



The MRC
KwaZulu-Natal
AIDS Forum

KZNE NEWS



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Ed's Say:

By Marlijn van Berne

Frequently asked questions about HIV vaccines

This issue of *E-News* sets out to highlight current and ongoing issues, debates and ventures in the HIV/AIDS arena.

Not least of these, the complexities surrounding the recruitment of volunteers to HIV vaccine trials. Currently well into phase I human clinical trials at the Chris Hani- Baragwanath Hospital in Soweto and the Medical Research Council's Vaccine Research Unit in Durban, each phase's successful progress to completion is largely dependent on its volunteer participants.

Phase I is a safety trial. Its main aim is to establish if the test vaccine elicits an immune response and to confirm that no significant side-effects are produced in humans. "These volunteers have made it possible for researchers to learn about the safety and potential benefit

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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.

Why an HIV/AIDS vaccine and how will it work? These are questions members of the HIV Vaccine Research Unit at the Medical Research Council in Durban are frequently asked – especially following the first inoculations with two of the HIV/AIDS test vaccines in humans in November 2003. Below some of the more commonly-asked questions relating to HIV/AIDS vaccines:

Q: Have scientists looked into a preventative vaccine that offers protection across the different strains or clades of HIV?

A: Scientists don't know yet how much cross-clade protection a vaccine might offer, e.g. if you used a clade C vaccine would you be protected against HIV A or B? Scientists have already identified clades A to K. These are regionally specific although Africa has most of these strains in circulation with clade C predominating in the sub-Saharan region. Ultimately we hope that a vaccine would offer broad, long-term cross-clade protection, but at this stage we don't know if that will be possible and we need to do more clinical trials to find that out. We know that for flu, for example, you need new vaccines all the time for the different strains so it seems likely that the different strains of HIV will be a factor in vaccine development.

Q: What are the side-effects of the vaccine?

A: The side-effects experienced so far in clinical trials in other countries are much the same as one expects with any vaccine, such as the flu vaccine. You may feel a bit tired; you could have a short bout of fever and pain at the injection site. However, you may also be unlucky and experience an allergic reaction. Of course, there are other non-medical side-effects, such as HIV-related stigma which could be caused by people not understanding what a vaccine or a clinical trial is.

Q: Do trial participants get paid?

A: Participants do get reimbursed a small amount for their out-of-pocket expenses, such as travel costs. However, they do not get paid for participating in a trial as this would be regarded as an inducement and may encourage them to take part simply because they need the money.

Q: So participants get vaccinated with progressively higher doses of the vaccine over time?

A: Yes. The trial is designed to test the safety of the vaccine, so the first group of participants enrolled, are enrolled at the low dose. Once safety has been ensured, only then will enrollment into the higher doses occur. This is specific to this HIV vaccine trial, i.e. not every vaccine trial is performed in this manner.

Q: Presumably there is a limit to the dose increases?

A: Yes, as with all vaccines and medicines there is a limit and it is important to understand that scientists wouldn't knowingly expose trial participants to dangerous doses of anything – this is why it is done progressively – constantly taking into account the possible side-effects and the immune response.

For more information on HIV vaccines and trials, please contact the SAAVI Vaccine Info-Line on 080 822 2463 (080 VACCINE) or visit the website saavi.org.za

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of experimental vaccines. They are also helping scientists to better understand the concerns of prospective HIV vaccine trial volunteers.”
– *National Institutes of Health press release.*

Challenges

The recruitment of volunteers has not come without its own set of challenges. Despite some pre-recruitment education to community, misinformation surrounding the trial and the vaccine has hindered efforts to enlist volunteers. Dr Colleen Pieterse, Medical Officer on the Durban-based vaccine trial, concurred that inaccurate information was in part to blame for the lack of volunteers. “It is imperative that *accurate* information gets put out in the community so that people can move beyond their pre-conceptions.”

Community educator and recruiter, Wendy Mkize, emphasised the need to reinforce information; “We need to return to the same area over and over again, until people understand.”

