at the University of Pittsburgh's medical school, who has done consulting for Merck and Co., Abbott Laboratories, Gilead Sciences Inc. and the IPM.

But the **microbicides**' promise is clouded. Last year, one of the most advanced **microbicide** trials was halted when early data indicated that more women became infected with HIV than those using a placebo.

EDITOR'S NOTE: Similar reports are available through Reuters (

http://today.reuters.com/news/articlenews.aspx?type=scienceNews&storyID=2008-01-30T234042Z_01_N30234081_RTRUKOC_0_US-AIDS-MICROBICIDE.xml) and Aidsmap (<http://www.aidsmap.com/en/news/4A06350C-9DFD-432A-9678-E1B9FCA2A7EC.asp>).

"URI pharmacy professor developing HIV cream"

Date: 30 January 2008

Source: *The Good 5 Cent Cigar*

Author(s): Tyler Will

<http://media.www.ramcigar.com/media/storage/paper366/news/2008/01/30/Campus/Uri-Pharmacy.Professor.Developing.Hiv.Cream-3175827.shtml>

Dr. Keykavous Parang, a pharmacy professor at the University of Rhode Island, has developed a chemical compound after 18 years of research that could prevent contraction of HIV, which causes AIDS. He is also researching a compound that could slow the growth of cancer cells.

The HIV-related compounds, which Parang calls "KP1" and "KP17," will be used in a cream that a woman could apply before sexual intercourse. The compounds in the cream would prevent contraction of HIV and also act as a contraceptive by killing the man's sperm. Parang said the scientists wanted to develop a cream that is HIV virus resistant, has no side effects, causes no irritation, can be used easily, is affordable and could be sold over-the-

counter.

"So what we are trying to do is develop a **microbicide**," Parang said.

The development of a vaccine has been abandoned by many scientists because HIV mutates quickly, and a new vaccine would be needed for every case; which is the same reason why a cure for the common cold hasn't been found, according to Parang. The topical nature of the HIV resistant cream avoids that problem while fulfilling many of the researchers' initial goals.

"We don't have a lot of other problems associated with the other drugs," Parang said.

A chief problem with anti-viral drugs, which are administered to AIDS patients, is that while the drugs slow the progress of AIDS in the body, they can destroy good red blood cells, and many of the drugs need to be taken for the rest of the victim's life.

"It's easier to develop because it's going to be topically administered," Parang said.

The cream could be available to consumers in 10 years, Parang said. In the first stages of testing, rabbits will be given a 50-gram dose, and if animal trials are successful, human volunteers will be tested. Some cellular tests have already been conducted.

"Results indicated that several compounds exhibit highly promising antiviral activity," Parang said.

Parang has received \$1.2 million in research funds during the last year for his HIV and cancer-related research projects, and a total of \$2.2 million since he arrived at URI seven years ago. Dr. Parang's research has been published more than 60 times. His scientific team includes Dr. Reza Mehvar, Dr. Gustavo Doncel, Dr. Solomon Snyder, Dr. Aaron Schuler, Dr. Chandravnu Dash, and Nestor Carballeira. He has two URI collaborators, Dr. Gonqin Sun and Dr. Geoff Bhotun.

"AIDS preventive measures only way to check the menace"

Date: 29 January 2008

Source: *The Rising Nepal*

Author(s): G.K. Pakavath

<http://www.gorkhapatra.org.np/content.php?nid=35178>

The international AIDS conference is different. Unlike other scientific meetings, the AIDS conference sets a trend. From a relatively small group of scientists meeting in Atlanta in 1985, the conference has grown into a powerful forum shaping opinion, attitudes and future response to the epidemic.

That being so, the 16th international AIDS conference in Toronto with close to 25,000 participants has sent out the message that the world should no longer keep its hopes limited to a distant and elusive vaccine but put in more efforts into preventing people from getting the virus.

Experiments on circumcision as a method of prevention have shown very promising results.

Microbicides, a gel that can be used by women to check the virus from entering her immune cells, is another real possibility and so is a daily pill taken by people who consider themselves in high-risk groups.

What does it mean for Nepal which arguably has a significant number of people living with HIV? The Nepalese epidemic is gradually getting concentrated in the rural areas with 58 per cent of the infections being reported from villages. Human behaviour here is not necessarily about indulgence, which is what stigmatises the disease, but more about survival.

Men migrating in search of jobs pick up the virus while looking for sex as they spend long years in dreary and desperate conditions. Poverty, illiteracy and complete lack of awareness become vehicles for the virus to dig deeper into these areas.

Few people ever go on anti-retrovirals, drugs that delay the onset of AIDS, in these villages. Even if they do, the free supply of these drugs is erratic. Moreover, travel to the city is costly, which leads to an abrupt stoppage of treatment, leading to an early death. Of the tens of thousands of people living with HIV, as per official estimates, only a few are on these drugs. Majority of them are with the full blown disease and need treatment urgently. Of these, only a small chunk of the patients are getting the medicines through various private donor agencies and the public health system.

Treatment of HIV is not only expensive but also inaccessible for most people. Unfortunately, these issues and voices remain relatively unheard of even though expression of dissent is an essential part of the conference matrix.

So even 20 years after the entry of AIDS, the issues here remain just as they were: public health systems have virtually collapsed and, therefore, seeking treatment for HIV is difficult, and most villages have no access to health facilities. In many of these villages, a quack uses a single injection on several patients without sterilising it.

The injection therapy is commonly used for the ailment. Such use of unsterilised needles, when seen in the villages with a visible epidemic, is quite frightening. Any strategy to check the virus cannot afford to ignore the crumbling state of public health systems.

Circumcision as the next best prevention method can hardly hold any excitement for Nepal. Even if the trials prove to be successful, strong cultural and religious barriers will not allow politicians and scientists to even discuss it as an option. A cheap **microbicide** may be the wonder gel that could prevent thousands of infections, but only among those who are adequately aware. Hundreds of newly married girls, aged 18-19, seen at HIV counseling and testing centres across hospitals in the country find out about the virus only when they are test positive during ante-natal check-ups.

A prevention pill cannot again be an option for the vast majority of those who practise high-risk behavior. If at all it works, it would be far too expensive and risky in places where there is only a rudimentary health system.

It is time to look into the more basic issues which may not need a large amount of money for research. Simple low-cost technology options that could help reach information and healthcare to every corner of the country is the answer. It is also time to hear more voices from Nepal at these conferences, whether in terms of showcasing its work, expressing its angst or sharing its concerns. For instance, a global push for countries to start testing routinely for HIV needs to be debated at forums like these.

Global commitment

Finally, our own government needs to be less defensive about its issues and especially about its numbers. There is global commitment. It is time to join with our own, and time to deliver to all.

"Seaweed-based gel offers women hope against HIV"

Date: 29 January 2008

Source: *Business Day (South Africa)*

Author(s): Tamar Kahn

<http://www.businessday.co.za/articles/national.aspx?ID=BD4A693738>

Researchers around the country are anxiously awaiting the results of the Carraguard **microbicide** trial, a large-scale study involving more than 6000 South African women. It is intended to demonstrate that a seaweed-based **vaginal gel** offers some protection against the human immunodeficiency virus (HIV).

It is the only **microbicide** study so far to have reached the end of a phase 3 trial, the last stage of research before companies can register a product with regulatory authorities and begin marketing it.

Although resources have been poured into **microbicide** research worldwide in recent years, none of the candidate products worked. Interest in the Carraguard study, the results of which are expected next month, is therefore especially keen.

In 2000, advanced research into a **microbicide** containing the spermicide nonoxynol-9 was stopped after it was found to do more harm than good. Last year's studies of the efficacy of a product based on cellulose sulphate were stopped on similar grounds.

Even a **microbicide** that turns out to be only partially effective against HIV would be a valuable addition to the scant arsenal against the virus. At present, only condoms offer reliable protection against sexual transmission of HIV, says Smruti Patel, one of the study's principal investigators.

A **microbicide** could also prove to be a life-saving alternative to condoms in situations where people refuse to use them, says her co-investigator Alana de Kock. In SA alone, more than 5,5-million people were infected with HIV, and young women were at particularly high risk.

"Regardless of how much information these women have, at the end of the day they depend on their men putting on a condom," says De Kock.

