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Jim Pickett is a one-man example of the blurring lines in HIV prevention. The longtime advocate became an early champion of rectal microbicide research as one of the founders of International Rectal Microbicide Advocates (IRMA), but is quite fluent in the language of vaginal rings and contraception. He's now logged many hours in the world of PrEP (pre-exposure prophylaxis), from on-the-ground demonstration projects of Truvada (a coformulation of the antiretrovirals tenofovir and emtricitabine) to interest in the early research on long-acting injectables. And as a gay man living with HIV, he's deeply immersed in the realities of sexual health and human rights that can affect the perception, reach and use of HIV prevention. As one of the planners of the first HIV Research for Prevention (HIV R4P) conference, coming up in South Africa, Pickett was packing his bags to join other crosscutting prevention researchers and advocates when he took a few minutes to talk with TheBodyPRO.com about why he thinks this conference could float all the boats of prevention technology.

I'm talking with Jim Pickett of International Rectal Microbicide Advocates and AIDS Foundation of Chicago. You're about to get on a plane and fly to South Africa. Where are you off to, and why?
I am headed to the first ever HIV Research for Prevention conference (HIV R4P). This is the first time that the biennial microbicide conference and the annual vaccine conference are coming together and sharing space. So it's the first time this field has really had a unified conference that's covering new prevention technologies broadly. It's pretty exciting.

It does sound exciting. Why is it important to have a unified conference?
Mainly, the different modalities, the different strategies are all starting to blur. So we're thinking about long-term injectables for PrEP. We're thinking about vaccines that are given with PrEP as a starter to make sure you have some protection before the vaccine comes into play. There's a blurring between treatment and prevention. We're using the drugs we've used for treatment in various ways for prevention. So it makes sense that we all come together and break the silo.

With all this blurring that's going on, what things are clear? Are there clear barriers, or clear opportunities, across the modalities that people will be talking about?
A huge thing that we've been talking about for a while and that will always need to be discussed is adherence. Adherence is such an issue with every single thing we do -- not just with new prevention technologies, but everything. Certainly, we've seen adherence issues gumming up trials, and making it so we can't get results from trials. There's this fantasy among some people that, when we have things like long-term injectables -- which could provide three months' protection -- that somehow adherence will be off the table. But a quarterly injection also requires adherence. It requires retention. It requires the ability to follow up. So I think we're going to always be dealing with this, both in terms of how we conduct trials -- so we can get
answers to the questions we’re asking -- and then, just as importantly, how these are implemented in the real world.

We have to continue to really listen to people and ask what they want, and help figure out what that is, and develop things that fit those needs, as opposed to creating things and then saying, "Here. This is something you should want." It needs to start with communities. I think it's always a struggle, that kind of balance.

We're also pretty clear that nothing's off the table. We have PrEP now. It doesn't mean we don't need vaccines. It doesn't mean we don't need microbicides. We have one kind of PrEP. And it's really just available in one country. So we have huge implementation needs around the rest of the world. But we also need to continue to support new technologies. A daily pill isn't going to work for everyone's lifestyle. We need things like microbicides. We need rings and gels. We need shots. Not everyone is going to want a shot. Some people are going to think about a shot every four times a year, and they're going to run the opposite way. So we need lots of different things for people.

Coming together is a really big statement around that. We're not thinking about just my intervention, or your intervention. We want interventions that work for people.

I'm wired for microbicides [as a long-time rectal microbicide advocate], but I want things that work. So when we showed that Truvada works with prevention, I became a full-throated PrEP advocate. And I'm going to continue to advocate for all these other things.

I want a vaccine. I want a therapeutic vaccine. Having us all together and sharing information, and sharing our different understandings, is going to be really fantastic.

It's a new relationship. We haven't done this before. So we'll see how we all blend together for the next several days in Cape Town.

You've been listening to people and asking what they want about rectal microbicides; what will the community voices be like at this conference? Is there a community participation component? How much of it is researchers, clinician's, advocates? What's the mix of people there and how will community voices be heard?

Microbicide conferences have always had a very strong community representation -- very strong community engagements, lots of activities. At the vaccine conferences, it was not nearly as robust. I'm very pleased we kept that robust community engagement. The day before the conference actually kicks off, on Oct. 27, there's going to be a day-long pre-conference, which is really designed for advocates. Other people are welcome to come, but it's got a focus on community and advocates. We'll probably have well over a hundred people there.

And we also open it up to locals. So you don't need to be registered for the conference to come to our day-long pre-conference. You can come and get lots of information and get looped in on what's happening in research advocacy without attending a long scientific conference. Throughout the conference there's a space that's been designated the Advocacy Corner, where we will have some light programming; but it's really meant to be a space where people are free to network and mingle casually, do ad hoc meetings.

What are some of the top stories you think can, or should, come out of this conference?
I think we're going to learn a lot more about adherence issues. We're going to learn a lot more about what's happening in implementation, in terms of PrEP. We're going to see lots of opportunities to do better.

I mentioned earlier that only the United States has really rolled out PrEP in any kind of way. It's not really happening anywhere else, outside of a demonstration project scenario. So I'm hoping that this will give advocates, researchers and other folks like funders and policy-makers the kind of kick in the butt we all need to start doing better on implementation.

And, speaking of the United States, while we've gotten it rolling, there's a lot we could do to improve here.

I think we'll also see some early data on long-term injectables. We'll hear some interesting updates on the rectal microbicide field, vaginal rings and newer strategies like films and nanofibers; we'll start getting glimpses of that. A lot of this is earlier in the pipeline.

I also expect to hear a lot about multipurpose technologies, which have really taken off in the last few years. That's the idea that we want products that do multiple things -- so, for a woman, a product that's a contraceptive and provides protection against HIV and an STD or two, for instance. Or a product that allows a woman to get pregnant, but she can get pregnant without having HIV come on board, or syphilis.

This idea of multipurpose technologies is really exciting; and they're starting to grab people's attention more and more.

We're also seeing developers thinking about (in terms of microbicides) products that are *dual compartment* -- something that would work in the vagina and the booty. Imagine one product that could go in either place. This could be a gel, or a lubricant, or it could be a film, or a nanofiber, for a person who has sex both anally and vaginally. If we just had one microbicide and it worked wherever you put it -- and we don't need to know *where* you're putting it, because we know it works and it's safe -- it would also take away some of the stigma that can be attached to anal sex and rectal microbicides, and some of the criminalization issues around the world.

A few years ago this would have been like crazy talk. But we're actually moving in that direction. And that's super exciting.

**That is super exciting.**

It is.

**Thanks for all this, and best wishes for your travels. Let us know what comes out of the conference.**

You bet!

*This transcript has been edited for clarity.*

*Julie "JD" Davids is the managing editor for TheBody.com and TheBodyPRO.com.*

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HIV PREVENTION CONFERENCE KICKS OFF IN CAPE TOWN

Mary Taruvinga
27 October 2014

A world conference on HIV research for prevention (HIVR4P) began Sunday here in Cape Town, South Africa, with the first scientific conference dedicated exclusively to biomedical HIV prevention scheduled to begin Tuesday.

The meeting builds on the best elements of the vaccine and microbicides meetings, and adds the latest research on an ever-expanding array of HIV prevention approaches and technologies.

Helen Rees, executive director for Wits Reproductive Health and HIV Institute, told journalists that HIV R4P ushers in a new era in prevention science.

“HIV R4P reflects the growing consensus that understanding, analysing and debating the cross-cutting issues that impact every field of biomedical prevention research will be central to shared efforts to defeat this global epidemic,” Rees said.

Across this conference week, daily plenary sessions, 30 oral abstract and two poster sessions, along with satellites, symposia, roundtables and networking lunches, will address the most compelling issues in the field from the latest research on vaccines, microbicides, pre-exposure prophylaxis and treatment as prevention, to emerging prevention approaches and the challenges of implementation and access.

HIV R4P has also been designed to represent the contributions and address the needs of attendees from every field of research and to include the unique perspectives of advocates, funders, policy-makers as well as private-sector leaders.

Interaction, discussion and debate between participants across many disciplines will be a hallmark of HIVR4P.

To facilitate the full representation of global expertise at the meeting, 300 full and partial scholarships have been granted to leading researchers and advocates who otherwise would be unable to attend the conference.

Approximately 1 300 researchers, clinicians, private sector leaders, advocates, policy makers and public experts from around the world will participate in the four day conference.

Rees said this conference was different from previous meetings as it will focus on various approaches.

“While previous meetings focused on individual prevention methods, R4P builds on a growing consensus that combination approaches will be most effective in driving down the epidemic. Understanding and analysing as well as debating the cross-cutting issues that impact on all HIV prevention research will be a cornerstone of HIV R4P,” she said.

This first biennial HIV R4P conference takes place at a critical moment in the epidemic where the search for effective biomedical HIV prevention options has progressed further and faster in recent years than at
any time since the epidemic began.

At the same time, countries continue to face multiple obstacles from the challenges of providing real and sustainable access to prevention advances, to the realities of tightening budgets and the advent of laws and policies criminalising the very lives of people at risk.

The R4P secretariat said there was need for concerted efforts and global contribution in responding to HIV epidemic.

“Whatever our field of expertise, our efforts to reverse this epidemic must include a commitment, not only to advance the science of HIV prevention, but also to support robust global responses to the epidemic and the full human rights of all people impacted by HIV.”

News Medical

POPULATION COUNCIL TO PRESENT RESEARCH ON NOVEL APPROACHES TO HIV PREVENTION AT HIV R4P 2014
Population Council
27 October 2014

The Population Council will present new research on novel approaches to HIV, sexually transmitted infections (STIs), and unintended pregnancy prevention at the HIV Research for Prevention Conference, (HIV R4P) in Cape Town, South Africa. HIV R4P, which runs 28–31 October, is the first global scientific meeting dedicated exclusively to research on biomedical HIV prevention.

Presentations by Council researchers include advances in the development of a microbicide /contraceptive intravaginal ring (IVR) to protect against HIV, HPV, herpes (HSV-2), and unintended pregnancy (oral abstract session 3, 28 October, 11:00 am–12:30 pm); the first-in-human safety and pharmacokinetics study of the Council’s ARV-based microbicide gel, PC-1005 (poster session, 29 October, 10:00–11:00 am and 5:00–6:30 pm); and the activity of the non-ARV microbicide griffithsin against HSV-2 and human papillomavirus (HPV) (poster session, 30 October, 10:00–11:00 am and 5:00–6:30 pm).

Other Council studies on the HIV R4P agenda include new research on the connection between bacterial vaginosis and HSV-2 susceptibility (oral abstract session 10, 28 October, 1:30–3:00 pm); studies on the factors affecting the uptake of HIV counseling and testing among young people (poster session, 29 October, 10:00–11:00 am and 5:00–6:30 pm); and research on the links between counseling and testing and sexual risk behaviors (poster session, 29 October, 10:00–11:00 am and 5:00–6:30 pm).

Council scientists are also advancing global research on multi-purpose prevention technologies (MPTs), new tools in development that are designed to protect against HIV, STIs, and/or unintended pregnancy with a single product. The Council will co-chair a conference roundtable on the topic (31 October, 8:30–10:00 am), and will co-sponsor a satellite session at HIV R4P addressing the promise of MPTs in combination HIV and STI protection (31 October, 1:30–3:30 pm).
“HIV, STIs, and unintended pregnancy are global health crises that together affect hundreds of millions of women and men worldwide,” said Naomi Rutenberg, Population Council vice president and director of the Council’s HIV and AIDS program, and co-chair of the MPT roundtable on MPTs on 31 October at 8:30 am. "Council researchers are working on new approaches to these critical sexual health challenges that are safe, effective, easier to use, and responsive to the needs and life circumstances of the people they are designed to help."

"Sexually active people are often at simultaneous risk for HIV, STIs that can increase their risk of HIV, and unintended pregnancy," noted Tom Zydowsky, who leads the Council’s pharmaceutical development program in HIV and AIDS. "The Council’s work to advance MPTs is based in our belief that better and more convenient options are needed to slow these interconnected global epidemics and help women and men to lead healthier lives."

Presentations by Council researchers at HIV R4P are listed below:

TUESDAY, 28 OCTOBER
Oral Sessions
A novel intravaginal ring (IVR) protects macaques against SHIV-RT infection and reduces HSV-2 shedding after repeated SHIV-RT/HSV-2 co-challenge
11:00 am–12:30 pm, Auditorium 2
Presenter: Thomas M. Zydowsky
HSV-2-driven changes in α4β7 expression correlate with increased susceptibility to SHIV ex vivo and in vivo
1:30–3:00 pm, Roof Terrace Room
Presenter: Elena Martinelli

WEDNESDAY, 29 OCTOBER
Poster Sessions
Socio-demographic factors associated with uptake of HIV counseling and testing (HCT) among Nigerian youth
10:00–11:00 am, 5:00–6:30 pm, Hall 2
Presenter: Ayodeji Oginni
Does HIV counseling and testing change sexual risk behaviors? Findings from a community health center (CHC) in North Central Nigeria
10:00–11:00 am, 5:00–6:30 pm, Hall 2
Presenter: Ibrahim Suleiman
ARV-based prevention for women: New data on HIV testing behaviors from potential users of vaginal microbicides in Mpumalanga, South Africa
10:00–11:00 am, 5:00–6:30 pm, Hall 2
Presenter: Martha Brady
Are Nigerian healthcare providers (HCP) prepared for men who have sex with men (MSM): Lessons from the mystery client survey in Nigeria
The anti-same sex marriage law implications on HIV interventions for men who have sex with men in Nigeria
10:00–11:00 am, 5:00–6:30 pm, Hall 2
Presenter: Chiedu Ifekandu
MZC and 1% TFV gel: Multipurpose prevention approaches
10:00–11:00 am, 5:00–6:30 pm, Hall 2
Presenter: José Fernández-Romero
First-in-human safety and pharmacokinetics (PK) of a MIV-150/zinc acetate/carrageenan gel (PC-1005)
10:00–11:00 am, 5:00–6:30 pm, Hall 2
Presenter: George W. Creasy

THURSDAY, 30 OCTOBER

Poster Sessions
Antiviral activity and mode of action of griffithsin against HSV-2 and HPV: Preliminary studies of a potential non-ARV combination microbicide
10:00–11:00 am, 5:00–6:30 pm, Hall 2
Presenter: José Fernández Romero

Reporting of adherence in the VOICE trial: Does disclosure of product non-use increase at the termination visit?
Reporting of challenges to adherence in VOICE: A comparison of quantitative and qualitative self-reports among women during and after the trial
10:00–11:00 am, 5:00–6:30 pm, Hall 2
Presenter: Barbara Mensch

Patterns of drug use among people who inject drugs (PWID) and their implications for sexually transmitted infections in northern Nigeria
10:00–11:00 am, 5:00–6:30 pm, Hall 2
Presenter: Desmond Iriaye

FRIDAY, 31 OCTOBER

Roundtable
Multipurpose Technologies
8:30–10:00 am, Meeting Room 1.60
Co-chairs: Naomi Rutenberg, Population Council; Manjula Lusti-Narasimhan, WHO
Panel: Judy Manning, Joseph Romano, Charu Mullick, Elizabeth Brown, and Elizabeth Bukusi

Satellite Session
Multi-Purpose Prevention Technologies (MPTs): The Future of HIV and STI Protection?
1:30–3:30 pm, Meeting Room 1.61–1.62
Co-chairs: José Fernández Romero, Population Council; Manjula Lusti-Narasimhan, WHO
Panel: Carolyn Deal, Betsy Herold, Dorothy Patton, Joe Romano, John Schiller, Tom Zydowsky

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CANADIAN RESEARCH WELL REPRESENTED AT HIV PREVENTION CONFERENCE
27 October 2014

The conference to be held from Oct. 28 to 31 is expected to attract up to 1,500 global leaders in HIV prevention, research, programs and policy. HIV R4P is the world's first and only scientific meeting dedicated exclusively to biomedical HIV prevention research.
Twenty nine oral and poster presentations will be made by Canadian researchers, 10 of whom received scholarships from the conference to present their work at HIV R4P. Presentation topics include: subject selection in HIV vaccine trials; the role of hormones in natural protection against HIV-1 in the Kenyan HIV-exposed seronegative cohort; and gay men involved in HIV — their concerns and hopes about pre-exposure prophylaxis (PrEP).
"The sample of Canadian research at HIV R4P is something we can celebrate," says Dr. Allan Ronald, senior scientific advisor of the Canadian HIV Vaccine Initiative (CHVI) Research and Development Alliance Coordinating Office (ACO). "It is also a testament to the ongoing international collaborations Canadian investigators have with researchers in other countries."

Among the Canadian presenters is Dr. Ken Rosenthal, a large team grant principal investigator whose work on innate, adaptive, and mucosal immune responses in HIV-1 exposed uninfected infants in South Africa is funded through the CHVI.

"The HIV R4P Conference is essentially looking at research for prevention, and Canada really has an important role to play in bringing HIV under control," says Rosenthal, who is also the first Visiting Scientist at the Cape Town HIV Vaccine Trials Network (HVTN) Immunology Laboratory. The state-of-the-art South African HIV vaccine research facility is supported by the Hutchinson Center Research Institute of South Africa (HCRISA), and funding for the laboratory's recent renovation was received from the Bill & Melinda Gates Foundation through the CHVI.

"The CHVI really is a driver for a number of reasons," Rosenthal says. "It builds linkages with investigators in developing countries which opens doors for Canadian research collaborations with colleagues in a global fashion."

Ronald adds that the CHVI has achieved some important outcomes since it started in 2007. "It has assisted with building regulatory capacity in low and middle-income countries, secured funding with the Canadian Institutes of Health Research (CIHR) and the Department of Foreign Affairs, Trade and Development (DFATD) for five collaborative scientific teams of Canadians with African colleagues, and facilitated with the Canadian private sector advances in the development of an HIV vaccine," he says. The CHVI brings together five Government of Canada Departments/Agencies and the Bill & Melinda Gates Foundation to advance progress on HIV vaccine research and development efforts. It also contributes to the prevention of mother-to-child transmission. The establishment of the ACO at the International Centre of Infectious Diseases in Winnipeg in 2011 has facilitated information exchange, collaboration and coordination across diverse national and international research efforts.

NBCNews.com

WHY CAN’T AN HIV VACCINE BE RUSHED LIKE EBOLA’S?
Tracy Jarret
27 October 2014

Scientists studying HIV say they’re under new pressure to come up with a vaccine because of the quick response to Ebola. Last week the World Health Organization announced that a trial Ebola vaccine could be rolled out in West Africa by January and the first human trials began in the United States.

While HIV researchers have made advances towards a vaccine, Sharon Hillier of the University of Pittsburgh, who is co-chairing a conference of more than 1,300 HIV researchers in Cape Town this week, called the virus "crafty" in its latency. Unlike Ebola, it can live inside the body for a long period of time without a person showing symptoms and will never leave.
There is another difference between Ebola and HIV. Ebola has survivors. HIV does not. Because there are survivors of Ebola, scientists have been able to create a model for immunity and test vaccines and cures, resulting in far more robust data than is currently available for HIV.

“It’s not unusual for viruses to take a long time to be figured out.” Amapola Manrique of the Global HIV Vaccine Enterprise said. “I think people are getting a little impatient here.”

Science Speaks

HIVR4P: Conference Co-Chair and “Vaginal Ecologist” Sharon Hillier Talk about “The Beautiful Ecosystem,” and How to Make It More Resistant to HIV
Antigone Barton
27 October 2014

“People around the world have mysterious notions about the vagina,” Sharon Hillier told a group of journalists and advocates today. Hillier, one of five co-chairs of HIVR4P, the first global conference devoted to biomedical HIV prevention research, is here to explain her work, which she sums up as making vaginas much more resistant to HIV.

First she has to clear up those mysterious notions. People think vaginas are dirty, she noted; they are not, she added, they are cleaner than your mouth.

“It is an ecosystem,” she said, “a beautiful one.” So one challenge is keeping it that way, or as she puts it, “make it better and don’t screw it up.”

To that end she describes herself as a “vaginal ecologist.” She has been immersed over the last couple of decades in the search for a vaginal microbicide, or as she prefers to put it, “a product designed to prevent or reduce the sexual transmission of HIV and other sexually transmitted diseases when inserted in the beautiful ecosystem.”

She is also interested in the eventual development of what are now called, with increasing frequency, “multi-purpose technologies,” products that can protect against HIV, other STIs and unintended pregnancy — a product, she says, she would want for her own daughter, although she is not a fan of the term (“Who wants to put a multi-purpose technology in your woo-woo?” she asks rhetorically).

But first she goes back to the days when it was hoped that the spermicide nonoxynol-9 could protect against HIV before it was discovered that the detergent in it “degraded the beautiful clear mucosa.” The research road of clinical trials in the search for a suitable microbicide since has been circuitous, leading to both disappointing dead ends (the Pro 2000 vaginal gel, for example, which showed promising results in a small trial that didn’t hold up in a larger one), a view of a destination, with the CAPRISA trial which showed an antiretroviral-based microbicide offered some protection against HIV, and obstacles — the VOICE (for Vaginal and Oral Interventions to Control the Epidemic — which showed that an effective
product is useless if it does not meet the needs of the women it is intended for, and which, Hillier says, “changed the way we do business.”

But the quest continues, she said, because developing microbicides — in different forms, of different duration of effectiveness, and for vaginal and rectal use — is important to controlling the epidemic. Receptive sex partners are highly vulnerable to HIV, she noted — vaginal transmission twice as likely as transmission through penile membranes, and transmission through anal membranes 20 times likelier than through vaginal tissues. Worldwide, data indicates that 92 percent of couples don’t use condoms. Now, confirmatory research of the Caprisa results is continuing, the ASPIRE trial of an antiretroviral loaded vaginal ring was launched in 2012 and is expected to produce results in late 2015 or early 2016, the Ring study of another antiretroviral vaginal ring is expected to yield results by late 2016, and early stage trials have begun on a potential rectal microbicide product.

Pressed, Hillier was willing to say a vaginal microbicide could have approval by 2019. The search won’t be over, though, said Hillier, who is looking forward to the development of a film that can dissolve in the vagina and disburse an effective microbicide, as well as to multi-purpose technologies — whatever their name might be. She knows more obstacles lie ahead, and tells how men have objected to the ring, saying they could feel it, when evidence suggests that is impossible. (“It’s just an interesting thing about who owns the vagina,” she noted.)

“If you can maximize choices, you can optimize effectiveness,” Hillier said. “We don’t want to develop another thing that’s like the condom — that works but nobody wants it.

Science Speaks

HIV R4P AND A REPORT FROM THE US CDC: EBOLA AND HIV REDUX
Antigone Barton
28 October 2014

Dr. Anthony Fauci of the U.S. National Institute of Allergy and Infectious Diseases was scheduled this morning at the HIV Research for Prevention (or as it is called by tweet-savvy organizers, HIV R4P) meeting, to pull the once disparate threads of what is now a joined endeavor of biomedical HIV prevention approaches together, in a talk about synergy.

But he couldn’t come in person, conference co-chair Dr. Helen Rees noted, because of another terrible tragedy, which had a familiar shame.

“Ebola started in three poor African countries, and the world watched, and the world didn’t mobilize,” she said. The other predictable events followed: While the toll multiplied, politicians made decisions based not on evidence but expediency, and the fact that efforts toward a potentially successful vaccine for what was considered a “tropical disease” had languished suddenly drew attention as the public health threat extended to better off countries. “Remind you of anything?” Rees asked. The question now, which as she put it is “can we think differently and can we do things more rapidly?” remained a question today, as the U.S. Centers for Disease Control and Prevention released an update on the state of the Ebola crisis in West Africa in an early release of its Morbidity and Mortality Weekly Report.
It shows that as of more than a week ago 9911 cases of the virus had been reported in Sierra Leone, Guinea and Liberia. That was week number 42 of the epidemic, according to an accompanying chart, which shows the crisis beginning with case numbers in the double digits at the end of March, climbing slowly and then steeply. The data, the report says, reflect reported cases, which comprise an unknown reflection of actual cases.

**Humanosphere**

**THE WORLD’S DEADLIEST KILLER DISEASE FROM AFRICA IS... STILL AIDS**
Tom Paulson
28 October 2014

CAPE TOWN, South Africa – Ebola has grabbed all the headlines, but HIV still remains the world’s deadliest infectious disease – killing nearly the same number of people every day that the Ebola outbreak in West Africa has so far killed in 9 months.

“We are in the middle of an extraordinary crisis,” said Tony Fauci, America’s top infectious disease doc and, officially, director of the National Institute of Allergy and Infectious Disease (NIAID). The crisis Fauci was referring to here in a video presentation at the opening day of the [HIV Research for Prevention](http://www.humanosphere.org/) conference featuring some 1,300 researchers, health workers, activists and policy makers was, of course, the Ebola outbreak. What’s happening in West Africa is indeed a global health emergency that deserves our full attention and assistance, he said.

In the United States, Fauci noted, the crisis is mostly “an epidemic of fear and concern” that, among other things, has prompted a few elected officials to do unwise and potentially counter-productive things (like putting healthy people into quarantine). Doing damage control at home meant Fauci had to cancel his plans to speak in person at this meeting.

South Africa is also in the middle of an extraordinary crisis. It is the epicenter of the global HIV/AIDS pandemic, with the highest prevalence of HIV infection in the world. Nearly one out of every five South Africans is infected with HIV. The country has been successful at getting millions of people on anti-HIV drugs, but there is a sense of desperation nevertheless.

“The call for an AIDS-free generation is aspirational,” said Helen Rees, one of South Africa’s leading medical researchers. “But we’re probably not going to get there any time soon.” Rees’ sober assessment is based on a cold-eyed look at the still-expanding spread of HIV worldwide – more than 2 million new infections per year, according to UNAIDS.

Funding by the international community for fighting AIDS in poor countries has gone flat, or even declined, in recent years even as new infections outpace the ability to get people on drug treatment. Out of some 26 million people who today need these life-saving drugs, only about 10 million are now getting them. Deaths from HIV overall are down thanks to major initiatives like Pepfar or the Global Fund, but still more than 1.5 million die from AIDS every year.

Ebola, most experts agree, is unlikely to ever compete with HIV’s horrific scope and scale. Some 30 years ago, when AIDS first emerged, the world reacted much like it is now doing for Ebola – with a sense of urgency and a good share of similarly hysterical and bad policy decisions to boot. But the
AIDS pandemic, even before the Ebola crisis, has not gotten much attention lately despite its still terrible global toll. That was partly what prompted the launch of this meeting, aka HIVR4P.

“There was a need to bring everyone working on prevention together, to share knowledge and create a more powerful synergy,” said Mitchell Warren, executive director of the AIDS Vaccine Advocacy Coalition. Prior to this, the vaccine scientists had their own meetings as did those working on microbicides (mostly vaginal gels that can kill HIV), on male circumcision (which studies show can reduce HIV risk by 60 percent) and other means of prevention.

Those holding the purse strings, like the National Institutes of Health and the Bill & Melinda Gates Foundation, wanted to see the HIV prevention community working more in concert, Warren said. This became even more imperative as those working on vaccines or other preventative methods were coming up with findings that had implications for treatment, he said, and vice versa.

Drugs developed for treating HIV are now being exploited for preventive use, so-called ‘PrEP’ or pre-exposure prophylaxis. All sorts of gels, vaginal (inserted) rings and delayed-release materials are being studied as a means to protect against HIV. The conference is overwhelming with all of its various techniques and technologies aimed at preventing HIV.

“We have a sense of optimism today,” said Naledi Pandor, the South African minister of science and technology. “Thirty years ago, the global picture was depressing, offering very little hope for most of those infected.”

Today, Pandor said, people who have access to drugs have dozens to choose from, many millions of lives have been saved and major success stories – such as the reduction in mother-to-child transmission of HIV and the overall decline in the AIDS death rate – gives us all many reasons to celebrate.

“However, the main challenges remain,” she said. “The epidemic continues to outpace our efforts to control it.”

And that is more than a scientific challenge. The Nobel Peace Prize laureate, and local Anglican archbishop emeritus, Desmond Tutu was among the speakers for the opening ceremony (also by video).

“We are at a point where we can tell how far away we are from victory,” Tutu said. And with perhaps an eye to how some governments and world leaders are reacting to the Ebola crisis by closing borders and refusing people entry based on nothing but fear, he added: “Prevention cannot be forced. It must be implemented within the context of human rights.”

Maybe officials here should heed their local hero. One of the rumblings at HIVR4P’s first day was about the government of South Africa’s refusal of entry to one of the world’s leading HIV/AIDS researchers, Wafaa El-Sadr of Columbia University.

Like many here who have learned that medicine and human rights go hand-in-hand, El-Sadr went to West Africa to offer her expertise there in the fight against Ebola. For doing so, South Africa has refused to let her come here to assist in the fight against HIV.
HIV R4P: RECOGNIZING TUTU
Antigone Barton
28 October 2014

If this new conference’s logo, which now is subtitled: “Shaping the Science of Prevention” had room for another line, it would be a reminder that goes way back, that some, in fact, have been saying since the very beginning.

