The challenges of developing new technologies for HIV prevention

A situation report on research and development of new HIV prevention technologies in Nigeria

By

M. O Ukpong and O Falobi

For

Nigeria HIV Vaccine and Microbicide Advocacy Group (NHVMAG)

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Table of Content

Editorial Page 3
Foreword
Abbreviations and acronyms
Summary

Introduction 8

Chapter 1: Situation report on HIV/AIDS in Nigeria 10
  Statistics 10
  Social and gender inequalities: a promoter of HIV infection 10
  The potential of new HIV prevention technologies and products for Nigeria 12
  Creating and enabling environment for research and development of new HIV prevention technologies in Nigeria 14

Chapter 2: Current status of research and development of new HIV prevention technologies 15
  Preparations for international collaborative HIV vaccine research 17
  Development of country specific candidate vaccine 17
  Phase III 6% cellulose sulphate trials 18
  Phase III Savvy trials 18
  Phase II trials of oral prophylactic use of tenofovir 18
  Other HIV prevention technologies 18
  Key players and institutions 18
  Regulatory process 22
  Civil society response 22
  National and international networking 23

Chapter 3: Situation report on HIV vaccine and microbicide research in Nigeria 25
  Successes of current response 25
  Gaps in current response 26
  Challenges for research and development of new HIV prevention technologies in Nigeria 35

Chapter 4: The way forward 37
  Recommendations 37
  Looking ahead 40
  Conclusion 42

References 43
Tables

Table 1:
New HIV Prevention Technology Development and Trials Sites, 2004
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Finally, to all advocates who look forward to seeing the realisation of a dream – the development, manufacture and access to new HIV prevention technologies in Nigeria in the nearest future – we together believe this write-up would help contribute to making a difference.

Morenike Ukpong
Omololu Falobi
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NHVMAG (pronounced ‘navmag’) is an acronym for the Nigeria HIV Vaccine and Microbicide Advocacy Group. It is a civil society group committed to mobilising popular participation and public support for HIV vaccine and microbicide research and development in Nigeria. Its mission is to halt the spread of HIV/AIDS in Nigeria by ensuring the availability of safe, effective and affordable HIV vaccine and microbicide products for all Nigerians as soon as it is available. NHVMAG works to ensure the proactive participation of Nigeria and Nigerians in global efforts for the development of HIV vaccine and microbicides. It recognises that there is an ethical imperative to seek, as urgently as possible, an effective and accessible vaccine and microbicide to complement other existing and emerging prevention strategies. NHVMAG is open to all Nigerian and seeks to partner with as many groups as possible.

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Situation Report on New HIV Prevention Technologies in Nigeria

Foreward
## Acronyms and Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Meaning</th>
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<tbody>
<tr>
<td>AAVP</td>
<td>African AIDS Vaccine Programme</td>
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<tr>
<td>AIDS</td>
<td>Acquired Immunodeficiency Syndrome</td>
</tr>
<tr>
<td>APIN</td>
<td>AIDS Prevention Initiative in Nigeria</td>
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<tr>
<td>ARV</td>
<td>Antiretrovirals</td>
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<tr>
<td>CBO</td>
<td>Community-Based Organization</td>
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<td>CDC</td>
<td>Centers for Disease Control</td>
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<tr>
<td>CONRAD</td>
<td>Commercial Sex Worker</td>
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<tr>
<td>CSW</td>
<td>European Agency for the Evaluation of Medicinal Products</td>
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<tr>
<td>ERB</td>
<td>Ethics Review Board</td>
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<tr>
<td>FBO</td>
<td>Faith Based Organisation</td>
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<tr>
<td>FHI</td>
<td>Family Health International</td>
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<tr>
<td>FMOH</td>
<td>Federal Ministry of Health</td>
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<td>FWI</td>
<td>Global Campaign for Microbicide</td>
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<tr>
<td>HEAP</td>
<td>HIV/AIDS Emergency Action Plan</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>HVTN</td>
<td>Human Vaccine trial Network</td>
</tr>
<tr>
<td>IAVI</td>
<td>International AIDS Vaccine Initiative</td>
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<tr>
<td>ICASA</td>
<td>International Conference on AIDS and STIs in Africa</td>
</tr>
<tr>
<td>IEC</td>
<td>Information, education and communication</td>
</tr>
<tr>
<td>IHV</td>
<td>Institute of Human Virology</td>
</tr>
<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
</tr>
<tr>
<td>JUTH</td>
<td>Jos University Teaching Hospital, Nigeria</td>
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<tr>
<td>LUTH</td>
<td>Lagos University Teaching Hospital, Nigeria</td>
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<tr>
<td>MSM</td>
<td>Men who have sex with men</td>
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<tr>
<td>MTCT</td>
<td>Mother To Child Transmission</td>
</tr>
<tr>
<td>NACA</td>
<td>National Action Committee on AIDS</td>
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<tr>
<td>NAFDAC</td>
<td>National Agency for Food and Drugs Administration and Control</td>
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<tr>
<td>NERB</td>
<td>National Ethics Review Board</td>
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<tr>
<td>NGO</td>
<td>Non-Governmental Organisation</td>
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<tr>
<td>NHVMAG</td>
<td>Nigeria HIV Vaccine and Microbicide Advocacy Group</td>
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<tr>
<td>NIH</td>
<td>National Institute of Health</td>
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<td>NIMR</td>
<td>Nigerian Institute of Medical Research</td>
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<tr>
<td>NIPRDT</td>
<td>National Institute of Pharmaceutical research and Drug Development</td>
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<tr>
<td>PLWHA</td>
<td>Persons Living with HIV/AIDS</td>
</tr>
<tr>
<td>SAAVI</td>
<td>South African AIDS Vaccine Initiative</td>
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<tr>
<td>Savvy</td>
<td>Savvy/CG13 microbicide study product</td>
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<tr>
<td>STIs</td>
<td>Sexually Transmitted Infections</td>
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<tr>
<td>UCH</td>
<td>University College Hospital, Ibadan, Nigeria</td>
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<tr>
<td>UMTH</td>
<td>University of Maiduguri, Nigeria</td>
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<tr>
<td>UPTH</td>
<td>University of Port Harcourt Teaching Hospital, Nigeria</td>
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<tr>
<td>UNAIDS</td>
<td>United Nations Agency for International Development</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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Summary
1 New prevention technologies and the future of the HIV/AIDS epidemic

