

The MRC KwaZulu-Natal AIDS Forum





Volume 2, Issue 1

January 2004



Ed's Say:

This issue of E-News focuses predominantly on providing a report-back on the 1st South African Conference on HIV/ AIDS held in Durban, in September.

Topics of particular interest included research, vaccine challenges, rolling out of ARVs and microbicide development.

Although there is a still long way to go in the fight against HIV/AIDS, it was clear that what is happening in the South African context is nothing short of inspirational.

Marlijn (marlijn.vanberne@mrc.ac.za)

About the AIDS Forum

The MRC AIDS Forum opened its doors to the public some 3 years ago. Its aim: to forge a bridge between science and community and to develop a monthly platform for various stakeholders involved in HIV/ AIDS to discuss issues, pertinent and relevant to the way in which we respond to the epidemic. The forum also hopes to improve communication and networking amongst Government, civil society, scientists, journalists and the community at large.

Microbicide and women controlled barrier methods – a review of the South African

review of the South African AIDS Conference symposium.

"Sub-Saharan Africa is by far the region worst affected by HIV, with twice as many young women as men infected. As such, there is an urgent need to develop and test women-controlled HIV prevention technologies such as vaginal microbicides, vaginal diaphragms and female condoms." – South African AIDS Conference 2003.

Although there are numerous technologies and views on preventing HIV infection among women worldwide, research into vaginal microbicides is worthy of more than a passing mention.

A basic definition of a microbicide is a substance that kills or inactivates pathogens. Often referred to as a 'barrier method' they can provide a barrier to transmission and are unique in the fact that they are controlled by women. Especially in the context of HIV/ AIDS, microbicides are designed for intra-vaginal application.

Once applied to the vagina, microbicides should prevent HIV and ideally, other sexually transmitted infections (STIs) as well, by blocking the mechanisms of cellular infection or, by killing the virus before infection. Microbicides will also be designed to be either contraceptive or non-contraceptive.

There should be different ways to deliver these microbicides into the public domain; either as a gel, cream,



suppository, film, sponge, wipe and/or vaginal or rectal ring. Most to-date research is focused on gels. According to Dr CH Lacey of the British Medical Research Council, research has shown that women are however less concerned with 'looks' and primarily want "something that works."

Dr Lacey expanded that research into 'single use microbicides' administered before sex showed some evidence of being effective up to 12 hours

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PUBLISHED BY THE MEDICAL RESEARCH COUNCIL

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Volume 2 | Issue 1 | January 2004

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(depending on the dosage). When asked if protection remained consistent for the entire 12 hour period, Dr Lacey said that indications are, that the percentage of protection persisted throughout.

Assuming that a 60% efficacy (effectiveness) microbicide is used for 50% of the time by non-condom users or inconsistent condom users, then 2.5 million infections should be prevented

over 3 years. This public health impact translates into substantial health savings said Dr Lacey.

He did however point out that research into microbicides is still at baseline in terms of protection trials; although they appear to work in test-tube and animal models, it is not realistic to expect results in the next 5 to 6 years, or even longer.

With a little help from our friends

by Marina R. Rifkin

HIV vaccines in SA

November marked the beginning of HIV vaccine trials in South Africa, with phase I clinical trials commencing at the Chris Hani Baragwanath Hospital in Soweto and the Medical Research Councils HIV Vaccine Research Unit in Durban. While monumental, these advances represent only the beginning steps in the development of a safe, effective and affordable HIV vaccine.

In order to conduct vaccine trials, healthy, HIV-negative people, over the age of 18, who give true informed consent, are needed to volunteer as HIV vaccine clinical trial participants. With two vaccine trials currently under way in South Africa and as many as three more expected to begin next year, thousands of volunteers will be needed as HIV vaccine clinical trial participants.

Recruitment paradox

One of the major challenges in conducting vaccine trials lies in recruiting the volunteers. Participation in a vaccine trial is not without risk and while the vaccine itself cannot cause HIV infection, there are physical and social risks volunteers must be aware of before consenting to participate in these trials.

Vaccine trials are governed by the ethical requirements that potential volunteers must be able to demonstrate their understanding of trial procedures and the potential consequences of participation. To satisfy this requirement, vaccine trials often require that all trial volunteers have completed matriculation before being eligible for enrollment.



A considerable obstacle has arisen surrounding the ability of a potential participant to give true informed consent and their corresponding willingness to participate in HIV vaccine trials. Although previous studies have found that higher levels of education of potential participants corresponded to greater understanding of trial procedures and risk, and increased ability to give true informed consent, it also translates into a decrease in willingness to participate. Thus, while educated individuals are able to give consent, they often chose not to.

University campuses provide a unique opportunity to overcome this dilemma. Although studies¹ have suggested that students are less willing to participate in HIV vaccine trials than non-students, researchers often target college students in their recruitment efforts for clinical trials, due to the ease with which they can be accessed and their ability to understand the trial procedures and thus, give true informed consent. ²

A new study

Beginning in February, a graduate student from the Johns Hopkins School

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of Public Health in the United States will be working with the Medical Research Council in Durban to conduct a small survey, pending approval, on the willingness of South African university students in KwaZulu-Natal to participate in HIV vaccine trials. The study will survey 150 students attending either the University of Natal-Durban or the Nelson R. Mandela School of Medicine. The primary objective of this study is to investigate the relationship between social, behavioural, and demographic

characteristics and willingness to participate in HIV vaccine trials, with the hope of strengthening recruitment efforts and gaining insight into how students make decisions about participating in HIV vaccine trials.