“HIV research progress will only succeed where human rights are respected,” conference co-chair Dr. Helen Rees said again today. It is a fact that has driven much of what brought people from around the world together here, and that has been repeated already multiple times — in the context of treatment and pre-exposure prophylactic use of antiretroviral medicine, in the context of vaginal and rectal microbicides, in the context of clinical trial design and good participatory practices. As recognition that human rights are integral to making meaning out of research, the conference opened with a new award, named for an old crusader. And the inaugural Desmond Tutu Award for HIV Prevention and Human Rights went to Tutu himself. Tutu, who has included in his life-long battles against poverty and injustice a fight for testing, treatment and care for those most affected by HIV and TB, accepted the award via video, giggling as he laboriously spelled out HIV R4P.

His daughter, Reverend Mpho Tutu, who described herself as “the low testosterone version” of Archbishop Tutu, “also easier on the eyes,” picked up the award in person, also paying tribute to the conference acronym.

“Oh my goodness, I sound like a teenager,” she said. “LOL, OMG.”

Times Live
http://www.timeslive.co.za/thetimes/2014/10/29/with-this-ring-i-thee-bed

WITH THIS RING I THEE BED
Katharine Child
29 October 2014

"We are very, very hopeful and optimistic," said University of Washington professor of allergy and infectious diseases Jarred Baeten, speaking at the HIV Research for Prevention Conference in Cape Town.

There are two ongoing trials, in sub-Saharan Africa and South Africa, in which women are given vaginal rings that secrete an ARV gel daily.

"Rings [with ARVs] would give women control over their sexual health," said Anthony Fauci, head of the American National Institute of Allergy and Infectious Diseases.

The need for the device is so urgent that the US Food and Drug Administration asked that the two trials run concurrently to speed up the process of licensing a product to bring to the market.

While it is a "scientifically proven fact" that taking ARVs as a preventive measure can protect against infection, designing a trial to show that products work for young women in Southern Africa has been difficult, University of Pittsburgh professor Sharon Hilliers said.
A study of more than 5000 women in South Africa, Zimbabwe and Zambia - known as the Voice trial - offered an ARV pill or an ARV gel for daily use, or a placebo.

But the trial failed because less than 30% of women used it regularly. "I will not forget that day [we got results] as long as I live," said Hilliers.

But she said that experience led to a change in the way monitoring was done to ensure compliance with the study guidelines.

Researchers know exactly how much product should be left in the ring after a month's use. Too much product means the ring has been removed during the month. The results are expected in 2016. The results from the South African-based Facts trial are expected next year.

More than 2000 women from nine sites were asked to use a gel containing ARV tenofovir before and after sex. A smaller trial showed that women who did this all the time had 50% protection from HIV. About 44% of women in Vulindlela, in rural KwaZulu-Natal are infected with HIV.

Global Health Technologies Coalition

FIRST-EVER CONFERENCE DEVOTED SOLELY TO HIV PREVENTION R&D TAKING PLACE IN UNCERTAIN FUNDING ENVIRONMENT
Marissa Chmiola
28 October 2014

In this guest post, Emily Donaldson—program coordinator at AVAC—and Tom Harmon—senior policy analyst at the International AIDS Vaccine Initiative (IAVI)—write about the state of HIV prevention research funding as the first-ever conference devoted solely to HIV prevention research and development (R&D) takes place in Cape Town, South Africa, this week.

Progress toward new tools to prevent HIV infection—including vaccines, microbicides, the use of antiretroviral treatment as HIV prevention, pre-exposure prophylaxis (PrEP), and a host of other options—is being presented and discussed at the inaugural HIV Research for Prevention Conference (HIVR4P) in Cape Town this week.

While much progress has been made over the last few years, a four percent decline in funding between 2012 and 2013 speaks to the uncertain nature of the global environment in which that research is taking place. Such cuts hinder the ability of the researchers in Cape Town and across the globe to continue their work and could delay progress toward efficacy trials and eventual rollout of new prevention options.

Investment data for almost every technology being discussed in Cape Town can be found in HIV Prevention Research & Development Investment in 2013: In a changing global development, economic, and human rights landscape—the most recent annual report by the HIV Vaccines and Microbicides
The data show that the US government continued to fund more than 70 percent of HIV prevention R&D efforts in 2013. The combination of recent funding cuts across all US government budgets and declines in European investment in HIV prevention R&D led to the overall decline in funding from the previous year. Relying on such a small number of very committed donors is problematic when one or more of those donors is forced to reduce their support. The report also highlights funding declines in nearly every category of HIV prevention R&D, underscoring an urgent need to sustain and diversify funding sources through partnerships between governments, philanthropies, and the biopharmaceutical industry. The 2013 data provoke a concern that HIV prevention R&D is increasingly becoming a lower priority for public agencies funding international development, as portfolios and priorities within those agencies shift. Global health and development negotiations such as those around developing successors to the United Nations’ Millennium Development Goals take place far from the context of most HIV prevention clinical trials, but such international commitment at the highest levels can keep HIV/AIDS a priority for development agencies that can bolster support for science, technology, and innovation in endemic countries to end the epidemic.

The report also compiles the number of volunteers taking part in HIV prevention R&D trials, which totaled almost 670,000 people in 2013. Most of these individuals are based in sub-Saharan Africa where the epidemic has its most profound impact and where several large-scale treatment-as-prevention and voluntary medical male circumcision trials and projects are underway. However, that balance doesn’t cut across all new prevention technologies—80 percent of volunteers in vaccine and PrEP trials reside in the United States and Europe. Ensuring that new HIV prevention options are appropriate and acceptable means testing them in partnership with those regions and those communities that need them most. Such communities are represented here at HIVR4P, and we’re excited by the opportunity to see them mingling with the experts working tirelessly to improve the state of HIV prevention R&D science and in turn hasten an end to the AIDS epidemic. However, they can’t do it without a diverse, committed investment base. Funding data show signals of vulnerability in support for HIV prevention R&D and support the need for policymakers and advocates to ensure that the state of the field remains a healthy one.


Windy City Media Group
GLOBAL HIV CONFERENCE; CHINESE AD; D7G FOUND NOT GUILTY
Andrew Davis
28 October 2014

HIV Research for Prevention 2014 (HIV R4P)—the world’s only global scientific meeting dedicated exclusively to biomedical HIV prevention research, including treatment as prevention, microbicides, pre-exposure prophylaxis (PrEP), vaccines and circumcision—is taking place in Cape Town, South Africa, on Oct. 28-31, according to a press release. Among those speaking/attending are Anthony Fauci of the National Institutes of Health, Anatoli Kamali of the MRC/UVRI Uganda Research Unit on AIDS and Helen Rees of Wits Reproductive Health and HIV Institute in South Africa.
The CEO of a Chinese e-commerce company has posted a banned gay advert on social media that has since gone viral, according to Gay Star News. The poster did not pass censors; however, Li Guoqing uploaded the advert to his Weibo account—the Chinese version of Twitter—anyway, making Dangdang the first mainland company to openly support LGBTI people. The poster was for the "Dare to Do, Dare to Be" campaign, which celebrates the company's 15th anniversary.

Designers Stefano Gabbana and Domenico Dolce were ruled not guilty of tax evasion by Italy's highest court, according to Forbes. The ruling overturned two sentences by lower courts that found them guilty of tax evasion, imposing 18-month jail sentences. Prosecutors had wanted the pair locked up for heftier three-year prison terms, but now the pair have been vindicated in the face of accusations they hid hundreds of millions of Euros.

CONFEX, a LGBT conferences and exhibitions company in Latin America, has confirmed the city of Merida in Mexico's Yucatan as the host of the fifth edition of its LGBT business expo, according to a press release. The expo is scheduled to take place Sept. 18-19, 2015. Designed to maximize networking business and educational opportunities, the event has continually grown since its inaugural event in 2011 in Puerto Vallarta, doubling in scale with its 2012 edition in Cancun and continued its growth in 2013’s International LGBT Business Expo in Guadalajara, Mexico and 2014’s edition in Vallarta-Nayarit. See www.lgbtconfex.com.

In Spain, a teenage girl was hospitalized after getting attacked with stones by her classmates because she's lesbian, Gay Star News noted. She was with a gay male friend as they were walking from home school in Spain's Murcia region. The teens were attacked by three schoolmates who followed them out of school grounds in the town of Caravaca de la Cruz. The attackers allegedly shouted terms such as "dyke" and "poofter" at the two classmates.

LGBTI Liberians have gone into hiding after church leaders said Ebola was a punishment from God for homosexuality, Gay Star News noted. LGBTI people in the capital of Monrovia have been harassed, beaten and a few have had their cars smashed. Liberia is the country worst hit by the current Ebola outbreak, with 4,500 infections and 2,700 deaths, and has enforced a curfew that people such as activist Leroy Ponpon said police used as an excuse not to help LGBTI people who asked for protection. A right-wing Malaysian newspaper, Mingguan Malaysia, has said supporting opposition leader Anwar Ibrahim means supporting the international LGBTI rights movement ahead of his sodomy trial, according to Gay Star News. Anwar has been prosecuted under the country's colonial anti-gay law four times in what LGBTI groups have called a politically motivated prosecution. He is appealing his March sentence of five years in jail.

Human Rights Watch has said that the public prosecutor of Perugia, Italy, should immediately drop charges against six gay rights activists accused of disturbing the peace because they kissed during a demonstration in March, SDGLN.com reported. The police conducted an identity check on the three men and three women after they held a spontaneous, uncoordinated protest against an anti-gay-marriage group calling itself the Sentinelle in Piedi, or Standing Sentries. "The charges would be laughable if they didn't reflect exactly the anti-gay sentiment the activists are fighting against," said Judith Sunderland, senior Western Europe researcher at Human Rights Watch.

In London, transport authorities have launched an investigation after a gay couple were reportedly thrown off a bus for kissing in August, The Guardian reported. Jack James, 23, said he and his partner were ordered off a number 89 bus near Blackheath in southeast London by the driver, who then reportedly verbally abused them. Ken Davidson, transport for London's head of bus operations, said, "All
customers have the right to use our services without fear of being abused, and offensive behavior is completely unacceptable."

In New South Wales in Australia, anti-gay gangs are reportedly targeting gay men at a cruising spot known as Braye Park, The Newcastle Herald noted. The publication reported that more than 100 men go to the park daily for casual sex. However, they have been followed by groups of young men keen to assault them in what some victims have described as serious hate crimes.

Concerned locals have called on Leicester Police to hunt a mystery monk who was circulating anti-gay leaflets in the UK city, according to Gay Star News. A man matching that description has previously been reported circulating anti-LGBTI material in cities around Britain from Brighton to Preston. Leicester police said they responded to concerns from individuals upset and offended by leaflets pushed through their doors, comparing homosexuality to perversion and pedophilia, and urging LGBT people to repent. The items even name a Gay Star News reporter, Jane Fae, who has written articles about this situation. Latvia has banned a Russian actor from entering the country after he said gay people should be "burned alive," according to Gay Star News. Foreign Minister Edgars Rinkevics said Ivan Okhlobystin, the controversial former priest, would not be allowed to give a one-man show about religion in Riga on Nov. 7. In December last year, Okhlobystin caused an international outrage after he said he would burn all gay people alive in the oven, calling them a "living danger to my children."

In the Philippines, prosecutors rejected a motion filed by the camp of U.S. Marine Pfc. Joseph Scott Pemberton, who sought to reduce the murder complaint filed against him to homicide, saying it would be premature to do so, GMANetwork.com reported. The 19-year-old Marine is the suspect in killing transgender woman Jeffrey "Jennifer" Laude, who was found dead in a motel Oct. 11. The motion was one of three filed by the defense, led by lawyer Rowena Garcia-Flores, during the preliminary investigation at the Olongapo Hall of Justice.

Business Day Live

PROMISING RESPONSE TO ‘THAI’ HIV VACCINE
Tamar Kahn
29 October 2014

BE THEY fat, thin or partial to alcohol, South Africans respond just as well to an experimental HIV vaccine called RV144 as their Thai counterparts, scientists announced on Tuesday at the inaugural HIV Research for Prevention (HIV R4P) conference.

The "Thai Trial" HIV vaccine is the only one to have shown even modest protection to date, so the fact that South Africans can mount an equally effective immune response to the shot marked an important step in the long journey to developing and licensing a product, said principal investigator Glenda Gray, president of the Medical Research Council.

An AIDS vaccine even 50% effective would be a "game-changer" in the fight against the disease, she said ahead of her presentation on Wednesday of the results of a small phase 1 trial called HVTN 097. There were 35-million people living with HIV worldwide, and 2.1-million new infections last year, according to the United Nations.
A key question by the researchers was whether South Africans would produce antibodies against HIV as effectively as Thais, who tend to be slimmer, said Prof Gray. Previous vaccine studies have found people's weight, ethnicity and alcohol consumption may influence how they respond to shots, but in this case it turned out that none of these factors had an effect, she said. "We saw wonderful immune responses, as good as in Thailand," she said.

More than half the women in the HVTN 097 trial were overweight or obese, broadly in line with the general population in SA.

The next step will be to test an improved version of the vaccine designed for the strains of HIV circulating in SA in a phase 1 trial called HPTN 100. It is due to start in January next year and, if successful, researchers would begin a much larger phase 3 trial in late 2016 or early 2017, expected to cost about R1bn. SA's HIV epidemic is primarily due to the clade (subtype) C strain of HIV. Thailand is affected by clade B. The conference has attracted more than 1,300 delegates presenting research on vaccines and other HIV-prevention strategies.

A promising new area of inquiry is injectable drugs that provide long-term protection against HIV. Since taking a daily pill is challenging for many people, scientists are hoping to develop products that can be taken at longer intervals, much like injectable contraceptives.

Pharmaceutical company GlaxoSmithKline presented results of a macaque study of the potential of a drug called cabotegravir.

It found cabotegravir was safe and provided a level of the drug in the monkeys that is expected to protect against HIV, said GlaxoSmithKline researcher William Spreen.

All Africa
http://allafrica.com/stories/201410281732.html
AFRICA: EBOLA- THE LESSONS FROM HIV
Emily Bass
28 October 2014

People infected with ebola will never form their own version of ACT UP. They can't. The course of the infection from diagnosis to severe, immobilizing illness is swift.

Post-diagnosis, quarantine is mandated. There so many things that led to the birth of the extraordinary AIDS activist movement--led by and for people living with the virus--including the fact that some of the first people diagnosed were white North American men who expected and felt entitled to a prompt response from a functioning health system.

But the lifecycle of the virus also played a role. A movement led by and for people living with a virus is only possible in the context of a virus that you can, yes, live with, work with, protest and organize with, without putting one's own health or the health of others at risk.

Ebola doesn't allow for this sort of organizing. So there just won't be a peaceful army of people living with ebola protesting the government inaction, underfunding and stigma driving this new epidemic. The good news is, there probably shouldn't be. If change depends on disease-specific based advocacy, there's going to be a lot of duplication, a lot of wheel-reinvention, a lot of competition for limited
resources and global attention. So it's both strategic (not to mention overdue) that long-time AIDS activists, many of whom have spent decades working on HIV, TB and malaria, are looking at how to apply the lessons from the ACT UP era to ebola, today.

There's now an ACT UP Against Ebola movement forming in the US, complete with its own Facebook page https://www.facebook.com/actupagainstebola?ref=nf. Some of the activity, both on the page and in rapid responses organized over the past week, are focused on replacing hysteria with rationality in the American Ebola response--which includes national guidelines issued by the US CDC as well as state-by-state policies that range from mandatory at-home quarantine for travelers returning from West Africa (a major disincentive to US health workers volunteering in those areas) to self-monitoring and fever reporting. (A great review of some recent activities can be found here -- with regular updates on the Facebook page.)

The US response is, of course, focused on fear--and not fighting an actual ebola epidemic. The larger question facing this group and all concerned health activists is: How do we develop and implement an agenda that makes the response in West African countries grappling with the virus more effective. One key step is bringing the voices of activists from these countries--Sierra Leone, Guinea, Nigeria, Mali, Liberia--to the fore. This hasn't happened, yet, but the conversations are beginning to percolate and shift into proactive outreach to help define specific goals and solidarity actions. "There are isolated individuals who are talking about it," says Micheal Ighadoro, AVAC Program Assistant and Nigerian AIDS activist. "We haven't started having the conversations as a group."

Here at HIV R4P, this solidarity is extending beyond civil society. In her opening plenary, the Minister of Science and Technology, Naledi Pandor, MP, said that she had just instructed her staff to look into initiatives that would bring South African expertise to the fore. These efforts--which could have had an even greater impact had they been triggered six months ago--are still essential. And as the AIDS epidemic has shown, when activists from all sectors work together--anything is possible.

This article originally appeared on WhatsUpHIV, a live blog set up to report all the developments from HIV R4P, the world’s first global research conference dedicated to biomedical HIV prevention.

New Vision

HIV CONFERENCE OPENS IN SOUTH AFRICA
By: Hilary Bainemigisha
28 October 2014

The first ever global scientific conference on HIV research for prevention has opened today (Oct 28) in Cape Town, South Africa. Dubbed HIV Research for Prevention 2014 (HIV R4P), the meeting brought together about 1,300 researchers, funders, advocates, clinicians, private sector partners and policy makers from 48 countries to usher in a new era in prevention science.

The conference was officially opened by the South African minister of Science and Technology, Naledi Pandor who welcomed the delegates to the country.
“South Africa is honoured to host the first ever conference because we have the highest burden of the disease in Africa,” she said. “Africa must assume responsibility of her problems and solutions. We should become our own client and not run to beg for other people’s attention. We must seek partnerships and that is why I am pleased with the international character of this conference.”

She thanked the science community for the work. “Today we are talking about 30 drugs approved for HIV, affordable and highly effective, a range of tools and convincing data that will deliver us to more technology. But we need to combine the biomedical with the behavioural strategies for zero infections, zero deaths and zero stigma.”

The conference is chaired by five of the world’s leading experts in HIV prevention research. They include one Ugandan, Dr Anatori Kamali, a clinical epidemiologist from the AIDS research centre in Entebbe. Others are Prof Sharon Hillier from USA, Dr Hunter Eric from USA, Prof Helen Ress from South Africa and Prof Robin Shattock from the UK.

Kamali said: “This meeting will build on the best elements of the vaccine and microbicide meetings that used to occur separately and add on the latest research on the ever expanding array of HIV prevention technologies.”

HIV Prevention science includes strategies like ARVs for prevention, microbicides (a gel inserted into the vagina hoping to stop HIV infection – trials are still ongoing), pre-exposure prophylaxis - PrEP (ARVs you can take before exposure to protect you from HIV), vaccine research and circumcision.

The four-day long conference will have 722 abstract presentations, 30% of which came from African researchers and institutions.

During the opening, the organisers announced an award that will be given in recognition for people’s work in HIV prevention. It was named the Desmond Tutu Award for Prevention and Human rights. Tutu was recognized as one of the leading global activists for HIV prevention and human rights. The first award was also given to him.

The archbishop, who was not able to attend, addressed the opening ceremony by televised conference. He called upon all to come together to fight against the enemy of society.

We are at a point where we can tell how far we are from victory”, he said “Prevention cannot be forced. It must be implemented within context of human rights.”

The award was received by his daughter who called for the full engagement of the faith sector in the fight against HIV.

The conference will close on Friday.

Medical Xpress

NEW RESULTS FROM VOICE ASSOCIATES TENOFOVIR GEL USE WITH LOWER HSV-2 RISK IN WOMEN
Microbicides Trial Network
28 October 2014

The risk of acquiring herpes simplex virus type 2 (HSV-2) was reduced by half among women in the VOICE trial who used a vaginal gel containing the antiretroviral (ARV) drug tenofovir regularly, according to researchers from the U.S. National Institutes of Health-funded Microbicide Trials Network (MTN) who conducted the study. The findings provide additional evidence that tenofovir gel, a product developed to protect against HIV, could potentially help in preventing one of the most prevalent sexually transmitted infections affecting sexually active women in sub-Saharan Africa.

No biomedical prevention method currently exists for HSV-2, the most common cause of genital herpes. Women are especially susceptible to infection because it is more easily transmitted from an infected man to his female sex partner than from a woman to a man. Because HSV-2 infection also greatly enhances the risk of acquiring and transmitting HIV, a product that protects against HSV-2 could have an important public health impact.

The results, which were based on an analysis of data involving more than 500 women in VOICE, were reported at the HIV Research for Prevention (HIV R4P) meeting in Cape Town today. Jeanne Marrazzo, M.D., M.P.H., from the University of Washington, presented the results on behalf of the VOICE study team.

VOICE – Vaginal and Oral Interventions to Control the Epidemic – was designed to test the safety and effectiveness of different ARV approaches used daily for preventing HIV among 5,029 women from 15 sites in South Africa, Uganda and Zimbabwe. The study’s primary results, which were reported in March 2013, found none of the products tested (tenofovir tablets, tenofovir/emtricitabine tablets – also known as Truvada®, and tenofovir gel) was effective in preventing HIV and that most participants had not used their assigned product daily as recommended. Drug was detected in less than a third of blood samples from women who were assigned to use either of the ARV tablets and in less than a quarter of samples from women asked to use tenofovir gel.

While the main questions VOICE was designed to ask concerned prevention of HIV, the team amended the protocol to explore whether any of these products also helped to protect women from acquiring HSV in response to results from another study called CAPRISA 004. CAPRISA 004 found tenofovir gel used before and after sex reduced the risk of HIV by 39 percent, a finding that was considered a major milestone for the field. But the study of 889 women in South Africa unexpectedly found that tenofovir gel also reduced the risk of HSV-2 by 51 percent compared to placebo, the first time that any kind of biomedical prevention method was shown to be effective against HSV-2.

There was very little difference in rates of HSV-2 acquisition between the tenofovir gel and placebo gel groups in VOICE, most likely because adherence to product use in the trial was low overall, Dr. Marrazzo believes. So, she and colleagues decided to focus their investigation on the women who they knew had used their product according to tests that detect the presence of drug in stored blood samples. "In this closer examination, we saw tenofovir gel was associated with a significant reduction in HSV-2 risk. The difference was actually quite profound between the two groups of women – those who used the gel and those who hadn't," commented Dr. Marrazzo, who led the VOICE study with Zvavahera Mike Chirenje, University of Zimbabwe-University of San Francisco (UZ-UCSF).

Women who used the gel regularly were 46 percent less likely to acquire HSV-2 compared to women who seldom or never used the gel (who had no detectable drug in their blood samples), a finding that was statistically significant and was adjusted to account for other potential risk factors, including age, marital status and number of sex partners.
There were 1,004 women in VOICE who had been assigned to use tenofovir gel, 566 of whom were HSV-2 negative at the time they enrolled. The analysis involved 527 of these women for whom blood samples from both their first quarterly visit and when the exited the study could be compared, which on average represented about one year on product. Of this cohort, 92 women acquired HSV-2, 77 of whom had no detectable drug in their blood samples versus 15 among women whose blood levels indicated regular use of tenofovir gel. Accordingly, HSV-2 incidence was 20.2 percent in women who didn't use the gel compared to 11.6 percent in women who did.

Dr. Marrazzo cautioned that while the results are very encouraging, additional data is still needed. FACTS 001, a Phase III trial that tested tenofovir gel used before and after sex (the same regimen as in CAPRISA 004), was designed specifically to determine whether the gel was safe and effective in reducing the risk of HSV-2 as well as HIV among 2,059 women in South Africa. Those results are anticipated to be available early 2015.

KPLU88.5

SEATTLE SCIENTISTS’ FRESH LOOK AT VACCINE COULD BE BIG BREAK FOR HIV PREVENTION

Gabriel Spitzer
28 October 2014

Even as momentum builds for an Ebola vaccine, researchers working to contain another virus say they’ve gotten their first big break in years. An older HIV vaccine candidate is showing new promise, and Seattle scientists will be leading a new trial of it early next year.

The vaccine is based on a formulation first tested in Thailand in 2003, and found to be just 30 percent effective after three years. But recently researchers tested the same vaccine on 68 people from South Africa, and found that it had similar effects even though it was tailored to the strain of virus common in Thailand, not Africa.

That means the vaccine could prove to be more widely applicable — and more effective — than previously believed.

“They think they can get it up to 50, 60 percent effective and have it be sustainable,” said Tom Paulson, editor of the global health news site Humanosphere. Paulson spoke from Cape Town, South Africa, where researchers announced the news at an AIDS prevention conference.

“If you can get it out there and it’s cheap enough, you’re going to save millions of lives. And people are fairly hopeful that this trial will succeed in finally giving the world an effective AIDS vaccine,” Paulson said.

A team led by the Fred Hutchinson Cancer Research Center will launch a trial of the vaccine in January. The Seattle-based center operates the world’s largest publicly-funded HIV vaccine trials network. The vaccine candidate will be optimized for the strain of HIV most common in Africa, while the U.S. military will study the Thai version in Thailand once again. HIV-AIDS kills an estimated 1.5 million people each year.
END IN SIGHT FOR INNOVATIVE HIV PREVENTION TRIALS

Zinhle Mapumulo
27 October 2014

Exciting HIV trials aimed at developing products that can prevent or reduce the risk of HIV transmission from men to women are nearing final stages.

The trials being conducted in South Africa and other countries are testing various prevention tools including a microbicide gel and vaginal rings containing antiretroviral drugs. The majority of the studies are expected to be completed next year. And if all goes well, the products which are sold by researchers as an empowerment HIV prevention tool for women, will be available in the general market within five years.

Speaking ahead of the HIV Research for Prevention conference which officially begins in Cape Town tomorrow, Sharon Hellier who is a principal researcher at the Microbicide Trials Network (MTN), said the ongoing microbicide trials are an answer for women.

“They give women the power to protect themselves from HIV. We know that some women find it difficult to negotiate safe sex due to various reasons but the discreet gel and vaginal ring gives them the opportunity to use protection without consent from their partners,” said Hellier.

Constant condom use has been the biggest stumbling block in HIV prevention with local and international studies showing that condom use is declining across the world. A more recent local study, 2012 SA National HIV Prevalence, Incidence and Behaviour Survey, – conducted by the Human Sciences Research Council – showed that condom use has decreased significantly in the past five years in men and women aged 15 to 49.

The survey also highlighted that men often have the power to decide on condom use in relationships. Hellier said it was for this reason that they are empowering women with microbicide products.

“Our whole idea (with microbicides or products developed to prevent the transmission of HIV or other sexually transmitted infections when applied in the vagina or rectum) is to maximise choices so that we can optimise effectiveness,” she said.

Hellier also explained that the advantage of microbicides is effective in such a way that they deliver a lot of drugs to the site of infection, which is the cervix and rectum. The cervix, which is part of the vagina, and anus are high risk areas of HIV infection with the anus being the highest due to the gut being thin and fragile.

The following trials are currently being conducted:

» Tenofovir gel
FACTS 001 is a large-scale trial of 1% tenofovir gel in South African women. It was launched in October 2011 and enrolled nearly 3000 women. The trial is testing the same BAT-24 dosing strategy evaluated in CAPRISA 004.

Results are expected in early- to mid-2015. If this trial confirms the CAPRISA 004 results, the next step would be to present the data to regulatory authorities for possible product licensure and possible access.
The CAPRISA 004 trial in 889 South African women found that tenofovir gel reduced women’s risk of HIV infection via vaginal sex by 39% overall. Women in the trial were counselled to use the gel within 12 hours before and after sex, a regimen known as BAT-24. The results were announced in July 2010.

» Dapivirine ring
Vaginal rings are products made of flexible plastic that fit inside the vagina and provide sustained delivery of drugs over a period of time. Some vaginal rings are already used to deliver hormonal contraception.

The Dapivirine ring is being tested for its ability to reduce the risk of HIV infection. It slowly releases the antiretroviral drug Dapivirine. A new ring has to be inserted every four weeks to maintain drug delivery. Two current trials are evaluating whether the ring is safe and effective at reducing the risk of HIV infection – ASPIRE (MTN 020) was launched by the Microbicide Trials Network (MTN) in 2012 and enrolled 2629 women in Malawi, South Africa, Uganda and Zimbabwe. Results are expected in late 2015 or early 2016.

The other trial, The Ring Study (IPM 027) is enrolling 1950 women at sites in Uganda and South Africa. Results are expected in late 2016.

» Rectile microbicide
The rectile microbicide gel trial will only recruit men in South Africa at first. Women will be recruited in follow-up trials. Participants will use an ARV-based gel with 1% of the drug Tenofovir.

The rectal trial will involve 186 men and transgender women from South Africa, Thailand, Peru and the United States. Results are expected at the end of 2014.

All Africa
http://allafrica.com/stories/201410281463.html
SOUTH AFRICA: RESEARCH AT THE CENTRE OF GOVERNMENT’S HIV PREVENTION
28 October 2014

Cape Town — Science and Technology Minister Naledi Pandor says research into the prevention of HIV is at the centre of government's strategy aimed at ending the epidemic that has held the world hostage for many years.

Addressing the opening of the HIV Research for Prevention 2014 (HIVR4P) conference at the Cape Town International Convention Centre, the Minister said government was willing to go into more partnerships that will promote research and innovation aimed at preventing and treating new infections in HIV.

Minister Pandor said she was pleased that the conference - which brought over 1300 delegates made up of researchers, academics and scholars to Cape Town - was being held for the first time ever in South Africa.