AIDS presents an unprecedented challenge. Recent figures released by UNAIDS and WHO show an estimated 37.8 million people now living with HIV worldwide. AIDS is the leading cause of death in sub-Saharan Africa, where the disease killed 2.3 million people in the year 2003 alone. AIDS poses a serious threat to the achievement of all key international development goals, not just those in health. In many countries, it is single-handedly reversing the hard-won development gains of the last 50 years.

Worldwide, it is recognised that the current AIDS prevention efforts – including HIV counselling and testing, promotion of abstinence, mutual fidelity, partner reduction, delay of sexual debut and condom use – must be sustained and increased, and new efforts to expand access to treatment are critical. At the same time, the rapid spread of the epidemic and its dire social, political and development ramifications highlight the urgent need to broaden the range of available prevention strategies and to see new prevention research in the context of a comprehensive AIDS control programme that includes prevention, care and treatment. This is in view of the fact that despite increased funding, political commitment and progress in scaling up presently available responses, the epidemic continues to outpace the global response.

While it is significantly important to scale up existing interventions so as to prevent new infections and save lives today, current responses will be limited even if fully implemented. Treatments can prolong life, but they are not a cure. Present prevention options can reduce rates of HIV incidence but will not end the epidemic. Without prevention options that can better meet the needs of people at risk of transmitting or contracting HIV, continued HIV incidence will place higher and higher demands on resources, making comprehensive programmes unsustainable.

In the long term, new prevention tools will play a critical role in ameliorating the effects of the AIDS epidemic especially in the settings that are hardest hit. To meet this need, a growing array of public, commercial and non-profit entities are engaging in the search for vaccines and microbicides to prevent HIV transmission.

Historically, research and development of new health technologies was limited almost exclusively to the industrialised world, and new products were licensed based on data from efficacy trials conducted mainly in Europe and the United States. This contributed to a lack of research on many urgent global health issues and major delays in the delivery of new products to the developing world which is presently worst affected by the HIV epidemic.

In a bid to reverse this trend, scientists and governments in developing countries are presently engaged in establishing a relevant scientific agenda for the development of new HIV prevention options – including product prioritisation; developing new clinical trial sites and facilities; training and supporting developing country scientists; and creating an enabling policy environment – all necessary priorities and prerequisites for
delivering new products to halt the spread of HIV. The focus is that of developing meaningful partnerships between scientists in developing and developed countries as well as ensuring community involvement and partnership in the development process thereby ensuring a scientifically driven, product-focused research programmes with ensured community ownership. This new scientific research paradigm should ensure the delivery of these most urgently needed products in the shortest time possible.

With scientifically driven, product-focused research programmes, researchers, policy makers and communities can benefit from research efforts that bring additional resources for training, testing and treatment. Development of new prevention technologies such as microbicide and vaccine will not only ensure more efficient options for controlling HIV infection; it will also ensure that this happens through partnerships that enhance the capacity of developing country scientists, strengthen infrastructure, and accelerate the availability of health products where the needs are greatest.
UNAIDS reported that at the end of 2003, 37.8 million people were living with AIDS globally with almost 5 million new infections in the same year alone. Seventeen million people, or 48% of the total, are women. In sub-Saharan Africa, 25 million people are living with the virus with the infection rate appearing to be stable only due to increased death from AIDS and an equally increasing rate of new infections. Presently, there are about 3 million new infections in the year 2003 alone in sub-Saharan Africa. Of the 17 million women living with the virus, 57% are from sub-Saharan Africa. Furthermore in Sub-Saharan Africa, 75% of HIV infected young people, aged 15-24, are women and girls. In other words, young women are three times more likely to be infected with HIV than their male counterparts with infection rate for women going up from 12 for 10 infected men in 2002 to 13 in 10 infected men in 2003.