Discussion also focuses on the need to broaden the community awareness/education programme to embrace all sectors of society, including businesses, and other key decision makers, such as health workers, religious leaders and politicians.

Said Dr Pieterse, “These people need to be in the forefront of the fight against HIV/AIDS. “Don’t only support our programmes, we need participants – and your taking part will give credence to your support.”

Stigma and discrimination have been associated with HIV/AIDS since the start of the epidemic and, sadly, stigma around joining a vaccine trial is proving to be another obstacle on the road to recruitment. Even though the participants in all phases of HIV vaccine trials are HIV negative, their participation in an HIV vaccine trial still may result in their being stigmatised or discriminated against.

Research by the Canadian HIV/AIDS Legal Network shows that potential recruits fear an unfavourable social reaction to their involvement in HIV vaccine research and consider this to be a primary risk associated with participation in a vaccine trial. One way to help preserve confidentiality around trial participation is for participants to attend trial-related appointments outside their normal working hours – organisers at both South African sites have ensured that

appointments are flexible enough to allow participants to attend outside working hours as needed. This does, however, beg the question, should we not be addressing the issue of stigma and breaking the silence rather than supporting it indirectly? Maybe then, those interested could volunteer, secure in the knowledge that it is safe to do so.

Does the vaccine itself cause HIV infection? To some, this is possibly one of the most talked about and potentially destructive obstacles on the road to recruitment. The answer, is categorically, NO. Unfortunately, explaining the intricacies of HIV science to, in some instances, a lay audience, is no mean feat. There is little room for ‘lost in translation’, especially when a safe and effective vaccine could mean the difference between life and death.

A stringent recruitment process is being followed at both South African trial sites. Volunteers are healthy, HIV-negative adults who are willing and able to give informed consent and have undergone intensive pre-recruitment education and counselling. Once accepted into the trial, volunteer visits to the trial sites include clinical monitoring, urine and blood tests, HIV testing and ongoing counseling over at least 12 months.

Why would you volunteer?

There are many reasons why an individual might volunteer, among them, the need to help stop the devastation wreaked by HIV/AIDS, to leave a legacy, and to protect one’s children and grandchildren. For some it is also a safe way to find out one’s status and get educated.

For others, it is an opportunity to become a vaccine advocate or a member of the Community Advisory Board (CAB). You can make a difference, even if it is not as a volunteer. Those interested, can join the weekly Vaccine Information Sessions (VIS) at the Medical Research Council in Ridge Road. Sessions take place every Tuesday from 10h30 to 11h30 and, from 16h00 to 17h00.

“All of these studies depend on the willingness of ordinary people to volunteer to participate in prevention studies,” – *National Institutes of Health press release.*

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

Vaccine trials volunteer eligibility:

Inclusion criteria

- HIV negative
- willing to receive HIV test results
- good general health
- acceptable methods of contraception for females of reproductive potential

- Hepatitis B surface antigen negative
- anti-hepatitis C virus antibody (anti-HCV) negative or negative HCV PCR if anti-HCV is positive; and
- access to participating site and available for follow-up during the 12 month study

Exclusion Criteria

- HIV vaccines or placebos in prior HIV vaccine trial
- measurable anti-VEE antibody
- high risk for HIV infection according to HVTN Risk Criteria

- ← immunosuppressive medications within 168 days prior to first study vaccine administration
- blood products within 120 days prior to first study vaccine administration
- Immunoglobulin within 60 days prior to first study vaccine administration
- live attenuated vaccines within 30 days prior to first study vaccine administration
- investigational research agents within 30 days prior to first study vaccine administration
- subunit or killed vaccines within 14 days prior to first study vaccine administration
- current tuberculosis prophylaxis or therapy
- active syphilis
- serious adverse reaction to vaccines. A person who had an adverse reaction to pertussis vaccine as a child is not excluded.
- autoimmune disease or immunodeficiency
- unstable asthma
- type 1 or Type 2 Diabetes Mellitus
- Thyroid disease requiring treatment

- serious angioedema within the past 3 years
- uncontrolled hypertension
- bleeding disorder
- malignancy unless it has been surgically removed and, in the opinion of the investigator, is not likely to recur during the study period
- seizure disorder requiring medication within the past 3 years
- Asplenia
- mental illness that would interfere with compliance with the protocol
- other conditions that, in the judgement of the investigator, would interfere with the study
- Pregnant or breast-feeding



Vaccine trial participant, Joan McCosh and Dr Vimla Reddy.