"We believe that it is absolutely vital that more and more attention is being paid to biomedical HIV prevention research.
"As a department, we are working very hard to encourage investment in research activities by African governments themselves because we believe that as Africa we must take greater responsibility for ensuring that we have dedicated research attention to a wide range of scientific field," she said on Tuesday.
HIVR4P 2014 is the world's first and only scientific meeting dedicated exclusively to biomedical HIV prevention research.

The conference is intended to serve as an opportunity for sharing and debating the latest advances and challenges in the field, and to promote critical discussions of the issues that will drive intervention-specific and comprehensive biomedical prevention research, discovery, development and implementation.

The conference was told that to date, 35 million people were currently living with HIV and Aids, and that most people living with the disease were in South Africa.

According to a survey by the Human Sciences Research Council, 400 000 new HIV infections occurred in South Africa in 2012, bringing to the total number of infected South Africans to 6.5 million - 1.2 million more than in 2008.

The Minister said these figures could not be ignored and said that her department in partnership with the Department of Health has prioritised research in prevention tools.

"... We believe as Africa we must take greater responsibility for ensuring that we have dedicated research attention for a wide range of scientific fields and in particular, that we must begin to assume responsibility both for researching our problem and for finding solutions to them.

"We must invest in young people, invest in young researchers, create the infrastructure and the capacity for us to be able to be a leading player in science and not be a client of others," she said. She said, however, that "Thirty years ago, the global picture was depressing. We were faced with increasing rates of HIV infections and there was very little hope for those infected during those years.

"Now ... the overall situation has improved significantly. Today we are talking about approximately 30 drugs that have been approved for use for people living with HIV and Aids and many more are in different shapes of research".

She said some of the prevention tools that have been created include the prevention of mother to child transmission, male circumcision, pre-exposure prevention, amongst others. The Minister also said research has shown that early treatment of infections in HIV positive people can reduce the risk of transmission of HIV, and that the use of ARVs in HIV negative people can reduce the risk of infection. She said it would take biomedical, behavioural and socio-economic interventions to achieve zero new HIV infections and zero discrimination.

South Africa has to date been able to put two and a half million people on ARV treatment, which has reduced the number of mother to child transmissions and brought down the number of people dying from HIV aids.

Meanwhile, the Minister said her department would soon sit down with researchers to discuss various ways in which research into Ebola can be encouraged. - SAnews.gov.za

City Press
HIV VACCINE COULD BE AVAILABLE IN SA BY 2019
Zinhle Mapumulo
28 October 2014

Preparatory work is well underway to license an HIV vaccine in South Africa. If all goes well, in terms of the follow-up trials set to begin in January until 2017, the vaccine could be available for general use by 2019.

The vaccine will be similar to the RV144 vaccine which made headlines across the world in 2009 when it showed that it could protect against HIV infection by up to 31% when tested in Thailand. The only difference with the vaccine to be tested from next year is that it will have an added protein that will target the HIV strain prevalent in South Africa.

This exciting news was revealed by Professor Glenda Gray of the HIV Vaccine Trials Network in South Africa at the HIV Research for Prevention conference currently taking place in Cape Town until Friday. Gray said she was excited about the prospects of licensing this much-needed vaccine in the country where one in five South Africans are HIV-positive.

She and her team conducted a trial in Soweto, Klerksdorp and Cape Town last year to test whether South Africans would have the same immune response to RV144 as that witnessed in Thailand. The reason for testing the immune response instead of how effective the vaccine is in preventing HIV infection was that physiological aspects like gender, age, ethnicity and body mass index often affect how different people respond to vaccines.

Women, for instance, respond better to vaccines than men while obese and heavy drinkers don’t respond well.

Speaking ahead of releasing the findings of the South African trial (which will happen tomorrow), Gray said the immune response of South Africans was as good if not better as that of the Thai despite the ethnicity and high levels of obesity in the 100 people that participated in the local study.

She said: “This is very unusual and it gave us courage to move forward and develop the target profile which we have presented to the Medicines Control Council of South Africa.”

MMC is responsible for the approval and registration of medicines for use in South Africa. It also ensures that clinical trials of both non-registered medicines and new indications of registered medicines comply with the necessary requirements for safety, quality and efficacy.

Gray said the MCC has given them a go-ahead to skip phase two of the trials and go straight to phase three where they will test the effectiveness of the vaccine. Two hundred people between the ages of 18 and 44 are expected to participate in the efficacy study which will begin in January. They will be given a vaccine similar to the one tested in the Thai and South African trial.

The difference with the new vaccine, said Gray, “is that it would contain a different protein which will target the HIV strain that is prevalent in South Africa”.

“The vaccine that was used in our previous trial was targeted at strains E and B which are prevalent in Thailand. The vaccine that we will test next year will be targeted at the C strain which is prevalent in South Africa so that we maximise the effect,” she explained.
Gray also mentioned that while the efficacy of the Thai study was moderated, at 31% after three years, South Africa was willing to license the vaccine even if the new trial showed an efficacy of 50%.

“We usually roll out partially effective interventions in HIV. We did the same with medical male circumcision (which showed a 60% reduction in the risk of HIV acquisition in men) and the same was done on prevention of mother to child transmission which was not 100% effective in the beginning,” she added.

Modern Ghana

NO SINGLE HIV PREVENTION METHOD CAN END AIDS: COMBINATION PREVENTION IS KEY
Bobby Ramakant
28 October 2014

As HIV prevention needs and contexts vary, it is important to expand the range of effective prevention options that people can use. Archbishop Desmond Tutu said in a video link at the first-ever international conference on all HIV-related biomedical prevention research, that “No single method of prevention can end this epidemic on its own.” That is why conferences on microbicides and vaccines merged to provide one single global platform to deliberate on a spectrum of biomedical prevention research for HIV. HIV Research for Prevention (HIVR4P) is being held in Cape Town, South Africa.

Professor Helen Rees, Executive Director, Wits Reproductive Health and HIV Institute and HIV R4P conference co-chair, explained the value of breaking the walls between vertical conferences on specific biomedical prevention options such as microbicide and vaccine. “There are commonalities. There are issues which HIV vaccine basic scientists might be looking at which may also be very important for microbicide or Pre-Exposure Prophylaxis (PrEP) scientists too and vice versa.” Challenges of adherence to drugs-under research or ways to modify trial design to fast track the process are also common across the sector of HIV prevention research. Mechanisms in which socio-behavioural research informs the basic science are also a priority across the board. By organizing one conference on biomedical prevention research for HIV, “we were able to look at these commonalities together while not losing the uniqueness of these specific fields” said Rees.

Synergy between different streams of HIV prevention is crucial so that new infection rate dips faster than ever before to end AIDS. South African Minister for Science and Technology Mrs GNM Pandor said at HIVR4P that more people get newly infected with HIV than those people living with HIV (PLHIV) who are put on antiretroviral therapy (ART). “There are 2.4 million PLHIV on ART in South Africa” said Pandor. It is important to underline that there are estimated 6.3 million PLHIV in South Africa as per latest data from UNAIDS. The road to scale up treatment for everyone is still long. Alongside scaling up ART to every PLHIV and other measures, we surely need to scale up effective prevention services radically.

“Increase in ART has resulted in reduction in number of people dying as result of HIV infection and significant reduction in mother to child transmission of HIV. We remain many years away from eliminating HIV. We are not investing in social sciences enough. We have to get the behavioural
Dr Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), USA, addressed HIVR4P via a video link. He said that HIVR4P is rightly addressing all biomedical prevention options at one forum. He said that non-vaccine prevention options and vaccine both are required to stem the pandemic.

Dr Fauci underlined that non-vaccine prevention options need to be taken regularly but vaccines once given does not have those adherence issues. “Non-vaccine prevention options are highly effective but requires continual adherence, whereas vaccine are often modestly effective but durable, and does not have continual adherence issues” said Fauci.

“Foundation of HIV prevention is infact HIV testing” said Fauci. HIV testing connects to two streams: if the test is positive then person should be connected to care continuum and if negative, then to prevention continuum. He said that there are gaps in care continuum and we must find ways to fill these gaps. Referring to prevention continuum, Fauci said that if the test is negative then the person is encouraged for counselling and risk stratification, and provided tailored prevention services from the ‘prevention toolbox’.

Fauci was referring to a range of HIV prevention options that have been proven to work effectively such as: HIV testing and counselling, treatment as prevention, voluntary medical male circumcision (VMMC), treatment of STIs, rectal and vaginal microbicides (both are currently under research), prevention or treatment of drug and alcohol use, provision of clean needles and syringes, education, behaviour modification, male and female condoms, blood supply screening, antiretroviral drugs for prevention of mother to child transmission of HIV (PMTCT), Post-Exposure Prophylaxis (PEP), and Pre-Exposure Prophylaxis (PrEP). Vaccines will also get added to this ‘toolbox’ once proven to be safe and effective in ongoing research studies, said Fauci. There is no effective HIV vaccine available today. Yet a safe and effective vaccine is critical to the control of HIV globally.

He also stressed to fashion combination prevention for ‘hotspots’ of HIV infection. He gave an example of Lake Victoria area in Kenya which has HIV rates comparable to places in Africa with highest HIV prevalence. This area is also known to have low male circumcision rates and unsafe sex work associated with fishing community is also reported. But rest of the Kenya does not have that high HIV rates. Combination prevention needs to be tailored in unique contexts and realities and if we do so, we could prevent “600,000 new HIV infections by 2030” said Fauci.

Times Live
http://www.timeslive.co.za/thetimes/2014/10/28/inject-not-swallow---a-new-treatment-for-hiv
INJECT, NOT SWALLOW- A NEW TREATMENT FOR HIV?
Katharine Child
28 October 2014

This was discussed at HIV Research for Prevention Conference held in Cape Town this week.

GlaxoSmith Kline and Jansen have each developed a new anti-retroviral to be used as an injection once a month instead of daily anti-retrovirals.

The companies, while usually competitors, are working together to test the injections together. This is because current treatments of HIV require more than an ARV drug. Each drug stops the virus replicating and counteracts the different ways the virus may mutates to beat the drugs.

Long-acting ARVs one day could help people adhere to treatment better as they wouldn't need to take a pill every day.

The injectables are also being tested to be used as prevention from HIV. Using specific ARVs once a day, while one is negative and engaging in risky behaviour, can protect against HIV. But taking a pill a day to prevent getting HIV can be difficult when one is healthy.

An injection every three months may be easier form of prevention, said Mitchell Warren, director of AVAC, a global advocacy organisation. "It's another option."

He said pharmaceutical companies did not usually get on board when developing HIV prevention options, but as the injections were being tested for treatment and prevention there was a great deal of enthusiasm from the drug companies.

Injections as treatment are about five to seven years away, he said. But initial testing has shown the idea can work.

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New Vision

WHAT IS EXPECTED FROM THE HIV CONFERENCE
Hilary Bainemigisha
28 October 2014

The world is waiting for good news as scientists and researchers gather in Cape Town, South Africa for the HIV prevention conference. The conference which kicked off today Oct 28, is the world's only global science meeting dedicated exclusively to biomedical HIV prevention research. It brought together 1,313 researchers, advocates, clinicians, policy makers, private sector and public health partners from 48 countries to discuss the science of preventing HIV transmission and multiplication.

After four days of discourse, hundreds of new research and round table discussions, HIV advocates and implementers will be expecting some hope on the new remedies, researches and strategies that will be recommended. Some of the exciting areas include the following. Advances in vaccine development
Glenda Gray of the South African Medical Research Council will be presenting results from the study of an HIV vaccine, the RV144, which has been tested among South Africans. RV144 was the first HIV vaccine to demonstrate a modest level of protection of 34% against infection when it was studied in volunteers in Thailand. The research is the first to report on the impact of the vaccine in other populations. According to Gray, the vaccine candidate produced immune responses in South African volunteers that were at least comparable to or better than those induced in the Thai study. This is promising news in the effort to develop a globally effective HIV vaccine, she said.

Advances in microbicide development

The potential of microbicides containing HIV antiretroviral drugs to prevent infection with herpes simple virus (HSV2) is being explored in a study that will be presented by Dr Jeanne Marazzo of the University of Washington, US. In the analysis of a previous HIV study, it was discovered that the participants reduced their risk for HSV-2 infection by 50% using the vaginal tenofovir gel that was not intended to treat herpes. HSV-2 is a common infection in sub-Saharan Africa, which increases the risk of HIV transmission and acquisition.

Advances in ARVs for prevention

Ian McGowan of the University of Pittsburgh School of Medicine, US said they are working on a product to produce a long lasting ARV which people can take once and get protected for about a week. Referring to it as the MWRI-01 study, the doctor says they are studying an intra-muscular TMC278 LA (injectable) among 36 people and so far, it had proved safe and well-tolerated. The next stage will be to try it over a wider range of people. Multiple dosing studies of this promising, long-acting approach to HIV protection are now planned.

William Spreen of GlaxoSmithKline (US) will also present the findings of a second study of the potential of injectable drugs hoped to provide more durable protection against HIV infection. The GSK1265744 is a long-acting injectable being given to monkeys once a week to protect them from acquiring their version of HIV. Initial studies are showing that it was safe and provided a level of drug that is predicted to provide robust protection against HIV infection. Ongoing animal studies are exciting and a precursor to possible future human study of this new approach to HIV pre-exposure prophylaxis (PrEP).

Among the cutting edge topics on the conference agenda are:

- the prospects for new, long-lasting prevention options
- the latest HIV antibody discoveries and their implications for vaccine development
- research into microbicides and other female-controlled prevention methods
- the use of antiretroviral therapy to reduce HIV infection and transmission
- the potential for multipurpose prevention technologies, which could block HIV and other sexually transmitted infections, or prevent pregnancy, simultaneously; and
- the behavioural and adherence challenges of prevention.

All Africa
http://allafrica.com/stories/201410281619.html
THE CURIOUS CASE OF THE SEX WORKERS WHO CAN’T GET HIV

Wycliffe Muga
28 October 2014

Some years ago, a small group of commercial sex workers - actively pursuing this line of work in a Kenyan slum (Majengo in Nairobi) were identified as having an innate immunity to the HIV virus. They had apparently been repeatedly exposed to HIV+ve customers, and yet had not once tested positive for HIV themselves. My question was, how is it that these women cannot get HIV infection, no matter how many HIV+ve men they have sex with? And why has this not led to any breakthroughs in the fight against AIDS?

The answer is that most 'live' HIV research is conducted using monkeys. Monkeys have their own variety of what in humans is HIV. It is called SIV - Simian Immunodeficiency Virus (as opposed to HIV being 'Human Immunodeficiency Virus) - and apparently can exist in the bodies of monkeys without doing any real harm. So research in monkeys can give all kinds of insights and data about how these viruses behave. But there are obvious ethical barriers to what can be done to study a human being who simply cannot get infected with HIV despite repeated (and indeed, overwhelming) exposure to the virus. This is a world-class conference on HIV. Many speakers are leaders in their fields. And yet what one hears all the time is, "Nobody knows". For example, nobody knows why those women in the Majengo slums cannot get infected by HIV despite being engaged in (mostly unprotected) sex work. Nobody knows why - in 70% to 80% of infections - it is a single virus only, that will move across the vaginal (or rectal) mucosa and pass on HIV infection between sex partners. It all suggests a selective process: but nobody knows how or why.

But that is the way of science: again, contrary to popular assumption, it is not about one heroic figure emerging who will somehow come up with the shattering insight which finds a key to an AIDS cure or an AIDS vaccine which effectively stops all new transmission.

Victory against AIDS will involve many small incremental steps, and the efforts of thousands of dedicated scientists around the world.

And this is why conferences as this one are important - they allow for networking opportunities between scientists, policy makers, the media, activists/advocates and many others who are collectively involved in the global effort to put an end to one of the most deadly scourges of our time, and possibly the greatest public health challenge of recent decades.

At the end of this first day in Cape Town, it is clear that I am not here to find out the answers to my questions, as provided by the top experts: I am here to learn what kind of questions the experts are asking each other.

Nam News Network

RESEARCH AT THE CENTRE OF PRETORIA’S HIV PREVENTION STRATEGY
29 October 2013

Research into the prevention of HIV is at the centre of the South African government’s strategy aimed at ending the epidemic which has held the world hostage for many years, says Science and Technology
Minister Naledi Pandor.

Addressing the opening of the HIV Research for Prevention 2014 (HIVR4P) conference at the Cape Town International Convention Centre Tuesday, she said the government was willing to go into more partnerships which would promote research and innovation aimed at preventing and treating new infections in HIV.

Pandor said she was pleased that the conference, which has brought together more than 1,300 delegates made up of researchers, academics and scholars to Cape Town, was being held for the first time ever in South Africa.

“We believe that it is absolutely vital that more and more attention is being paid to biomedical HIV prevention research. As a department, we are working very hard to encourage investment in research activities by African governments themselves because we believe that as Africa we must take greater responsibility for ensuring that we have dedicated research attention to a wide range of scientific field,” she said.

HIVR4P is the world’s first and only scientific meeting dedicated exclusively to biomedical HIV prevention research. The conference is intended to serve as an opportunity for sharing and debating the latest advances and challenges in the field, and to promote critical discussions of the issues that will drive intervention-specific and comprehensive biomedical prevention research, discovery, development and implementation.

The conference was told that to date, 35 million people were currently living with HIV and AIDS, and that the most people living with the disease were in South Africa.

According to a survey by the Human Sciences Research Council, 400,000 new HIV infections occurred in South Africa in 2012, bringing to the total number of infected South Africans to 6.5 million, or 1.2 million more than in 2008.

Pandor said these figures could not be ignored and said that her department in partnership with the Department of Health has prioritised research in prevention tools.

“We believe as Africa we must take greater responsibility for ensuring that we have dedicated research attention for a wide range of scientific fields and in particular, that we must begin to assume responsibility both for researching our problem and for finding solutions to them<” she said.

“We must invest in young people, invest in young researchers, create the infrastructure and the capacity for us to be able to be a leading player in science and not be a client of others.”

She noted, however, that 30 years ago, the global picture was depressing. "We were faced with increasing rates of HIV infections and there was very little hope for those infected during those years. Now .... the overall situation has improved significantly. Today we are talking about approximately 30 drugs that have been approved for use for people living with HIV and Aids and many more are in different shapes of research," she added.

She said some of the prevention tools which had been created include the prevention of mother to child transmission, male circumcision, and pre-exposure prevention, amongst others.

Pandor also said that research had shown that early treatment of infections in HIV positive people could reduce the risk of transmission of HIV, and that the use of ARVs in HIV negative people could reduce the
risk of infection.

She said it would take biomedical, behavioural and socio-economic interventions to achieve zero new HIV infections and zero discrimination.

South Africa has to date been able to put two and a half million people on ARV treatment, which has reduced the number of mother to child transmissions and brought down the number of people dying from HIV aids.

Meanwhile, the Minister said her department would soon sit down with researchers to discuss various ways in which research into Ebola can be encouraged. - -NNN-SA NEWS

Health Medicine Network

SOUTH AFRICA CLAIMING TO BE “LEADING PLAYER” IN HIV RESEARCH

South African doctors and researchers seem to be gaining confidence in their decades-long battle against HIV, international delegates at a conference in Cape Town say.

The HIV Research for Prevention Conference is dedicated to biomedical HIV prevention research. A nurse, left, speaks with a patient at an AIDS centre in South Africa, which strives to be a leading player in HIV science. (Schalk van Zuydam/Associated Press)

Sub-Saharan Africa remains the epicentre, with nearly 1 in every 20 adults living with HIV and accounting for 71 per cent of the people living with the illness worldwide, according to the World Health Organization.

South Africa’s minister of science and technology, Naledi Pandor, told the conference today it’s time the country assumed more responsibility “to be a leading player in science and not a client of others.” The country’s government provides anti-retroviral medications to nearly 40 per cent of HIV-infected South Africans. On the research front, new labs, scientists, technicians and funding commitments are on the rise.

“They’re very competitive for research funding elsewhere,” said Canadian HIV researcher Cate Hankins, currently deputy director of science for the Amsterdam Institute for Global Health and Development. Conference co-chair Anatoli Kamali, of Uganda’s Medical Research Council, pointed out that a third of the research papers being presented this week are from African researchers.

Professor Robin Shattock of Imperial College London is another co-chair of the conference. Shattock said it makes sense to have people work across fields of prevention rather than working in a bubble.

The conference aims to build linkages between investigators in developing and developed countries to open the door to collaboration.

Before the conference closes on Oct. 31, scientists plan to present 550 research papers, such as new results on microbicidal gels and vaginal rings, to try to prevent HIV infections.
HIV PREVENTION’S RESEARCH REMAINS HIGH ON SA AGENDA
29 October 2014

Science and Technology Minister Naledi Pandor says research into the prevention of HIV is at the centre of government’s strategy aimed at ending the epidemic that has ravaged world communities for years.

Addressing the opening of the HIV Research for Prevention 2014 (HIVR4P) conference at the Cape Town International Convention Centre, Pandor said government was willing to invest in partnerships that promote research and innovation that prevents or treats new HIV infections.

She said she was pleased that the conference - which brought over 1,300 delegates including researchers, academics and scholars to Cape Town - was being held in South Africa for the first time.

"We believe that it is absolutely vital that more and more attention is paid to biomedical research into HIV prevention.

"As a department, we are encouraging investment in research activities by African governments themselves because we believe that as Africa we must take responsibility for ensuring that we have dedicated research in this field," she said.

Pandor said the conference is aimed at sharing and debating the latest advances in the scientific field while promoting critical discussions of the issues that drive intervention-specific and biomedical prevention research, discovery, development and implementation.

She said that to date, 35m people were currently living with HIV and Aids, and that most people living with the disease were in South Africa.

According to a survey by the Human Sciences Research Council, 400,000 new HIV infections occurred in South Africa in 2012, bringing to the total number of infected people to 6.5m - 1.2m more than in 2008.

Pandor said these figures could not be ignored and that her department in partnership with the Department of Health has prioritised research in means of prevention.

"We believe as Africa we must take responsibility for ensuring that we have dedicated research into for a wide range of scientific fields and in particular, that we must begin to assume responsibility both solving these problems," she said.

"We must invest in young people, invest in young researchers, create the infrastructure and the capacity for us to be able to play a leading role in medicine and science and not simply be a recipient of foreign research," she said.

"Thirty years ago, the global picture was depressing. We were faced with increasing rates of HIV infections and there was very little hope for those with the disease. Today the situation has improved significantly as almost 30 drugs that have been approved for use for people living with HIV and Aids and many more are in in the process of being developed."
She said some of the advances include the prevention of mother to child transmission, male circumcision and pre-exposure prevention.

The Minister also said research has shown that early treatment of infections in HIV positive people can reduce the risk of transmission of HIV, and that the use of ARVs in HIV negative people can reduce the risk of infection.

She said it would take biomedical, behavioural and socio-economic interventions to achieve zero new HIV infections and zero discrimination.

In South Africa, 2.5m people are receiving ARV treatment, which reduced the number of mother to child transmissions and brought down the number of people dying from HIV aids.

Eyewitness News
http://ewn.co.za/2014/10/29/HIV-prevention-could-end-epidemic

HIV ADVOCACY GROUP: PREVENTION OF INFECTION COULD END EPIDEMIC
Giovanna Gerbi
29 October 2014

The United States (US) Global Advocacy for HIV Prevention says it's positive that if new infections are prevented, the epidemic will be stopped.

More than 1,000 health workers, policy makers and researchers from around the world are attending the HIV R4P Conference in Cape Town this week.

The organisation's Mitchell Warren says in the future there will be several additional prevention and treatment methods, along with antiretrovirals.

“The people on treatment are not always able to maintain and what we say adhering; being able to take their pill every day. We know that for any condition, if you take vitamins, if you take the contraceptive pill as a woman, taking a pill every day is hard.”

IOL Sci Tech

THAI HIV VACCINE HELPS SA PATIENTS
Kerry Cullinan
29 October 2014

Pretoria - The only HIV vaccine in the world that worked slightly in Thailand also seems to work on South Africans.

Despite being fatter than Thai people and exposed to a different strain of HIV, 100 South Africans responded in a similar way to a vaccine that protected about a third of Thai people against HIV.
“We were excited to see the vaccine got exactly the same (immune) responses in South Africans as in Thailand,” Medical Research Council president Dr Glenda Gray told the inaugural HIV Research for Prevention conference on Tuesday.

The Thai vaccine, known as RV144, protected 31 percent of people who received it in a massive clinical trial in Thailand involving 16 400 people.

Once the Thai results were known in 2009, the global HIV research community decided it was a priority to test the vaccine in a country with a high HIV rate, said Gray.

For the past two years, the immune responses of the 100 South Africans vaccinated in Soweto, Klerksdorp and Cape Town have been under the microscope.

“We had to be pragmatic,” said Gray. “The vaccine had to work for fat people, and women and people who drink alcohol because we South Africans drink a lot.”

Satisfied that the South Africans reacted as hoped, researchers are now preparing for a bigger trial with a modified vaccine that contains the strain of HIV most common in southern Africa. This trial, involving 200 people, starts in January but could leapfrog into a massive R1-billion trial within a year if the people respond according to the Thai trial.

“We have already set our ‘go or no go’ criteria, based on the Thai trial. If we meet these, we can go straight into a Phase 3 trial of 7 000 people by the end of 2016,” said Gray.

The Thai trial combined two vaccines. The first aimed to prime people’s immune systems to recognise the types of HIV most common in Thailand (sub-types E and B) and the other, injected later, aimed to boost their immune systems to fight infection.

The “primer” vaccine now has to be modified to contain HIV sub-type C, which is most common in South Africa.

Discussions have already been held with the Medicines Control Council to license the vaccine by 2019 if the Phase 3 trial goes well, and also to vaccinate children along with the current HPV vaccine to prevent cervical cancer, said Gray.

Science and Technology Minister Naledi Pandor opened the conference by appealing to African governments to invest in health research to “assume responsibility for finding solutions to our problems”.

She welcomed the inaugural conference, which aims to unite all biomedical efforts to prevent HIV, from vaccines to microbicides and condoms.

“The challenge is to translate our new health knowledge into products that are effective, affordable and accessible,” said Pandor. – Health-e News

All Africa
http://allafrica.com/stories/201410290325.html
There is lots of talk about sex at the Cape Town Convention Centre at the moment: words like anal sex; vaginas and penises are constantly popping up. No, this is not the Sexpo - it is HIV R4P, the archly-named international conference on biomedical methods of protecting ourselves against getting infected with HIV.

It is wonderfully non-judgemental - who you choose to have sex with, how often and in what manner - is totally irrelevant. The only subject of interest is how you stop a virus from destroying a human body. The consequences for the intimate and emotional aspects of sex have not been entirely overlooked. As one of the many leading scientists here, Jared Baeten, professor of global health, medicine and epidemiology at the University of Washington, remarked: "We must remember that sex is not just a clinical activity. There is a whole generation which has grown up knowing only fear in relation to sex." But, with more than two million people becoming newly infected last year, we need to throw everything at the virus.

At the ICC this week, four scientific prevention methods are under the spotlight - none are fail-safe and some are still nowhere near ready for universal use.

Medical male circumcision is the most accessible: it has been proven that a man who is circumcised reducing his risk of getting HIV from an infected partner by at least 60%. Vaccines are still the holy grail and we are inching closer to finding one that works but we’re not there yet.

Another option being tried is Pre-exposure Prophylaxis: this means someone who is not HIV positive but is at risk takes anti-retrovirals as precaution. It is suggested it is used by an HIV-negative person if their sexual partner is HIV positive. Or in high risk groups - like the receptive partner in men who have penetrative sex with men. But obviously it is difficult to persuade someone who is not sick to take drugs which are potentially toxic. And it is very expensive as a public health option.

Treatment as prevention does work, however, when taken by an HIV-positive person, as it reduces his or her viral load and thus makes them far less likely to infect a partner.

The most promising option is microbicides, which are inserted into the vagina or rectum before and/or after sex. The results of a big study carried out in Cape Town are due early year and, so far, it is looking very hopeful.
Professor Glenda Gray, head of the South African Medical Research Council, announced this at the HIV Research for Prevention conference in Cape Town yesterday.

After 30 years of trying to find a vaccine for HIV, scientists announced success in 2009. The vaccine, named R144, tested in Thailand, had offered people who received it almost 60% protection from the virus for the first year.

After three years, recipients of the vaccine were 31% less likely to get the virus. Scientists wanted to test the vaccine in South Africa because even 30% to 40% protection against HIV would reduce the rate of new infections, said Gray.

Before a large trial can go ahead next year, researchers needed to show two things. "We had to prove that the vaccine was safe to use on South Africans and that it provoked an immune response," said Gray. An immune response means the body reacts to the vaccine and starts to fight what it believes is HIV. But an immune response does not mean the vaccine works against disease.

One hundred volunteers in Soweto and Klerksdorp were given the vaccine last year. "It provoked an immune response equal and in some cases better than in the Thai trial," said Gray. It was safe to use.

This means a new trial can start in January to test if the vaccine works to prevent HIV. Should this trial be successful, 7000 people will be enrolled from 2016 for one final trial.

The Thai vaccine is being modified to fight against the African strain of the virus.

It will be also strengthened to try to get it to offer protection from HIV for a longer period than the Thai vaccine did. Participants will get a booster vaccine after a year.

It is not expected the vaccine will offer complete protection from the virus, but even if it offers some protection, researchers will try to get it approved by the Medicines Control Council for use and sale. Application for approval is expected to take place in 2019.