Carraguard contains carrageenan, a seaweed derivative that has been classed as generally safe for human consumption by the US Food and Drug Administration. Carrageenan has a long history in the food and cosmetics industry. It is used to thicken ice cream and baby food, and gives skin creams an slippery texture, says Dr Sumen Govender of the Population Council, one of the study's sponsors. Other funders include the Bill and Melinda Gates Foundation and USAID.

Laboratory and animal tests have already demonstrated that Carraguard acts as a mechanical barrier against HIV, and stops the virus entering the mucosal cells lining the vagina.

Studies on human volunteers in six countries, including the US, SA and Thailand, showed the product was safe and well tolerated by both women and men before scientists began enrolling volunteers for the final stage of the research , conducted in SA .

SA was chosen because the research had to be done among HIV-negative women who were at high risk of getting the disease, which meant working in a community with a high background incidence of the disease, says De Kock. Sites were selected in Gugulethu, Soshanguve and Isipingo, all communities with high HIV prevalence.

In Gugulethu for example, 28,8% of women attending ante-natal clinics in 2006 were HIV positive.

The women were divided into two groups, with half getting the **microbicide** gel and half getting a dummy version that appeared identical. Neither the researchers nor the volunteers knew which arm of the trial the women belonged to.

The volunteers were given regular counselling, and advised to use condoms and the gel every time they had sex, since no one knew whether they were getting the candidate product or the placebo, or indeed whether the candidate product would work, says De Kock. The women used a small plastic applicator to insert about a teaspoon of the clear, odourless gel into their vagina up to an hour before they had sex.

If it turns out that Carraguard is indeed effective against HIV, much must still be done before it finds a spot on pharmacy shelves. If an effective product is to have a significant effect on the HIV epidemic, it will have to be swiftly registered by the authorities and manufactured at an affordable price, says Govender.

Whether or not the trial results are what they hope to hear, De Kock and her colleagues believe the work they have done to teach women about their reproductive health has been a worthy undertaking in its own right.

The volunteers were screened for cervical cancer, HIV and other sexually transmitted infections, and treated. They were also counselled.

"The women came in quite ignorant about their own bodies, and are now much more educated. Women have also improved their communication about HIV and have got their partners to start using condoms," she says.

"Feminization of HIV/AIDS a serious threat to Nepal"

Date: 28 January 2008

Source: *American Chronicle*

Author(s): Surya B Prasai

<http://www.americanchronicle.com/articles/50403>

EDITOR'S NOTE: *The text below is an excerpt of a much larger article, which is available for public access at the above website.*

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In December 2007, World AIDS Day was marked in Nepal and the rest of South Asia with a new roll out theme to "Stop AIDS: Keep the Promise". Going by such leadership challenges, it is equally important to find a national leadership structure supporting young Nepali role models from the arts, cinema, drama, popular music and social activism. Their role should be to motivate the younger generation away from AIDS, help the country imbibe full working AIDS strategies, not merely something that looks good on paper or was applied successfully elsewhere, but is also accepted at the people's level. While acting locally, Nepalis, must at the same time ponder globally on the possibility of applying new scientific or bio-medical research discovery that might advance the cause of an effective vaccine, **microbicide** pill or an ultimate toxin that will get rid of AIDS. The other important factor is Nepal does not have an effective communications and behavior change strategy to deliver on the global AIDS prevention and control promises. It also does not have able field workers and health personnel to support one-on-one in-patient service delivery, care and support. It lacks qualified counselors, dieticians, clinicians, lab technicians, doctors and other

scientists who can face the truth of long term impact mitigation. Nepal also must move quickly towards universalizing pre-and post-test counseling particularly for women. Nepali health authorities must ponder: are they playing with the right data, the actual numbers infected within the immediate service zone and the potential numbers to deal with in the future? Are they so far only making promises or also getting involved in alleviating the suffering of those affected by HIV/AIDS, particularly in the remote corners of Nepal where pockets of HIV/AIDS are larger than anticipated and women do most of the daily work ? In other words, are Nepalis in leadership positions ready to narrow the discrimination gap and lighten the heavier toll their society will have to face in future due to the feminization of HIV/AIDS in Nepal? It is time Nepal took a serious look on this issue and come up with effective national strategy to give Nepali women and young girls a definite respite from HIV/AIDS.

"Talkin' about dem AIDS"

Date: 25 January 2008

Source: *Housing Works AIDS Issues Update*

http://www.hwupdate.org/update/2008/01/talkin_about_dem_aids.html

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Hitting the bars

Post-rally, about 20 activists, or "Team Bird Dog" as Health GAP's Kaytee Riek named them, headed to the debate parties for Clinton and Obama at nearby bars. The teams cheered when Clinton was asked a question that mentioned HIV/AIDS (though the question didn't actually address it directly). While Clinton was a no-show to her party, Obama showed up and shook hands, giving bird-doggers - who sat cross-legged by the stage to make sure they were in the very front when the candidate arrived - a brief moment to ask questions. First time bird dogger Christine Park asked Obama about his commitment to fight violence against women and its link to the feminization of AIDS. He said he was committed to that, and because of his support of female-controlled prevention efforts, he sponsored the **Microbicide** Development Act (see last week's Update story). Currently the MDA is floundering and advocates hope it will go to committee in the House and the Senate.

"I was pleased with his responsiveness, but now we need to follow up on it and makes sure he sticks to his commitments," said Park, the campaign organizer for the 41 Million Strong Campaign, which is an organization of women of color united to raise awareness about and demand an end to Violence Against Women and HIV/AIDS.

Following the success in Myrtle Beach, C2EA will continue to push candidates nationally as well as locally to fight HIV/AIDS. "The most exciting part of the rally was hearing all those voices demanding an end to HIV/AIDS on the national level," Bryant said. "Imagine that energy if they can do it back home? They will scare the hell out of their city council members."

EDITOR'S NOTE: The above is an excerpt from a recent edition of Housing Works. The full issue is available at the above website.

"The NAPWA/TAEP HIV/AIDS Policy Report"

Date: 31 December 2007

Source: *Poz Magazine*

Author(s): Robert Greenwald, Megan Hughes, Lindsey Murtagh, et al., et al

http://www.poz.com/articles/napwa_aids_report_2141_13781.shtml

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Research

In addition to making efforts in education and prevention, the 110th Congress has introduced two bills designed to expand HIV/AIDS research. The Comprehensive Tuberculosis B Elimination Act of 2007 (S. 1551), which remains in committee, expands research on the relationship between tuberculosis and HIV/AIDS. The **Microbicide** Development Act (S. 823 and H.R. 1420) would promote the development of **microbicides** that could prevent the transmission of HIV and other sexually transmitted diseases. This bill has been introduced in the past. It remains to be seen whether it will be enacted by this Congress.

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EDITOR'S NOTE: *The above text is an excerpt of a larger article publicly available at the above website.*

"Are condoms the answer to rising rates of non-HIV sexually transmitted infections? Yes"

Source: *BMJ. 2008 Jan 26;336(7637):184.*

Author(s): Markus J Steiner, Willard Cates

<http://www.bmj.com/cgi/content/full/336/7637/184?ct=ct>

Consistent condom use can reduce the spread of HIV, and Markus Steiner and Willard Cates believe condoms are the answer to other sexually transmitted infections. But Stephen Genuis argues that a more comprehensive approach is needed

Condoms can and should play a central role in halting the rising rates of sexually transmitted infection other than HIV. For people who are sexually active, condoms remain our best solution to reducing risks of acquiring sexually transmitted infections (if uninfected) or transmitting these infections (if infected). Strong evidence from laboratory studies and mounting clinical studies shows that condoms effectively reduce the risk of transmission. In addition, for specific populations, increased levels of condom use have been associated with decreases in reported sexually transmitted infections.

Condoms work

Condoms protect the wearer and his partner from infection by covering the penile glans and shaft, which are the major portals of entry and exit of sexually transmitted pathogens. Laboratory studies indicate that latex condoms are an

effective physical barrier against passage of even the smallest sexually transmitted pathogens.¹

When placed on the penis before any genital contact and used throughout intercourse, the condom prevents direct contact with semen; genital lesions and subclinical viral shedding on the glans and shaft of the penis; and penile, vaginal, or anal discharges. Thus, condoms reduce the risk of infections that are transmitted primarily to or from the penile urethra such as HIV, gonorrhoea, chlamydia, trichomoniasis, and hepatitis B. Condoms also reduce the risk of infections that are transmitted primarily through skin or mucosal surfaces when these areas are covered by the condom, such as genital herpes, syphilis, chancroid, and human papillomavirus infection.