This global picture is very similar to that of the Nigerian HIV epidemic. Reports of the 2003 HIV sero-prevalence sentinel survey released in April 2004 by the Federal Ministry of Health show that the national prevalence had dropped from the 5.8% reported in 2001 to 5.0% with a range from 1.2% to 12.0% for the various states. The number of people living with HIV/AIDS is presently estimated at between 3.2-3.8 million persons. In addition, the average prevalence amongst women in the reproductive age group 15-29 years is slightly above the national prevalence (5.4%). Specifically, the prevalence is 5.6% in women age 20-24 years, 5.4% for women 25-29 years and 5.2% for women 15-24 years (page 29; 2003 HIV sero-prevalence sentinel survey report). There is also a high HIV prevalence amongst persons with primary and secondary levels of education which suggests additional risk of exposure for female students (page 8; 2003 HIV sero-prevalence sentinel survey report). Identified risk factors for the HIV infection in Nigeria are heterosexual sex and blood transfusion in addition to social and gender inequality.

Social and Gender Inequalities: a promoter of HIV infection

That HIV prevention is difficult in Nigeria comes as no surprise. Most societies in Nigeria hardly talk openly about sex; effecting changes in how, when and with whom people have sex is never easy. Indeed, if support for sexual and reproductive health and rights is taken as a marker of attitudes to issues of sex and sexuality, then the inadequate and uneven progress made in the country on ensuring gender equity in sexual and reproductive health rights – a far cry from the international objectives set out at the International Conference on Population and Development in Cairo in 1994 (and revised in 1999) - shows how challenging the environment is.

Social inequalities and marginalisation add to these difficulties and skew the impact of HIV on different groups. In Nigeria, gender inequities present particular challenges to HIV prevention. Biologically, women are four times more susceptible to HIV infection than men when exposed to HIV during sexual intercourse. Moreover, in Nigeria, women disproportionately lack access to information and services, and do not have the power to insist on sexual and reproductive health rights or HIV prevention choices. Current prevention options, such as male condoms or mutual fidelity, require the
cooperation of male partners. Although female condoms have provided an additional option in some countries, uptake in Nigeria has been low, partly due to limited support for procurement and introduction. As a result women make up 53% of all people living with HIV in the country and are becoming infected 1.2 times faster than men. Young women are particularly at risk, representing 52% of people living with HIV between the ages of 15 and 24. As UN Secretary General Kofi Annan, has said, ‘in Africa, AIDS has a woman’s face.’ Likewise in Nigeria, HIV/AIDS has a female face.

The Potential of New Prevention Technologies and Products for Nigeria

One of the agenda for consideration listed in the UNAIDS 2003 report on global HIV/AIDS situation is the need to implement strategies that take into account the disproportionate impact of the epidemic on women, girls and orphans. Effective new prevention technologies such as microbicides, HIV vaccines, the use of antiretrovirals as prophylaxis against HIV infection, prevention of mother to child transmission through breast milk and the development of rapid tests kits would offer considerable benefits if added to existing HIV prevention efforts. Despite the gloomy picture that HIV infection presents in the country, it should not be forgotten that more than 90% of the population have not acquired HIV. Enabling them to remain HIV-free is a massive challenge, with the protection of young people an urgent priority. These new prevention technologies would help to cut off a potential chain of infections resulting from the primary infection thereby protecting and preventing new infections from developing; infections that would eventually drive the need for increased spending on ARVs.

**Potentials as a female control option:** Both vaccination and microbicides could put women in control of prevention decisions. Equally, vaccines and microbicides may overcome difficulties associated with condoms, such as lack of choice over contraceptive function or perceived loss of intimacy. Microbicides delivered in long-acting or sustained release formulations could be applied many hours or even days prior to sexual relations so that, like vaccines, they would not interfere with sex. In addition, microbicides may be effective against a broad range of STIs. Vaccines hold the promise of protection from HIV that is not dependant on repeated use. Ideally, effective vaccination will protect individuals from HIV infection before they become sexually active or begin other potentially high risk activities including being blood product recipients.

**Potentials for the general population:** All new HIV prevention technologies would indeed offer increased protections to the generally larger uninfected population. The possibility of use of Tenofovir, an antiretroviral drug as a prophylactic agent in uninfected individuals is a research concept that presently is being pursued with vigour.