Gray said: "If it even offers 50% protection from the virus, I will rejoice. It would be a global game changer."

A vaccine could be used with circumcision, vaginal gels and antiretrovirals in a package to slow the rate of infections down, said Dr Anatoli Kamali from the Ugandan Medical Research Council.

Africa STI
HIV VACCINE TRIAL PASSES FIRST HURDLE IN SOUTH AFRICA
Mary Engel
29 October 2014

The first in a series of clinical trials designed to build on the promise of an HIV vaccine that showed modest protection when tested in Thailand has passed a key hurdle, according to a new study. It paves the way for larger HIV vaccine trials to move forward in South Africa.

The trial found that the so-called Thai vaccine induced comparable immune responses when tested in South Africa as it had in the original trial. This early phase of testing was designed to see how a different
population’s immune system would respond, not—yet—whether the vaccine would protect against HIV. The results, announced Tuesday at a conference in Cape Town, are significant because participants in the Thai and South African trials varied in ethnicity, body mass index, gender and age, all of which could have affected response.

“We want to be able to develop a vaccine that can go to high-risk men and women of varying ages and weight and genetic makeup,” said Dr. Larry Corey, president and director emeritus of the Fred Hutchinson Cancer Research Center and principle investigator of the Hutch-based HIV Vaccine Trials Network, which conducted the study. “[The results of this study] tell us we should be able to do that, so that’s wonderful news.”

The 2009 Thai study was widely considered a turning point in HIV vaccine research because it marked the first time an experimental vaccine showed any protection against HIV. Participants who received the vaccine were 31 percent less likely to be infected by HIV than those who received a placebo. That was not enough protection to warrant licensing the vaccine, but it was the first evidence that developing a protective vaccine was even possible.

Dr. Anthony S. Fauci, director of the National Institute of Allergies and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health, called the new findings “encouraging news as we move toward evaluating a modified and potentially improved version of the vaccine regimen in South Africa.” NIAID, sponsored the study and funds the HVTN, the largest publicly funded global collaboration working to develop an HIV vaccine. NIAID and HVTN are part of a public-private partnership formed in 2010 specifically to follow up on the 2009 Thai vaccine study.

A second clinical trial, slated to begin in South Africa in January, will test a new version of the Thai vaccine that has been modified to both boost its potency and durability and make it potentially more responsive to the subtype of HIV that is found in South Africa, called clave C, rather than the subtype found in Thailand, or clave B. If that small trial shows that the modified vaccine is safe and again induces the anticipated immune system responses, the plan is to expand it to a larger trial in late 2016 or early 2017 that would test for efficacy, or whether the vaccine actually protects those who receive it from being infected with HIV.

“We are very excited about moving forward,” said Dr. Glenda Gray, president of the South Africa Medical Research Council and HVTN co-principle investigator and director of its Africa programs, at a media conference today in Cape Town. If all goes according to plan, results of the larger trial could be seen in two years, by 2019, Gray said.

Since 2009, scientists have been working to analyze the data of the Thai trial, gain insight into the types of antibodies and cellular immune responses induced and come up with modifications that would make the vaccine more potent and durable. Researchers also worked to develop a clave C insert for the vaccine to be tested in South Africa; as with the original Thai vaccine, the insert uses HIV pieces that are made in a laboratory and cannot cause HIV infection.

Developing a vaccine to protect against HIV has been challenging for a number of reasons. The virus kills the very immune cells used in defending the body against it. It mutates rapidly within individuals and across geographical locations, making it a moving target for vaccines. And until the 2009 Thai trial results, no vaccine candidate had shown any protection, so there were no known “correlates of protection” that scientists could search for as an early sign of whether a vaccine might be effective or use as a target for improving vaccines. South Africa has the largest HIV epidemic in the world, with an estimated 6.1 million people infected with the virus, or almost 18 percent of the population. This means
that not only is the need for a vaccine great, but that clinical trials there can be both smaller and done more quickly precisely because the population being tested is at higher risk and more likely to encounter HIV.

Because it is unethical to deliberately expose people to HIV, testing to see whether a vaccine provides protection involves waiting several years and seeing how many people become infected naturally. (Again for ethical reasons, all participants are counseled on HIV prevention and offered options such as condoms and male circumcision to reduce the risks of contracting the virus.) Scientists and participants alike are “blinded,” or kept ignorant, of whether the injection each trial participant receives is the experimental vaccine or a placebo; the two groups are compared and statisticians tally which had more infections.

Public health experts generally want a vaccine to protect at least 70 to 80 percent of people vaccinated, but scientists and government regulators are likely to consider licensing an HIV vaccine if it protects at least 50 percent of those who receive it.

“I think we would rejoice if we had a vaccine efficacy of 50 percent,” Gray said. “We would learn so much, and could focus on improving it. Having an efficacious vaccine would be a game-changer at a global scale.”

Gray will formally present the latest study’s findings Wednesday at the HIVR4P (Research for Prevention) Conference, the first global conference to bring together all scientists working on HIV prevention science, including vaccines, microbicides and pre-exposure prophylaxis. She and other scientists stressed that a combination of measures may be required to effectively prevent HIV infection. Mary Engel is a staff writer at Fred Hutchinson Cancer Research Center. Previously, she was a writer covering medicine and health policy for newspapers including the Los Angeles Times, where she was part of a team that won a Pulitzer for health care reporting.

4 Traders

GeoVax Labs: Presents HIV VACCINE CLINICAL TRIAL DATA

ATLANTA, GA, United States, via ETELIGIS INC., 10/29/2014 - -GeoVax Labs, Inc. (OTCQB: GOVX), a biotechnology company developing innovative human vaccines using its novel DNA/MVA platform technology, today announced that its Chief Scientific Officer, Harriet L. Robinson, Ph.D., gave an oral presentation entitled Elicitation of Immune Responses by a DNA/MVA Vaccine in ART Treated Patients in a Treatment Interruption Trial. Dr. Robinson delivered the presentation at the HIV Research for Prevention 2014: AIDS Vaccine, Microbicide and ARV-based Prevention Science (HIVR4P) conference in Cape Town, South Africa.

Dr. Robinsons presentation focused on GeoVaxs Phase 1 trial(GV-TH-01) investigating the therapeutic potential of itsDNA/MVA vaccine regimen (GOVX-B11) in HIV-infected patients, which was completed earlier in 2014. GOVXB11 wastered for safety and immunogenicity in nine HIV-infected patients who were on antiretroviral drug therapy (ART). After completing the inoculation series, patients suspended ART for a12 week period and were observed for their ability to control
virus reemergence in the absence of drugs. ART was reinstituted after 12 weeks, and trial participants were observed for an additional 6 months.

Strong safety data results were observed throughout the trial. In GeoVax’s final analysis of the study, the Company concluded that GOVX-B11 enhanced CD8+ T cell responses in essentially all participants and that most vaccine-elicited CD8+ T cell responses were critical for the recognition and killing of cells harboring a reactivated infection. However, GOVX-B11 did not prevent viral reemergence or control reemergent virus to levels that minimize immune escape. Dr. Robinson noted during her presentation that the Company’s analysis of the data and observations from the trial suggest that the DNA/MVA vaccine might contribute to cureregimens in which participants remain on ART while being treated with a shock agent timed to reactivate latent virus at a peak vaccine response.

Based on data and observations from GVTH01, GeoVax is now planning an additional clinical trial to further develop its HIV immunotherapy program. Current antiretroviral therapies, though highly effective at suppressing HIV viral load, are unable to eliminate HIV infection entirely. A major challenge in the development of HIV therapeutics is the ability of HIV to persist in host cells in a latent proviral form, invisible to the immune system and inaccessible to antiretroviral drugs. In response to this problem, the NIH and other leaders in the HIV field have developed a new concept: the shock and kill strategy, in which patients remain on drugs while one drug (shock agent) is used to reactivate latent HIV and a second drug (kill agent) is used to recognize and eliminate cells that harbor the reactivated virus. A shock and kill therapy could potentially contribute to a cure for HIV. GeoVax is now planning a Phase 1b trial to evaluate the use of its DNA and MVA vaccines as an approach to a cure.

About GeoVax:
GeoVax Labs, Inc. (OTCQB: GOVX) is a biotechnology company developing human vaccines using its novel DNA/MVA vaccine delivery platform. The Company’s lead development program is focused on vaccines to prevent, and treat, Human Immunodeficiency Virus (HIV) infections. Recently it has initiated a program to develop an Ebola virus vaccine. GeoVax’s unique two-component HIV vaccine, a recombinant DNA and arecombinant modified vaccinia Ankara (MVA), is designed to stimulate both anti-HIV antibody and anti-HIV T cell immuneresponses. GeoVax’s DNA and MVA vaccines are used in a prime/boost protocol in which priming is done with the DNA and boosting with the MVA. Priming and boosting can also be done with the MVA. Both the DNA and MVA express the three major proteins of the HIV virus: Gag, Pol, and Env, and produce non-infectious virus-like particles. GeoVax’s vaccines are unique in expressing virus-like particles that display the native form of the trimeric membrane-bound HIV-1 envelope glycoprotein. Clinical trials for GeoVax’s preventative HIV vaccines have been conducted by the US National Institutes of Health supported HIV Vaccine Trials Network (HVTN) with funding from the National Institute of Allergy and Infectious Disease (NIAID). Overall, GeoVax’s vaccines, in various doses and combinations, have been tested in close to 500 humans. GeoVax is using its MVA vaccine platform to develop a vaccine to prevent acquisition of the Ebola virus. Efforts are focused against the current epidemic version of the virus. For more information, go to www.geovax.com.

Forward-Looking Statements:
Certain statements in this document are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act. These statements are based on management’s current expectations and are subject to uncertainty and changes in circumstances. Actual results may differ materially from those included in these statements due to a variety of factors, including whether: GeoVax can develop and manufacture its vaccines with the desired characteristics in a timely manner, GeoVax’s vaccines will be safe for human use, GeoVax’s vaccines will effectively prevent HIV or Ebola infection in humans, vaccines will receive...
regulatory approvals necessary to be licensed and marketed, GeoVax raises required capital to complete vaccine development, there is development of competitive products that may be more effective or easier to use than GeoVax's products, GeoVax will be able to enter into favorable manufacturing and distribution agreements, and other factors, over which GeoVax has no control. GeoVax assumes no obligation to update these forward-looking statements, and does not intend to do so. More information about these factors is contained in GeoVax's filings with the Securities and Exchange Commission including those set forth at "Risk Factors" in GeoVax's Form 10-K.

All Africa
http://allafrica.com/stories/201410290326.html
AFRICA: IF IT WORKS, WE SHOULD USE IT
Eric Mcheka
29 October 2014

"While numbers and slogans are important in themselves, focus should also be given to interventions that are making positive impact," that's how Mitchell Warren, Executive Director of AVAC, opened the 2014 HIV R4P Advocates' Pre-Conference Workshop.

In his talk, titled, HIV Prevention: Research, reality & context, Warren observed that, "method mix is needed by the community members and not the policy maker." And so it is critical for civil society to push for access to the full range of biomedical interventions which research has proven efficacious, like PrEP (Pre-exposure prophylaxis) and VMMC (voluntary medical male circumcision). Such interventions have to be embraced by policy makers in Africa, if the quest to end the AIDS epidemic by 2030 is going to be achieved.

Warren summed up by saying that, "It is therefore incumbent upon us to ensure that all our efforts are aimed at rolling out interventions that would save more people from contracting HIV in our communities." I couldn't agree more.

This article originally appeared on WhatsUpHIV, a live blog set up to report all the developments from HIV R4P, the world's first global research conference dedicated to biomedical HIV prevention.

All Africa
http://allafrica.com/stories/201410290968.html
AFRICA: THE WITCHCRAFT POTENTIAL OF FORESKINS
Wycliffe Muga
29 October 2014

TUESDAY, OCTOBER 28: SESSION BY DR SEMA SGAIER OF THE BILL AND MELINDA GATES FOUNDATION
When the programme of Voluntary Medical Male Circumcision (VMMC) was first announced in Uganda (around 2007) one of its greatest critics was the Ugandan President, Yoweri Museveni. This was somewhat surprising because President Museveni had long been praised all over the world, as an African leader who had taken a place at the frontline of his country's fight against AIDS (Uganda then having the dubious record of being one of the countries most devastatingly affected by HIV.)
On the face of it, President Museveni appeared to have a point: His argument was that this claim that male circumcision had been proved to reduce HIV transmission by 60% would be understood by most Ugandan men to be the long-dreamed-of get-out-of-jail-free card. And that on the assumption that the chances of getting infected had been drastically reduced, they would engage in wanton promiscuity which would ultimately INCREASE - rather than reduce - the incidence, and ultimately the prevalence of HIV.

And since this was at a time when it was widely anticipated within Africa, that sooner or later a 'silver bullet' against AIDS would be discovered in some sophisticated lab in Western Europe or North America (more or less what seems to be happening with Ebola now) this seemed to be a perfectly valid argument.

But, as it turns out, President Museveni was wrong. The VMMC programmes have been perhaps the single most important intervention against AIDS thus far, in the countries where such programmes were rolled out. Already about 6.0 million men have voluntarily submitted to circumcision and the target set is for 20 million men by 2016 or thereabouts. And "risk-compensation studies" have since demonstrated that the men, who undergo such circumcision, are not in fact any more reckless in their sexual conduct than those who do not.

Of course - in my view, anyway, and as this is a self-selected cohort - there is the question of whether it is not the case, that such men who have already demonstrated a willingness to take steps to protect themselves and their families from the scourge of AIDS would be the very men most likely to be very careful and least reckless in their sexual conduct. And in any case, any man who is enrolled in this programme receives the most intense counselling imaginable, and all kinds of ancillary clinical services. Surely these too contribute to the drop in new HIV infections among circumcised men.

Back to the question of foreskins: With 6.0 million men circumcised over just a few years, well, that is a ton of foreskins: what do you do with them?

Of course the point here is that any medical intervention taking place within Africa - whether successful or not - will be subject to all kinds of rumours and speculations as to what the REAL objective is (e.g. "Might this be a new family planning method?" Or, "Why would anyone want to harvest so many foreskins, unless they knew that there is some kind of powerful juju which such foreskins can be used for?" Which would automatically lead to "Shouldn't they be paying us for these valuable foreskins??")

Just so you know: Dr Sgaier assured us that ALL the foreskins are treated as "biological waste" and are promptly incinerated

*This article originally appeared on [WhatsUpHIV](http://allafrica.com/stories/201410290969.html), a live blog set up to report all the developments from HIV R4P, the world’s first global research conference dedicated to biomedical HIV prevention.*
In a teaching session conducted by Prof Helen Rees, a really important question was raised; something absolutely fundamental for the public health policy aspects of the fight against HIV.

Here is the question: In light of the steady diminishing in global funding for HIV research, what really is the more important goal: to reduce HIV infection. Or to seek to stop HIV altogether?

In short, should we go flat out for the ideal solution? Or should we be content with doing the best we can, given the limitations that reduced funding imposes?

One (partial) answer is to focus on key populations. For example, in sub-Saharan Africa which accounts for about 42% of all HIV-related deaths and infections and yet is the one part of the world with the lowest access to health services, one might ask: What are the social drivers of this epidemic? Why are people vulnerable, and who are the people most at risk?

In most of Africa, young women are the most at risk. In some parts of the world, the most vulnerable are intravenous drug users. In the US, it is men who have sex with men. But in the East African coast, intravenous drug use is an escalating problem.

One of the most frustrating aspects of HIV research is that every solution seems to create a fresh challenge. An example is in the use of anti-retroviral drugs in prevention of HIV infection. Pre-Exposure Prophylaxis (or PrEP as it is known) has been found to be dramatically effective with sero-discordant couples (one partner HIV positive; the other negative) and prevents one partner from infecting the other. The logical extrapolation of this is that what works with sero-discordant couples should work just as well with the general population; and so everyone considered to be at risk of HIV infection, should take up the same treatment regimen.

But then here is the question: Would someone who was not already infected agree to take Anti-Retroviral drugs for years on end, to prevent infection? This seems especially unlikely as some ARVs have unpleasant side effects?

While trying to get some idea from online sources of condom use across Africa, for example, I came across this: While the supply of condoms increases year on year, this does not guarantee an increase in their use. Poverty, relationship with parents, peers and partners, limited HIV information and education, gender dynamics, and beliefs and attitudes about HIV have all been found to work against condom use across sub-Saharan Africa - (See more at: http://www.avert.org/hiv-aids-sub-saharan-africa.htm#sthash.56lEGGxj.dpuf)

This article originally appeared on WhatsUpHIV, a live blog set up to report all the developments from HIV R4P, the world’s first global research conference dedicated to biomedical HIV prevention.

AIDSMAP

RESEARCH FOR PREVENTION CONFERENCE OPENS WITH REAL HOPE FOR AN HIV VACCINE
Gus Cairns
29 October 2014

“There’s only one Berlin patient still. But by this time next year he will at least be joined by 40-50 Portland monkeys.” This was vaccine researcher Louis Picker, summarising in quotable form why the outlook for the development of an effective HIV vaccine is brighter than it has been for years, in a Satellite session in advance of the HIV Research for Prevention conference (R4P) in Cape Town, which opens fully today.

Picker was speaking about his research into a vaccine which created a lot of interest before and at last year’s AIDS Vaccine conference in Barcelona (the R4P conference results from a merger between the annual AIDS Vaccine conferences and the biennial Microbicides conferences). Picker said that by next year, this number of monkeys infected with SIV, the monkey equivalent of HIV, who were also previously given a ‘replicating vector’ vaccine, will have had no detectable HIV anywhere in their bodies for more than 70 weeks – and that probably means not one single infected cell.

The rationale behind Picker’s vaccine is explained in last year’s report but in brief, it uses HIV genes packaged inside a vector – a shell of protein derived from the envelope of another virus, in this case cytomegalovirus (CMV), a ubiquitous virus of the herpes family. The vaccine works not by preventing SIV infection but by stimulating such a strong, broad immune reaction to the virus that replication in the infected monkey is suppressed, often to undetectable levels, with infected cells eventually being cleared completely.

This vaccine stimulates the cellular or CD8 branch of the immune system – the one that kills off infected cells rather than directly targeting viruses. Picker told Aidsmap why CMV is such an ideal candidate for such a vaccine,

“Firstly we know that CMV is unlikely to be dangerous. Nearly everyone has it already. Secondly, despite this, they can be infected with successive strains. Thirdly, it has evolved to generate an immune response in the body that is exactly right – it’s not one that’s strong enough to get the body eliminate it (such strong reactions cause the majority of symptoms in viral illnesses) but is just strong enough to stimulate cells to keep turning out new copies of CMV and, in the case of our vaccine, new SIV antigens. It is both harmless yet persistent, which is its strategy for survival and is what you need.”

He also seen no reason why it should not work in humans – “We have in fact given monkeys a vaccine based on human CMV and that worked too.”

The biggest mystery remains why some monkeys did not respond to the vaccine. But in the latest group of experimental animals, the odds have shifted slightly: whereas in previous groups the success rate was exactly 50%, in the most recent batch to be vaccinated, 16 out of 27 responded (nearly 60%). All but two of the monkeys who have responded to the vaccine have so far eventually lost every sign of viral infection. There were two ‘breakthrough’ infections, though in one case the monkey never developed a detectable blood plasma viral load, just immune signs that it still had viral replication occurring somewhere at a very low level.

This vaccine, if it worked in humans, could also probably deal with re-infection with HIV. As is well known from cases where people get treatment very early, like the “Mississippi baby”, and from bone marrow transplant recipients, HIV can seem to disappear entirely from the body and the person can become HIV-negative in an antibody test – but, off treatment, the virus has so far always eventually reappeared often after a considerable gap in time – well over two years in the Mississippi case. The one exception is Timothy Ray Brown, the ‘Berlin patient’, in whom an accidental immune
reaction similar to the one engineered by Picker’s vaccine may have mopped up residual HIV-infected cells.

Picker illustrated this by showing how SIV apparently disappeared completely from a group of monkeys who were treated with antiretroviral (ARV) drugs almost immediately after infection. No replicating virus (RNA, as opposed to viral genes, DNA) was found in them by any method and in two monkeys from whom the researchers extracted large number of T-cells (30 million each), they found exactly one copy of SIV DNA in one monkey and four in another. These hard-to-eliminate cells are ones that lie deep in the follicles (crevices) of the lymph nodes and are not detected by the normal CD8 cells that eliminate virally-infected cells.

Picker then did an experiment that could not be done on a human – he injected these cells into HIV-negative monkeys – all of whom developed typical SIV infections with high viral loads, showing that SIV and HIV ‘rebounds’ may potentially be generated by possibly only one infected cell. However when he did the same thing to monkeys that had received the CMV vaccine, none of them developed infections.

The CMV vaccine may also be useful in chronic infection. There are two ongoing experiments in chronically-infected monkeys that have been put on ARV drugs and given the vaccine. These will be taken off the drugs in a treatment interruption so see if - as Picker predicts- they are able to stay off ARVs for a while. He told Aidsmap that he does not expect the complete clearance of infection seen in monkeys vaccinated prior to infection, as viral diversity and the number of infected cells is so much greater in chronic infection, but he does expect prolonged treatment breaks to be achievable. If these experiments go well then human trials of the CMV vaccine could begin by 2016.

Health 24
TALKING ABOUT SEX AND HIV AT HIV R4P
29 October 2014

HIV R4P is the archly-named international conference on biomedical methods of protecting ourselves against getting infected with HIV.

It is wonderfully non-judgemental – who you choose to have sex with, how often and in what manner – is totally irrelevant. The only subject of interest is how you stop a virus from destroying a human body. The consequences for the intimate and emotional aspects of sex have not been entirely overlooked. As one of the many top international scientists here, Jared Baeten, professor of global health, medicine and epidemiology at the University of Washington, remarked on http://whatsuphiv.blogspot.com: "We must remember that sex is not just a clinical activity. There is a whole generation which has grown up knowing only fear in relation to sex."

But, with more than two million people becoming newly infected last year, we need to throw everything at the virus.

At the ICC in the last week of October 2014, four scientific prevention methods are under the spotlight – none are fail-safe and some are still nowhere near ready for universal use.
Medical male circumcision is the most accessible: it has been proven that a man who is circumcised reducing his risk of getting HIV from an infected partner by at least 60%.

Vaccines are still the holy grail and we are inching closer to finding one that works but we’re not there yet.

Another option being tried is Pre-exposure Prophylaxis: this means someone who is not HIV positive but is at risk takes anti-retrovirals as precaution. It is suggested it is used by an HIV-negative person if their sexual partner is HIV positive.

Or in high risk groups – like the receptive partner in men who have penetrative sex with men. But obviously it is difficult to persuade someone who is not sick to take drugs which are potentially toxic. And it is very expensive as a public health option.

Treatment as prevention does work, however, when taken by an HIV-positive person as it reduces his or her viral load and thus makes them far less likely to infect a partner.

The most promising option is microbicides, which are inserted into the vagina or rectum before and/or after sex.

The results of a big study carried out in Cape Town are due early year and, so far, it is looking very hopeful. HIV R4P is the first global conference to feature the latest research on all forms of biomedical HIV prevention.

About HIV R4P
HIV R4P is the first global conference to feature the latest research on all forms of biomedical HIV prevention, being held at the CTICC until 31 October 2014.

Through both abstract and non-abstract driven sessions, the conference will support cross-fertilization between research on HIV vaccines, microbicides, PrEP, treatment as prevention and other biomedical prevention approaches, while also providing a venue to discuss the research findings, questions and priorities that are specific to advancing each modality. Read more at HIV R4P.org.

African Seer

HIV VACCINE TRIALS EXPECTED TO BE IN ZIMBABWE NEXT YEAR

ChristyA
29 October 2014

Clinical trials to test the effectiveness of the first ever HIV vaccine, R144 are expected to commence next year in Zimbabwe and other African countries, a senior government official has said.

University of Zimbabwe (UZ) executive director of Collaborative Research Programme, Mike Chirenje, said the trials will commence in April and are expected to bring a positive transition in the country’s Health sector which is still battling with the HIV virus.

He was speaking at a journalists' workshop to prepare for the inaugural HIV Research for Prevention (HIVR4P) global conference which is currently under way in Cape Town, South Africa.
"The first vaccine trial will commence around April next year, so we need the media to work with us on reporting about the vaccine and also tell people what the level of efficacy will be," he said.

An Aids vaccine is a substance that teaches the immune system how to create effective anti-HIV immune response.

No vaccines exist to date but scientists are still pursuing candidates that would help control the virus in people who receive vaccines while negative and later get infected.

RV 144 was introduced in 2009 when scientists announced that the vaccine found modest levels of protection among individuals who received it in Thailand.

This was the first evidence in people, or proof of concept that an Aids vaccine can reduce the risk of HIV. RV144 enrolled over 16 000 Thai men and women who received a series of six immunisations including Alvac HIV (the prime) and AIDSVAXB/E (the boost).

Vaccine recipients had 31% reduced risk of HIV infection compared to placebo (pre-exposure prophylaxis (PrEP) recipients.

Even higher levels of protection were seen in the first year after immunisations. Speaking at the official opening of HIVR4P conference yesterday, Jarred Beaten of University of Washington, said vaccines could be the way to go and there was every reason for countries to make trials.

"Prep is not one-size-fits-all. Tenofovir containing pills are not feasible for everyone. There is an encouraging pipeline of new PrEP prevention strategies that will deliver options but it would be naïve for us to imagine that any one of these will work or be workable for every person. What is needed are prevention options," he said.

Meanwhile, to build on RV144, an international initiative known as the P5, or Pox-Protein Public Private Partnership, has mapped out a series of follow-up trials and also co-ordinated selection of a new protein boost, meant to improve on the AIDSVAX candidate.

In addition some participants from the RV144 trial received one more additional boost shots to evaluate whether immune responses could be strengthened with further immunisations and the results are expected this year.

P5 is planning efficacy trials in South Africa and Thailand in late 2016 or early 2017.

Bio Medicine

WOMEN WHO TOOK PART IN VOICE SPEAK UP ABOUT WHY THEY DIDN’T USE HIV PREVENTION PRODUCTS
Lissa Rossi
29 October 2014
Many of the women at first acted surprised. Some insisted the blood tests were wrong. But most conveyed to researchers why they had not used the study products assigned to them as participants in VOICE, a large HIV prevention trial that, as a likely consequence, did not find any of the three products that were tested to be effective.

The women were among 127 former VOICE participants who, as part of a behavioral sub-study called VOICE D, agreed to take part in in-depth interviews and/or focus group discussions after learning the results of blood tests indicating their actual patterns of product use during the trial. The researchers hoped that sharing individual test results would elicit candid discussion about the challenges women experienced in using the products during VOICE, and help to understand the study's disparate results, which were initially reported in March 2013.

Although behavioral measures of adherence, including women's own reports, indicated that 90 percent of the 5,029 women in VOICE had followed the daily regimens, tests to detect drug in stored blood samples conducted at the end of the trial revealed that less than 30 percent had actually used their product regularly (either tenofovir tablets, tenofovir/emtricitabine tablets – also known as Truvada® - or tenofovir vaginal gel).

Findings of VOICE D, which were presented at the HIV Research for Prevention (HIV R4P) meeting in Cape Town today, shed new and important light about women's use and nonuse of products in HIV prevention trials. Both VOICE and the VOICE-D sub-study were conducted by the U.S. National Institutes of Health-funded Microbicide Trials Network (MTN).

"We wanted women to open up, to feel comfortable and to talk candidly about their experience participating in VOICE. We hoped that providing women with their individual drug levels would be an impetus for them to be more forthcoming and frank. This is exactly what happened," explained Ariane van der Straten, Ph.D., M.P.H., of the RTI International/Women's Global Health Imperative (RTI/WGHI) program in San Francisco, who led VOICE D and was the lead behavioral scientist on VOICE.

Dr. van der Straten described one woman who said she didn't use the vaginal gel because it leaked and she feared it would do harm to her uterus. She also admitted giving some to a friend who was a sex worker and pouring unused gel into the toilet. Another woman who had been assigned to one of the oral tablet groups said, among other things, that she was told by friends and family that taking the tablets would make her sick or give her HIV. This same woman insisted her blood tests were wrong, because she purposively took the pills prior to coming for her study visits so the drug would show up in her blood test.

"Even those who refused to admit nonuse provided insightful information," commented Dr. van der Straten.

VOICE D was conducted at a third of the 15 VOICE sites in South Africa, Uganda and Zimbabwe and was designed to explore the contextual and trial-specific issues affecting actual and reported product use and sexual behaviors during women's participation in VOICE. Stage 2 of VOICE D, which was implemented in response to VOICE final results, involved former VOICE participants who had been assigned to one of the active arms and then preselected based on drug levels: low (women whose tests detected no drug); inconsistent (those whose drug levels varied) and high (women who had drug detected in 75 to 100 percent of their blood samples). The cohort also included 13 women who had acquired HIV during VOICE.
Drug level results were presented to women by study staff who had not been involved in the conduct of VOICE using a simple visual tool. A teapot represented the pattern of adherence, depending on whether it was empty, full or half-full, while a teacup – 6 for every teapot – represented a study visit in which blood was collected and tested.