Although clinical studies have shown inconsistent protective effects for most sexually transmitted infections other than HIV,² much of this can be attributed to limitations in study design. Limitations in measurement of self reported condom use and exposure to infected partners complicate interpretation of results.³ Moreover, the levels of protection from condoms are likely to differ between infections because of variations in their routes of transmission, infectivity, and prevalence.

Despite these limitations, a recent systematic literature review of 45 published studies of condom use and gonorrhea and chlamydia provides strong evidence that condoms reduce risk in both men and women.³ Many of these studies did not measure critical factors such as exposure to infected partners, consistent and correct condom use, or incident infection. The observed protective effects are therefore likely to be underestimates. When one of the 45 studies was adjusted for infection status by using a case crossover analysis, the protective effect of condoms increased dramatically.⁴ Recent well designed studies have also shown consistent and correct use of condoms can reduce herpes simplex virus⁵ and cervical human papillomavirus infection.⁶

One problem with relying on condoms to halt the rising rates of infection is that the promotion of condoms remains controversial in many countries, including the United States. The data are clear, however. Other than abstinence, which is difficult to achieve, condoms are the most effective means of stopping the spread of sexually transmitted infections. We need to focus on ensuring consistent and correct condom use rather than denigrating condoms as being less than perfect.

Two recent reviews,^{7 8} show that behavioural interventions featuring condom promotion are associated with increases in reported condom use and, to a lesser extent, decreases in incidence of sexually transmitted infection. One theoretical concern is that condom promotion could lead to risk compensation - men who use condoms may feel safer and consequently engage in more frequent sex or sex with more partners, thus increasing the risk of transmission. The most recent review of 174 condom related prevention approaches, however, concluded that sexual risk reduction interventions do not increase unsafe sexual behaviour.⁹ In addition, a recent systematic review showed adding condom promotion to interventions focusing on abstinence does not undermine the abstinence message.¹⁰ Despite this reassurance, we must continue to be vigilant when promoting the use of condoms to avoid giving users a false sense of security; we should refer, for example, to safer sex rather than safe sex.

Condoms in context

Like any prevention tool (such as seat belts, airbags, smoking cessation programmes, virginity pledges) condoms are not 100% effective. Preventing sexually transmitted infection, just as with other health conditions, requires incremental, partially effective steps to produce collectively effective (but not perfect) prevention programmes.¹¹ Controlling the spread of infection will require different, mutually reinforcing techniques.

Although combined prevention strategies can greatly reduce the spread of sexually transmitted infections,¹² they need to be carefully designed and implemented. Accurate messages about condoms must build on a wide range of risk avoidance and risk reduction approaches. These approaches include delayed initiation of sexual intercourse, mutual faithfulness, and selection of low risk partners.

Together with condoms, these reinforcing epidemiologic truisms have been labelled both now and in the past as an ABC strategy: abstinence, be faithful to one partner, and use condoms.¹³ Moreover, a full alphabet of prevention strategies is needed for an optimal effect on HIV transmission, as well as other sexually transmitted infections (box). Condoms have a pivotal role in this larger armamentarium of strategies.

What does this mean for clinicians who counsel patients about sexual health? Firstly, people who abstain from intercourse or who are uninfected and mutually monogamous eliminate the risk of infection entirely. Secondly, people who choose to be sexually active can be reassured that condom use reduces the risk of most infections. Thirdly, condoms, like any other prevention tool, work only when used properly - consistent and correct use is essential for optimal risk reduction.

A to Z of prevention strategies for HIV and other sexually transmitted infections

- A Abstinence
- B Be faithful
- C Use condoms
- D Don't use drugs or share needles
- E Empower women in sexual decision making
- F Involve faith based organisations in HIV prevention programmes
- G Get treated if infected
- H Avoid high risk, high transmission environments
- I Promote safe injection
- J Join groups promoting HIV prevention policies
- K Know your infection status
- L Listen to peer educators
- M Make voluntary male circumcision more available
- N Get adequate nutrition to promote longer survival
- O Support orphans and vulnerable children
- P Implement perinatal HIV prevention programmes
- Q Improve quality of voluntary counselling and testing services
- R Reduce other sexually transmitted infections that facilitate HIV transmission
- S Fight stigma against people infected with HIV
- T Pursue topical **microbicides**
- U Use contraceptives to prevent unintended pregnancies in women who are HIV positive
- V Support vaccine research
- W Mobilise for political will
- X Examine interventions through evidence based reviews
- Y Engage youth in prevention programmes
- Z Advocate for comprehensive A to Z programmes

EDITOR'S NOTE: References for this article are available at the above website. The other side of this "Head to Head" is available for public access at
http://www.bmj.com/cgi/content/full/336/7637/185?ijkey=146eb4cb97e68d9e61f162055761e350b7bc3f76&keytyp2=tf_ipsecsha

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4. PUBLISHED RESEARCH: MICROBICIDE-SPECIFIC

"Differentiating normal from abnormal rates of genital epithelial findings in vaginal microbicide trials"

Author(s): van de Wijgert JH, Kilmarx PH, Jones HE, et al

Reference: N/A 77(2):122-29.

http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T5P-4RFKKN5-4&_user=10&_coverDate=02%2F29%2F2008&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C00050221&_version=1&_urlVersion=0&_userid=10&md5=686816f3ae153c26365c604c47fe2e8c

Published Abstract: *Background* Candidate vaginal **microbicides** could cause genital irritation, which in turn could facilitate HIV transmission instead of preventing it. While genital epithelial findings are documented in a standardized manner in most **microbicide** trials, little is known about background rates and predictors for many types of genital findings. *Study Design* A secondary analysis was conducted using data from a Phase II expanded safety study of the candidate **microbicide** Carraguard(R) gel (Population Council, NY, USA) in Thailand. Genital findings were identified by visual inspection of the cervix, vaginal walls and external genitalia during pelvic exams prior to gel use (screening and enrollment) and during gel use (at 2 weeks and Months 1-12). Women were interviewed about potential risk factors for genital findings at every visit and tested routinely for sexually transmitted and vaginal infections. *Results* A total of 258 genital findings were identified in 152 woman-years of follow-up. Genital findings were positively associated with older age, increased parity, self-report of genital symptoms, positive HSV-2 serology, bacterial vaginosis by Nugent scoring and the presence of a genital finding at baseline. Furthermore, vaginal findings were positively associated with vaginal practices and yeast infections. Genital findings were negatively associated with use of hormonal contraception, inconsistently associated with frequency of sex and applicator use, and not associated with condom use. *Conclusions* Several factors that are common in women of reproductive age account for the background rate of genital epithelial findings in this population.

"Killing of Neisseria gonorrhoeae, Streptococcus agalactiae (group B streptococcus), Haemophilus ducreyi and vaginal Lactobacillus by 3-O-octyl-sn-glycerol"

Author(s): Moncla BJ, Pryke K, Isaacs CE

Reference: N/A Epub ahead of print.

<http://aac.asm.org/cgi/content/abstract/AAC.01023-07v1?ct=ct>

Published Abstract: The **microbicide** candidate octylglycerol inactivates sexually transmitted bacterial pathogens at concentrations which spare normal vaginal flora (lactobacillus). Standard minimum cidal concentration assays and time kill assays revealed the drug concentrations and times required for inactivation. Octylglycerol concentrations must exceed the binding capacity of any human serum albumin to be effective.