“To date there have been no social harms or stigma in the over 80 volunteers screened, nor in the 18 volunteers actually enrolled and vaccinated in the trials underway”

Dr Andrew Robinson,
HIV Vaccine Research Unit,
MRC, Durban.

For further information, please contact Wendy or Nobuhle on +27 (0)31 203 4700 or contact the toll-free vaccine info-line 080 VACCINE.

COMMUNITY SPOTLIGHT

A look at drama and AIDS

DramAidE, a vibrant HIV/AIDS NGO which uses drama methodologies to communicate effectively about sexuality and HIV/AIDS with young people, is set to launch a project that allows students to deal more effectively with the risk of HIV infection and stigma at 27 Higher Education campuses nationwide.

Thanks to the recently received PEPFAR funding [Presidents Emergency Programme for AIDS Relief]; DramAidE has developed the DramAidE Health Promoters Project in Higher Education Institutions [Universities and Technikons] throughout South Africa.

Based on the rationale that ‘young people are highly influential in their communities and are the future leaders of society’ DramAidE aims to reach some 680 000 students living on Higher Education campus residences in South Africa. Through the placement of young people living openly and positively with HIV on 27 campuses the Health Promoters Project will use a dialogue-orientated strategy which effectively helps students deal more effectively with their personal health and relationship problems. This, in turn, is linked to concepts of living openly with HIV, HIV prevention, voluntary counseling and testing (VCT), gender and cultural sensitivity and stigma reduction themes. This project is



DramAidE teaches ‘forum theatre’ to local school clubs as means of encouraging self-help ventures

funded by Johns Hopkins University Population Communications Services [JHU/PCS], Baltimore, USA.

DramAidE have also created specific materials for KZN schools which were very well received at a recent UNESCO conference in Thailand. The ‘Woza Nazo’ [secondary

schools] and ‘Naku Okwethu’ [primary schools] projects involved researching, developing and disseminating culturally appropriate and gender sensitive life-skills materials for schools. The project has reached over 150 school teachers, peer educators and community educators, and impacted on the school communities in the

target region in Northern KZN.

Funding for DramAidE has come from tenders awarded by the KZN and National Departments of Health and Education, for life skills training and communication campaigns. Grants from the African Medical Research Foundation [AMREF], Johns Hopkins University Population Communications Services [JHU/PCS], the Norwegian Students Academy International Helpfund [SAIH], and Richards Bay Minerals support and the DramAidE projects.

DramAidE has offices at both the Universities of Zululand and KwaZulu-Natal. These offices are administrative centres, as all of DramAidE's work is done in educational institutions and the areas in which they are situated. DramAidE employs 16 staff members, 8 male and 8 female.

It is DramAidE policy to employ graduates from the previously disadvantaged University of Zululand, and to provide additional training for all staff members. Five staff members are currently registered for part-time MA degrees, with a focus on researching DramAidE projects.

The DramAidE Board includes academics from the Universities of Zululand, KwaZulu-Natal and Johns Hopkins, USA. It also includes representatives from AMREF, from the National Association of People living with HIV/AIDS (NAPWA), the Provincial Government Department of Education and Culture, and the Department of Health.

For further information please contact Prof Lynn Dalrymple at Lyndal@iafrica.com



"Should we review our current recommendations and prescribe food combinations?"

The information explosion in nutrition science very often creates the impression that available information is contradictory. Consequently, it is no longer easy to distinguish between fact, misinformation and fiction. The Nutrition Information Centre of the University of Stellenbosch (NICUS) was established to act as a reliable and independent source of nutrition information.