The complementary effects of HIV vaccines and microbicides have also been outlined in various studies. While microbicides are designed to act directly against HIV, the vaccines act indirectly, simulating immune responses that in turn combat HIV infection. They complement themselves in terms of breath, duration and onset of protection. While HIV vaccines presently being developed are clade or subtype specific (though recent studies point to the possibility of developing efficacious vaccines against
diverse HIV subtype) in comparison, microbicides are expected to be equally effective for all known HIV subtypes.

On the other hand unlike microbicides, vaccines many protect not only against sexual transmission of HIV (presently research is limited to assessing the effectiveness of candidate products for vaginal transmission) but also, transmission via other routes of exposure including parental transmission and possibly mother to child transmission (MTCT) during gestation and breastfeeding.

While recipients of vaccines wait for weeks after immunization to achieve peak responses and may need repeated booster immunization the immediately effective microbicide could be used for conferment of protection. Though, there may be need to be reapply the topical microbicide but then, its time of onset of action is sooner than that of vaccines though its effects is of shorter duration.

The development of highly sensitive non invasive rapid test kits for HIV infection would enhance the prompt and correct diagnosis of HIV infection. The less invasive the procedure, the greater the chances that people would like to take the test. In addition, the cost of the test may also reduce as fewer materials would be need for the processing of results. With increased sensitivity and specificity of tests kits, the need for confirmatory tests may eventually be eliminated and the less the tendencies for false negatives and false positive results. Results of tests can also be obtained immediately following counseling sessions thereby enabling clients to start instituting precautionary behaviour measures immediately once tests results are known.

**Potential benefits for PLWHA:** Microbicides and HIV vaccines would represent an important and necessary tool in the lives of people infected with HIV by protecting reproductive health and promoting healthy sexuality. On one hand, the microbicide can protect against sexually transmitted infection other than HIV, which poses a larger danger when one’s immune system is challenged. A broad acting microbicide found effective against multiple STIs would help prevent contraction of these dangerous infections when used by recipient sexual partners.

For women, it may even promote healthy vaginal conditions to ward off yeast infections or bacterial vaginosis. In line with the United Nations agencies recommendation of a three prong approach to prevent the transmission of HIV to infants, a developed microbicide would help to prevent primary infection among parents to be, prevent unwanted pregnancy amongst HIV positive women and prevent HIV transmission from HIV positive women to their infants. When used in the vagina by an HIV positive woman, it may help protect the partner who may not use condoms. There would also be non contraceptive microbicides developed along side with contraceptive types. The non contraceptive microbicides will give positive women who want to have babies the ability to do so with less risk to the HIV negative partner while the contraceptive microbicides would give women another way to avoid unwanted pregnancy. And as the science and research of microbicide

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**Potential benefactors of new HIV prevention technologies in Nigeria**

- women
- expectant mothers
- the general population
- persons living with HIV/AIDS
- Men who have sex with other men
- The health system
advances, it would be able to formulate vaginal wash to help prevent mother-to-child transmission of HIV during childbirth as a backup for antiretroviral intervention.

On the other hand, the focus of HIV vaccine development is to develop both a preventive and a therapeutic vaccine. A therapeutic vaccine would prevent the progression of HIV infection and thus would be highly beneficial for anyone infected with HIV. Its goal is to enhance antiviral activity, enhance immune reconstitution and facilitate preventive efforts. Its development is highly important in view of the limitations of chemotherapy especially in terms of cost, access and need for toxicity monitoring.

Presently, the use of Nevirapine reduces the incidence of MTCT of HIV infection to just about 2-5%. Nevirapine helps to prevent transplacental transmission of HIV infection. However, transmission of the infection via the breast milk is still quite high and presently accounts for the large number of infections seen in children. A lot of research efforts are going on into discovering ways to reduce this form of HIV infection transmission in positive mothers. The pasteurization of breast milk at 60°C for 20 minutes has been shown to kill the virus. However, the devise is too expensive and so is not affordable for individual use. Also, because of the high level of stigma associated with HIV infection, positive mothers still go ahead to breastfeed the child despite being counseled on the implications for transmitting the infection to the child. This is because eyebrows are raised when a nursing mother does not breastfeed the child and this increases the tendency for community members to suspect the mother as being HIV positive. Although microbicide might be a possible promising substance for the attenuation of the virus in the breast milk when added to the breast milk, there are presently no global research in this direction. There are various other international researches going on on the possibility of developing drugs that could prevent HIV transmission through the breast milk.

**Potential benefits for MSM:** There are researches focusing on the development of rectal microbicides which would be of significant benefit for all persons practicing anal intercourse including MSM. HIV is significantly more easily transmitted to a receptive partner (male or female) during anal sex than during vaginal sex. There is an ongoing phase 1 trial of a prospective rectal microbicide (Carraguard). This would definitely be of great benefit for the identified MSM population in Nigeria and others who practice anal intercourse.