"Mucosal transmission of R5 and X4 tropic HIV-1 via vaginal and rectal routes in humanized Rag2(-/-)gammac(-/-) (RAG-hu) mice"

Author(s): Berges BK, Akkina SR, Folkvord JM, et al

Reference: N/A Epub ahead of print.

http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=18207484&dopt=AbstractPlus

Published Abstract: Studies on HIV-1 mucosal transmission to evaluate early events in pathogenesis and the development of effective preventive/prophylactic methods have thus far been hampered by the lack of a suitable animal model susceptible to HIV-1 infection by either vaginal and/or rectal routes. In this regard, while primate-SIV/SHIV and cat-FIV models provided useful surrogate platforms to derive comparative data, these viruses are distinct and different from that of HIV-1. Therefore an optimal model that permits direct study of HIV-1 transmission via mucosal routes is highly desirable. The new generation of humanized NOD/SCID BLT, NOD/SCIDgammac(-/-), and Rag2(-/-)gammac(-/-) mouse models show great promise to achieve this goal. Here, we show that humanized Rag2(-/-)gammac(-/-) mice (RAG-hu) engrafted with CD34 hematopoietic progenitor cells harbor HIV-1-susceptible human cells in the rectal and vaginal mucosa and are susceptible to HIV-1 infection when exposed to cell-free HIV-1 either via vagina or rectum. Infection could be established without any prior hormonal conditioning or mucosal abrasion. Both R5 and X4 tropic viruses were capable of mucosal infection resulting in viremia and associated helper T cell depletion. There was systemic spread of the virus with infected cells detected in different organs including the intestinal mucosa. R5 virus was highly efficient in mucosal transmission by both routes whereas X4 virus was relatively less efficient in causing infection. HIV-1 infection of RAG-hu mice by vaginal and rectal routes as shown here represents the first in vivo model of HIV-1 transmission across intact mucosal barriers and as such may prove very useful for studying early events in HIV-1 pathogenesis in vivo, as well as the testing of **microbicides**, anti-HIV vaccines/therapeutics, and other novel strategies to prevent HIV-1 transmission.

"No increase in cervicovaginal proinflammatory cytokines after Carraguard use in a placebo-controlled randomized clinical trial"

Author(s): Bollen L, Blanchard K, Kilmarx PH, et al

Reference: N/A 47(2):253-57.

<http://www.jaids.org/pt/re/jaids/abstract.00126334-200802010-00017.htm;jsessionid=Hf3CTsvx5vvG1VZwp5mBnhCC358Kgy2fvb67CyNdHNpk2vJRQTy7!252154061!181195629!8091!-1>

Published Abstract: *Background:* Assessment of cervicovaginal cytokine levels may be helpful to evaluate subclinical epithelial inflammation during safety evaluations of candidate **microbicides**. *Methods:* Fifty-five HIV-seronegative Thai women were enrolled in a safety trial of the candidate **microbicide** Carraguard and were randomized to use Carraguard or placebo gel before vaginal sex. Cervicovaginal lavages were collected at baseline and after 1 month of gel use; levels of interleukin (IL)-1[β], IL-6, IL-8, and secretory leukocyte protease inhibitor (SLPI) were measured using microwell plate-based enzyme immunoassays. Median levels were compared between the baseline and 1-month follow-up visits using paired t tests; the median change between groups was compared using Wilcoxon rank sum tests. Women were examined for the presence of genital findings; the association between genital findings and cytokine levels was studied. *Results:* No increase in levels of proinflammatory cytokines after use of Carraguard gel or placebo gel was observed during the study. The median change from the baseline to 1 month of follow-up was not significantly different between Carraguard and placebo groups (IL-1[β]: -0.3 pg/mL vs. -3.93 pg/mL; $P = 0.4$, IL-6: -0.3 pg/mL vs. 0 pg/mL; $P = 0.3$, IL-8: -40.1 pg/mL vs. -53.2 pg/mL; $P = 0.8$, and SLPI: -26.5 pg/mL vs. 12.6 pg/mL; $P = 0.07$). Genital findings with intact epithelium were found in 16 (29%) women; these women tended to have somewhat higher IL-6 levels than those with normal epithelium (14.9 pg/mL vs. 8.8 pg/mL; $P = 0.08$). *Conclusion:* We found no increase in proinflammatory cytokines after Carraguard and placebo gel use, suggesting that neither gel causes inflammation. Further studies to assess the role of cytokines in **microbicide** safety studies are warranted.

"Phase I study of the functional performance, safety and acceptability of the BufferGel(R) Duet(TM)"

Author(s): Ballagh SA, Brache V, Mauck C, et al

Reference: N/A 77(2):130-37.

http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T5P-4RFKKN5-3&_user=10&_coverDate=02%2F29%2F2008&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C00050221&_version=1&_urlVersion=0&_userid=10&md5=243d1668791775d95b0e80378d799159

Published Abstract: *Background* The purpose of this study was to assess the functional performance of the BufferGel(R) Duet(TM), a buffering **microbicide** and spermicide gel applied to the cervix and vagina by a novel applicator that also serves as a mechanical barrier. *Study Design* This was a noncomparative Phase I safety trial in 30 healthy couples, aged 20-50 years, at low risk for sexually transmitted infections, who agreed to use the gel-device combination twice in 1 week and respond to detailed questionnaires about their experience. The female participants were examined with colposcopy before and 6-18 h after using the second device. *Results* Based on written

instructions alone, 25 women successfully placed and 28 women successfully removed the device. Three women reported feeling the device dislodge around the time of intercourse. The product was equally acceptable to both men and women. Most users concluded that intercourse was the same or better with the device than with no product. About 73% would choose Duet over male condoms, and no one preferred the standard diaphragm. Colposcopic findings were noted in 79% of women with external genital findings (9) or cervicovaginal peeling (18) predominating. Only one finding breached the epithelium. Most product-related adverse events were mild (10/11) and confined to the genitourinary tract. *Conclusions* The successful placements and acceptability suggest that further product development is warranted and could target over-the-counter use. During increased duration of use or more frequent dosing, cervicovaginal monitoring is advised based on the extent of peeling and external colposcopic findings in this short-term study.

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5. PUBLISHED RESEARCH: RELEVANT BASIC AND TRANSLATIONAL SCIENCE

"Quality assurance questionnaire for professionals fails to improve the quality of informed consent"

Author(s): Lavori PW, Wilt TJ, Sugarman J

Reference: N/A 15 January 2008;4(6):638-49.

<http://ctj.sagepub.com/cgi/content/abstract/4/6/638>

Published Abstract: *Background* The informed consent process for research warrants improvement but approaches designed to enhance informed consent need testing in the context of actual clinical research. *Purpose* Test the cumulative effect of a retrospective quality assurance questionnaire intended to enhance awareness in the person obtaining informed consent on the quality of the informed consent in clinical trials. *Methods* In the Veterans Affairs Cooperative Study 'Enhancing the Quality of Informed Consent- Self Monitoring', 30 study sites are randomly assigned from five clinical trials to either use a new quality assurance questionnaire after each informed consent encounter or the standard process of obtaining informed consent. The quality of informed consent is evaluated using independent telephone interviews of 836 subjects who had given consent to participate in the clinical trials and the authors' study. The main outcome measures are two previously validated scores derived from an independent telephone interview, measuring the overall quality of consent as well as the degree of 'therapeutic misapprehension'. Patients and assessors are blind to the study arm assignment. *Results* Subjects report complete (93%) or some (6%) satisfaction with the consent process of the 'parent' clinical trial, and 91% recognize no consequences to non-participation. Concerning the 'primary purpose' of the parent trial, 67% indicate understanding of the research purpose, 41% that the research is to benefit others, while 14% think the research is directed to their own benefit; 60% report no risk to participation and 65% report at least one expects direct benefit. Interviewers assess 77% of subjects as showing full appreciation of the 'voluntariness' of participation. The quality assurance questionnaire do not provide an appreciable effect on the quality of informed consent. Using mixed model methods to account for the group randomization, near zero, non-significant effects have been found for the overall assessment score (-0.034 on a 0-10 point scale, standard error 0.099, P = 0.73) and for the score measuring 'therapeutic misconception' (-0.005 on a 0-5

point scale, standard error 0.137, $P = 0.97$). Permutation methods yield similar results. Confidence intervals are narrow enough to exclude any clinically important effect. *Limitations* The intervention may work in a more homogeneous patient population, or one that is not sampled. The outcome measurement relies on a short, anonymous, telephone interview (to minimize burden and eliminate bias), but a longer, face-to-face interview may be more sensitive to differences. A 'checklist' tied directly to the outcome measures may show an effect. *Clinical Trials* 2007; 4: 638-649. <http://ctj.sagepub.com> *Conclusions* Despite prior beliefs, a standardized quality assurance tool do not enhance informed consent in actual clinical trials. Future research is needed to rigorously evaluate proposed methods to enhance informed consent prior to widespread introduction.

"From the NIH: proceedings of a workshop on the importance of self-obtained vaginal specimens for detection of sexually transmitted infections"

Author(s): Hobbs MM, van der Pol B, Totten P, et al

Reference: N/A 35(1):8-13.