The reaction of women in the low adherence group was mostly surprise (41 percent) and disbelief (37 percent). Only 10 percent initially accepted their results; some remained in disagreement while others came to accept them. Among women in the high adherence group, 65 percent expressed happiness.

To help understand the reasons for not using the products, researchers asked the participant to select from and rank order 20 theme cards (e.g., I was too busy to take the products every day; I had to hide when taking my products). **Fears about the products and their side effects were the most common themes among low adherers and were fueled by peer participants, relatives and community members' negative attitudes about the products.**

In total, seven presentations on different aspects of VOICE D are being reported at the R4P meeting, including three oral presentations today on Stage 2 results and two oral presentations yesterday on Stage 1 results.

Stage 1 of VOICE D involved 88 women who took part in individual one-time in-depth interviews after exiting VOICE, most of whom were interviewed before the trial's results were publicly reported and shared with participants and communities. Stage 1 was designed in part to better understand women's perceptions and understanding of various risk behaviors, including anal sex. Yesterday, Zoe Duby, MPhil, from the Desmond Tutu HIV Centre, University of Cape Town, presented findings indicating there was widespread misunderstanding and misinterpretation by participants of questions being asked of them about anal sex.

**INFORMATION:** In addition to Dr. van der Straten, VOICE D was also led by Barbara Mensch, Ph.D., of the Population Council, and Elizabeth Montgomery, Ph.D., also of RTI/WGHI.

This work was supported by the U.S. National Institutes of Health grants UM1AI068633, UM1AI068615, UM1AI06707.

VOICE was funded by the National Institute of Allergy and Infectious Diseases (NIAID), with co-funding from the Eunice Kennedy Shriver Institute for Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health. The study products were provided by Gilead Sciences, Inc., of Foster City, Calif., and by CONRAD, of Arlington, Va. Viread (oral tenofovir) and Truvada are registered trademarks of Gilead Sciences. In 2006, Gilead assigned a royalty-free license for tenofovir gel to CONRAD and the International Partnership for Microbicides of Silver Spring, Md.

**About the MTN**

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transmission of HIV – from the earliest phases of clinical study to large-scale trials that support potential licensure of these products for widespread use. More information about the MTN is available at http://www.mtnstopshiv.org.

City Press

NONCOMPLIANCE DERAILS MAJOR HIV TRIAL
Zinhle Mapumulo
29 October 2014

A major HIV trial might have failed because seven out of 10 participants did not use as directed products given to prevent the infection, a new study has revealed. The findings of the VOICE D study were presented at the HIV Research for Prevention conference today in Cape Town.

Results showed that some women feared that the vaginal gel containing an antiretroviral drug would harm their uterus while others stopped taking the ARV drugs they were given because family and friends said the tablets would make them sick.

More than 5000 women from South Africa, Uganda and Zimbabwe participated in this major trial which was expected to confirm the results of smaller study, CAPRISA 004, conducted in KwaZulu-Natal. The CAPRISA study found that a microbicide gel containing Tenofovir can reduce the risk of HIV infection by 39% if used before and after sex.

Due to the promising results of CAPRISA, a larger confirmatory trial had to be conducted. But the VOICE had to be stopped before completion by the board that reviews clinical trials data because it was found that none of the products given to participants were effective in preventing HIV.

There were two gel groups – one received a gel containing a highly effective ARV Tenofovir and the other received a placebo gel which contained no active ingredient. The other three tablet groups – one received Tenofovir, the other Truvada (combination of two ARVS Tenofovir and Emtricitabine) and the last group received a placebo tablet.

All groups, which were divided into a thousand each, were instructed to use their assigned study product every day. However, results of the VOICE D study which was the follow-up of the trial which was stopped revealed that less than 30% had actually used their products regularly. Explaining why researchers had gone back to conduct a follow-up trial after VOICE was stopped, Dr Ariene van der Straten said: “We wanted women to open up, and talk about their experience participating in the trial.”

“We hoped that providing women with their individual drug levels would be an impetus for them to be more forthcoming and frank. And this is exactly what happened,” she said.

Van der Straten mentioned one woman who didn’t use the vaginal gel because it leaked and she feared it would harm her uterus. The same woman also gave some of the gel to her friend who is a sex worker. Speaking on the sidelines of the conference, Sharon Hellier who is a principal investigator at the Microbicide Trials Network (MTN), explained that poor adherence to trial products had a negative implication on the outcomes of trials.
She urged participants to use products as instructed saying, “we would not be able to defeat HIV if we do not use different tools to fight it.”

“We have to try all that we can. And we can only know if something works if people try it out during trials,” she added.

Bright Surf


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29 October 2014

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Healthline News

NEW HIV DRUG AND A VAGINAL RING TO PREVENT STDs PREMIER AT HIV PREVENTION CONFERENCE

David Heitz
29 October 2014

Development of an HIV vaccine remains slow and, so far at least, vaccine candidates have not been very promising in terms of conferring total protection against the virus. But those gathering this week for the first-ever HIV Research for Prevention (HIV R4P) conference in South Africa were buoyed by news of research on injectable pre-exposure prophylaxis drugs and microbicides.

**Promising Clinical Trials for New Injectable Drug**

Speaking at a press conference on Monday, Dr. Ian McGowan of the University of Pittsburgh offered preliminary news about clinical trials for TMC278-LA, a long-lasting, injectable form of rilpivirine. Rilpivirine is a powerful new non-nucleoside reverse transcriptase inhibitor, or NNRTI. The drug is being studied both for use in HIV treatment and prevention.

In trials conducted on 36 men and women with HIV, the drug suppressed their viral loads to undetectable levels within a month, McGowan reported. “The injection was very well tolerated and safe and acceptable,” McGowan said, calling its ability to suppress viral load “profound.”
On the prevention side, large amounts of the drug remained in rectal tissue four months after injection, “showing remarkable persistence of the antiretroviral effect,” McGowan said. However, very little of the drug persisted in vaginal tissue after four months.

Larger phase II trials, including 225 subjects, are set to begin in Pittsburgh in December.

New Ring Gives Protection Against HIV and Herpes

In a separate development, Meredith Clark of CONRAD, a nonprofit organization dedicated to contraception and HIV and AIDS research, presented work showing that tenofovir reservoir vaginal rings not only protect against HIV, but also herpes.

Dr. Jeanne Marrazzo of the University of Washington in Seattle said that Clark’s findings were intriguing because herpes and HIV “go hand in hand.”

Because the disease presents open sores, people with herpes are more likely to transmit the virus, and people with herpes also are more likely to contract it.

Research is also underway that could offer doctors a way to determine exactly where a person’s HIV infection came from, a sort of “virus fingerprint” that could offer clues toward better treatment and prevention.

Future Not So Rosy for a Vaccine; Use Available Tools

Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, told attendees via video that while he does believe an HIV vaccine will eventually come to fruition, it may only be modestly effective.

Fauci stressed the importance of using tools already at our disposal, such as Truvada as pre-exposure prophylaxis, or PrEP.

With any non-vaccine prevention method, adherence is the biggest challenge, according to Fauci. He stressed that the best prevention is testing and focusing prevention efforts on so-called “hot spots” where the virus is prevalent.

Fauci cited San Francisco’s Castro district as an example, and urged health workers to “push” PrEP. Truvada as PrEP is “close to 100 percent effective when taken four or more times per week,” he said.

When a person tests negative for HIV, a risk assessment should be performed, with prevention methods tailored to that particular person, Fauci urged. In a separate presentation, Dr. Chris Beyrer, director of the Johns Hopkins Center for Public Health and Human Rights in Baltimore, discussed why PrEP is so underutilized in the United States.

Beyrer cited stigma against homosexuality and lack of access to basic medical care as roadblocks to implementing this important prevention tool. Certain populations, Beyrer said, are at especially high risk of transmission and do not receive the preventative care they need.

Beyrer said, “Sex workers are really facing systematic discrimination in healthcare facilities. Transgender women worldwide are 48.9 percent more likely to contract HIV. Now that’s a health disparity.

New Vision
The vaginal gel, whose trial included Uganda, has produced exciting results, announced here in Cape Town, South Africa. According to results of a study analysis done by Microbicide Trials Network (MTN), the ARV tenofovir, which was tried on women to see if it could stop them from HIV infection, reduces women’s risk of catching genital herpes (HSV-2) by 46%. The results were announced today Oct 28 during the HIV Research for Prevention conference in Cape Town.

During that trial, named CAPRISA 004, researchers wanted to see if a tenofovir gel, when applied into the vagina before and after sex, can help a woman to avoid HIV infection. But many women in the study did not use the gel. They told lies that they did and so, the study’s primary results, which were reported in March 2013, showed 39% success.

In the later analysis of the blood samples that would be taken from participants during trial visits, they realised that women were telling lies. Very few actually used the gel. But in women who used gel regularly, the risk of acquiring herpes was reduced by 42%.

Researchers from the US funded MTN told scientists in Cape Town that the new discovery provided additional evidence that tenofovir gel could potentially help in preventing herpes, one of the most prevalent sexually transmitted infections affecting sexually active women in sub-Saharan Africa.

So far HSV-2 genital herpes has no cure. Women are especially susceptible to infection because it is more easily transmitted from an infected man to his female sex partner than from a woman to a man. Because HSV-2 infection also greatly enhances the risk of acquiring and transmitting HIV, a product that protects against HSV-2 could have an important public health impact.

“The results were based on an analysis of data involving more than 500 women in the VOICE trial,” Prof. Jeanne Marrazzo from the University of Washington, said as she presented the results on behalf of the VOICE study team.

VOICE – Vaginal and Oral Interventions to Control the Epidemic – was designed to test the safety and effectiveness of different ARV approaches used daily for preventing HIV among 5,029 women from 15 sites in South Africa, Uganda and Zimbabwe.

However, the study of 889 women in South Africa found that tenofovir gel also reduced the risk of HSV-2 by 51%.

Women who used the gel regularly were 46”% less likely to acquire HSV-2 compared to women who seldom or never used the gel (who had no detectable drug in their blood samples). In statistics, 46% is considered significant.

IOL Lifestyle
http://www.iol.co.za/lifestyle/women-likely-to-get-protection-from-hiv-study-1.1772854#.VFJUJPnF8jo

WOMEN LIKELY TO GET PROTECTION FROM HIV-STUDY
Kerry Cullinan
Johannesburg - Within a few years, women might be able to insert a vaginal ring to protect them from HIV infection and pregnancy.

Rings that slowly release antiretroviral (ARV) medicine into a woman’s vagina are in advanced clinical testing, with trial results expected next year. Researchers believe it will be easy to insert a contraceptive into the ring as well.

“About 92 percent of couples globally don’t use condoms, so it is important to develop other options,” said Sharon Hillier from the University of Pittsburgh Medical School in the US.

The ring will offer women a discreet way of preventing HIV, undetected by their partners. Some of the world’s top HIV researchers are in Cape Town this week at the first global HIV Research for Prevention (HIVR4P) conference.

Using antiretroviral medication to prevent – not just treat – HIV is emerging as one of the most powerful weapons to contain the epidemic in the absence of a vaccine.

ARVs taken immediately after HIV exposure – in rape cases or when health workers are injured by needles while treating HIV-positive patients – have been known to prevent HIV.

More recently, the results were released of Dr Myron Cohen’s 10-year study of couples where one person was HIV-positive and the other negative.

It found that if the HIV-positive partner was on ARVs and their viral load was undetectable, their negative partner was 96 percent protected from HIV infection. A number of “treatment as prevention” studies have also shown that ARVs taken shortly before sex by people at high risk of HIV offer protection against HIV. Truvada, a pill that combines the ARVs tenofovir and emtricitabine, reduced HIV transmission in gay men by 42 percent.

Long-acting injections containing ARVs that would have to be given only every two to three months are also in the pipeline, researchers said on Wednesday.

These would make it much easier for people to adhere to treatment and are also being tested to see whether they can protect HIV-negative people from the virus. Wits University’s Professor Helen Rees, who is a conference co-chair, said it was more realistic to control rather than eradicate the epidemic at this stage.

Dr Anthony Fauci, head of the US National Institute of Allergy and Infectious Diseases, told the 1 300 delegates that comprehensive HIV prevention rested on the “synergy between vaccine and non-vaccine research”.

Researchers envisage that people can be offered a “smorgasbord” of prevention methods – including condoms, ARVS and the possibility of a partially effective vaccine.

Since 2009, when a vaccine trial in Thailand showed “modest” protection for around 30 percent of people after two years, researchers have been unravelling exactly how it worked.
One of the key focus areas is how some of the Thai trialists were able to develop antibodies to partially protect themselves from HIV, and the quest for “broadly neutralising antibodies” is a cornerstone of vaccine research.

The Thai vaccine has been tested on South Africans in the past two years, and they showed the same antibody response.

Within 18 months, South Africa could host a massive trial of a modified and improved version of the Thai vaccine involving 7 000 people and costing R1 billion, according to Medical Research Council president Dr Glenda Gray. – Health-e News Service

REGULAR HIV PREVENTION COUNSELLING REDUCES RISK OF INFECTION
Bobby Ramakant
31 October 2014

"Foundation of HIV prevention is infact HIV testing" said Dr Anthony Fauci of National Institutes of Health at the opening plenary (via video link) of the HIV Research for Prevention (HIVR4P). But mobilizing people to go for voluntary and repeated counselling and testing for HIV has indeed been a challenge. It is even a steeper challenge to mobilize key populations such as men who have sex with men (MSM) to go for HIV testing repeatedly.

There are two case studies from Thailand: first case study looked at very innovative ways to mobilize people, particularly MSM, to opt for testing and repeat test regularly. The other case study looked at a large number of MSM people over a period of many years on whether regular HIV counselling and testing had an impact on HIV risk reduction?

Test BKK
Asia Pacific Coalition on Male Sexual Health (APCOM) has recently launched the second phase of their innovative City-Based HIV testing campaign, TestBKK, which encourages gay men in particular to get tested every three to six months. Using TestBKK the highly engaging tagline: “Suck F*#K Test Repeat.” It aims to normalise HIV testing among young gay men and make it a regular part of their health routine. The campaign emphasizes the importance of knowing one’s HIV status, and the TestBKK.org website reads, “casual disregard for HIV does not make the disease go away.”

Test BKK uses light-hearted, often humorous videos, with the message: “There are more awkward things than getting tested.” and “Afraid of things you have done in your past? Knowing is better than not knowing.” The first, which shows a young man masturbating to a sex video, before his family bursts into the room yelling “Surprise, happy birthday,” much to the young man’s horror, has received more than half a million YouTube views.

“TestBKK is designed to direct MSM to supportive clinics called ‘Premium Testing Services’, and to send the message, “Don’t be afraid,” said Midnight Poonkasetwattana, Executive Director, APCOM. “The campaign encourages young men to attend testing sites that will be respectful and sensitive to their lifestyles and orientation,” he said. APCOM’s TestBKK plans to roll out the campaign in other Asian cities, including Ho Chi Minh City, Jakarta and Manila.
Study results from Thailand emphasize the need to continuously encourage people to practice safe sex and regularly access the comprehensive HIV testing services in order to prevent HIV acquisition. Dr Wipas Wimonsate from Ministry of Public Health and Centers for Disease Control and Prevention (CDC) Collaboration in Thailand presented the study results at the HIV Research for Prevention (HIVR4P) conference in Cape Town. He said that multiple HIV counselling sessions to encourage safe sex practices helped men who have sex with men (MSM) in Bangkok stay HIV-uninfected.

1260 MSM were enrolled in April 2006 for this study and followed up until March 2014 at the Silom Community Clinic @TropMed. This follow up is still ongoing. Most of the study participants were between 22-29 years old at the time of enrollment. They had a maximum of 16 study visits with a mean of 11 and a standard deviation of 5. Among 1260 MSM participants, 239 of them acquired HIV.

At every visit, the participants received comprehensive HIV testing services which included: provision of condoms and lubricants, HIV testing, symptomatic testing and treatment of sexually transmitted infections (STIs), CDC recommended pre/post HIV test counselling and HIV information and risk reduction counselling. “We found that HIV incidence among our participants was associated with being young, using drug for sexual pleasure, inconsistent condom use, practicing receptive anal sex, engaging in group sex, and diagnosis with syphilis infection at time of enrollment” said Dr Wimonsate to Citizen News Service (CNS).

He added that “data shows that HIV incidence was not statistically significantly different by year of follow-up. This means that participants in the study could be found with seroconversion at any point in the study, even among those with higher number of visits. Therefore, being HIV uninfected was not a prerequisite for having a higher number of visits.

Chances of remaining HIV uninfected were 1.3 times higher for each subsequent visit. Remaining HIV uninfected was also associated with practicing only insertive sex, using condom consistently, and abstaining from participating in group sex.” One limitation of the study Dr Wimonsate pointed out was that MSM participants came from urban areas of Thailand and perhaps larger studies may be needed to generalize results across the country.

“More visits to healthcare centres and safe sex practices were independently associated with remaining HIV uninfected, regardless of other baseline demographic factors such as having sexually transmitted infections (STIs) and other behavioral factors. It remains unclear why MSM with greater number of visits were more likely to remain HIV uninfected, although some studies reported that HIV counselling has a moderate and significant effect on increasing protected sex among urban MSM.”

All Africa
http://allafrica.com/stories/201410301342.html
AFRICA: THE THORNY ISSUE OF ETHICS
Wycliffe Muga
30 October 2014
Suppose that a research team of scientists came up with an AIDS vaccine that was 50% effective. What would you recommend that they do with it?

1. Do some more research to try and make it 100% effective?
2. Rush out to make it available to those who need it most?
3. Study its long-term side-effects, bearing in mind that - as was famously the case with Thalidomide - some cures are worse than the disease?

These are questions that AIDS researchers have been grappling with for decades now. And they are also questions that already engage those who are at the centre of the storm, in the global rush to find a cure for Ebola.

A similar dilemma arises when you seek to implement AIDS interventions in an at-risk population which is criminalized in the statute books of the specific country. Take commercial sex workers, for example: In Germany and The Netherlands, where commercial sex work is perfectly legal, it is relatively easy to come up with programmes directed at this at-risk population.

But in many African nations, not only is sex work illegal, but the mere act of carrying a bunch of condoms can get a woman arrested for prostitution. How then can you protect such vulnerable populations, when the cheapest and most effective barrier to infection may be impractical for them?

It is one of the unavoidable issues of AIDS research that an element of choice has to be built into the interventions proposed, as what works for the general population, may not work with the most-at-risk populations.

This has led to a call from some advocates for decriminalizing sex work, as a potent intervention against HIV infection. Also the need for "sex-worker-friendly" health services.

This article originally appeared on WhatsUpHIV, a live blog set up to report all the developments from HIV R4P, the world’s first global research conference dedicated to biomedical HIV prevention.

All Africa

AFRICA: WHY WE YOUNG WOMEN HAD TO RESORT TO PUTTING UP THE VISIBLE PANTY LINE
Yvette Raphael
30 October 2014

Cape Town — Wednesday was the day we were finally going to be seen and heard: the day that young women from Burundi, South Africa Uganda and Kenya were going to make it all about us. While everyone was in plenary session, we young women plotted to get the most attention when researchers, policy makers and the conference elite walked out of the plenary. Well, we did succeed in catching their collective eye with our visible panty line (VPL) - a clothes line with colourful, sexy lingerie clipped to it.
This attracted scores of conference-goers to our corner. But while everyone was curious, not everyone wanted to participate in the activity—which involved writing messages and clipping them to the line. Instead, I watched as the usual suspects wrote messages about issues affecting young women and a few wrote about strategy ideas to improve the young women's agenda. I was secretly waiting for a researcher to prove me wrong. None did.

This is disappointing because we young women have a lot to say to researchers about the prevention options we want - if only they would listen. For instance, we know that PrEP works. We know young women between the ages 19-24 are most affected in many parts of the world. We also know this group hasn't been a priority for demonstration projects of PrEP (pre-exposure prophylaxis).
I attended two oral poster presentations on PrEP and microbicides adherence in women. Speaker after speaker explained that they had gathered evidence about how women lie in about product use (aka adherence) trials.

I wanted to say to them: "We do not lie as a choice but as a negotiation. Women lie to their partners, to their family, to their community and in trials because we prioritize other people and not themselves. Some of reasons given to explain that "the lies" were - "I did not use the gel because my partner does not like the slipperiness", "My partner felt it and I had to remove it."

Women who didn't use a PrEP or microbicide containing an ARV had their samples measured for detectable drug in the blood. They were told their pharmacokinetic levels that indicated no product use.

"I beg you to forgive my PK levels," was one of the responses I observed. Why do we do it?
After all these lies, I rush back to the Advocates Corner and our Visible Panty Line.

Phew, these young women, like our mothers, have submissively found their space on the floor. And then the old women came and the heterosexual man came: again they wanted to help young women. This is what they should do or shouldn't do. But why don't they want to listen to the women themselves? I am livid: they are doing it again! They are gagging young women.

This article originally appeared on WhatsUpHIV, a live blog set up to report all the developments from HIV R4P, the world’s first global research conference dedicated to biomedical HIV prevention.

All Africa
http://allafrica.com/stories/201410301522.html
SOUTH AFRICA: THE NEXT WAVE OF PREVENTION- RING FENCING HIV
Kerry Cullinan
30 October 2014

A range of new products, including vaginal rings and antiretroviral (ARV) injections, may soon be on offer to prevent HIV.

Within a few years, women might be able to insert a vaginal ring that will both protect them from HIV infection and pregnancy.
Rings that slowly release ARV medicine into a woman's vagina are in advanced clinical testing, with trial results expected next year. Researchers believe it will be easy to insert a contraceptive into the ring as well.

"About 92 percent of couples globally don't use condoms, so it is important to develop other options," said Sharon Hillier from the US University of Pittsburgh Medical School.

**The ring will offer women a discreet way of preventing HIV undetected by their partners.**

Some of the world's top HIV researchers are in Cape Town this week attending the first global HIV Research for Prevention (HIVR4P) conference.

Using antiretroviral medication to prevent - not just treat - HIV is emerging as one of the most powerful weapons to contain the epidemic in the absence of a vaccine.

ARVs taken immediately after HIV exposure - in rape cases or when health workers are injured by needles while treating HIV positive patients - have been known to prevent HIV.

PrEP gets real?

More recently, the results of Dr Myron Cohen's 10-year study of couples where one person was HIV positive and the other negative, were released. It found that if the HIV positive partner was on ARVs and their viral load was undetectable, their negative partner was 96 percent protected from HIV infection. Researchers envisage people will be offered a "smorgasboard" of prevention methods - including condoms, ARVs and the possibility of a partially effective vaccine.

A number of "treatment as prevention" studies have also shown that ARVs taken shortly before sex by people at high risk of HIV offer protection against HIV.

Truvada, a pill that combines the ARVs tenofovir and emtricitabine, reduced HIV transmission in gay men by 42 percent.

Long-acting injections containing ARVs that would only have to be given every two to three months are also in the pipeline, researchers said yesterday.

These would make it much easier for people to adhere to treatment and are also being tested to see whether they can protect HIV negative people form the virus.

Wits University's Professor Helen Rees, who is a conference co-chair, said it was more realistic to control rather than eradicate the epidemic at this stage.

Dr Anthony Fauci, head of the US National Institute of Allergy and Infectious Diseases, told the 1300 delegates that comprehensive HIV prevention rested on the "synergy between vaccine and non-vaccine research".

Researchers envisage that people can be offered a "smorgasboard" of prevention methods - including condoms, ARVs and the possibility of a partially effective vaccine.

Since 2009, when a vaccine trial in Thailand showed "modest" protection for around 30 percent of people after two years, researchers have been unraveling exactly how it worked. One of the key focus areas is how some of the Thai trialists were able to develop antibodies to partially protect themselves from HIV, and the quest for "broadly neutralising antibodies" is a cornerstone of vaccine research.

The Thai vaccine has been tested on South Africans over the past two years, and they showed the same antibody response. Within 18 months, South Africa could host a massive trial of a modified and
improved version of the Thai vaccine involving 7000 people ad costing R1-billion, according to Medical Research Council President Dr Glenda Gray. - Health-e News Service.

An edited version of this story first appeared in the 30 October editions of The Cape Argus and The Star newspaper.

All Africa
http://allafrica.com/stories/201410301319.html
AFRICA: YOUNG WOMEN INFLUENCING THE AGENDA
Definate Nhamo and Terezia Njoki Otieno
30 October 2014

Cape Town — In a session on Reproductive hormones and HIV risks, the data showed the need for the ECHO trial, which is a proposed trial that would evaluate three different contraceptive methods (DEPO-provera, the Jadelle implant and the copper IUD) in relation to HIV acquisition. There's been a lot of debate and discussion about ECHO recently.

The presentation by Christine Wall on hormonal contraception use and the risk of female to male HIV transmission in a Zambian Cohort showed no HIV risk for men in discordant relationships. Elizabeth Byrne's presentation showed there is some risk of HIV acquisition among injectable progestogen contraceptive (IPC) users in South Africa compared to women who were not using hormonal methods. Byrne also looked at why this might be. She looked at both the natural hormone, progestogen and progestin (the synthetic form of the hormone). Women who are not using hormonal contraceptive and are 'cycling naturally'--getting their periods--have regular changes in levels of progestogen. IPC users have high levels of progestin due to the contraceptive. In both of these groups of women, elevated hormone was linked to elevated levels of HIV target cells in the cervix.

At the end of this session, Helen Rees, one of the principal investigators of the proposed ECHO trial spoke to the continued need for this trial. She remarked that the data--including presentations from this session--were confusing and/or contradictory, thus the need to get adequate and accurate answers from ECHO as to to whether hormonal contraception increases the risk of HIV. She spoke to the real possibility of the ECHO trial happening noting that it "appeared" it would move forward. This wasn't a firm confirmation--an important clarification since the session chair suggested that it was certain.

In a lunch-time session at the Advocates Corner, young women advocates and researchers had a dialogue on young women's access to HIV prevention: past, present and future. Young women from Uganda, Kenya, Burundi, South Africa, Zimbabwe and other regions, raised issues of lack of sexual and reproductive health (SRHR) access, including family planning and information. One participant noted that the young women want to use pre-exposure prophylaxis (PrEP) but it is not available. American advocate Anna Forbes stressed that the initial demonstration projects have not targeted young women even though they are more at risk for HIV infection. Plans are underway for demonstration studies for young women in South Africa and Kenya that will answer if PrEP is feasible among young women. There is therefore a need for young women to start influencing the agenda to address their specific needs.

During a presentation today on PrEP and Microbicides adherence in women, extensive evidence was presented on why some women were not using the products. There was evidence presented on why
some women did not use the product. Reasons ranged from having non-supportive partners, fear of possible side effects to peer pressure. The researchers described the impact of discussing "PK" data with participants in VOICE. PK stands for pharmacokinetics, and in this case it refers to the presence of detectable drug in the women's blood (both the gel and the oral pill in VOICE had tenofovir-based drugs). Adherence to the products was very low in all the VOICE arms--and there was no evidence of protection in any arms.

In a follow up protocol known as VOICE-D, study sites talked to women about their product use, and then also shared the PK data for individual women. Women who said they had adhered very well sometimes changed what they disclosed when their PK data was shared--showing that they had not It was exciting to hear that giving women P.K results initiated discussion on product use. One of the interesting points in the session seemed to be that there is a difference in how long it takes for PrEP to begin to provide protection in women versus men--we'd like to follow up and learn more. Very little was presented on why some women did use the microbicide products in the VOICE trial.

Rianovosti

NEW HIV PREVENTION MEDICINE TO BE RELEASED SOON
30 October 2014

New antiretroviral medicine (ARV) that would prevent women from potential HIV infection and pregnancies are said to be in the advanced stages of clinical testing with trial results expected next year, the Independent reported Thursday.

Soon, women would be able to insert a vaginal ring that would slowly release ARV medicine and decrease chances of contracting HIV infection; researchers also believe it is possible to add contraceptives into the ring, as well.

“About 92 percent of couples globally don’t use condoms, so it is important to develop other options,” said Sharon Hillier from the University of Pittsburgh Medical School in the United States, as quoted by the Independent.

Some of the world’s top HIV researchers have gathered in Cape Town, South Africa this week to attend the first global HIV Research for Prevention (HIV4P) conference to tackle the rising issue of HIV infection, Canadian CBC News said.

Sub-Saharan Africa, in particular, remains the epicenter of HIV infection, with almost 1 in every 20 adults infected. The region accounts for 71 percent of total worldwide infections, according to the World Health Organization (WHO).

One of the greatest challenges has been determining how to prevent HIV infection among young women. In Africa, women have the greatest risk of contracting HIV, as condoms, faithfulness or abstinence are usually difficult for women to control, said the Guardian
Researchers analysing data from a trial examining the use of anti-retrovirals as prevention for HIV, have found that circumcision offered high protection to both men and their female partners against syphilis.

An article about the study in the upcoming November edition of The Lancet praised the fact that circumcision was now benefitting women.: “This is the first study to our knowledge that has reported a statistically significant reduced risk of incident syphilis among female partners with circumcised male partners.”

Syphilis can cause irreversible brain damage and damage to a person’s heart. Pregnant women with syphilis can have complications during pregnancy or a sicker baby.