**Impact on the HIV epidemic:** Even with limited initial efficacy, studies show that vaccines and microbicides could add significantly to the effectiveness of current prevention strategies. Initial modeling by the London School of Hygiene and Tropical Medicine has suggested that a 60% effective microbicide used by 20% of people currently in contact with HIV prevention services in the 73 low-income countries could avert over 2.5m infections in 3 years after its introduction.iii A study commissioned by the World Bank and the European Commission has estimated that a 50% effective HIV vaccine delivered to 65% of adults could reduce infection rates by 25% - 60% depending on the nature of the epidemic in which it is used.iv

**Impact on the health system:** Presently, prevention programmes are not reaching all the people that need them. Less than one in five people worldwide have access to
prevention programmes. This disparity increases as the level of education, regional development and education decreases. The already weakened health system is made to cope with an increased burden of caring for the sick. These research programmes help to strengthen health structures and systems where they exist, facilitate and enhance prevention programmes and help increase the access of infected persons to ARV treatment programmes. Examples of developing countries which have strong research and development programmes for new HIV prevention technologies include Brazil, Uganda and Thailand. These countries have harnessed the strengths of these programmes to improve their health care delivery systems and in turn, make a positive impact on the national HIV prevalence level. Presently these countries have recorded a decrease in their national HIV prevalence levels.
3

Status of HIV vaccine research in Nigeria

Brief background on international vaccine research efforts

In November of 2002, the Vaccine Research Centre of the National Institute of Allergy and Infectious Diseases, National Institutes of Health (VRC) of the NIH launched a Phase I clinical study of a novel DNA vaccine directed at the three most globally important HIV subtypes, or clades. The vaccine, developed by the VRC, incorporates HIV genetic material from clades A, B and C, which cause about 90 percent of all HIV infections around the world. This is the first multigene, multiclade HIV vaccine to enter human trials and marks an important milestone in the search for a single vaccine that targets U.S. subtypes of HIV as well as clades causing the global epidemic.

This VRC initiated vaccine research is a follow up to previous HIV vaccine research efforts which had started before 1987 in the USA. During a VRC organized meeting held on July 31st 2001 meeting on the development of HIV candidate vaccines for the developing world, participants recommended that testing of multivalent vaccines should proceed and that, due to practical limitations, the clades selected should be representative rather than country specific.

There are trials presently being conducted in 19 countries, including African countries like Uganda, South Africa, Botswana and Kenya, on more than 30 possible vaccines. Unfortunately, none of the studies focus on the clade predominant in the West African subregion and in Nigeria - the AG recombinants (CRF02). Most of these trials had focused on Clades A, B, C and E, the prevalent strain in the Americas, Europe, Asia and Southern, Central and Eastern Africa.

In the two decades since the virus was identified, only one vaccine candidate has completed human trials. The result of that completed phase III trial conducted in Thailand showed that the product could not induce significant protection. Preliminary results from the second phase III trial been conducted in USA study also shows that the vaccine failed to confer protective efficacy in the majority of the population. A full report is still been expected.

There are another 27 candidate vaccines undergoing phase I trials, four at phase II trials. Twenty of these phase I/II trials were completed in developing countries, the majority in Thailand (nine trials), but also in Brazil, Cuba, Haiti, Kenya, Peru, Trinidad and Uganda. Only five phase I/II HIV vaccine trials were conducted in Africa with ongoing trials in Uganda and Botswana.

This slow pace in global HIV vaccine development drive is not just due to the ever changing face of the virus but in addition, and very majorly so, the global neglect of the vaccine quest.

While there is continued dialogue between those institutions with the expertise to develop vaccines and countries, including African countries, in which testing is needed and critical to the process of development of an effective vaccine, many questions still
remain unanswered such as whether viral genotype or route of transmission affect efficacy. In order to address these questions, multiple parallel trials in different populations, as well as close and continuous international coordination and cooperation, are needed so as to address the urgent need to develop a vaccine that can protect against a wide variety of genetically diverse viruses.

To this effect, the G-8 endorsed the establishment of a Global HIV Vaccine Enterprise, a virtual consortium to accelerate HIV vaccine development by enhancing coordination, information sharing, and collaboration globally on April 29, 2004. With this endorsement, the USA would be investing $488 million in HIV vaccine development in fiscal year 2004 and $533 million in 2005. Other G-8 members and donors were urged to increase their commitment. The Nigerian Government was present at the meeting and would be expected to make similar commitments to international HIV vaccine research and development efforts.

The National HIV/AIDS Emergency Action Plan (HEAP)

The HIV/AIDS Emergency Action Plan (HEAP) was developed as a response strategy to the HIV/AIDS epidemic. It is the product of a consultative participatory process involving all sectors, states, all tiers of government in all the six geopolitical zones in the country. The development process also had input from partners and international collaborators and stakeholders. The plan was launched in 2001. It highlights over 200 activities which the Federal Government of Nigeria intends to pursue over the period of 2001 to 2004. Most of the activities were conceived as short term high impact interventions whose implementation will form the base for a medium term strategic plan for HIV/AIDS in Nigeria as well as act as a bridge to the definition of a longer term vision for the future.