<http://www.stdjournal.com/pt/re/std/abstract.00007435-200801000-00003.htm;jsessionid=HfFSdC6d0nTg2xjcJ785zTKFPIB8hfZRjVxTn9BvX3R42Cf6hp!252154061!181195629!8091!-1>

Published Abstract: On June 27, 2006, the NIH conducted a workshop to review published data and current field practices supporting the use of self-obtained vaginal swabs (SOVs) as specimens for diagnosis of sexually transmitted infections (STIs). The workshop also explored the design of studies that could support FDA clearance of SOVs for STI testing, particularly for specimens collected in nonclinical settings including patients' homes. This report summarizes the workshop findings and recommendations. Participants concluded that self-obtained vaginal swabs are well accepted by women of all ages and that SOVs perform as well as or better than other specimen types for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* detection using transcription-mediated amplification. In addition, workshop participants recommended the validation of SOV testing by public health practitioners and manufacturers of STI diagnostic tests to expedite incorporation of SOVs as a diagnostic option in clinical and nonclinical settings for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing. Similarly, SOVs should be explored for use in the diagnosis of other sexually transmitted pathogens.

"Human immunodeficiency virus viral load in blood plasma and semen: review and implications of empirical findings"

Author(s): Kalichman SC, Di Berto G, Eaton L

Reference: N/A 35(1):55-60.

<http://www.stdjournal.com/pt/re/std/abstract.00007435-200801000-00013.htm;jsessionid=HfFXG2hn4VS1TSQD3TTIB00LSjMLcL558nQZVXJvJ7nbRtYnJpGm!252154061!181195629!8091!-1>

Published Abstract: The majority of human immunodeficiency virus (HIV) infections in the world are sexually transmitted and quantities of HIV in genital fluids are an important transmission risk-determining factor. Estimating men's sexual HIV infectiousness from blood viral load hinges on the association between HIV in blood plasma (BPVL) and semen viral load (SVL). This article reviews research on the association between BPVL and SVL as reported in 19 empirical studies (N = 1226). Findings yielded a mean correlation between BPVL and SVL of 0.45 (SD = 0.20, median = 0.45, range = 0.07-.64). SVL was generally lower than BPVL, but this pattern was variable across studies. Co-occurring sexually transmitted infections (urethritis), nonsuppressive HIV treatments, and drug resistance account for the variability in observed correlations. HIV disease progression does not reliably influence the association between BPVL and SVL. Research is needed to determine the degree to which BPVL as well as SVL predict HIV transmission.

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6. EPIDEMIOLOGY

"Kenya: 1000 new HIV infections"

Date: 29 January 2008

Source: *The East African Standard (Nairobi)*

Author(s): Elizabeth Mwai

<http://allafrica.com/stories/200801281632.html>

About 1,000 people in Nairobi have been infected with HIV since post-election violence broke out. Crime Scene Investigation (CSI) says 950 new infections occurred in the capital city's slums in two weeks. CSI Chief Executive Officer, Mr Muriigi Kinyanjui, on Monday said more than 500 women have been raped, 95 per cent in gang rapes with an average of three participants. Using the 1994 Rwanda Genocide Model, Kinyanjui said, more than 90 per cent of the dominant partners had HIV/Aids.

"Estimating that the dominant participant initiated the rape and all were spontaneous, implying that no protection was used, then the subsequent participants contracted the deadly virus," he said. Nationally, more than 1,200 women have been raped in the ongoing post-election skirmishes. Speaking on the telephone, Kinyanjui said the situation was more complex because a number of women also had the virus at the time of the rape.

He attributed the statistics to the geography, saying mass rape mostly occurred in the slums where HIV prevalence is high. Kinyanjui said research had shown that 85 per cent of those who participated in the mass rape incidences would eventually succumb to Aids in eight years if they did not seek treatment and stop engaging in unprotected sex. He said studies had shown that rapists had a tendency to endanger their victims and themselves.

"If this is the case, it means that rapists will die from Aids-related complications in three years," Kinyanjui said. He added that figures for new HIV infections in Mombasa, the Rift Valley and Kisumu would be released soon once the data had been compiled.

7. OTHER PREVENTION APPROACHES

"Delhi women get condom vending machines"

Date: 28 January 2008

Source: *IBN*

Author(s): Pramendra Gupta

<http://hamropalo.com/health/1199.html>

In an attempt to popularise female condoms, vending machines have now been installed in some places in Delhi. The first of its kind, the machines have been installed at four of the capital's hotspots, and made it all the more easier for women to buy cost effective female condoms. And the procedure to use it may not be complicated at all.

"All you have to do is insert a Rs 100 note in the machine and the pack automatically comes out," says a customer, Poonam. One pack of Velvet costs Rs 100 and contains three pieces. Though HLL has made female condoms cost effective, the big question is who is their target consumer and have they really been able to make it popular among women? Says General Manager, HLL, S G Sridhar, "Now women are more independent and progressive, and they can make their choices."

The female condom like the male condom has its advantages and disadvantages. But it certainly lets the woman take her own call if her partner refuses to use a condom. "A lot still needs to be done as far as awareness and acceptance of the product amongst women is concerned," says gynaecologist, Dr Nirmala Vijaykumar.

And what do the women have to say about it? "It's a great idea and I don't mind my partner using it," says a customer. "It will take some time but now women are becoming more and more aware," adds another. While another says, "It depends on how user friendly it is."

Where the male condom had failed, the female condom is seen by social workers as a reliable substitute, not only from the health perspective but also as an empowerment tool for women to avoid unplanned pregnancies.

8. POLITICS AND POLICY

"Brazil government distributes millions of condoms to prevent AIDS spread during Carnival"

Date: 27 January 2008

Source: *Associated Press*

<http://www.signonsandiego.com/news/world/20080127-1553-brazil-carnival-condoms.html>

Health officials on Sunday began distributing millions of condoms to fight the spread of AIDS and other sexually transmitted diseases during Brazil's five-day Carnival. The government expects to hand out some 19.5 million condoms by Carnival's end on Ash Wednesday, Feb. 6, state news service Agencia Brasil reported, under the program first launched several years ago.

"We have to let society know the importance of prevention," Health Minister Jose Gomes Temporao said as he kicked off the campaign at a Rio de Janeiro cultural center.

Church officials in Brazil - home to the world's largest Roman Catholic population - have opposed the condom program, as well as another plan to hand out morning-after pills during Carnival in the city of Recife.

"The church has nothing against having fun during carnival, but the banalization of human sexuality is something we cannot tolerate," Bishop Antonio Augusto Dias Duarte of the Life and Family Commission of the National Conference of Brazilian Bishops said last week. "It will only serve to diminish inhibitions and encourage orgiastic behavior."

About 80 percent of young men polled by the Health Ministry reported using condoms, although just 40 percent of women said they insist on it, Temporao said, without giving more details on the survey. Nearly 600,000 Brazilians are HIV positive, of whom 200,000 are being treated, he said. The United Nations has praised Brazil's AIDS treatment program, which provides free anti-viral medications that significantly improve life expectancy, as a global model.

"Uganda: merging health services can reduce HIV infections"

Date: 27 January 2008

Source: *New Vision*

Author(s): Irene Nabusoba, Alice Emasu

<http://allafrica.com/stories/200801280675.html>

Imagine going to a health centre where you can enrol for HIV prevention, testing and treatment programmes, family planning and other reproductive health services. This is the approach that experts at the recently concluded fifth African Population Conference in Arusha, Tanzania want governments to adopt.

Integration, as the scholars, researchers, demographers, policymakers and implementers, at the meeting held every four-years called it, is a critical path in achieving the Millennium Development Goals especially those relating to reduction of HIV infections, plus improving maternal and child health.

The experts argued that integration of related services like Family Planning (FP), Reproductive Health (RH) and Antiretroviral treatment (ART) would help reduce new infections by a two-fold because it is cost effective, reduces stigma, bridges a gap of inaccessibility to services and ensures spill-over benefits.

"Integration of services into one-stop-healthcare centres makes systems more supportive especially for People Living with HIV/AIDS. This approach simply uses a client's visit to address other health and social needs," said Dr. William Stone, from the Department of Obstetrics/Gynaecology at the University of Aga Khan, Nairobi.

Stone was discussing 'Lessons from integration of reproductive health, family planning, and HIV/AIDS programmes', findings from two pilot projects running in Ghana and Uganda. He noted that in most developing countries where new HIV infections are still high, efforts are being geared into Prevention of Mother To Child Transmission (PMTCT) programmes alone. "But it should be a whole package of preventing infections, unwanted pregnancies, post abortion care, PMTCT, treatment and care," Stone said. He revealed that in one of their studies, 39,000 HIV positive births were averted through PMTCT while 71,000 were prevented through emphasis of FP. He hailed the later saying, "When you avoid unintended pregnancies, you avert more infections."