The preliminary results of this research should be available in July 2004. If you have any questions regarding this study, please contact Marina Rifkin at +27 (0) 31 203 4700 or by e-mail at marina.rifkin@mrc.ac.za or mrifkin@jhsph.edu.

- Perisse A, Schechter M, Moreira R, et al. Willingness to participate in HIV vaccine trials among men who have sex with men in Rio de Janeiro, Brazil.
- J AIDS 2002. 25 (5): 459 463.
- Westblom TU, Belshe RB, Gorse GJ, et al. Characteristics of a population volunteering for human immunodefi-ciency virus immunization. Intl J STD AIDS. 1990;1 (2): 126 -128.

Challenges in HIV vaccine research in South Africa.

Although progress in the AIDS vaccine arena is slow, global efforts have proved significant, this according to Dr Tim Tucker, Director of the South African AIDS Vaccine Initiative (SAAVI).

Addressing visitors to the 1st South African AIDS Conference, Dr Tucker said that animal data in particular, had shown significant potential. He warned however, that there were still major hurdles ahead and that past strategies used in HIV vaccine research had been unsuccessful.

On a more positive note, vaccine research in a South African is moving into a new and exciting phase. Despite concerns expressed by international stakeholders as to South Africa's ability to conduct research of this standard, we have now started clinical trials. "South Africa has South Africans working in South African laboratories developing South African vaccines," said Dr Tucker. Developing a South African vaccine is proving to be a joint-venture of some magnitude:

Making the vaccines are the Universities of Stellenbosh and Cape Town, in conjunction with the Medical Research Council. Their primary concern is with:

- CTL activity
- Neutralizing antibodies
- · Cross subtype immune protection
- Manufacturing
- Toxicity testing
- Regulatory body submission
 Testing the vaccines are the MRC, the
 University of Witwatersrand (peri-natal)

HIV research unit), Arum Health Research (Anglo Gold) and a University of Cape Town-based consortium (University of Cape Town, Stellenbosh and the MRC). Their primary concern is with:

- Phase I / II: Infrastructure & Personnel
- Phase III: Massive cohorts;
 Demographics; HLA; Viral diversity;
 Immune responses; Antibody and CD8 / CD4
- Adolescents

Immunology assessment is conducted by Stellenbosch University, University of Cape Town., MRC and NICD (the National Institute of Communicable Diseases). Their primary concern is with:

- Correlates of immunity in animal models and human studies.
- Standardized assays
- Move to "service laboratory" component: regulatory body quality data

Behavioural science data is conducted by the University of Witwatersrand, Stellenbosch University and the MRC. Their primary concern is collect data from trial participants:

- · Willingness to participate
- Compliance over time: trial and risk reduction
- · Stigma of volunteering
- Social harm

Ethical issues are reviewed and addressed by HAVEG, the HIV/AIDS vaccine ethics group based at the University of Natal, Pietermaritzburg. Their primary concern centers on issues

such as:

- Informed consent; taking into account cultural variation and measure of knowledge
- · Standard of care
- · Develop national guidelines
- Training of IRBs & stakeholders

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From the 25th of October 2003, the AIDS Forum has had a regular column in the Daily News, as part of their monthly health supplement. Articles will focus on upcoming or past forum topics.

ENJOY!

Picture Callery



 L - R: "Madiba meets with the SA AIDS vaccine team" - from L to R: Prof. Carolyn Williamson, Dr Glenda Gray, Dr Athmanundh Dilraj, Madiba, Winnie (Soweto Community Advisory Board CAB), Tim Tucker and Dr Andrew Robinson.



2. Gaetane Le Grange (TAI) presenting at the Mtunzini



 L - R: Shaun Mellors (Ex AIDS Forum Co-ordinator & HIV/AIDS Consultant), Gerrit Maritz (Faculty Coordinator, Centre for the Study of AIDS) and Johan Maritz (Trainer & Consultant, Centre for the Study of AIDS)



4. AIDS Forum Co-ordinator, Marlijn van Berne, at the ICASA Conference in Kenya.



 L - R: AIDS Forum Co-ordinator, Marlijn van Berne, HVTNs Andrew Lambert and Jennifer Hyman (Global Health Council).



 L – R: Cece Fadope (Nigeria Internews Network), AIDS Forum Co-ordinator Marlijn van Berne & Mia Malan (Kenya Internews Network).



7. 13th ICASA Conference, Nairobi, Kenya

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Community preparedness or the education of community around vaccine trial impacts and issues, has been taken on board by SAAVI. SAAVI is primarily concerned with:

- Broad community education; documents and materials as well as sectors
- Lobbying
- · Protection of volunteers
- Legal framework

Lastly there is the *data and bioinfor-matics* unit concerned with:

High quality research and trial data.

In closing, Dr Tucker was asked if vaccines might be used as therapy (not preventative but as treatment). He responded by saying that although SAAVIs current mandate is searching for a 'preventative way forward, SAAVI would share and give access to their research if it was shown to be of benefit to therapeutic researchers.'

VIS

Vaccine Information
Sessions (VIS) are held
every Tuesday at 10h3011h30 & 16h00-17h00,
1st floor boardroom,
Medical Research Council,
491 Ridge Road,
Overport.

Those interested in learning more about HIV vaccines or participating in vaccine trials are welcome to attend the VIS meetings. For further information please contact: Nobuhle or Wendy on 031-2034700 or the toll free number: 080 822 2463.