Three the 16 guiding principles of the HEAP which has relevance to new HIV prevention technology research and development are:

a. to increase awareness and sensitisation among the general population and strategically targeted stakeholders
b. to stimulate research, documentation and research networks in Nigeria
c. to recognise that a proactive and aggressive response to gender issues rests at the very heart of the development of a cohesive and crosscutting strategy for the prevention and mitigation of HIV/AIDS impact on Nigerian society

In line with its guiding principles, the document then went on to strategise the document into two components namely:

a. creation of an enabling environment
b. specific HIV/AIDS interventions

This comprehensive document focused on integrating all prevention, care and support structures into a comprehensive plan for HIV mitigation and control for the country. Strategic plans and programmes to be implemented for each of the two focused components of the documents were well enumerated. However, the document did not make specific notes on national strategies for HIV vaccine and research and development.
National policy on HIV/AIDS

The 2003 edition of the National Policy on HIV/AIDS is a revised edition of the national HIV/AIDS policy. This document is meant to complement the HEAP. The overall goal of the policy is to control the spread of HIV/AIDS in Nigeria and to mitigate the impact to the point where it is no longer of public health, social and economic concern. The document has 12 specific objectives of which two are relevant to new HIV prevention technology research and development. These are:

a. removal of all possible barriers to HIV/AIDS prevention and control
b. stimulation of research, monitoring and evaluation programmes

Structurally, the policies focus on five strategic components for achieving its 12 goals. The document notes that one of the problems there are to its programme implementation is the difficulty in achieving sexual behaviour change and increasing condom use during risky sexual behaviour amongst its citizens (paragraph 1 page 10). Where little success has been achieved, the process of achieving this had been slow. The need to remove barriers to successful and fruitful prevention intervention programmes therefore remains a challenge. One of the identified strategies is to scale up existing prevention programme and make them more effective by ensuring the monitoring and evaluation of programmes and encouraging Nigerian related researches to ensure programmes are specifically tailored for Nigerians. In line with the identified need for monitoring, evaluation and research, the fifth outlined strategy of the policy document is Programme Management and Development.

To promote and enhance programme management and development, four strategies were identified including the need for research and development of HI vaccine (page 40-41). The document highlights two directions the government would be focusing its effort for vaccine research and development. These are:

a. Defining and implementing strategic initiatives designed to promote and accelerate development of a nationally based vaccine research protocol
b. Ensuring the compilation of HIV vaccine research protocols with NACA and the FMOH.

These would be done through the academic and research institutions and ministries with the international support and collaboration

National HIV Vaccine Development Plan

The National HIV Vaccine Development Plan is a comprehensive document which recognises the need to ‘facilitate the research and development of both preventative and therapeutic HIV vaccines which will be cheap, effective, safe, easily administered, stable under adverse weather conditions and able to induce protective immunity against prevalent strains of HIV in Nigeria and West Africa’.

The document listed four objectives which include:

a. The articulation of a comprehensive, well articulated, well coordinated, long term strategy for the development and evaluation of safe, immunogenic and efficacious preventive, therapeutic and perinatal HIV vaccines in Nigeria
b. To develop and explain the policies and procedures for the planning, implementation, oversight, administration and evaluation of HIV vaccine related research activities in Nigeria.

c. To facilitate and support the conduct of scientifically and ethically appropriate HIV vaccine trials in Nigeria.

The document took into cognisance efforts and support of regional and international commitments to the development of new prevention technologies in its development efforts. It spelt out in details technical and ethical review processes for proposals and protocols for HIV vaccine research (item 7.3 & 7.4), prerequisites for conducting efficacy studies (item 8.0), monitoring of vaccine trials (item 7.6) and the specific research agenda for HIV vaccine trials in Nigeria (Item 9). Item 7.7 spells out the need for communicating with and providing the public with information on ongoing HIV vaccine research effort in the country by NACA. The National Vaccine Working Group will oversee to the overall implementation of the document. It has the responsibility of vetting all HIV vaccine trials, serves as a liaison to stakeholders in both the federal and state governments and also serves in an advisory capacity to the Federal Ministry of Health Regulatory Process for approval of drugs, vaccines and biologicals.

The comprehensive document also carefully outlined the roles of all stakeholders including the Federal Government, the FMOH, NACA, the National Ethics Board, the regulatory agency (NAFDAC) and the National Vaccine Working Group. This is all towards ensuring efficiency and streamlines all HIV vaccine research and development related activities.
4

Status of microbicide research in Nigeria

Brief background on international microbicide research

Topical microbicides are antimicrobial agents formulated for application to the surface of the vagina and/or rectum for the prevention of HIV transmission during sexual intercourse. This prevention strategy is urgently needed throughout the world because many individuals at high risk of transmitting or acquiring HIV infection cannot or will not use condoms with every act of sexual intercourse. Reasons for lack of effective condom use include power imbalances in relationships that result in the inability of the receptive partner to negotiate condom use, physical discomfort and decreased sexual pleasure.