Research shows that in many of the worst hit countries in sub-Saharan Africa, 10-30% of pregnant women are HIV positive, many of whom end up with unintended pregnancies and stealthy abortions because healthcare systems operate in isolation and fear of disclosure keeps many away. It also happens with orphans and vulnerable children plus youths. "Healthcare systems have not been tailored to suit the reproductive, family planning and ART needs of youths, orphans and women would be ideal," says Stone.

In Uganda, a recent report; 'Unintended Pregnancy and Induced Abortion in Uganda: Causes and Consequences', notes that because an estimated 440,000 Ugandan women aged 15-49 are HIV positive, the reproductive and sexual health of HIV-infected women, including their access to and use of contraceptives and post abortion services is of great importance. The report says that pregnant HIV-infected women are hesitant about having children because they fear for their health, and the safety of the newborn child.

Elly Mugumya, the executive director Reproductive Health Uganda (former Family Planning Association of Uganda) says integration of services is something that has been long overdue. "Given that HIV is a sexuality issue and interlinked, we should have considered integration right from the beginning of our fight against the scourge," Mugumya says.

He says that integration as an approach comprehensively addresses the causative factor. "Prevention is better than cure. It is the most effective and resourceful approach. We should ensure that new infections are minimised and that the sick live. Let's not wait to give ARVS and build orphanages. This can only be possible through integration of FP, RH and ART," Mugumya stresses. On whether service providers would end up spreading wings with minimum effects on ground. Mugumya says, "That cannot happen unless provision of services is not matched. Like the case of FP, it is not that we have failed to deliver because of integration.

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

"F.D.A. plans to post inspectors overseas"

Date: 25 January 2008

Source: *The New York Times*

Author(s): Gardiner Harris

<http://www.nytimes.com/2008/01/25/business/25fda.html>

The Food and Drug Administration intends to post inspectors to embassies and consulates throughout the developing world in hopes of improving the quality of the food and medicines increasingly flowing to the United States, a top official said Thursday. The agency's commissioner, Dr. Andrew C. von Eschenbach, said that he wanted to have "boots on the ground" in nations like India and China and regions like Central and South America and the Middle East.

The agency already sends inspectors to dozens of countries each year to inspect pharmaceutical plants and clinical trial sites. But Dr. von Eschenbach said in a briefing with reporters that he wanted the agency's presence abroad to be on an "ongoing and continuous basis rather than episodic and periodic." "Right now, we come, we leave," he said. The inspectors would primarily "build capacity and bring others in to do inspections that are certified," Dr. von Eschenbach said.

The agency has long helped to train foreign food and drug inspectors and even advise in the writing of legislation to empower foreign versions of the F.D.A. As recently as 1996 in Canada and 1999 in Australia, health regulators did not have the authority to inspect clinical trial sites, said Dr. David Lepay, a senior adviser for clinical science at the agency. "So much of our work has been trying to get authorities who can do something legally in their own countries to develop laws and regulations and put them in place operationally," he said.

In recent years, as more food and drugs have been produced abroad for sale in America, the F.D.A. has been less able to ensure the products' safety. The agency inspects less than 1 percent of imported foods. Some on Capitol Hill have called for a large increase in the agency's budget to improve such inspections. The Bush administration, however, has not endorsed those calls. Instead, F.D.A. officials have sought to bolster the aggressiveness and effectiveness of foreign health regulators, hoping to prevent unsafe items from being brought to American docks in the first place.

Dr. von Eschenbach said that his plan to post inspectors abroad was still in its infancy. He was not sure whether he would ask for additional financing from Congress for the inspectors or find money in his present budget for them, he said. He also said that he had yet to work out with the State Department how such inspectors might interact with other parts of the federal government. In addition, host nations would have to request their presence, he said.

In December, the United States and China agreed to a greater American role in certifying and inspecting Chinese food products, including an increased presence of American officials at Chinese production plants.

"IOM backs national clinical-effectiveness effort"

Date: 25 January 2008

Source: *FierceBiotech*

http://www.fiercehealthcare.com/story/iom-backs-national-clinical-effectiveness-effort/2008-01-25?utm_medium=nl&utm_source=link

In a new report, the Institute of Medicine is recommending that Congress establish a national program to evaluate the clinical effectiveness of products and services, in an effort to give providers a single, reliable source of information. This dovetails with recent recommendations by researchers with The Commonwealth Fund, who argue [1] that the

country should establish a "Center for Medical Effectiveness and Health Care Decision-Making."

Right now, IOM members note, clinicians have far too many sources to evaluate when looking at the clinical effectiveness of treatments and products, and researchers sometimes end up duplicating existing effectiveness research. The 16-member group, which includes academics, providers and insurers, would like to see Congress ask HHS to create a well-funded program with the resources and clinical expertise to offer a single, unified review of major clinical effectiveness issues.

"Museveni advises on AIDS fight"

Date: 25 January 2008

Source: *New Vision*

Author(s): Raymond Baguma

<http://www.newvision.co.ug/D/8/13/608490>

The fight against HIV/AIDS should focus on vulnerable groups including refugees, internally displaced persons, fishing communities, truck drivers, sex workers and the disabled, President Yoweri Museveni has said. "Detailed studies in Uganda have found these to be driving the AIDS infections upwards. These groups are normally hard to reach," said the President in a speech read by ethics and integrity minister Dr. Nsaba Buturo.

This was at the launch of the IGAD Regional HIV/AIDS Partnership Programme at Serena Hotel yesterday. IGAD is a regional grouping consisting of Djibouti, Eritrea, Kenya, Somalia, Sudan and Uganda as its members.

The four-year \$15m project to be hosted in Uganda, will be financed by the World Bank under the Africa Catalytic Growth Fund. The project aims at strengthening collaboration in addressing HIV/AIDS. It targets refugees, IDPs, cross-border and mobile populations in IGAD states.

Museveni hailed the spirit of brotherhood among the member states and for uniting to fight HIV/AIDS. He said the ABC strategy was still relevant in the fight against AIDS, but added that there is need to embrace other strategies to reduce infection rates. "Programmes like prevention of mother to child transmission must be scaled up and we must support efforts to find an AIDS vaccine," he said.

"Premarital AIDS and hepatitis tests become mandatory"

Date: 09 January 2008

Source: *Arab News*

Author(s): Lulwa Shalhoub

<http://www.arabnews.com/?page=1§ion=0&article=105463&d=9&m=1&y=2008>

Engaged Saudi couples who are about to marry will have to undergo extra premarital medical tests beginning this new Hijra year. AIDS and Hepatitis B and C will join the other mandatory medical tests that are already required in order to continue issuing marriage certificates.

"This is a decision that we have been working on and decided to implement starting this Hijra year 1429," Dr. Ibrahim Al-Omar, director general of Labs and Blood Banks at the Ministry of Health, told Arab News. Premarital medical tests were previously done to test genetic compatibility including blood genetic diseases that are spread in Saudi Arabia, such as thalassemia, due to consanguineous marriages that are common in Saudi society. According to Al-Omar, the test will be available in health care centers that offer pre-marital medical tests starting first of Muharram. AIDS test was previously obligatory on foreign men who want to marry in Saudi Arabia.

According to the World Health Organization (WHO), 80 percent of hepatitis patients do not take serious procedures to treat their disease until it becomes chronic, and 20 percent of them develop cirrhosis. Five percent of the 20 percent would have liver cancer in the following 10 years of their lives. AIDS is transmitted by blood and sexual intercourse. Hepatitis is an infectious disease that is easier to contract than AIDS transmitted by blood and body fluids. Early diagnosis of the disease saves more than \$5,000 spent on every patient, according to statistics mentioned at the 38th Annual Medical Conference for Abdominal System Diseases in Washington August 2007.

Hepatitis B is considered far more contagious and common than HIV (human immunodeficiency virus); both infections are incurable and fatal, though with proper treatment and lifestyle measures carriers of HIV or hepatitis viruses can keep the symptoms at bay and extend their lives considerably. Testing for the infections is vital because the viruses remain dormant for years in carriers without showing any symptoms but place others a risk of infection.