Guidelines for the nutritional management of HIV/AIDS

Nutritional assessment

Although body weight per se, may underestimate the degree of wasting in HIV/AIDS, it is important to keep track of the changes in body weight. The patient's weight should be charted regularly to assess whether a lot of weight is lost within a short time, or it is slow progressive weight loss. Dietary intake should also be assessed regularly in combination with physical and work-related activity as well as employment status to determine food and nutrient intake.

Nutrient needs: Energy

Acute infectious illness, such as HIV/AIDS, is accompanied by a complex variety of nutritional and metabolic responses within the body. The response to infection is associated with an increase in the energy requirements of the patient and various degrees of lean tissue breakdown. Individual energy and protein needs depend on the health status of the HIV/AIDS patient. Even more energy will be required in the

presence of secondary disease (opportunistic infections). It is generally recommended that individuals with HIV/AIDS need approximately 30 to 35 kCal per kilogram for maintenance of body weight or 40 - 45 kCal per kilogram if severe weight loss has occurred (see nutritional recommendations).

Protein

HIV/AIDS patients are known to have high losses of protein (nitrogen), which may result in malabsorption due to diarrhoea, loss of fluids, electrolytes and other nutritional reserves. The breakdown of protein and other reserves due to fever may also worsen under-nutrition and further impair resistance against the infection. An increase in protein breakdown, for example, leads to muscle wasting in these patients. The protein intake of the diet is important to ameliorate the wasting of muscle tissue. An intake of 1,0 - 1,4 g per kilogram body weight or 15 percent of energy of total daily intake or approximately 75 - 105 g per day is usually sufficient. In the presence of severe wasting, malabsorption or secondary opportunistic infections, 1,5 - 2,0 g per kilogram of body weight may be needed. (see nutritional recommendations)

Fat

Tolerance of fat varies from person to person. In the presence of malabsorption or diarrhoea, a low-fat diet may relieve some of the symptoms. A low-fat diet according to the prudent dietary guidelines as part of a varied diet is indicated.

Vitamins and minerals

The response to infection includes a profound impact on the micronutrient status of the patient. Vitamins and minerals are compounds that are essential for normal growth and maintenance of body functions, playing key roles in many different metabolic processes in both health and disease. The increased energy needs and tissue breakdown associated with infection are thought to increase the requirements of micronutrients such as vitamin A, E, B6, C, D and folate. It is also known that a decrease in blood levels of trace elements such as iron, zinc and selenium as well as magnesium occur during the infection. Importantly, these apparent deficits are reported to occur early on in infection and deserve attention early in the management of these patients.

A number of studies have reported low blood levels of vitamins A, B6, B12, C, E, folate and carotenoids as well as selenium, zinc and magnesium in the HIV/AIDS patient. Some studies reported these low blood levels despite the fact that the patients were eating an apparently adequate diet. It would appear that the intake of micronutrients at levels recommended for healthy individuals may not be adequate for HIV infected people.

Despite extensive studies, little is known about the exact vitamin and trace element requirements in HIV/AIDS. A good multivitamin and mineral supplement, therefore, which provides 100 to 150 percent of the Recommended Dietary Allowance (RDA), is advisable since it will be most unlikely that a person with HIV will be able to meet the requirements for vitamins and minerals with diet alone due to a poor appetite.

Special Nutritional concerns for children with HIV/AIDS

General nutritional recommendations for children include high-energy, high-protein and micronutrient-dense food. Protein needs may vary from 150% - 200% and energy from 100%

- 200% of the Recommended Dietary Allowance (RDA). A multivitamin and mineral supplement providing a 100% of RDA should be given.

Nutritional counselling

Food safety is important, since immunosuppressed people are highly susceptible to food-borne pathogens. Therefore, special care should be taken with uncooked food products such as eggs, fish, meat and unpasteurised milk. The following can be used to increase the safety of food and drinking water:

- Always wash your hands before touching food or water.
- Wash all vegetables and fruit thoroughly.
- Avoid touching farm animals.
- Boil water for one minute at rapid boil and store in a clean, closed container or use bottled water
- Cook all meat fish and eggs completely before eating in a hygienically prepared kitchen.
- Use only pasteurised milk and dairy products.
- Thaw all foods in the refrigerator and not at room temperature.
- Keep shelves, counter tops, other kitchen utensils, sponges and towels clean at all times.
- Use different cutting boards for foods intended to be served raw than for foods that will be cooked.
- Exercise caution consuming foods or beverages out of home or when travelling.