More than 50 candidate agents have shown in vitro activity against HIV and other STDs. Several of these agents have demonstrated safety and efficacy in animal models. By March 2004, there were 44 microbicide candidates in preclinical development and 18 in clinical development. Phase I/II studies of some of these new products, including 6% cellulose sulphate and Pro 2000, have demonstrated safety. Presently, there are four of these microbicide candidates in phase III trials. Results of these phase III trials will be out in the next three years, and they could be on the market in another five years.

Several formulations of nonoxynol-9 (N-9) have been tested at various concentrations in humans for safety and effectiveness. Four randomized controlled trials have shown that use of N-9 does not protect against HIV infection. Higher doses and more frequent use of N-9 have been linked to increased findings of genital lesions which increase the susceptibility to HIV infection. N-9, the first prospective microbicide, was therefore found not to be effective in protecting against HIV infection.

Efforts are therefore focused on developing other products for use as microbicides, an additional strategy that hopefully would expand options among affected populations and increase the population that may be protected from infection. They should complement HIV vaccines in terms of breath, duration and onset of protection. While HIV vaccines presently being developed are clade or subtype specific (though recent studies point to the possibility of developing efficacious vaccines against diverse HIV subtype) in comparison, microbicides are expected to be equally effective for all known HIV subtypes. In addition, while microbicides are designed to act directly against HIV, the vaccines act indirectly, simulating immune responses that in turn combat HIV infection. The complementarity of these products facilitates the need for simultaneous and focused development of microbicides to the non-exclusion of an HIV vaccine.

Background on national microbicide research

Nonoxynol-9 studies in Nigeria: The Port Harcourt Teaching Hospital conducted research on the acceptability of the gel or foam of Nonoxynol-9 film for STI/ HIV prevention amongst the Nigerian populace. This study was done in the late ‘90s, in partnership with Liverpool University. The study was carried out among female
students of a higher school in Port Harcourt and was to have lasted for about three years. About 2,850 eligible female students, aged between 16 and 20 were to be enrolled for the study. It was actually planned that all female students in the university were to be registered for the study but about 95% of them were eventually registered at the end of three school years.

The study design entailed the administration of baseline questionnaires to all eligible students. Clinic cards bearing their study numbers were also issued. All interviewed students were invited to the field clinic located within the school’s sickbay.

Questionnaires were reviewed by an employed field coordinator who registered the students in the clinic books noting their sexual status. All none sexually experienced (NSE) girls were given urine test and reproductive health counselling. Few of them who presented symptoms of virginal discharge or itching were tested and treated.

All sexually experienced girls underwent STD screening at their first visit at the clinic. Those who were positive for any STD were treated and a confirmatory test performed. Serum samples were also collected for a ‘blind’ HIV/AIDS test. After this none sexually active (NSA) participants, meaning those without current sexual partners were given reproductive health counselling and asked to return if they change their status or if they have other reproductive health problems.

The third category of participants, those with current sexual partners or sexually active (SA) were introduced to the microbicides and those who were interested were enrolled.

The Microbicides were of two kinds - vaginal foam and film both containing the active ingredient nonoxynol 9. Participants were asked to choose either of the two microbicides and were given a coital diary. The diary was for the purpose of recording information such as partner profile (age, occupation, place met, how long between first met and first intercourse, etc. Different sheets were used for different partners). The diary was also used to record the type of sexual activity that took place, for instance, anal, virginal and oral and also if the microbicides was used at every intercourse. The participants were asked to return after a week for a review.

At Week 1 visit, if volunteers had used the microbicide, a high vaginal swab will be taken and the participant asked to return after three weeks. The same process was observed with this second visit. Besides all these, all sexually active participants were required to do full STD screening every three months.

It was the duty of the field workers to remind participants of their appointments. They also traced participants who had STDs. Drugs were sometimes given to infected participants to give to their partners and a few partners also came to the clinic to be treated.

About 50% of the eligible participants eventually used the microbicides. However, as soon as the UNAIDS multi-centre N9 effectiveness study results were released and it was found that Nonoxynol-9 causes cervical abrasion when used repeatedly, further analysis of the results from the study was terminated and the trial discontinued..
wealth of baseline data on STIs from that study was never shared with the Nigerian researchers.

**Phase I 6% sodium cellulose trials:** Cellulose sulphate based microbicide products are adsorption inhibitors; they provide a physical barrier that keeps HIV and other pathogens from reaching the target cells. A Phase 1 (Safety and acceptability) study was done between the 16th December 2001 and 4th July 2003 by the Centre for Research in Reproductive Health (CRRH), Sagamu, Nigeria. This was a multi-centre study involving the Department of Obstetrics and Gynaecology, Makerere University, Kampala, Uganda; the National Institute for Research in Reproductive Health, Mumbai, India and the Institute of Tropical Medicine, Belgium. The study was funded by WHO and sponsored by CONRAD, USA. The study was approved by the Scientific and Ethical Review Group of WHO/RHR. Ethical approval was obtained in country from Research and Ethics Committee, Olabisi Onabanjo University Teaching Hospital, Sagamu.