Al-Omar told Al-Watan newspaper that the ministry's medical labs and centers around the Kingdom conducted 731,473 premarital medical tests for men or women since it became mandatory in the Hijra year 1425 until 1427. Of whom, 678,166 were proved healthy. As for blood disorders, people who have sickle cell trait are 4.26 percent while those affected with sickle cell anemia are 0.23 percent. People with thalassemia trait are 2.63 percent while those affected with it are 0.076 percent.

"Drug company trials come under increasing scrutiny"

Source: *Lancet*. 2008 Jan 19;371(9608):191-192. *World Report*.

Author(s): Samuel Loewenberg

<http://www.thelancet.com/journals/lancet/article/PIIS0140673608601191/fulltext>

Despite several scandals in recent years, ranging from the death of 11 children in Nigeria to allegations of coverups in the USA resulting in billion-dollar lawsuits, the procedures for monitoring clinical trials by the drug industry remain wanting. Samuel Loewenberg reports.

Last month, three executives from Pfizer were served with arrest warrants in relation to a 1996 clinical trial in which 11 Nigerian children died and scores more suffered debilitating injuries. The warrants are the latest development in an ongoing civil and criminal lawsuit against Pfizer, totalling over US\$9 billion.

The lawsuits allege that Pfizer, which was testing an experimental antibiotic treatment for cerebrospinal meningitis called trovafloxacin (Trovan), did not inform the families of the children about the dangers of taking part in the trial,

and that the company withheld treatment that could have saved the childrens' lives.

Meanwhile, a US Congressional oversight committee has launched an investigation into how clinical trials are done in the USA and abroad. The committee has begun its inquiry by asking for documents from Schering-Plough Corporation and Merck and Co related to the companies' clinical trial data on cholesterol drugs.

The increased scrutiny of drug testing comes at a precarious time for the embattled pharmaceutical industry. Over the past decade, drug companies have moved around half of their clinical trials to the developing world. With the globalisation of human experimentation, allegations of negligence or malfeasance have been levelled not only against large pharmaceutical companies but also against many well known academic research centres, such as Harvard and Johns Hopkins in the USA.

The controversies highlight the array of ethical questions that arise with doing experiments in low-income countries, including the difficulties of gaining informed consent from illiterate populations, the responsibility to provide medical care for trial participants, and to what extent there is regulatory oversight for trials done overseas.

A report by the Inspector General's Office that oversees the US Food and Drug Administration (FDA) found that some companies specifically went abroad because of lax regulations, and that the FDA does little oversight outside of US borders. Currently, the rules governing human experimentation in the developing world are a patchwork of codes and guidelines from international and national regulators, which patients' advocates and medical ethicists say are easily abused.

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

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9. HIV/AIDS FUNDING

"Bill Gates touts 'creative capitalism' in Economic Forum speech"

Date: 24 January 2008

Source: *The Seattle Post Intelligencer*

Author(s): Matt Moore

http://seattlepi.nwsourc.com/local/6420ap_world_forum_gates.html

Bill Gates offered his vision Thursday for a new kind of capitalism that benefits the poor as well as the rich. Microsoft Corp.'s chairman and co-founder, one of the world's wealthiest men, said business must work with governments and nonprofit groups to stem global poverty and spur more technological innovation for those left behind.

"We have to find a way to make the aspects of capitalism that serve wealthier people serve poorer people as well," he told an auditorium packed with corporate leaders and politicians at the annual meeting of the

World Economic Forum. "I like to call this idea creative capitalism."

Gates outlined how business worldwide can expand the reach of market forces to offer the benefits of science and technology to all. "This is how I see the world, and it should make one thing clear: I am an optimist," he said. "But I am an impatient optimist. The world is getting better, but it's not getting better fast enough, and it's not getting better for everyone."

To illustrate his push toward more social responsibility, he announced that Redmond, Wash.-based Microsoft teamed with Dell Inc., the Round Rock, Texas-based maker of personal computers, to sell a Red-branded PC. The Red brand includes products sold by American Express Co., Apple Inc., Motorola Inc., and other companies that give a slice of the revenue to the Global Fund to Fight AIDS, Tuberculosis and Malaria. It was first announced at the forum's 2006 meeting by U2 singer Bono. Gates said the Red-branded products have generated \$50 million for the fund in the last year and a half.

"As a result, nearly 2 million people in Africa are receiving lifesaving drugs today," he said.

Gates, who last March was estimated by Forbes magazine to be worth \$56 billion, is a crowd-favorite in Davos. But his appearances in recent years have focused more on philanthropy than on commerce. He is relinquishing his daily duties at Microsoft later this year to focus on philanthropical work full time and his speech Thursday had tinges of a lighthearted farewell, if only to the corporate world.

"As you all may know, in July I'll make a big career change. I'm not worried; I believe I'm still marketable," he said, drawing laughter. "I'm a self-starter, I'm proficient in Microsoft Office. I guess that's it. Also I'm learning how to give money away."

Gates and his wife run the Bill and Melinda Gates Foundation, which supports health care in poor countries and funds research on effective measures to deal with large global health problems. To date, the foundation has paid out \$7.8 billion in grants for global health.

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10. PHARMACEUTICAL INDUSTRY

"Nonprofit drug firm launched"

Date: 28 January 2008

Source: *The Hartford Courant*

Author(s): Eric Gershon

<http://www.courant.com/news/custom/topnews/hc-biotech0128.artjan28,0,261247.story>

Connecticut's best-known biotech industry group has decided it wants to do more than promote hometown drug makers - it wants to make drugs, too. New Haven-based CURE has quietly spun off a nonprofit company, Developing World Cures Inc., that intends to develop low-cost pharmaceuticals for people in the world's poorest countries. The

idea is to produce drugs that for-profit companies have found too risky as investments, while also developing Connecticut's biotechnology industry, CURE's main purpose.

"If they have a billion dollars to spend and they're a for-profit company with shareholders, they have to spend that money on something where they're likely to make it back," said Paul Pescatello, president of CURE, which stands for Connecticut United for Research Excellence. World Cures, he said, wouldn't face the same obligation.

Modeled after California's Institute for OneWorld Health, which calls itself the "the first U.S. nonprofit pharmaceutical company," World Cures would focus on treatments for diseases such as malaria, river fever, heartworm, hookworm and tuberculosis, though the founders are just starting to consider the options. As with for-profit drug makers, World Cures would need years and tens of millions of dollars to produce marketable drugs. Fundraising has barely begun and the company has just two employees.

But both are biotechnology veterans, and the spirit of the times may also favor the project, given an increasing push by Bill Clinton, Bill Gates and other prominent Americans to convince the corporate world that making money can be compatible with serving the needy.

"The timing of this is very good given Bill Gates' address to the World Economic Forum, where he basically called upon capitalists around the world and in the First World to think about how technology, and bioscience, as part of that, are going to alleviate issues of human suffering," said Matthew Nemerson, president of the Connecticut Technology Council, which is not directly involved in CURE's new project.

Peter Farina, a CURE board member who recently retired from Boehringer Ingelheim Pharmaceuticals, will serve as chief executive. Denice Spero will be president. Both are Ph.Ds. In a 28-year career at Boehringer, Farina, who is 61 and lives in Westchester County, N.Y., near Boehringer's Ridgefield operation, worked on immunology and virology projects, including HIV drugs. At retirement he was senior vice president for development. Spero, 49, of Redding, was Boehringer's vice president of drug discovery sciences.

"I've spent the majority of my adult life working on research and development in the pharmaceutical industry," Farina said Friday. "I thought it would be appropriate for me to give something back. Working on neglected diseases in developing countries is one way for me to give back." Farina and Spero are bringing expertise and contacts to the enterprise, not investment capital, he said.

Patents On A Shelf

World Cures does not expect to grow fast, reaching perhaps 20 employees in four years, Pescatello said. But it anticipates having a big head start on traditional biotechs once it gets to the drug development stage: World Cures will rely on scientific discoveries, including actual drug compounds, donated by universities and for-profit companies that have abandoned them or simply decided not to commercialize them. In the course of research, many biotech and drug companies make discoveries "applicable to bacterial infection or pneumonia or tuberculosis or malaria, but not relevant to what they're doing," Pescatello said. "They patent it, but it's not part of their business plan, so they put it on a shelf."

Scientists at World Cures would try to put these scraps to use. They might reformulate existing drugs for use by a greater variety of consumers, for example - making pediatric medicines safe and effective for the elderly, or altering

drugs used in one climate for another, Farina said. In some cases, World Cures might even transform veterinary medicines for human use. And it would work with existing drugs no longer protected by patents.