The finding is significant, said researcher Professor Jared Baeton, from the University of Washington, because “syphilis is a strong risk factor for HIV and reduced syphilis risk could add to HIV prevention”.

An existing sexually transmitted disease increases a person's risk of contracting HIV so less cases of syphilis could translate into fewer HIV infections. Less sexually transmitted infections as a result of circumcision also would save countries money on syphilis treatment, according to an editorial in the Lancet.

Baeton also said "reducing syphilis would be an exciting extra benefit to circumcision roll-out".

In a bid to reduce HIV infection rates, more than six million men in 14 countries in East and Southern Africa have been circumcised since 2007, with the World Health Organisation hoping that 20 million men in Africa will get the snip by 2020. Circumcision reduces a man's chance of contracting HIV by 60%.

To understand circumcision’s role in reducing the chance of getting syphilis, researchers had analysed data from the Partners trial, which had studied 4176 couples in Kenya and Uganda in which one partner was positive and the other negative.

Results from the analysis showed an HIV negative man who was circumcised was 42% less likely to get syphilis and a HIV positive man had 62% protection from syphilis. Women with a circumcised partner was 59% less time to get syphilis, with up to 75% protection if they were HIV negative.

New data presented on Tuesday at the HIV Research for Prevention conference in Cape Town showed women who used anti-retroviral gel in a trial to see if it worked against HIV were 46 % less likely to acquire Herpes compared to women who seldom or never used the gel.

University of Washington doctor Jeanne Marrazzo who did the work said more research is needed.

There is no anti-retroviral gel on the market yet.
SOUTH AFRICAN TRIAL RENEWS HOPES IN FAILED HIV VACCINE COMBO

Emily Mullin
30 October 2014

An HIV vaccine regimen that failed in a notable clinical trial conducted in Thailand has been given a new chance to prove itself.

In a trial in South Africa, the two experimental vaccines in the famous 2009 "Thai trial"--one from Sanofi (SSNY) and another developed by VaxGen--passed a key hurdle, eliciting robust immune responses in 100 healthy adults.

The findings are significant considering participants in the two trials varied in ethnicity, body mass index, gender and age--all factors that were previously shown to impact the protective effect of the vaccines. Known as RV144, after the original Thai trial, the vaccine combo has been the only such regimen to show any promise against HIV. Even then, the candidate only demonstrated a modest level of protection in a study of more than 16,000 adults.

The investigational HIV vaccine combo combines Sanofi Pasteur's ALVAC-HIV vaccine, a modified canarypox vaccine, and AIDSVAX B/E vaccine, a glycoprotein 120 vaccine developed by VaxGen and now owned by the San Francisco nonprofit Global Solutions for Infectious Diseases. The regimen, originally designed to protect against two common strains of HIV in Thailand, is a prime-boost approach that uses ALVAC-HIV to prime and AIDSVAX B/E to boost immune response.

In 2009, the candidate was only 31% effective at reducing the risk of HIV transmission among trial participants. Researchers think the vaccine may have provided better protection against HIV sooner after vaccination and the effect waned over time.

The results from the South African trial, called HVTN 097, bode well for researchers hoping to test an improved version of the experimental vaccine regimen in South Africa beginning next year. The findings were presented at the HIV Research for Prevention conference this week in Cape Town.

TENOFOVIR GEL USE ASSOCIATED WITH LOWER HSV-2 RISK IN WOMEN

Lesley Odendal
30 October 2014

The risk of acquiring herpes simplex virus type 2 (HSV-2) was reduced by 46% (aIRR:0.54, 95%CI:0.30-0.97, p=0.038) among women who regularly used the vaginal gel containing tenofovir, according to a secondary analysis of the Vaginal and Oral Interventions to Control the Epidemic (VOICE) trial presented at the HIV Research for Prevention conference (R4P) in Cape Town, South Africa.
There was no significant difference in the age, marital status, country, practice of anal sex, HIV status or hormonal contraceptive use between those who did acquire HSV-2 and those who did not.

“The findings provide additional evidence that tenofovir gel, a product developed to protect against HIV, could potentially help in preventing one of the most prevalent sexually transmitted infections in sexually active women in sub-Saharan Africa,” said Dr Jeanne Marrazzo, who was presenting the study on behalf of the VOICE study team.

No biomedical prevention method currently exists for HSV-2, the most common cause of genital herpes. Women are especially susceptible to infection because it is more easily transmitted from an infected man to his female sex partner than from a woman to a man. “Because HSV-2 infection also greatly enhances the risk of acquiring and transmitting HIV, a product that protects against HSV-2 could have an important public health impact,” said Dr Marrazzo.

Although the phase 2B, randomised, double-blind VOICE study was designed to test the safety and efficacy to prevent HIV of daily Truvada(tenofovir 300mg plus emtricitabine 200mg) as pre-exposure prophylaxis (PrEP), daily tenofovir (300mg) as PrEP, a 1% tenofovir-containing gel (similar to that used in the CAPRISA 004 study) to be used as a vaginal microbicide, the team amended the protocol to explore whether any of these products protect women from acquiring HSV.

This was done in response to the CAPRISA 004 study which unexpectedly found that tenofovir gel also reduced the risk of HSV-2 by 51% compared to placebo. Other studies have shown that daily tenofovir plus emtricitabine PrEP did not reduce HSV-2 acquisition among men who have sex with men (MSM), but that is did reduce HSV-2 acquisition by 30% in serodiscordant couples in the Partners PrEP study.

In this secondary analysis, researchers focused on women with high adherence to the tenofovir gel according to their pharmacokinetic results, which measures the levels of the drug in their blood. Adherence in the original VOICE trial was poor with tenofovir detected in less than a quarter of samples from women asked to use the tenofovir gel.

The analysis found that HSV-2 incidence was 20.1% (95%CI: 15.9-25.2) in women who did not use the gel, compared to 11.5% (95%CI: 6.4-18.9) in women who used the gel regularly. 566 of the 1004 women assigned to use the tenofovir gel were HSV-2 negative at the time of enrollment. In follow up of 527 of these women, 92 women acquired HSV-2 (an overall incidence of 17.9%, 95%CI: 14.5-22.0 over 513 person-years), 77 of whom had no detectable drug in their blood sampled versus 15 whose blood levels indicated regular use of the gel. A comparison of the pharmacokinetic levels in participants’ blood samples were taken from both their first quarterly visit and when they exited the study 12 months later. There was also no significant difference in the number of incident HSV-2 infections between the group who received a placebo vaginal gel (17.0%, n=90 of 529) and those who received the tenofovir gel but had no tenofovir plasma detected in their blood samples (19.2%, n=77 of 402) (aIRR:1.11, 95%CI:0.82-1.51, p=0.499).

Dr Marrazzo admitted that one of the limitations of the study is that it is a secondary analysis based on a subset of participants, which is subject to bias.

While the results of this study are encouraging, additional data are still needed. FACTS 001, a phase III trial that tested tenofovir gel used before and after sex (the same regimen as in CAPRISA 004), was designed specifically to determine whether the gel was safe and effective in reducing the risk of HSV-2 and HIV among 2059 women in South Africa. These results are anticipated to be available early next year.
Researchers have determined the dose of an injectable formulation of the integrase inhibitor cabotegravir (formerly GSK744) that will be taken into efficacy trials to see if it can be used for pre-exposure prophylaxis (PrEP). \textit{Studies in animals were presented earlier this year} suggesting that drug levels stayed high enough in the body for it to be injected quarterly, and now studies of drug concentration in humans have confirmed that an 800mg intramuscular injection will be given once every twelve weeks in efficacy trials. Progress on an injectable formulation of another drug, rilpivirine, received a setback, however, when animal studies showed it lost its efficacy against viral challenge after only 18-21 days.

\textbf{Cabotegravir}

Bill Spreen of GlaxoSmithKline reminded the \textit{Research for Prevention} conference in Cape Town that experiments in monkeys had shown that cabotegravir almost completely protected a group of monkeys from infection with a monkey-adapted version of HIV. Drug level monitoring studies in human volunteers have found that at a dose of 500mg produces level of the drug that stay within the therapeutic level for as long as 16 weeks and that the drug’s ‘half-life’ – its rate of elimination in the body – is 25 times longer with the injectable formulation than with the oral cabotegravir pill that is being developed for HIV treatment. They calculated that an 800mg dose every twelve weeks should result in trough levels of drug that are still over eight times the 90\% inhibitory concentration ($IC_{90}$) of the drug – the level that should reduce viral replication by 90\%.

\textit{It is important to study the concentration of a drug being used for PrEP in the genital tissues as well as in the blood, as this is where HIV gets into the body in most cases. Here they made some interesting findings. Using a dose of 400mg, or half the dose to be taken into efficacy studies, they found that the concentration in tissues was considerably lower than it was in the blood. The concentration in vaginal tissue was 28\%, in the cervix 16\% and in the rectum 8\% of blood plasma concentrations. This is not unexpected as the same is found when drugs are dosed orally. There was also an expected variation by body weight. Drug elimination rates were 35\% higher in the 10\% of volunteers with the lowest BMI (body mass index) and 20\% in the corresponding proportion of heaviest volunteers. These differences, however, are not sufficient to need different doses for different body weights.}

What was more unexpected was that men turned out to eliminate the drug considerably faster than women – from 2.8 times faster in the lowest-BMI subjects to 3.1 times faster in the heaviest ones. This is probably because women have higher levels of fatty tissue, which releases the drug more slowly. Spreen commented that different doses for men and women might be needed if phase II studies suggested this made a clinical difference. These will start next year.

\textbf{Rilpivirine}
What is less certain is whether another drug will be taken forward as injectable PrEP. This is TMC278LA, which is an injectable formulation of the non-nucleoside reverse transcriptase inhibitor rilpivirine (Edurant, also in Eviplera/Complera).

This drug was recently given to laboratory mice that are genetically adapted to become infected with HIV. In a study where mice were challenged with a single HIV variant a week after receiving TMC278LA, no mice were infected compared with every mouse in a control group that only received a placebo injection.

In a second experiment, the mice were challenged with three separate strains of HIV a week after receiving the PrEP injection, and were then challenged with a fourth strain two weeks after that (three weeks after PrEP).

One out of eight mice did become infected with one of the three viral strains in the first challenge. However, and disappointingly, another five mice became infected with the fourth strain of virus they received at week three.

Interestingly, signs of infection appeared only after a delay of up to a month and in one mouse, an infection with one of the first three viral strains only became apparent after a two-week delay, suggesting that the TMC278LA was slowing down viral replication, but the fact that three-quarters of the mice eventually became infected with challenge virus may put a question mark over injectable rilpivirine as PrEP.

Humans are less like mice than monkeys, however, and presenter Olivia Snyder commented that the metabolised drugs faster, so TMC278’s effect could last longer in humans. Further experiments are going ahead to quantify the dosing interval needed, but clearly this drug is not going to be useful for PrEP, though it could have limited use as treatment in some patients.

CBC News

MICROBICIDES AN “EMPOWERING TOOL” TO PREVENT HIV INFECTION IN WOMEN
30 October 2014

Microbicides, products specifically aimed at protecting women from HIV without the need to negotiate condom use, are missing in the scientific response to the AIDS pandemic, say researchers working to bridge the gap.

In North America and Europe, HIV is most prevalent in the gay population. But in sub-Saharan Africa, where the virus has taken the greatest toll, the face of the epidemic is a young African woman, said Elizabeth Bukusi, deputy director of research and training at the Kenya Medical Research Centre.

"We need an option that women have the choice about using," Bukusi said. "If she can't protect herself because her partner will not put [a condom] on, we need her to have something she can use to protect herself."
At Crossroads, a poor township with one of the highest rates of HIV in South Africa, residents are recruited for various HIV prevention studies. In return, participants are offered health care and the community receives educational and recreational programs.

For two years, Ntanda Kiwana has attended a clinic for monthly checks as part of a trial to see whether a vaginal ring with a long-acting microbicide embedded in it can prevent women from becoming infected.

"I don't even feel it," she said.

Prof. Sharon Hillier of the University of Pittsburgh is principal investigator for the Microbicide Trials Network, directing research projects in seven countries.

"I think microbicides are just the kind of empowering tool that give women the chance to control their own health," Hillier said.

There are several microbicide designs that work to provide a physical barrier to keep out HIV and other sexually transmitted viruses from attaching to the vaginal walls or boost natural vaginal defences, such as by manipulating acidity levels.

So far, one study has shown a microbicide gel is partially effective against HIV. Researchers say two large studies reporting results in 2015 will likely confirm and possibly surpass that finding.

Two trials with microbicidal rings will release results shortly after. If the trials are successful, the products could be available to use commercially in a few years.

The HIV Research for Prevention Conference in Cape Town ends tomorrow.

AVAC (Africa Science News)

NIGERIAN ADVOCATE OYELAKIN TAIWO OLADAYO POSTHUMOUSLY WINS 2014 OMOLOLU FALOBI AWARD FOR EXCELLENCE IN HIV PREVENTION RESEARCH COMMUNITY ADVOCACY
31 October 2014

Oyelakin Taiwo Oladayo, a passionate advocate for the rights of young people living with and affected by HIV and AIDS, has posthumously received the fifth Omololu Falobi Award for Excellence in HIV Prevention Research Community Advocacy. The award was accepted on behalf of his family by fellow Nigerian advocate Olayide Akanni during the closing plenary of the HIV Research for Prevention (HIVR4P) conference.

Taiwo focused his work on the rights and dignity of those who are most marginalized. He helped form the first network of young people living with HIV in Nigeria (APYIN). He also helped create Youths and Adolescents Network on Population and Development in Africa (AFRIYAN) and, recently, the Network of Young People Living with HIV in Africa (AY+N).
Taiwo was the co-chair of the Global Network of People Living with HIV Y+ Leadership Initiative. He was also a 2013 AVAC Advocacy Fellow hosted by Positive Treatment for Action in Nigeria. His Fellowship project sought to amplify the voices of young women as plans for Option B+ were being considered in Nigeria, and ensured their recommendations were included in national prevention plans. On Thursday, 17 April 2014, Oyelakin Taiwo Oladayo was killed in a car accident in Lagos.

The Omololu Falobi Award highlights the essential role of community advocacy and leadership in HIV prevention research. It celebrates the life and values of the late Omololu Falobi, a long-time HIV advocate and journalist who founded Journalists Against AIDS (JAAIDS) in Nigeria.

Falobi was an instrumental pioneer member of the Nigerian Treatment Access Movement, and co-founded the New HIV Vaccine & Microbicide Advocacy Society. Omololu was killed in Lagos, Nigeria in October 2006. The award serves as an ongoing legacy that recognizes his commitment and lasting contributions to HIV prevention research advocacy.

“Omololu was a visionary leader and activist, who accomplished much in his too-short life. He dedicated himself to powerful advocacy for HIV and HIV prevention research in Nigeria, Africa and worldwide,” said Olayide Akanni. “His legacy lives on through this award and through the work of JAAIDS. Taiwo reminds us of our friend Omololu in many ways. He was a brilliant young Nigerian advocate lost to us too soon. He embodied Omololu’s ideals in many ways by making the work of HIV advocacy his life’s work as well. In his short professional life, he proved himself a leader and an inspiration to many; he believed that HIV prevention research was an important part of addressing the epidemic.”

“Taiwo’s work is an inspiration for us all. He exemplifies the passion and commitment that is the lifeblood of advocacy and activism. We must all continue to speak with his voice and amplify his message,” said Anna Forbes, recipient of the 2012 award.

For the 2014 award, the coordinating committee, with endorsement from past recipients, past reviewers and advocates, unanimously decided to present the award to Taiwo instead of seeking nominations for deserving candidates. A plaque and cash award will go to the family he left behind, including his new bride and his father.

“Taiwo’s passion for his work inspired all of those around him. I know his work made a difference in the lives of young women and other Nigerians living with HIV. I am so happy that his fellow advocates have given him this honor,” said Abiola Oladayo, his wife.

The award was presented by Manju Chatani-Gada of AVAC, who directs the AVAC Advocacy Fellows Program.

“Taiwo had many dreams and many aspirations for the future - as an international activist, as a photo documentarian, as a politician, as many things. Like Omololu, Taiwo lived his life in a hurry. And like him, he left his mark on all those who met him,” Chatani-Gada said. “Taiwo’s work exemplified the spirit of this award to recognize community advocates’ critical role in research and in getting new options to those who need it most.”
AFRICA: THE WAY WE WERE- AND THE WAY WE SHOULD BE

Steven Wakefield
30 October 2014

Cape Town — This blog reads best with a Gladys Knight and the Pips singing "The Way We Were" in the background.

Especially the lyrics: Can it be that it was all so simple then, Or has time rewritten every line, And if we had the chance to do it all again, Tell me, would we? Could we?

Today at the R4P HIV conference there was a wonderful session of six ten minute presentations under the topic "Good Participatory Practice In HIV Prevention." These sessions provided an excellent follow-up to the plenary talks this morning "Targeting Biomedical Preventations to Different At-Risk Populations". We heard some clear suggestions on how GPP had been used to expand and extend community engagement. Each presenter noted specific examples of practical utilization of these principles.

Unfortunately there was little time to note three important factors: 1) The relationships that lead to successful GPP implementation are best actualized when scientific leadership provides resources (sufficient dollars, rand, euros... ) to hire and trust staff to navigate relationships. 2) Persons must be trained after they express a willingness to serve science and scientific endeavors on behalf of their communities. They give an incredible amount of time and energy in love for their communities and in as responding volunteers to improve life locally. 3) The shaping of the science of prevention requires a dialogue that results in better understanding for community and researchers but also demands willingness to discover new paths forward as both roles work for better life.

It is not just about the proper conduct of science. It is not just about fighting a virus. Back in the 80s as we marched on the steps of City Hall in Chicago, Dr. Renslow Sherer asked "is this a rally about HIV/AIDS, human rights, sexual freedom or what?" I answered "yes". GPP ensures we all work for a better human experience in the face of a virus that continues to mystify.

This article originally appeared on WhatsUpHIV, a live blog set up to report all the developments from HIV R4P, the world’s first global research conference dedicated to biomedical HIV prevention.

All Africa
http://allafrica.com/stories/201410301292.html

AFRICA: WE NEED TO TAILOR STRATEGIES TO SUIT SPECIFIC COMMUNITIES

Rob Newells
30 October 2014

One of the challenges we have had in the United States around PrEP implementation, particularly among black men, is mistrust of the medical establishment. Even as the Affordable Care Act serves to address issues with health care access, many black men remain suspicious of doctors and pills. For a community plagued by health disparities and other structural challenges, resistance to PrEP may also be an issue of power dynamics. During the Wednesday plenary at HIVR4P, we heard about a community concern that biomedical interventions like PrEP inherently shift the focus of control toward
the medical establishment and government bureaucracies, and away from community. How do we overcome implementation challenges if the community does not feel it has control - or worse - if the community feels like it is being controlled?

Over the first two days of HIVR4P, what has piqued my interest is the idea presented by both Anthony Fauci and Chris Beyrer that HIV prevention strategies need to be tailored to specific populations. It's really common sense. One size does not fit all. As Dr. Beyrer said in his Wednesday plenary presentation, there may be different standards for different populations, even in the same community.

We know that treatment as prevention is an effective strategy for people living with HIV. PrEP works for men who have sex with men, serodiscordant couples, and people who inject drugs. There is hope for vaginal rings and microbicide gels that would benefit female sex workers. ARV-based prevention is a power tool in the toolbox of HIV prevention options, but it will serve us well to remember that combination prevention is not just about combining biomedical interventions.

Biomedical interventions are the shiny, new toys in the HIV prevention world. They are the electric drill and the nail gun in our prevention toolbox, but we can't forget that the screwdrivers and hammer are still in there, too, and they have to be just as available as the power tools.

An article published as part of Lancet's HIV and Sex Workers series in July 2014 suggested that "new biomedical technologies must be additive to, not replacements for, more established prevention modalities."

Just because we have new, effective ways to prevent HIV transmission does not mean we can afford to retreat from evidence-based prevention methods. We need to understand the local epidemic, identify key populations, and develop tailored combination prevention approaches, including behavioral and biomedical prevention options, and the community must be involved every step of the way.

This article originally appeared on *WhatsUpHIV*, a live blog set up to report all the developments from *HIV R4P, the world’s first global research conference dedicated to biomedical HIV prevention*.

**All Africa**

http://allafrica.com/stories/201410301308.html

**AFRICA: PREP FOR A NEW ERA**

Emily Bass

30 October 2014

It was an exciting morning for pre-exposure prophylaxis (PrEP) using daily oral TDF/FTC (brand-name Truvada). In the morning plenary session, Chris Beyrer, of Johns Hopkins University and president of the International AIDS Society, spoke about HIV prevention in sex workers, gay men and other men who have sex with men. Beyrer pointed out that there is only one country implementing PrEP - the United States - at a national level.

"I can't wait until the PrEP era begins," Beyrer said. "Hopefully it is going to be soon." Beyrer is a staunch human rights advocate - founder and director of the Center for Health and Human Rights at Johns Hopkins - and it is good to hear support for PrEP in the context of a rights-based response. As he noted, there are many concerns in civil society about biomedical interventions like PrEP and ART for treatment and prevention, since the medical establishment is, often, linked with the state - eg governments that
may be actively criminalizing and persecuting the very populations who are being targeted with new biomedical strategies. Beyrer's embrace of both rights and biomedical interventions is exactly what's needed - and it will be exciting when the PrEP era, as he defines it, begins.

Speaking of the PrEP era, it took a leap forward while the plenaries were taking place, as the French research agency ANRS released a press release announcing that its IPERGAY trial, which had been designed to evaluate intermittent PrEP use, had found evidence of efficacy and was going to end its randomized, placebo-controlled design.

Briefly, this trial was launched after the iPrEx trial of daily oral PrEP showed efficacy in gay men, other men who have sex with men and transgender women. It sought to test intermittent use and had a placebo arm - a design decision that raised ethics questions from the outset, given the evidence of efficacy from iPrEx.

The investigators had explained that since PrEP was not available or evaluated in France, the design was warranted. Plenary speaker Brigid Haire, who gave a compelling, nuanced talk on trial ethics and biomedical prevention, mentioned these questions specific to IPERGAY - perhaps at the precise moment that the press release was being released announcing the changes in the trial. (Kudos to Haire and indeed anyone who isn't checking email compulsively during conferences ...)

In a delicious turn of phrase, Haire referred to the "tantalizing whiff of data" from the UK PROUD study of PrEP in gay men and other MSM. This trial found compelling evidence of efficacy earlier this month - a finding that triggered a review of the IPERGAY protocol. It's exciting when a field evolves in real time - let's hope it keeps happening, as fast as Beyrer suggests it should.

This article originally appeared on WhatsUpHIV, a live blog set up to report all the developments from HIV R4P, the world's first global research conference dedicated to biomedical HIV prevention.

All Africa
http://allafrica.com/stories/201410301283.html

SOUTH AFRICA: SEX WORKERS- THE STRUGGLE CONTINUES
Amanda Luyenge
30 October 2014

Particularly in South Africa were sex work hasn't been legalised, sex workers are at risk of contracting the virus every day and those who have contracted it struggle to access treatment. Decriminalising sex work has been under discussion since 1994 but until this day, the struggle continues and so does the spread of HIV.

The HIV Research 4 Prevention conference kicked off this Wednesday morning by looking at targeting biomedical preventions for different at risk populations. You might be wondering what an "at risk population" is, well this is a group of people who share a characteristic/s that causes each member to be vulnerable to a particular event, in this case HIV.

Sex Workers are seen as a population at risk of HIV because they make a living by having sexual intercourse and sexual intercourse is the main form in which HIV is transmitted. They are at risk because
they are not protected by the law. Instead the law turns its back on them and they are left in the little corner with little access to anything, particularly treatment.

Dr Chris Beyer, a researcher from the Johns Hopkins Bloomberg School of Public Health pointed out a few barriers in HIV treatment and prevention around sex workers. Sex workers are ashamed of visiting health care centres to get medical treatment because people will look askance at them and so they would rather carry on and keep spreading HIV.

If we plan on reaching an HIV free generation, we need to look at this at-risk population because, with increasing unemployment, the number of sex workers increases.

In a session on Reproductive hormones and HIV risks, the data showed the need for the ECHO trial, which is a proposed ...

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IAVIREPORT

VACCINE FROM THAILAND SHOWS PROMISE IN SOUTH AFRICA
29 October 2014

Glenda Gray, executive director of the Wits Health Consortium’s perinatal HIV research unit in South Africa, presented data today at the HIV R4P conference in Cape Town indicating that the prime-boost vaccine candidates initially tested in the RV144 trial in Thailand—the only HIV vaccine trial to date to show any efficacy—induced cross-clade immune responses in a Phase I safety trial conducted in South Africa, with immunogenicity similar to or greater than that of the responses induced in Thai volunteers. The vaccine, designed for testing in Thailand where clade B and recombinant E/A HIV predominates, was found 31% effective in preventing HIV infection among Thai volunteers. Meanwhile, clade C HIV is the predominant strain in South Africa.

This January, researchers here will start a Phase I study evaluating a clade C-specific HIV vaccine regimen, along with a new adjuvant, known as MF59, aimed at boosting the potency of the vaccine candidates and the durability of the immune responses it induces. Gray said on Tuesday that if results from this Phase I study are encouraging, then Phase III efficacy trials of this vaccine regimen are expected to begin sometime in 2016 or 2017. Efficacy trials will involve as many as 7,000 volunteers. Even if the vaccine regimen is only partially efficacious, Gray doesn’t see this as a problem. “A partially efficacious intervention to prevent HIV acquisition would have public health benefit,” she says. Ultimately regulators will decide, but licensure for a vaccine could come with efficacy as low as forty or fifty percent. Researchers are already considering how different partially effective prevention strategies might be used in concert. “When we found that male circumcision worked, we rolled that out in our trials,” she says.

Combining a partially effective vaccine with antiretroviral-based pre-exposure prophylaxis could be another approach, Gray says.
The MF59 adjuvant, developed by the pharmaceutical company Novartis, is currently used to boost responses to flu vaccine. Novartis, however, earlier this year sold most of its vaccine unit to rival GlaxoSmithKline in a US$7 billion deal. It’s unclear how Novartis’s sale may impact the production of the vaccine candidates for the South African trial. But for now Gray says there aren’t any delays. “It hasn’t had any effect. Not yet.” – Michael Dumiak

Infection Control Today

MODEL BY NIH GRANTEES EXPLAINS WHY HIV PREVENTION DOSING DIFFERS BY SEX

A mathematical model developed by NIH grantees predicts that women must take the antiretroviral medication Truvada daily to prevent HIV infection via vaginal sex, whereas just two doses per week can protect men from HIV infection via anal sex. This finding helps explain why two large clinical trials testing HIV pre-exposure prophylaxis, or PrEP, in women failed to show efficacy. Participants in the VOICE and FEM-PrEP trials of Truvada and tenofovir (another antiretroviral) for HIV prevention were counseled to take one of the medications daily. However, because they actually took the antiretroviral only about 29 percent of the time in VOICE and about 36 percent of the time in FEM-PrEP, the PrEP strategy did not work.

Angela D.M. Kashuba, PharmD, of the University of North Carolina, and colleagues determined what intracellular ratios of active tenofovir and emtricitabine, the drugs that compose Truvada, to the DNA molecules with which they compete are necessary to prevent HIV replication. Next, using data from an early clinical trial in women, the researchers created a mathematical model that predicts these ratios in vaginal, cervical and rectal tissues given standard doses of medication taken two to seven days per week. Then, the scientists calculated the percentage of a study population that would achieve the effective drug-to-DNA-molecule ratio by taking tenofovir or Truvada at each dosing frequency. The model forecasts that two standard doses per week of Truvada or a daily standard dose of tenofovir would achieve the target ratio in rectal tissue across a study population. A daily standard dose of Truvada would achieve the target ratio in vaginal tissue in more than 75 percent of a study population, according to the model, and in cervical tissue in half of the population. A daily standard dose of tenofovir would achieve the target ratio in cervical and vaginal tissues in less than half of a study population, the model predicts.

It is easier to achieve the target ratio in rectal tissue than in cervical and vaginal tissues, according to the scientists, because the concentration of DNA molecules is lower and of tenofovir is higher in rectal tissue than in the female genital tract.

Both men and women who are prescribed Truvada for PrEP should take the pill daily as directed, according to Centers for Disease Control and Prevention guidelines.


Source: National Institutes of Health (NIH)
Cape Town — Wednesday was key populations day at the HIVR4P conference. Key population is HIV jargon for groups that have disproportionately high rates of HIV infection – so groups that might be more at risk for HIV infection.

The morning plenary sessions focused on HIV prevention needs of key populations, human rights and making sure research works for these groups.

An afternoon session on “Good Participatory Practices” in HIV prevention research focused on the nuts and bolts of engaging communities – including key populations – in research.

The end of the day brought a sometimes impassioned, but always informative discussion among advocates, representatives of key populations (gay men, sex workers, people who use drugs) and the media about working together.

This article originally appeared on WhatsUpHIV, a live blog set up to report all the developments from HIV R4P, the world’s first global research conference dedicated to biomedical HIV prevention.

HIV and Hepatitis

Tenofovir reaches lower levels in vaginal and cervical tissue compared with rectal tissue, helping to explain why pre-exposure prophylaxis (PrEP) did not protect women as much as gay and bisexual men in clinical trials, and suggesting that women having vaginal sex may need to take PrEP more often than people having anal sex, researchers reported at the HIV Research for Prevention meeting this week in Cape Town.