Nutritional recommendations

- Decreased appetite: HIV/AIDS often adversely affects nutritional intake, due to poor appetite, thus placing patients at risk for malnutrition. Six smaller meals (or eat every two to three hours) per day are indicated instead of three meals.
- The meals should be appetizing in appearance and taste and provide enough energy and protein.
- Increase energy and protein intake: Commercially available high-energy and protein drinks (balanced in terms of micro- and macronutrients) may be used effectively to meet the increased requirements.
- Household ingredients, such as sugar, vegetable oil, peanut butter, eggs and non-fat dry milk powder can be used in porridge, soups, gravies, casseroles or milk-based drinks to increase the protein and energy content without adding to the bulk of the meal.
- At least 500 - 750 ml of whole milk or yoghurt should be consumed daily (use in porridge and in the preparation of foods like custards, puddings and cream soups).
- Add generous amounts of sugar, butter, peanut butter, margarine, cheese, mayonnaise and cream to foods (if tolerated)
- Dairy products are a good protein source. Cultured dairy products like yoghurt are



easier to digest than milk. If milk causes cramps or a feeling of fullness it is best to avoid it in the diet, but it is quite possible that yoghurt and sour milk will be tolerated.

- Beans, seeds and peas are good sources of protein and are cheaper than meat, eggs and milk products.
- Cover desserts with whipped cream.
- Use honey or jam on bread.
- Vitamin and minerals: Try to eat at least five to six portions of fruit and vegetables per day. Pure fruit juice can be used to decrease the bulk of the diet. Approximately half a glass of fruit juice is equal to one portion of fruit.
- Alcohol should be avoided.
- A multivitamin (containing all the vitamins) and mineral supplement, providing 100 to 150 percent of the the RDA per tablet is advisable, since it will be most unlikely that a person with AIDS will be able to meet the increased requirements for vitamins and minerals with diet alone (due to poor appetite). Any supplements, however, should preferably be given after consulting an expert health professional.
- Nutritional suggestions for symptoms caused by opportunistic infections and malignant diseases:
 - Nausea: Eat small, frequent meals (every two to three hours) and avoid high-fat greasy foods. Avoid lying down after eating. Food is best tolerated at cool or room temperature. Dry, salty crackers, pretzels, biscuits and cookies may also be tolerated. Simple foods such as rice, scrambled eggs, toast, noodles, bananas, mashed potatoes and custards may also be better tolerated. Allow plenty of fresh air in the house. Disperse cooking odours.
 - Sore mouth or throat: Eat soft, moist food at cool or room temperature (mashed potatoes, macaroni and casseroles). Use a straw to drink. Avoid spicy or acidic foods. Also avoid carbonated beverages and salty or acidic foods.
 - Dry mouth: Serve food with a sauce or gravy and consume foods with liquids at mealtimes. Drink extra liquids between meals. Concentrate on good oral hygiene.

Chewing sugarless gum or sucking mints may help.

- Diarrhoea: Try to eat six small meals per day. Fluid replacement is very important to prevent dehydration. Try to drink water and re-hydration drinks after every loose stool. (Home recipe for oral rehydration therapy (remember hygiene): 1 litre of cooled boiled water, 8 teaspoons of sugar and 1/2 teaspoon of table salt). A low fat and dairy diet may be indicated (damaged to the surface of the gut may cause intolerance to lactose; drinking milk or eating milk products can cause cramps, abdominal distress and diarrhoea in some people). Avoid gas forming foods and drinks (e.g. peas, lentils, cabbage, cauliflower, broccoli, onion, nuts, cucumber, beans, bran, garlic and beer). Avoid alcohol and caffeine, since both may have a dehydrating effect. Moderate fibre intake. Concentrate on soluble fibre (fruit, oats, and legumes). Limit the intake of fructose (fruit sugar) by avoiding apple and pear juice as well as grapes, honey, dates, nuts, figs and soft drinks. Eat and drink bananas, potatoes, fish, meat, apricot juice, tomato juice to replenish sodium (salt) and potassium. Eat foods that have been brought to room temperature.