This nonprofit business model is emerging as multinational drug companies come under criticism from activists who say the industry is putting profits ahead of world health by enforcing patent protections for costly drugs for AIDS and other conditions. The industry points to distribution programs it has in place, and says innovation flourishes best when patent rights are protected.

The Institute for OneWorld Health has already proven that nonprofit drug development has potential. Founded in 2000, the San Francisco-based company has raised about \$100 million from the Bill and Melinda Gates Foundation alone, and is devising treatments for three diseases common in the developing world - malaria, diarrhea and visceral leishmaniasis (VL), a parasitic disease that is usually fatal if left untreated. OneWorld is now testing an injection for VL in India.

Like any early-stage company, what World Cure now needs is money and product. CURE has made a small, undisclosed initial investment, Pescatello said, but "several million dollars" will be necessary for the first few years. The first phase of operations, barely begun, involves finding and acquiring intellectual property that could be turned into new drugs.

Small biotech firms often own discoveries they're not using, and big pharmaceutical companies "typically have very large libraries of chemical compounds" they're not planning to exploit, said Timothy Shannon, chief executive of CuraGen, a Branford biotech company specializing in cancer drugs, and a member of CURE.

Once World Cures has the materials and research it needs, and is confident of converting them into treatments for actual diseases, it will try to raise big money from philanthropies to underwrite development, testing and manufacturing of the drugs. Money raised through charity would also help establish prices affordable in the developing world. This will likely cost hundreds of millions of dollars per drug.

A Pfizer spokeswoman said the company, which is a CURE member and has major research operations in Groton and New London, has not been involved in the creation of Developing World Cures, but "sees great value in the mission of this new important venture" and is "investigating the possibility of partnering with them in the future."

The technology council's Nemerson said big pharmaceutical companies may well decide that it is economically efficient - and politically expedient - to let nonprofit drug developers put their incidental discoveries to work.

He said, "The pressure of the global community is going to come down on people who are perceived as being able to solve these problems, but are not able to convince their own investors and shareholders that there's a return in investing the money to find those solutions."

"Cipla on firm ground in patent challenge"

Date: 26 January 2008

Source: *The Economic Times (India)*

Author(s): Khomba Singh

http://economictimes.indiatimes.com/News/News_By_Industry/Healthcare__Biotech/Pharmaceuticals/Cipla_on_firm_ground_in_patent_challenge/rssarticleshow/2732754.cms

In what could strengthen Cipla's patent challenge against global major Gilead Science's patent application for its key HIV drug, Viread, in India and also reduce the prices of its generic copies, the US Patent and Trademark office has rejected Viread patent application in the US.

A release by the US-based Public Patent Foundation (PUBPAT) said, "The US Patent & Trademark Office has rejected four key HIV/AIDS drug patents held by Gilead Sciences that relate to the drug known generically as tenofovir disoproxil fumarate (TDF), a key weapon in the battle against HIV/AIDS. Gilead markets TDF in the US under the brand name Viread."

In its application, PUBPAT had argued that Gilead's drug was not a new invention and that the company had not disclosed this to the US patent office. However, Gilead can appeal against the decision.

In India, Gilead is facing pre-grant opposition from domestic major Cipla and patient groups fighting for access to HIV medicines. In a strategic move, the American company had entered into a technology transfer arrangement with 10 Indian pharma companies to allow them to manufacture the drug.

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11. ANNOUNCEMENTS

Behavioral Interventions for Prevention and Control of Sexually Transmitted Diseases

<http://jama.ama-assn.org/cgi/content/extract/299/4/460-a?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=behavioral+interventions&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>

In this era of high-technological medicine, do behavioral interventions still have a role? Decidedly so, absent effective prevention, ie, vaccines. The authors of the forward of this book, H. Hunter Handsfield, MD, and Edward W. Hook, MD, review the efforts of Surgeon General Thomas Parran, who in 1937 published *Shadow on the Land: Syphilis*, which mapped behavioral efforts to control that disorder. The advent of the antibiotic era pushed behavioral interventions largely aside until the emergence of AIDS. In their introduction, the editors of *Behavioral Interventions for Prevention and Control of Sexually Transmitted Diseases* acknowledge that biomedical interventions still trump social and behavioral preventive measures. Given the lesser funding that social and behavioral efforts receive, it is particularly important that clinicians know what is efficacious and effective.

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EDITOR'S NOTE: The full write-up of this new book is available at the above website.

Call For Proposals for AVAC-funded projects to support Community Consultations on Good Participatory Practice Guidelines (CC-GPP)

<http://avac.org/gpp.htm>

Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials is a document that was drafted by a multidisciplinary international group including community advocates, research staff, and NGO representatives. The group was convened by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and AVAC. A draft version of the guidelines was then further refined through broad consultation involving a wide range of stakeholders. To download a copy of the full text of this document (in English), visit http://avac.org/gpp/gpp_en.pdf. UNAIDS is currently translating the document into additional languages which will be available soon.

This is a living document. It will only be useful if it is put into practice, evaluated, edited, updated and made part of the ongoing dialogue around prevention research worldwide.

To that end, AVAC has recently announced a call for proposals for AVAC-supported projects to support Community Consultations on Good Participatory Practice Guidelines (CC-GPP). In addition to funding, AVAC is committed to providing technical support and related materials (including a user-friendly GPP summary document) to interested groups.

IAVI Releases Publications Discussing Impacts of AIDS Vaccine Trials in Developing Countries

<http://www.iavi.org/viewfile.cfm?fid=47633>

IAVI is pleased to announce the publication of our newest Policy Research Working Paper, *The Journey Toward an AIDS Vaccine: Perspectives on Conducting Trials in Developing Countries*. Also available is an accompanying Policy Brief (<http://www.iavi.org/viewfile.cfm?fid=47635>).

Based on nearly 100 key interviews with stakeholders involved in vaccine trials in Africa, Asia, and Latin America, the paper highlights the broad range of impacts these studies have had, at individual, community, national, and global levels, above and beyond their value in increasing scientific knowledge.

We believe that this review shows concretely that even though we are still searching for an effective preventive vaccine, the "journey" continues to yield a wide range of benefits in the areas of scientific capacity building, increased access to health information and services, and stronger community, scientific, and regulatory institutions in developing countries.

The paper also highlights some of the problems and issues that have arisen as a result of AIDS vaccine trials, such as stigma, misinformation, and unrealistic expectations; it notes how more recent trials have addressed these problems, and suggests further ways that these can be mitigated.

In light of recent developments in the field, including the decision in September and October of last year to halt the trials of the leading Merck Adenovirus vaccine trials, it may be more important than ever to recognize that these trials

continue to add significant value in terms of knowledge, skills, and institutional development.

Job Posting: Senior Communications Expert position that supports the NIAID Division of AIDS Vaccine Research Program

https://online.hjf.org/psc/eapp/EMPLOYEE/HRMS/c/HRS_HRAM.HRS_CE.GBL?Page=HRS_CE_JOB_DTL&Action=A&JobOpeningId=203194&SiteId=1&PostingSeq=1

A Senior Communications Expert position that supports the NIAID Division of AIDS Vaccine Research Program is currently open for applications. Please visit the above website for position responsibilities and application procedure.

Women's Health and Disease: Gynecologic, Endocrine, and Reproductive Issues

<http://www.nyas.org/annals/detail.asp?annalID=854>

The entire span of a woman's reproductive years and beyond is the scope of this volume, which presents research covering events from first menstruation through the post-menopausal years. Special care has been taken to balance basic research and clinical information.

The volume comprises chapters on first menstruation, hypothalamic amenorrhea, implantation and recurrent abortion, XX metabolic syndrome, endometriosis, menopause, osteoporosis, minimally invasive surgery, assisted reproduction, ultrasound imaging in obstetrics, estrogen receptor modulators, and urogynecology. Papers on fertility drugs and gynecologic cancer, contraception today, prenatal genetic diagnosis, cloning and stem cells, transdermal hormone therapy, and estrogen and brain function will also be included.

Authors from the International Federation of Gynecology and Obstetrics will address issues such as, Is there an optimal rate for cesarean section? and fistulas in Africa, as well as perinatal mortality in Europe.

This volume is the latest proceedings of a series of meetings that has been held in Athens for over a decade, and the participants are internationally known authorities in their fields.

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