Truvada (tenofovir + emtricitabine) was shown to be highly effective in the iPrEx trial of mostly men who have sex with men (MSM). Once-daily Truvada reduced the risk of HIV infection by 42% overall, rising to 92% among participants with blood drug levels indicating regular use. A mathematical model suggested that taking Truvada 4 times per week would provide 99% protection, and in an open-label extension of
iPrEx, none of the men who took Truvada this often according to blood drug level measurements became infected.

The Partners PrEP and TDF2 trials, which looked at heterosexual couples in Africa, found that PrEP using Truvada or tenofovir alone reduced the risk of HIV acquisition by about 65% to 75%. But effectiveness was lower among African women in the Fem-PrEP and VOICE trials. This has been largely attributed to poor adherence, but biological factors may also play a role, as tenofovir concentrations may not be as high in the female genital tract compared with rectal tissue.

Mackenzie Cottrell and Angela Kashuba from the University of North Carolina and colleagues used a mathematical model to predict how often people would need to take Truvada to achieve adequate protective drug levels.

This pharmacokinetic-pharmacodynamic model incorporated tissue concentrations of tenofovir diphosphate and emtricitabine triphosphate -- the active forms of the drugs -- and the ratios of these nucleoside/nucleotide analogs to endogenous or natural DNA nucleosides (dATP and dCTP) needed to inhibit HIV. Laboratory cultures of vaginal, cervical, and rectal cells were treated with tenofovir and emtricitabine for 24 hours before exposing them to HIV.

In addition, the researchers incorporated data from a Phase 1 clinical trial looking at the pharmacokinetics of tenofovir, emtricitabine, maraviroc (Selzentry), and raltegravir (Isentress) in women's vaginal, cervical, and rectal tissue. 48 women received a single dose of tenofovir or emtricitabine at 50%, 100%, or 200% of the licensed dose, and researchers measured drug concentrations in their vaginal, cervical, and rectal tissue over 48 hours.

The model predicted that after 7 days, a 200 mg dose of emtricitabine would produce ratios exceeding the 90% effective concentration (EC90) in vaginal tissue in >85% of the population, in cervical tissue in 50% of the population, and in rectal tissue in 75% of the population. A 300 mg dose of tenofovir produced ratios exceeding the EC90 for <50%, <50%, and 100% of the population in vaginal, cervical, and rectal tissue, respectively.

While 2 weekly doses of tenofovir/emtricitabine maintained drug levels above the EC90 in rectal tissue in 100% of the population, even with daily dosing only >75% and 50% of the population exceeded the EC90 in vaginal and cervical tissue.

"This model predicts available clinical trial data, whereby [tenofovir/emtricitabine] is [approximately] 70% effective in women with >80% adherence and >90% effective in MSM with [approximately] 30% adherence," the researchers concluded.

Importantly, this study looked at vaginal and cervical tissue versus rectal tissue, not women versus men. PrEP trials of heterosexual women have generally assumed that the women are mostly having vaginal sex, but of course many women have anal sex as well.

"It is easier to achieve the target ratio in rectal tissue than in cervical and vaginal tissues, according to the scientists, because the concentration of DNA molecules is lower and of tenofovir is higher in rectal tissue than in the female genital tract," according to a National Institute of Allergy and Infectious Diseases press release summarizing the study.
As this research is still at an early stage, both men and women who are prescribed Truvada for PrEP should take it daily as directed according to Centers for Disease Control and Prevention (CDC) guidelines, the release stresses.

10/31/14

**Reference**


Other Source


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**All Africa**


**AFRICA: SO WHEN WILL THE NEXT BIG THING BE AVAILABLE FOR GENERAL USE?**

31 October 2014

The one question research scientists dread most - but one which journalists are obliged to ask - is, "So when will this be available for general use?"

What makes this question so difficult to answer is that there is a large gap between the successful implementation of an early medical trial and and the products arising from this trial actually reaching the intended market.

After the creation of a new intervention against HIV, for example, there will still be the issues of regulatory approval; scaling up production to obtain economies of scale; arranging for distribution channels etc.

All this will be even more difficult with the Next Big Thing in the fight against AIDS: Multipurpose Prevention Technologies (or MPTs).

For example, research is under way to test the efficacy of vaginal rings embedded with antiretroviral drugs, (the dapivirine vaginal ring) as an intervention to prevent HIV infection.

If and when efficacy is proved, application for regulatory approval for general use is the next step. Hopefully, one day, it will be possible to embed slow-release drugs in the same vaginal ring, for three different interventions: microbicides to block HIV infection; other microbicides to fight the more routine sexually transmitted infections (STIs); and contraceptives.

In theory this would take the question of "extending choice" to a whole new level. Women could decide which combination of options would best address their individual needs.
But in practice, there are bound to be problems - especially in Africa - even with something this innovative. For there is a long-entrenched resistance to contraception in much of Africa, where large families are still preferred. And of course there is the continuing stigmatization of those who are HIV+ve. Still, what is crucial about this new approach, and the research into these new technologies, is that it puts the woman in charge, which in itself represents a great leap forward.

This article originally appeared on WhatsUpHIV, a live blog set up to report all the developments from HIV R4P, the world’s first global research conference dedicated to biomedical HIV prevention.

IAVI Report

CREATING CONNECTIONS IN CAPE TOWN
Michael Dumiaik
31 October 2014

South African health minister Aaron Motsoaledi, hobbling with his foot in a boot, arrived this morning in Cape Town after flying overnight from a lung health congress in Barcelona.

Heading directly to the huge convention center here that this week was hosting the first-ever HIV R4P conference, a gathering of researchers and activists working on all HIV prevention efforts, Motsoaledi wasted no time in making connections. “We have the highest levels of HIV and tuberculosis co-infection in South Africa and indeed in Southern Africa,” he said. “They are two sides of the same coin.”

While South Africa, and the world beyond, continues to make progress against HIV, Motsoaledi says no single intervention will take care of it all. As a former political activist in poverty-stricken Limpopo during South Africa’s brutal apartheid regime, the minister showed some familiarity with creating systemic change over time, by taking small steps and enduring great hardship and suffering.

Some 1,300 specialists from around the world came to Cape Town in order to present results and draw a picture of the current situation in the global response to HIV. Some grumbled that there wasn’t enough of a chance to really mix — and yes, perhaps the schedule could’ve been friendlier in this regard — while others thought there might have been too much mixing, creating a diluted environment.

Winding up this year’s HIV R4P, the group on stage urged those in the Cape Town audience to think about the bigger picture. Given that, US Global AIDS Chief Medical Officer Douglas Schaffer’s reference to the recent US$200 million initiative to bring antiretrovirals to 300,000 children in African countries who are living with HIV is a welcome one.

“We all know that the best way to break the back of any infectious disease epidemic is through a vaccine,” says Motsoaledi. And a combination of approaches to protect against HIV will need to reach different kinds of people and populations, he added. Specialists will have to work together, which is what the first HIV R4P, sometimes successfully, establishes as a goal. Over the next few weeks, we’ll be sorting through more of the congress and these themes in the pages of IAVI Report and VAX. Stay tuned.
If you like movies at all, by now you will have seen - many times - the scene in romantic comedies in which a woman walks into her bathroom to perform a simple test which will tell her (with a high degree of accuracy) whether or not she is pregnant.

OK, for all I know it is not just romantic comedies which have this scene as a standard feature. Maybe it is equally common in science fiction; or thrillers; maybe even in zombie movies. I wouldn't know. I only watch comedies.

But here is the point to consider: is there any way to inject humour into a movie scene in which a man or woman goes into the bathroom to administer a self-test to find out if he or she was infected by HIV?? I don't think so. It is possible to make fun of a woman getting pregnant when she did not want to. But HIV is far too serious for humour.

In any event, for all the decades that the AIDS scourge has ravaged the planet, it has been the established procedure to first submit to intensive counselling (usually by a certified counsellor) and only then have the HIV test done. It has been understood all along that you have to prepare people psychologically for the possibility of the tragic news that they are HIV+ve.

So, going by the Health Systems Trust of South Africa website, here is the good news: "Home-testing kits for HIV have reached the shelves of pharmacies, despite concerns on their accuracy and the wisdom of testing oneself for the virus that causes AIDS. For just R70 and five minutes, the do-it-yourself test promises quick, easy and 99% accurate results to one of the most serious questions facing South Africans."

And, on the same webpage, here is the bad news: "AIDS counsellors are concerned that DIY tests bypass the counselling necessary to prepare for an HIV diagnosis... Deputy AIDS director Celicia Serenata said the Health Department did not encourage the use of home AIDS tests but there was no legislation to regulate their sale."

This article originally appeared on WhatsUpHIV, a live blog set up to report all the developments from HIV R4P, the world's first global research conference dedicated to biomedical HIV prevention.
A man caught my eye this week. It's somewhat fitting that a symbol of "human endeavour" (per the artist) is bearing witness to this week's HIV R4P Conference - itself a testimony to ongoing global efforts to push the boundaries of HIV prevention science.

He's an 8-meter-high sculpture towering over passersby of the Cape Town International Convention Centre. His name is Olduvai, a nod to the Rift Valley area that scientists believe was home to some of humankind's oldest ancestors Olduvai even sports the same color as the red ribbon that has come to mark HIV/AIDS awareness and support.

Yet it is women who bear the burden of the HIV/AIDS epidemic. It is women who make up the majority of HIV-positive adults in sub-Saharan Africa; women who are often forced to withdraw from school or employment to take care of HIV-infected relatives - or themselves; and young women who are twice as likely worldwide to be infected as young men.

Several presentations have highlighted progress in developing new prevention tools and new ways to deliver existing tools - from new insights into cellular mechanisms to advances in developing vaginal rings, gels and tablets to rolling out options like PrEP and combination prevention packages. There have also been some exciting announcements, including the termination of the placebo arm of ANRS's IPERGAY study due to high PrEP effectiveness.

We still have work to do for women. As we head into the last sessions of the conference, I am already looking ahead to R4P 2016. By then, we could have results from three Phase III trials of two women-initiated products: 1% tenofovir vaginal gel used around the time of sex (developed by CONRAD with results expected in early 2015) and the dapivirine monthly vaginal ring (developed by the International Partnership for Microbicides with results expected in 2016).

In yesterday's plenary, Chris Beyrer stressed the need to "know your epidemic." We know the impact of the epidemic on women - and I'm so encouraged by the progress being made to help them protect themselves. Perhaps the next time I see Olduvai, he'll be heralding a new prevention landscape for women.

**MPTs - yeah, you know me!**

During the opening plenary, South African Minister of Science and Technology Naledi Pandor likened the conference's name (R4P) to a hip-hop song. Naturally, I thought immediately of a 1990s song that describes what it's like to have multiple sexual partners and whose title is an acronym referring to some... anatomical areas.

A perfect vehicle through which we can promote sexual and reproductive health and draw attention to multipurpose prevention technologies, right?

Maybe it's not the best conference theme song after all. But stay tuned tomorrow for a roundtable and a separate satellite session on MPTs. Going is as easy as 1-2-3...

This article originally appeared on What'sUpHIV, a live blog set up to report all the developments from HIV R4P, the world's first global research conference dedicated to biomedical HIV prevention.
Crossroads in Cape Town is your classic African "tough neighbourhood". It is a shanty town - a slum. So how do you go about getting volunteers from a place like that - a place in which all authority is usually viewed with doubt and suspicion - to participate in clinical trial which involves such potentially sensitive interventions as "vaginal rings", "vaginal gels" and "vaginal microbicides"?

How do you make sure that, in a township with a history of violent protests, rumours that your new clinic is really a front for a thriving business in the accumulation and sale of human blood, will not lead to a large and angry mob, turning up with used tyres and gallons of kerosene, and proceeding to burn the place to the ground?

These are some of the challenges which the Desmond Tutu HIV Foundation faced when it opened the doors of its Emuvundleni Research Centre situated in New Crossroads. Devoted to HIV prevention trials (including vaccines, microbicides and pre-exposure prophylaxis) it had to find a way to conduct research on perhaps Africa's most intensely stigmatized disease, in one of Africa's most unforgiving neighbourhoods.

The Community Engagement Coordinator explained that, in their experience, the key was to make it clear, in every way, that the local communities were "much more than a source of trial participants". The centre had to be seen as deeply invested in the well-being of the community. Relationships and bonds had to be formed which transcended the immediate medical needs of the participants. Youth engagement programmes had to be conceived and implemented.

Above all, and to preclude any possibility of negative "pushback" from the community after the study was already fully launched, there had to be prior diligent and prolonged counselling to ensure that when "informed consent" was given, it really was truly well informed. Hence an elaborate filtering procedure was needed to ensure that all who were enrolled knew what they were in for - including potential side effects.

"No short-cuts, when it comes to informed consent" has been the guiding principle for volunteer enrollment. And that is why the Desmond Tutu Emuvundleni Research Centre building is now being expanded to create room for more labs and other research facilities - when it could otherwise so easily have been burnt down.

This article originally appeared on *WhatsUpHIV*, a live blog set up to report all the developments from HIV R4P, the world’s first global research conference dedicated to biomedical HIV prevention.
Africa: What We Talk About When We Talk About Women
Emily Bass
31 October 2014

Cape Town — Women are at the heart of the AIDS epidemic—and at the forefront of the search for successful solutions - as activists, educators, trial volunteers, nurses, care givers and so much more. Here in South Africa, this is clear and, on the face of it, simple enough. But listening to sessions over the past few days is a reminder of all the ways that even the simplest statements need to be complicated.

Here are a few examples:

1) At yesterday's amazing plenary on key populations, Chris Beyrer, Johns Hopkins researcher and President of the International AIDS Society, talked about how the definitions and measurements of sex work among women in prevention trials really varied quite a bit. These trials don't just ask, "Are you a sex worker?" (There's many reasons for this; and it is worth acknowledging that for some trials receiving US funding, language is or has been affected by the Bush-era requirement that PEPFAR grantees repudiate sex work--a provision that's since been overturned by the US Supreme Court but is still being enacted for complex, bureaucratic reasons). Anyway--back to the question: some trials simply ask women whether they are sex workers. This is a hard question to answer for women who have faced extreme stigma and discrimination in the health setting. In other trials, they ask about number of sex partners, exchanging sex for money, food and so on and interpret from there who is engaged in sex work. Beyrer's point was that these questions and definitions weren't standard--and that makes it hard to say, with clarity, what kind of sex work women are doing (or not) in some trials--and therefore complicates the issue of what we do or do not know about sex workers.

2) In a session on hormonal contraceptives and HIV risk that was packed with interesting information, there was a presentation on the differences between the genital tracts of women from the US and from Africa. Wait? I thought. No one has ever done this? Guess what? It didnt seem they had. And guess what else? There are differences. In the Contraceptive Hormone Induced Changes (CHIC) study, women from Pittsburgh in the US and Zimbabwean women are providing samples and information to help investigators understand how the genital tract changes with contraceptive use. The data presented were baseline--eg without contraceptive use. And they found, after controlling for many other factors, that the Zimbabwean women had higher concentrations of CD4 cells in their cervix than US women. (These were all HIV negative women). What causes these differences? The researcher didn't know. But this isn't the first time that the field has paused and realized that immune profiles are different in different parts of the world. So-called "normal" ranges of laboratory values are often set based on information from US or high income individuals--and vaccine trials have had to do preparatory work to re-calibrate and re-define normal in other parts of the world. Clearly, work remains to be done on what this means for women.

3) Liars and housewives: There was a major session on adherence among participants in the VOICE trial. Many participants did not use the gel or pills as prescribed in the protocol--even though they said that they did at study visits, and even returned the right number of pills. After the trial, researchers went back to try to understand why women said one thing and did another. They found out lots of interesting things that I won't go into here--though you can and should watch the webcast of this session. But what a lot of advocates--civil society, HIV positive women, young women--heard in that session was explicit and implicit questions about "why women lie?" A much-tweeted remark from researcher Ariane van der Straten said " We all lie all the time, every day. These women are just like us." This was welcomed (at least I think that's what the tweeting meant) but it still left us all labelled as liars. That language hasn't...
sat well with many of the women advocates here and I think we need to be careful how we talk about these findings together, because the liar label is a hard one for anyone to bear. In that way, too, we are all similar. That same day, there was a presentation on early safety and acceptability research on long-acting injectable ARVs--another potential prevention strategy. In the Q&A, a researcher who was asked about acceptability said, that while they've gathered some information it was all from "Pittsburgh housewives." What? Have we returned to the 1950s? In an earlier post, I raised a jargon alert.

"Housewives" sets off a major non-jargon alert--that language is not just casual, it's dismissive and almost certainly inaccurate.

We can and must do better, watch our language, work together as women in all our diversity--including transgender women. As poet elder Adrienne Rich once said, this is the "dream of a common language." 

This article originally appeared on WhatUpHIV, a live blog set up to report all the developments from HIV R4P, the world’s first global research conference dedicated to biomedical HIV prevention.

**Vaccine News Daily**


**POSITIVE RESULTS EMERGING FROM HIV VACCINE CLINICAL TRIAL IN SOUTH AFRICA**

Matt Mackinder

30 October 2014

An investigational HIV vaccine that had positive effects in a RV144 clinical trial conducted in Thailand was shown to be safe and portrayed robust immune responses when given to 100 healthy adults in South Africa.

The results from the HIV Vaccine Trials Network 097 study performed in South Africa were presented recently at the HIVR4P conference in Cape Town. The results from the trial bode well for plans to test a similar experimental vaccine in South Africa next year.

“The HVTN 097 study clearly shows that the investigational HIV vaccine regimen is safe in South Africans and induces comparable if not somewhat stronger immune responses than seen among Thais in the RV144 trial,” National Institute of Allergy and Infectious Diseases Director (NIAID) Anthony S. Fauci said. “The findings are encouraging as we move toward evaluating a modified and potentially improved version of the vaccine regimen in South Africa.”

The NIAID sponsored the HVTN 097 study.

Since 2009, scientists and researchers have looked at and dissected RV144 data to see what types of antibodies and cellular immune responses a preventive HIV vaccine may need to induce.

“Vaccines specifically designed to elicit immune responses more closely directed to the circulating strains of HIV in sub-Saharan Africa have been constructed,” HVTN Principal Investigator Larry Corey said. “Clinical trials of these HIV subtype C vaccines that are based upon those used in RV144 and HVTN097 are planned to begin in South Africa in early 2015.”
EGPAF

EGPAF AWARD RECIPIENT PRESENTS RESEARCH TOWARD ELIMINATING MOTHER-TO-CHILD TRANSMISSION

Jeff Safrit
31 October 2014

This week in Cape Town, South Africa, the first **HIV Research for Prevention (HIVR4P) Conference** became the major venue for global HIV vaccine, microbicide, and additional HIV prevention research. During the conference, **Susie Zeegen Postdoctoral Award recipient Lindsay Wieczorek**, Ph.D., presented her research evaluating the role of **neutralizing antibodies (NAb)** in mother-to-child transmission of HIV. NAb are an essential component of our immune response against HIV and other disease-causing pathogens. In fact, most successful vaccines against diseases such as measles and influenza rely on these antibody responses to protect us from disease.

**Understanding how mother-to-child transmission of HIV happens or is prevented in the absence of anti-HIV drugs is still a topic of important research, more than 30 years since HIV was discovered as the cause of AIDS. We do know that an HIV-positive pregnant woman has a 40% chance of transmitting HIV to her baby, either in utero, during the birth process, or during breastfeeding. Amazingly, 60% of infants born to HIV-positive women will not become infected, despite being exposed to HIV during pregnancy and breastfeeding. Why? We don’t really know.**

One possibility is that NAb against HIV play a role in protecting the infant from infection. Anti-HIV NAb develop over time in HIV-infected individuals and are present in HIV-positive pregnant women. These antibodies can also be transferred to the infant in utero and during breastfeeding. The role of maternal NAb in the protection of infants from infection is being debated, with some research pointing towards a protective role, and other research showing no effect or even an increase in possible infection.

In the **project presented at HIVR4P**, Dr. Wieczorek and her team looked at the anti-HIV NAb response in Thai mothers who transmitted HIV to their infants versus those who did not. They found that mothers with NAb responses against HIV were more likely to have transmitted HIV than mothers that did not have these antibodies. What is not known, however, is whether these NAb responses could act against the virus that was present in the mother and, thus, the virus transmitted to the infant. Because transmission took place even in the presence of these NAb, the likely answer is that the NAb were not effective against the transmitted virus.

So where does this leave us? Clearly, the role of anti-HIV NAb in the transmission of HIV from mother-to-child (or prevention thereof) is still being debated. Answering this question definitively will be a critical part of the search for a successful vaccine against HIV.

Hats off to Dr. Wieczorek and her team for moving in that direction!

**Lindsay Wieczorek, Ph.D.,** a scientist at the **U.S. Military HIV Research Program (MHRP),** investigates the link between the body’s natural immune response to HIV and maternal-to-child transmission. A graduate
of the University of Wisconsin, Johns Hopkins University, and Catholic University, Lindsay was recently given the Susie Zeegen Fund Postdoctoral Award, named for Susie Zeegen, one of the co-founders of the Elizabeth Glaser Pediatric AIDS Foundation.

Jeff Safrit, Ph.D., is EGPAF’s Director of Clinical and Basic Research, and is based in Los Angeles, CA.

AIDSMAP
http://www.aidsmap.com/page/2918356/

INJECTABLE RILPIVIRINE SHOWS PROMISE IN PHASE 1 TRIALS- BUT MAY WORK BETTER FOR ANAL THAN VAGINAL SEX

Gus Cairns
1 November 2014

A phase one dose-finding and safety study in humans of TMC278 LA, a long-acting, injectable formation of the antiretroviral (ARV) drug rilpivirine, found that a single 1200-mg dose could produce sustained drug levels in rectal tissues that could offer protection against HIV for three months, and did in fact suppress viral replication in so-called explants (biopsies of rectal mucosal cells) for that length of time. However – and to the surprise of researchers presenting this study at the HIV Research for Prevention conference in Cape Town – drug levels seen in vaginal and cervical cells were only about half of those seen in rectal cells, and viral replication was not suppressed in vaginal and cervical biopsies taken from women given TMC278 LA.

Detailed results – drug levels

Ian McGowan of the University of Pittsburgh presented results from a study that gave 24 women and 12 men a dose of either 600mg or 1200mg TMC278 LA. This was given as either one injection in the buttock (600mg) or two (1200mg) with one hour between shots.

Importantly, McGowan was only presenting here the tissue-concentration results in women – including the rectal ones. As Tuesday’s presentation on cabotegravir showed, absorption rates of these injectable drugs may differ between women and men.

In terms of the whole group of 36 volunteers, eight of the participants were black and three Hispanic, with the others largely white, and their average age was 29.

There were adverse events: in fact mild adverse events were nearly universal, but these consisted of mild or moderate pain at the injection site for three days or so, which might involve a bit of discomfort sitting down, but nothing worse, and the two serious adverse events seen were not related to the drug. The 600mg dose produced sustained levels of rilpivirine in the blood of more than twice the IC90 (the amount needed to suppress viral replication by 90%) for over 28 days while the 1200mg dose produced levels of more than four times the IC---90. Levels equivalent to the IC-90 were reached after 56 days in the 600mg dose and after 100 days, over three months, in the 1200mg dose.

In vaginal, cervical and rectal fluids, vaginal concentrations were about twice as high as rectal ones. Only the 1200mg dose produced levels above the IC90 in rectal fluids.
In vaginal and rectal tissues, however, the situation was reversed, with roughly double the concentration in rectal than vaginal or cervical tissues. In rectal tissues, levels above the IC90 persisted for 64 days in the 600mg dose and over three times the IC90 in the 1200mg dose.

**Detailed results – protection from HIV infection**
This study uses what is called an explant model to determine if the drug is inhibiting HIV. Obviously one cannot inject people with HIV to find out if the drug works, but one can do the next best thing – take biopsies of rectal, vaginal and cervical cells, keep them alive in laboratory dishes, and try and infect the cells with HIV.

Rectal cells taken from women given TMC278 LA four weeks after they received their injection were completely resistant to HIV infection in the lab dish. Cells biopsied 56 days after injection with 1200mg of drug were still resistant to HIV infection, and only slightly susceptible to infection with the 600mg dose. By day 64, cells taken from people given the 600mg dose were susceptible to HIV infection but were still resistant to infection with the 1200mg dose, eventually becoming susceptible after 84 days. In contrast, and to the researchers’ surprise, vaginal and cervical cells taken from women given TMC278 LA showed no signs of benefiting from the drug – they were just as susceptible to infection after the injection as before.

This is surprising because one would have expected some effect, even if a weakened one. McGowan and principal investigator Linda-Gail Bekker reminded the audience that the explant-cell technique is only an assay, a surrogate measure of protection, and may not be reflected in the real world. MGowan added that the next step was to perform multiple-dose phase I studies in which women and men were given three doses of the drug.

It is possible that women may need more than one dose for concentrations to build up to protective levels in vaginal and cervical tissue. A modelling study presented at the same conference found that levels of the nucleoside drugs tenofovir and emtricitabine – the drugs in Truvada – reached lower levels in vaginal rather than rectal tissue, and this study may indicate that the same is true on the non-nucleoside drugs like rilpivirine. This does not necessarily mean that injectable rilpivirine may not work for women but Bekker was asked whether it was ethical to start phase II trials early next year without evidence of efficacy in women. She said: “We certainly intend to counsel women volunteering for the study that there is no evidence yet that it is at all effective.” The phase II study, HPTN 076, will take place in lower-risk women in Zimbabwe and South Africa, and men who have sex with men in South Africa and the United States next year.

After a presentation on Tuesday that found that TMC278 LA offered reasonable but rather short-term protection against HIV infection in mice, this study adds another layer of complexity to the data we have on injectable rilpivirine.

**A case of drug resistance caused by injectable PrEP**
One further case report presented to the conference added to the issues that may need to be taken into account if these injectable, long-acting formulations are to be used for HIV prevention. Kerri Penrose of the University of Pittsburgh presented a case report of a person who had developed HIV drug resistance to rilpivirine because she acquired HIV during the time the drug levels in her body were slowly declining. The study participant’s infection was a surprise, because the trial for which she volunteered was intended for women at low risk of HIV. Nonetheless, she tested positive for HIV 84 days after being given a 300mg dose of TMC278LA – half the minimum amount in the studies discussed above. By this time, seven weeks after her injection, drug levels of rilpivirine in her body were below the level needed to prevent HIV infection, so this cannot be seen as a ‘PrEP failure’ – no one would have expected
this relatively small dose to work by this time. At the first drug-level test after her diagnosis, she had 7.5 nanograms per millilitre (ng/ml) of rilpivirine in her blood; the IC-90 for rilpivirine is about twice this, 12 ng/ml.

Having enough drug in your body to slow down viral replication but not enough to stop it is how drug resistance arises, because only drug-resistant mutations survive. Although she was infected with ‘wild type’, non-drug-resistant virus, she developed drug resistance and, a month afterwards, 19% of the HIV in her blood had resistance mutations to rilpivirine and other NNRTI drugs. However, the presence of resistant virus was relatively fleeting; as rilpivirine levels fell further, and also because she started HIV treatment, the wild-type virus came to predominate and five months after her diagnosis NNRTI resistance had disappeared.

This study shows that a major issue in the long-acting injectables may be how to stop taking them if one is still at risk of HIV, as drug may persist in the body for months. Clearly the best idea is to cover the ‘long tail’ with oral PrEP but this may not always be obtainable in the low-income settings in which the use of injectable PrEP is being contemplated.

References
Penrose KJ et al. Selection of rilpivirine resistant HIV-1 in a seroconverter on long-acting rilpivirine (TMC278 LA) from the lowest dose arm of the SSAT 040 trial. HIV Research for Prevention Conference, Cape Town. Abstract OA27.01. 2014. See webcast here.

Global Post

SCIENTISTS CALL FOR MORE AFRICAN-LED RESEARCH AND DEVELOPMENT
Emily Judem
1 November 2014

CAPE TOWN, South Africa — A rising call for African-led research has permeated Cape Town this week as HIV researchers and scientists from around the world flooded the city for the first HIV Research for Prevention Conference.

As we move toward an AIDS-free generation, experts say, research should be growing in the places that bear the biggest burden of the disease. Grace Naledi Mandisa Pandor, South Africa’s minister of science and technology, announced at the conference’s opening, “We want customers. We don’t want to be anyone’s client any longer.”
This sentiment was indeed reflected here at the Cape Town International Convention Centre, where nearly 40 percent of the conference’s 1,313 delegates came from Africa and about 30 percent of the research studies presented came from African institutions and investigators.

An array of languages and accents bounced off of the wood-paneled walls as researchers, advocates and clinicians flooded the hallways Tuesday through Friday.

African-led scientific research is, in fact, on the rise, and not just in the field of HIV prevention. Reed Elsevier, a publishing and information company headquartered in London and Amsterdam, reported that the number of research papers published in scientific journals with at least one African author more than quadrupled between 1996 and 2012.