NICUS offers a free information service and for further, personalised and more detailed information, please contact NICUS or a dietitian registered with the Health Professions Council of South Africa (previously known as the South African Medical and Dental Council). References available on request.

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HIV/AIDS: A women's disease

By Nitasha Moothoo-Padayachie.

Ms Padayachie is a journalist working for the Agenda Feminist Media Project – journal.intern@agenda.org.za

The MRC KZN AIDS Forum held a meeting on 23 March 2004 in Durban. This forum is an initiative by the Medical Research Council (MRC) to bridge the gap between science and the community; to develop a monthly platform for various stakeholders involved in HIV/AIDS to discuss issues that are pertinent and relevant to the way in which we respond to the pandemic; and, to improve communication and networking amongst the various stakeholders including government, civil society, scientists and community. Dr Mark Colvin of the MRC presented updated statistics on HIV.

The Reproductive Health Research Unit released a report called HIV and Sexual Behaviour among Young South Africans. This national survey released in April 2004 confirms that South Africa is in the grips of a devastating HIV/AIDS epidemic in which the peak incidence occurs among 15 to 24-year olds. Key findings demonstrate once again that young women are more vulnerable to HIV infection than men. The main reasons for this being poverty and power relations, which play a significant role in increasing HIV transmission.

With respect to forced sex and coercion, the survey found that among all sexually experienced youth who participated in the survey (67% of all those surveyed), only 30% of sexually experienced females reported really wanting their first sexual experience compared to 83% of sexually experienced young males. HIV prevalence among young people aged 15 to 24 is 10%, but, of this, 77% are women. The age group that is most affected are those between 20 and 24.

The fact that only 30% of girls welcomed their first sexual encounter is alarming, as it means that most women surveyed, were pressured into their first sexual experience. The fact that 83% of the men and boys in the study welcomed their first experience, shows that there is a definite gender divide in sexual encounters (the 83% refers to those who welcomed their first experience not the number who were experienced).

Dr Colvin's study also revealed that of the pregnant women who had HIV testing done at antenatal clinics in 2001, African and Coloured women between the ages of 25 and 29 had the highest HIV prevalence rate. The HIV and Sexual Behaviour among Young South Africans national



survey, and Dr Colvin's study, are definitely linked in terms of the outcome of statistics. It is likely that the fact that young, inexperienced girls are having an unpleasant first sexual encounter, contributes to the rise in HIV-positive pregnant women, especially among African and Coloured women.

According to Dr Colvin's findings, the most important demographic predictors of HIV are race, age, province of residence, marital status and gender. Education and economic status were not significant independent predictors of HIV status. The only behavioural variables that were independently associated with HIV were history of another sexually transmitted infection (STI) and whether or not the individuals' behaviour had changed because of the HIV/AIDS pandemic.

Although all these variables are highlighted as predictors of an increased likelihood of infection, it is important to note that gender is an important predictor of HIV/AIDS as revealed by the statistics which show women are at a higher risk of acquiring HIV/AIDS and that the nature of sexual relationships in girls contributes to the prevalence of HIV/AIDS.

"Sexual partners are on average four years older, making it more difficult for women to refuse unwanted sex or negotiate the use of condoms. Six percent of all sexually active youth said they had been physically forced to have sex." (Reproductive Health Research Unit, 2002).

Gender plays a major role in the HIV/AIDS pandemic.

Picture Gallery

Visuals of World Vaccine Day!



1. Cllr Dube chats with Dr A Robinson (Director: MRC HIV Vaccine Research Unit, HVRU) and vaccine trial participant, Joan McCosh



2. Traditional Healers applaud vaccine day



3. Sinikithemba choir



4. Patria Mpanza, traditional healer (HIVAN)