“I think we’ve grown both in number and also in quality and in reach,” said Linda-Gail Bekker, chief operating officer of the Desmond Tutu HIV Foundation headquartered in Cape Town, and president-elect of the International AIDS Society. “I think some of the best science is coming out of Africa now.”

The Emavundleni Research Center in Crossroads — a township in Cape Town — one of several run by The Desmond Tutu HIV Foundation, conducts six to nine trials at once.

Discussions about HIV prevention research in Africa, ranging from vaccine trials to microbicide efficacy, peppered the conference this week.

This is a marked change from 25 years ago, when Anatoli Kamali began his career in HIV prevention research. Kamali, a clinical epidemiologist and the deputy director of the MRC/UVRI Uganda Research Unit on AIDS, co-chaired the conference and said that no formal AIDS prevention research institutions existed in many areas when he first became involved with HIV/AIDS research in the late 1980s.

“There was kind of fighting for resources to provide care … and many countries which were recovering from longtime wars,” Kamali said. His home country of Uganda suffered from decades of instability and violence, which Kamali said left the country without sufficient infrastructure.

Kamali said he has seen a steady increase in HIV prevention research in Uganda over the years. Still, there’s a long way to go, said Prince N. Bahati, senior director of global advocacy and policy at the International AIDS Vaccine Initiative, who pointed to weaknesses in the education and training systems in many countries and said there is a dire need for more researchers throughout Africa.

He added that 25 percent of the world disease burden is in Africa, but Africa consumes less than one percent of global health spending.

And though the number of papers published by African researchers have increased dramatically, these still only make up about 2 percent of the total, according to the Reed Elsevier report.

Why is it important to make sure that Africa is a leader in HIV prevention research?

Bekker points to the importance of having people on the ground who have a connection to the communities most affected by the epidemic.

“HIV is very much grounded in the community — it happens at the primary health level, and it is something that really works into the fabric of society,” she said. “Therefore I think it’s quite important that people understand that context and that the research is done with that kind of framework.”
Kamali turned to a statistic: More than 70 percent of the people living with HIV worldwide are in Africa.

“We’ve got the burden,” said Kamali. “So we must be part of the solution.”

Times of Zambia
http://www.times.co.zm/?p=41165
CAPETOWN HOSTS HIV PREVENTION CONFERENCE
Davies M. M Chanda
1 November 2014

From Cape Town, South Africa, where the Global Conference was taking place all of last week, I received the following update: Researchers, health advocates and policy makers from around the world will focus their attention this week on Cape Town, South Africa, as HIV Research for Prevention (HIV R4P) opens today at the Cape Town International Conference Centre.

Approximately, 1,300 leaders in the fight against HIV/AIDS will participate in the four-day conference, the first global scientific meeting focused exclusively on biomedical HIV prevention.

“HIV R4P will showcase state-of-the-art efforts to slow and halt this epidemic from around the world,” noted Lynn Morris of the National Institute for Communicable Diseases (NICD) in Johannesburg.

“While HIV R4P is a truly global conference, research from African scientists will play a particularly significant role at this meeting.”

The conference opening plenary, “State-of-the-Art: Biomedical Prevention in 2014” sets the tone for this historic meeting with an overview of most significant research progress in efforts to slow and one day end the global AIDS epidemic. South African Minister of Science and Technology Naledi Pandor will keynote a programme that includes:

Lynn Morris of NICD (South Africa) presenting on Prospects for an Antibody-based HIV Vaccine. Morris will discuss the recent discoveries of broad and potent neutralising antibodies against HIV that are bolstering efforts to develop an HIV vaccine.

Jared Baeten of the University of Washington (U.S.) addressing Advances in Antiretroviral-based Prevention Research, including groundbreaking new approaches such as using antiretroviral treatment (ART) to reduce the infectiousness of HIV-infected persons and the use of oral, topical and injectable ART pre-exposure prophylaxis (PrEP) to prevent HIV infection.

Anthony Fauci of the US National Institutes of Health, speaking by video on Comprehensive HIV Prevention, addresses the potential synergies between HIV vaccines and other proven and emerging forms of prevention, the opportunities to use new prevention methods in combination and the challenges of making new prevention tools available to the millions of people worldwide who need them.

Research highlights from across the spectrum of biomedical HIV prevention research – including microbicides, pre-exposure prophylaxis (PrEP) and vaccines – are featured on the HIV R4P opening press
conference programme today. Among those highlights:

Ian McGowan of the University of Pittsburgh School of Medicine (US) presents A Phase 1 Open Label Safety, Acceptability, Pharmacokinetic, and Pharmacodynamic Study of Intramuscular TMC278 LA (the MWRI-01 study). That analysis in 36 women and men found that the long-acting antiretroviral drug, TMC278, was safe and well-tolerated, and provides the potential for protection against HIV infection. Multiple dosing studies of this promising, long-acting approach to HIV protection are now planned. A second study of the potential of injectable drugs to provide more durable protection against HIV infection is being presented here by William Spreen of GlaxoSmithKline (US).

HIV PrEP Dose Rationale for Cabotegravir (GSK1265744) Long-Acting Injectable Nanosuspension indicated that a quarterly injection of the long-acting integrase inhibitor cabotegravir in macaques was safe and provided a level of drug that is predicted to provide robust protection against HIV infection. Ongoing animal studies are a precursor to possible future human study of this new approach to HIV pre-exposure prophylaxis (PrEP).

The potential of microbicides containing HIV antiretroviral drugs to prevent infection with herpes simple virus (HSV2) is explored in Association of Tenofovir (TFV) Detection with Reduced Risk of Herpes Simplex Virus type-2 (HSV-2) Acquisition in the VOICE (MTN 003) Study, presented by Jeanne Marazzo of the University of Washington (US).

The analysis of VOICE, a randomised, double-blind, placebo-controlled trial of oral and vaginal tenofovir for HIV-1 pre-exposure prophylaxis, found that women who used tenofovir gel had a reduced risk for HSV-2 infection. HSV-2 is a common infection in sub-Saharan Africa, which increases the risk of HIV transmission and acquisition.

Turning to HIV vaccines, a study of the RV144 HIV vaccine in South Africans is being presented by Glenda Gray of the South African Medical Research Council. RV144 was the first HIV vaccine to demonstrate a modest level of protection against infection when it was studied in volunteers in Thailand.

The research presented here today, HVTN 097: Evaluation of the RV144 Vaccine Regimen in HIV-uninfected South African Adults, is the first to report on the impact of the vaccine in other populations. The study found that the vaccine regimen produced immune responses in South African volunteers that were at least comparable to or better than those induced in the Thai study – promising news in the effort to develop a globally effective HIV vaccine.

“The advances in vaccine, PrEP and microbicide research presented today at HIV R4P confirm that we have entered one of the most rewarding, and challenging, phases of HIV prevention research since the epidemic began” said HIV R4P co-chair Sharon Hillier of the University of Pittsburgh School of Medicine.

“The interactive, interdisciplinary nature of this meeting in particular provides an exceptional opportunity to discuss what many believe will be the most effective approach to slowing the global epidemic – the use of new and emerging prevention modalities in combination.”.

About HIV R4P
HIV R4P is the world’s first and only scientific meeting dedicated exclusively to biomedical HIV prevention research. Through both abstract and non-abstract driven sessions, the conference will support cross-fertilisation between research on HIV vaccines, microbicides, PrEP, treatment as prevention and other biomedical prevention approaches, while also providing a venue to discuss the
research findings, questions and priorities that are specific to advancing each modality. Conference partners include the Aaron Diamond AIDS Research Center; amfAR, the Foundation for AIDS Research; the French National Agency for Research on AIDS and Viral Hepatitis (ANRS); the Bill & Melinda Gates Foundation; the Government of Canada; CONRAD; Crucell; the Elizabeth Glaser Pediatric AIDS Foundation; Gilead Sciences; GlaxoSmithKline; the International AIDS Vaccine Initiative; the International Partnership for Microbicides; the Medical Research Council; the US National Institute of Allergy and Infections Diseases at the NIH; the NIH Office of AIDS Research; PEPFAR; Sanofi Pasteur; UNAIDS; USAID; ViiV Healthcare; and the Welcome Trust. Significant in-kind support was provided by AVAC: Global Advocacy for HIV Prevention; Emory University; Imperial College, London; Medical Research Council/UVRI Uganda Research Unit on AIDS; University of Pittsburgh and the Wits Reproductive Health and HIV Institute of the University of the Witwatersrand.

Then I received the following letter from Samuel Kumar of Kitwe from the Zambia AIDS research Foundation:

Dear Enock,

I am pained by so many talks in HIV forums but there is not much awareness about PEP and PreP, Each time I read in the papers about child defilement my heart stops, defilement has no place in any society and yet we have not popularise the concept of post exposure prophylaxis (PEP) to treat those young girls who have probably been exposed to HIV as a result of child defilement. If the media could help spread greater awareness about PEP then we would make a huge leap in halting HIV.

PEP is an ART regimen given to those people who most likely have been exposed to HIV, one such situation is rape and child defilement. The ART is taken for 28 days, and should be started as early as possible but before 72 hours. And the probability of not contracting HIV is 80 per cent, and if the candidate does not contract HIV, then we have a life saved from HIV, this is a wonderful approach, and the candidate wouldn’t have to be taking ART for the rest of her life.

This is a concept that can help children exposed to HIV. There is another approach called pre-exposure prophylaxis (PreP), for example in an husband and wife relationship, let’s assume the husband is HIV positive and for some reasons he is not consistent in using condoms with his HIV negative partner, the in such an event, the female partner could be a suitable candidate for PreP, it’s a single pill called truvada taken regularly by the negative partner, and if the blood levels of the drug is High then there is a 90 per cent chance the female negative partner will not contract HIV.

If only forums like SRHR and other NGOS could take greater initiative to create awareness on PEP and PreP then we could halt HIV cold in its tracts.

All Africa
http://allafrica.com/stories/201411032021.html

AFRICA: EXCITING NEW HIV PREVENTION PRODUCTS IN PIPELINE
Kerry Cullinan
3 November 2014

Vaginal rings filled with antiretrovirals (ARVs), ARV injections and partially effective vaccines are some of the HIV prevention weapons under development.

Nonthando Kewana will soon know if her monthly trips to the Emavundleni Research Centre in Crossroads have made history.
For almost two years, 25-year-old Kewana has been paying monthly visits to the centre to get a vaginal ring that slowly releases an antiretroviral into her body.

She is part of the final phase of a big clinical trial, and researchers expect to know by mid-2015 whether the ring can protect women from HIV.

"I was scared when I saw the ring, and I thought it might go all around my body but I don't even feel it," Kewana said this week, as she waited for her monthly appointment. "My partner also can't feel it."

The ring is a white, silicone hoop about the size of the circle made when a woman's thumb and forefinger join up.

Over 3000 women around the continent are involved in the ASPIRE trial, which is testing whether the ARV called Dapivirine can protect women from HIV through the simple ring that stays in place for a month.

"I decided to come here to see if I can protect myself from HIV, because I am so scared of it," said Kewana, who witnessed her older sister die of AIDS.

Emavundleni is part of the Desmond Tutu HIV Foundation headed by world-renowned HIV expert Professor Linda-Gail Bekker.

"This area encapsulates the worst of Cape Town's HIV epidemic, with about 28 to 30 percent of pregnant women testing HIV positive," said Bekker this week. "HIV is particularly high in the very informal parts, where people are newly urbanized and don't have ready access to healthcare. That is why this research has to happen here."

The centre was set up 10 years ago in a shipping container and has since grown into a two-storey building. Researchers have worked very hard to win the trust of community members and encourage them to take part in a number of HIV trials. Currently, over 500 people from Crossroads and Nyanga are involved in various HIV and TB prevention trials.

New HIV prevention trials to take science out of lab and into communities
This week, the globe's leading brains researching biomedical ways of preventing HIV met in Cape Town for the inaugural HIV Research for Prevention conference.

"We have six and a half million people living with HIV in South Africa, and treating them with ARVs for the rest of their lives is an enormous public health undertaking," said Bekker. "There is an urgency to turn off the taps [of infection] and come up with new prevention methods."

Using ARV medication to prevent - not just treat - HIV is emerging as one of the most powerful weapons to contain the epidemic in the absence of a vaccine.

ARVs taken immediately after HIV exposure - in rape cases or when healthworkers are injured by needles while treating HIV positive patients - have been known to prevent HIV.

Three years ago, the results of Dr Myron Cohen's 10-year study of couples where one person was HIV positive and the other negative, were released. The study found that if the HIV positive partner was on ARVs and their viral load was undetectable, their negative partner was 96 percent protected from HIV infection.
A number of "treatment as prevention" studies have also shown that ARVs taken shortly before sex by people at high risk of HIV offer protection against HIV. For example, Truvada, a pill that combines the ARVs tenofovir and emtricitabine, reduced HIV transmission in gay men by 42 percent.

Long-acting injections containing ARVs that would only have to be given every two to three months are also in the pipeline, and one of these will be tested at Emavundleni from February.

These injections would make it much easier for people to adhere to treatment and are also being tested to see whether they can protect HIV negative people from the virus.

Wits University's Professor Helen Rees, who was a conference co-chair, said it was more realistic to control rather than eradicate the HIV epidemic at this stage.

However, the long-term aim is still a vaccine to prevent HIV, and there are some exciting developments. Six years ago, the world heard the results of the only vaccine that showed any protective effects, protecting around one-third of Thai people in a huge trial.

For the past two years, the same Thai vaccine has been tested on 100 South Africans - and despite being much fatter than their Thai counterparts, their immune systems also reacted to the vaccine in the same way.

The vaccine is now being modified to contain the strain of HIV most common in South Africa, and by January and 200 more South Africans will be vaccinated with it. But it could leapfrog into a massive R1-billion trial within a year if the people respond according to the Thai trial.

"We have already set our 'go or no go' criteria based on the Thai trial and if we meet these, we can go straight into a Phase 3 trial of 7000 people by the end of 2016," said Medical Research Council President Dr Glenda Gray.

The Thai trial combined two vaccines. The first aimed to prime people's immune systems to recognise the types of HIV most common in Thailand (sub-types E and B) and the other, injected later, aimed to boost their immune systems to fight infection.

The "primer" vaccine now has to be modified to contain HIV sub-type C, which is most common in South Africa.

Discussions have already been held with the Medicines Control Council to license the vaccine by 2019 if the Phase 3 trial goes well, and also to vaccinate children along with the current HPV vaccine to prevent cervical cancer, said Gray, who added that even if the vaccine only gave 50 percent protection, government would probably still license it.

Given the trickiness of HIV and the diversity of people's sexual practices, HIV researchers say they want to be able to develop a range of different HIV prevention products - including perhaps a partially protective vaccine.

*Edited versions of this article first appeared in the Saturday Star and Weekend Argus newspapers.*
THE HUMBLE HEART OF THE WAR ON HIV
Zinhle Mapumulo
3 November 2014

The only feature that distinguishes the building housing the Emavundleni Research Centre in Crossroads, Cape Town, from its neighbours is a fresh coat of paint and a neat palisade fence.

But this grey, two-storey building in one of South Africa’s most dangerous areas might soon become part of medical history.

Inside the centre, researchers are hard at work on a range of HIV-prevention studies: candidate vaccines, microbicides – gels and vaginal rings containing different antiretrovirals – and pre-exposure prophylaxis (PrEP) trials.

So far, each of these interventions has shown positive results when tested for efficacy on humans. If they work, they have the potential to stop the spread of HIV and make the dream of an “Aids-free generation” a reality.

The PrEP trials have been particularly exciting.

It has been shown in several local and international studies that the regime can reduce the risk of HIV infection – in people who do not yet have the virus – by more than 80% if used correctly. But it’s the latest findings from a vaccine trial conducted at the Emavundleni Research Centre last year that are causing a flutter among researchers.

The centre was one of three in the country which tested if an HIV vaccine called RV144 was safe, tolerable and induced an immune response among South Africans.

RV144 had already performed well in trials in Thailand in 2009. It had reduced the risk of HIV infection by 60% in the first year of vaccination and by 31% in the third year. The news from South Africa was even better, with trials at Emavundleni, Klerksdorp and Soweto revealing that the vaccine induced a much better immune response in South Africans than it did among the Thai.

Professor Glenda Gray, director of the HIV Vaccine Trials Network in South Africa, could not contain her excitement when discussing the RV144 results this week.

Gray was speaking at the inaugural HIV Research for Prevention conference in Cape Town, and announced: “This brings us a step closer to finding a vaccine.

“The fact that the immune response of South Africans was as good, if not better, than those of the Thai gives us hope that the vaccine is closer than we think,” she said.

A stumbling block in finding a vaccine has been the nature of HIV – it constantly mutates and scientists have struggled to find a vaccine that can kill all strains.

The genetic make-up of different races and sexes and differences in body mass indices have also been a problem.

For instance, women respond better to vaccines than men, while obese people and alcohol abusers don’t respond well.
Gray said: “We feared that the response of South Africans may not be as good as the Thai because of our obesity levels. We were taken aback when we saw the results – this [response] is very unusual.”

Now she and her teams at Emavundleni and the two other sites are preparing to start another human trial in January. In this phase, 200 people between the ages of 18 and 44 will take part. The trial will test the efficacy of the vaccine which has been modified to target HIV Subtype-C, which is prevalent in South Africa.

The Thai vaccine contained proteins that target strains which are more common in Thailand. The South African participants will first get a jab of the original vaccine used in the Thai trial. A year later, they will receive boosters containing the modified vaccine.

Dr Surita Roux, site investigator at the Emavundleni Research Centre, said she and her team were looking forward to starting the new trial.

Roux has been working in the field of HIV-prevention research for 15 years. She says conducting trials came with challenges – especially because of the stigma around the disease. But she does not think it will be difficult to recruit the 35 people Emavundleni must enrol for the upcoming trials.

She says it wasn’t always easy to get people involved.

“There were times when we spent six to nine months convincing people to participate in our trials,” said Roux.

“There were rumours that we took tons of participants’ blood and sold it. Others said we were infecting participants with HIV.”

But residents in Crossroads and neighbouring Nyanga have warmed to the modest centre with its big ambitions in the seven years that it has been operating, she says.
between vertical conferences on specific biomedical prevention options such as microbicide and vaccine.

“There are commonalities. There are issues which HIV vaccine basic scientists might be looking at which may also be very important for microbicide or pre-exposure prophylaxis (PrEP) scientists too, and vice versa.”

Challenges of adherence to drugs under research or ways to modify trial design to fast track the process are also common across the sector of HIV prevention research. Mechanisms in which socio-behavioural research informs the basic science are also a priority across the board.

By organising one conference on biomedical prevention research for HIV, “we were able to look at these commonalities together while not losing the uniqueness of these specific fields” said Rees. Synergy between different streams of HIV prevention is crucial so that new infection rate dips faster than ever before to end Aids.

Speaking at HIVR4P the Minister for Science and Technology Naledi Pandor said more people get newly infected with HIV than those people living with HIV (PLHIV) who are put on antiretroviral therapy (ART). “There are 2.4 million PLHIV on ART in South Africa” said Pandor. It is important to underline that there are an estimated 6.3 million PLHIV in South Africa as per latest data from UNAIDS.

The road to scale up treatment for everyone is still long. Alongside scaling up ART to every PLHIV and other measures, there is surely a need to scale up effective prevention services radically.

“The increase in ART has resulted in a reduction in the number of people dying as result of HIV infection and a significant reduction in mother to child transmission of HIV. We remain many years away from eliminating HIV. We are not investing in social sciences enough. We have to get the behavioural aspects right in HIV prevention research,” said Pandor.

“As we know, no single method of prevention can end this epidemic on its own, our focus remains in offering a package of HIV prevention together. We need to respond to the epidemic in a more comprehensive manner than merely offering individual interventions.”

Developing safe and effective HIV prevention tools are critically important but not enough. “We need to move research outcomes into clinical practice, which continues to remain a challenge,” said Pandor. She was right on spot. Female condoms were approved by the US FDA in 1993 but lot more needs to be done to roll them out to every woman in need of protection against unintended pregnancy and/or sexually transmitted infections (STIs) including HIV.

Undoubtedly more work needs to be done to ensure there is no delay in taking research outcomes forward to yield public health benefits.

Dr Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), USA, addressed HIVR4P via a video link. He said HIVR4P was rightly addressing all biomedical prevention options at one forum.

He said non-vaccine prevention options and vaccine both are required to stem the pandemic. Fauci underlined that non-vaccine prevention options need to be taken regularly but vaccines, once given, do not have those adherence issues. “Non-vaccine prevention options are highly effective but requires continual adherence, whereas vaccines are often modestly effective but durable, and do not have continual adherence issues,” said Fauci.
“The foundation of HIV prevention is in fact, HIV testing,” said Fauci. HIV testing connects to two streams: if the test is positive then the person should be connected to a care continuum and if negative, then to a prevention continuum.

He said there are gaps in the care continuum and we must find ways to fill these. Referring to a prevention continuum, Fauci said if the test is negative then the person is encouraged for counselling and risk stratification, and provided with tailored prevention services from the “prevention toolbox”. Fauci was referring to a range of HIV prevention options that have been proven to work effectively such as: HIV testing and counselling, treatment as prevention, voluntary medical male circumcision (VMMC), treatment of STIs, rectal and vaginal microbicides (both are currently under research), prevention or treatment of drug and alcohol use, provision of clean needles and syringes, education, behaviour modification, male and female condoms, blood supply screening, anti-retroviral drugs for prevention of mother to child transmission of HIV (PMTCT), post-exposure prophylaxis (PEP), and pre-exposure prophylaxis (PrEP).

Vaccines will also be added to this “toolbox” once proven to be safe and effective in ongoing research studies, said Fauci.

There is no effective HIV vaccine available today. Yet a safe and effective vaccine is critical to control HIV globally.

He also stressed the need to fashion combination prevention for “hotspots” of HIV infection. He gave an example of the Lake Victoria area in Kenya which has HIV rates comparable to places in Africa with the highest HIV prevalence. This area is also known to have low male circumcision rates and unsafe sex work associated with its fishing community. But the rest of the Kenya does not have those high HIV rates. Combination prevention needs to be tailored in unique contexts and realities and if we do so, we could prevent “600000 new HIV infections by 2030” said Fauci.

AIDS MEDS
MORE PrEP NEEDED TO PREVENT HIV VIA VAGINAL THAN ANAL SEX
3 November 2013

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Greater dosing of Viread (tenofovir) or Truvada (tenofovir/emtricitabine) as pre-exposure prophylaxis (PrEP) is needed to reach effective levels in vaginal and cervical tissue than in rectal tissue, HIVandHepatitis.com reports. These findings help shed light on why two trials of PrEP among women, VOICE and FEM-PrEP, which tested both Viread and Truvada, had such poor efficacy in preventing HIV.

Presenting their work at the HIV Research for Prevention meeting in Cape Town, South Africa, researchers determined the necessary ratios of active tenofovir and emtricitabine to the DNA molecules the drugs work against to prevent HIV from replicating. Then they drew data from a Phase I clinical trial examining how tenofovir, emtricitabine and other antiretrovirals are absorbed into women’s vaginal, cervical and rectal tissue. The researchers used this data to create a mathematical model that predicted
the ratios of active drug to DNA molecules in a theoretical study population that took either Viread or Truvada two to seven days a week.

According to the model, two doses of Truvada per week or daily dosing of Viread would maintain the necessary ratio in rectal tissue throughout a population. On the other hand, a daily dose of Truvada would yield this ratio in vaginal tissue in more than 75 percent of a cohort of women, and in the cervical tissue of only half of the women. Daily Viread would yield the target ratio in cervical and vaginal tissues in half of a population of women.

Not only is the concentration of tenofovir higher in rectal tissues, but the concentration of DNA molecules it targets is also lower when compared with vaginal and cervical tissues.

The iPrEx open-label extension (OLE) study recently estimated that men who have sex with men and who take Truvada an average of two to three times a week reduce their risk of contracting HIV by 84 percent. A previous analysis of the iPrEx study estimated that taking Truvada an average of twice a week reduces the risk of contracting HIV by 76 percent.

All these findings notwithstanding, the Centers for Disease Control and Prevention guidelines still stress the importance of adhering to PrEP’s daily dosing. iPrEx OLE estimated that PrEP is 100 percent effective among MSM when taken daily, and an analysis of iPrEx estimated that daily dosing’s efficacy is 99 percent.

To read the HIVandHepatitis story, click here.

To read a press release about the research, click here.

To read the study abstract, click here.

Science Speaks

HIV R4P: WITH COMBINED HIV BIOMEDICAL PREVENTION APPROACHES COME OPTIMISM, CIRCUMSPECTION

Antigone Barton
4 November 2014

“We were all pretty sad sacks, after seeing all these vaccine trials and not really seeing anything,” Dr. Mary Marovich said early last week, reflecting on the state of the HIV vaccine research field just a few years ago. Marovich, of the National Institute of Allergy and Infectious Diseases, was emphasizing the contrast between then and now.

Those few years since trials of a Merck HIV vaccine candidate showed slightly higher rates of infection among those taking the product over those taking the placebo, while other trials had shown no difference at all, have been superseded by a series of discoveries on the shape of the virus itself, on
antibodies that can have the broadly neutralizing effect needed to attack the virus’s shifting forms, on responses from the immune cell the virus attacks, the possibility that an approach that is clearing a simian version of HIV from monkeys could lead to a therapeutic vaccine resembling a cure for humans, and, still most encouragingly, on the trial of the RV 144 HIV vaccine regimen in Thailand, the one trial to yield results of a regimen showing effectiveness against the virus.

All of these developments have years of research and testing ahead of them at best before they can lead to a vaccine against HIV that can be used, and realize the long-hoped for dream of permanently turning the epidemic back. For none of these advances, in fact, will any responsible researcher project a time when that might be the case.

At this first international meeting to bring researchers from all biomedical HIV prevention approaches together under one roof, neither the time and disappointments leading up to this point, or the uncertainty of how much more time lies ahead, did anything to dampen a sense of optimism and ambition that AVAC director Mitchell Warren sums up as “momentum.”

It is a momentum that comes not just from the advances in HIV vaccine science, but a gathering force of advances across the HIV biomedical prevention field that includes progress in topically applied microbicides to protect individuals from HIV infection, prophylactic use of antiretroviral treatment — PrEP to protect uninfected individuals, and treatment of infected individuals as prevention of HIV transmission. The potential for the sum of those advances to be greater than their individual impacts has driven an optimism that has researchers talking about which preventive product might be used by who, and in what combination with other prevention products, most of which do not exist yet for distribution, all of which face obstacles in the resource poor, heavily HIV burdened environments where they are needed most.

At the same time, a heightened circumspection about what is not known about both the needs and challenges of many of the people for whom making these products available and usable will be most critical, and about what additional surprises science might still spring drove the content of much of the conference.

Much of this circumspection stems from VOICE, a three-country, multi-site randomized clinical trial to test the potential effectiveness of Vaginal and Oral Interventions to Control the Epidemic, which revealed that while some of the products might have been successful if used, many of the women, particularly the young, unmarried women whose need for such products has driven researchers, did not use the products enough to prove they worked. But this humbling news had also followed the FEM-PrEP trial of oral pre-exposure antiretroviral medicine to prevent infection, which as researchers put it at the time “reinforced the key role of adherence,” because too few participants actually took the product. It also followed the MDP 301 trial of a microbicide gel which was not effective, but more importantly, as the disappointing results led, in Mazabuka, Zambia to misreporting and widespread suspicion of the product and the trial, revealed a massive failure on the part of researchers to communicate with community leaders, journalists, and by many indications, the participants themselves.

Conference co-chair and Microbicide researcher Sharon Hillier called the revelations of the VOICE trial a “life-changing experience” that “has changed the way we do business.” In fact, she and others point out that the very concept of “adherence” has been held up for re-evaluation. “I think we misjudged whether of not these products were going to fit into the lives of these young people,” she reflected. This, in turn, fuels hopes that two trials of antiretroviral-containing silicone rings to be worn in the vagina for 30 days or more will meet those needs. In addition, even while a proven useful delivery system of a reliable
topical HIV prevention method still lies ahead, the possibilities of rings or other technologies that can prevent other sexually transmitted infections and unintended pregnancies along with HIV were the topic of talks and sessions throughout the conference.

It is a different era from that when what was thought to be impossible, improbable or impractical dominated discourse surrounding the epidemic. At the same time, themes of good participatory practices and community involvement throughout the conference, seemed to replace an old confidence that scientific soundness on its own could end the epidemic.

That turn, from what Glenda Gray, president of the South Africa Medical Research Council called “all breakthrough, no follow through,” made the view of a day when HIV is controlled, by science, by governments, by communities and by individuals clearer if still distant.

Obstacles yet unanticipated could still slow the way there. While the Ring and ASPIRE trials with the potential for a long term rather than daily prevention product they offer, answer one of the challenges raised by VOICE trial participants, the trials started before the still emerging feedback from the VOICE trial emerged. And when asked if the VOICE trial raised concerns about communication with participants in The Ring and ASPIRE studies, Zeda Rosenberg, chief executive officer of product developer International Partnership for Microbicides, did not answer.

Some answers from those trials will be on the way by the time the next HIV R4P conference meets in Chicago, Illinois in 2016. That’s also when what all the optimism and ambition of this conference is leading will be clearer too, Warren said, “It will be real if we actually act differently after Cape Town.”

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