The primary objective of the randomised, close-label comparative study was to determine and compare the effect of twice-daily vaginal application of 3.5 ml 6% Cellulose Sulphate (CS) or 3.5 ml K-Y Jelly for seven consecutive days on symptoms and signs of irritation of the genitalia, cervix and vagina and epithelial disruption as seen on colposcopy among sexually abstinent and sexually active women. The secondary objectives were to assess changes in vaginal health by results of wet mount and Gram stain as well as assess the acceptability of the microbicide.

Sixty women aged 19 - 44 years (mean: 32 years in each group) were recruited from Sagamu, Nigeria. The women were divided into two groups based on consecutive recruitment and randomised placement. Women in one group were required to abstain from intercourse during product use while intercourse was allowed in the second group. Vaginal health was monitored by the results of bacteriological investigations while product acceptability was assessed by the administration of structured questionnaires to volunteers.

The study showed that the differences noted from the colposcopy examinations of the vagina and cervix of women in the two trial arms was not significant and therefore, twice daily vaginal applications of 6% cellulose sulphate appear to be safe and well tolerated. Similar results were obtained by investigators in Mumbai and Kampala.

**Lime use as microbicides:** Interest in the use of lime could prove to be both an effective contraceptive and a microbicide with anti-HIV potential without destruction of the vaginal mucosa. The Nigerian study was based on preliminary reports from health care workers in Northern Nigeria that noted that significant number of female commercial sex workers in the region douche with lime juice before or after sexual intercourse with clients.

In October 2003, a pilot study was then conducted in the northern Nigerian cities of Maiduguri, Kano and Abuja to explore the specifics of the use of limes by the CSWs and to assess the feasibility of designing a more detailed study, including a statistical analysis of the possible associations between the use of lemon or lime juice, HIV status, sexually transmitted infections and pregnancies. The principal investigator was
Professor Malcolm Potts, Professor of Population and Family Planning, University of California, Berkeley working with other investigators from UC Berkeley and collaborating with a Nigerian non-profit organization named Girl Child Concerns. The study was sponsored by Venture Strategies for Health and Development, the Bixby Program, and the Center for Entrepreneurship in Health and Development of the School of Public Health, University of California, Berkeley. The study protocol was approved by the UC Berkeley Protection of Human Subjects Committee.

One hundred and four commercial sex workers were recruited for the study. Forty-four women used lime juice when they had intercourse and 60 did not. Users usually mix the juice of one to four limes with water and then douche with the solution.

There were insufficient numbers in the feasibility study to provide statistically significant results, but the trends that became apparent suggest that the douching with lime juice may have a protective effect against vaginal infections. Compared with non-users, fewer lime users had vaginal discharge, candida or trichomonias infection. Lime users had healthier vaginas and fewer grade 4 inflammatory. The feasibility study demonstrated that the population of CSWs in two of the three cities and the skills of the collaborating professionals in the region make an expanded study possible. Strong recommendations were then made by the investigators to initiate an expanded study as soon as possible.

**National policy on microbicide research and development**

The HEAP identified the need to empower women to determine their own standards of sexual behaviour. It outlined limited strategies to enhance women empowerment. There were however, no specific plan or strategies outlined to support researches into the development of microbicide. None of the national policies on HIV/AIDS made references to microbicide.
5
Current status of research and development of new HIV prevention technologies

National vaccine research and development

Preparations for international collaborative HIV vaccine research: For any HIV vaccine research process, it is important to put basic structure in place such as the development of a good research site fitted with basic infrastructures, building of in-country manpower skills and experience, and the development of cohort for the study.

The Asokoro Hospital, Abuja, is being developed as an initial site for conducting phase I and II HIV vaccine clinical trials as well as a site to help build in country capacity for vaccine research. Initial rehabilitation was undertaken indirectly by the Federal Ministry of Health through the Hospital’s Management Board in preparation for possible international collaborative studies on various phases of HIV vaccine trials. The hospital has adequate space available with a fully prepared and cooperative hospital management team. The staff had also been fully mobilized for possible international collaborative HIV studies. Its laboratory is also equipped to handle specimen and process basic data information for such researches. One of its strong asset as a centre for clinical trial studies is the fact that the hospital is a good community hospital.

Training of staff members to enable them to undertake such ‘high tech’ research begun via Fogarty International training grant in February 2004. It has since done a surveillance study amongst populations with high risk behaviours as well as an incidence study (seroconversion study) amongst various Nigerian populations.

The CDC/IHV/NIH vaccine HVTU site assessment of the hospital was done in February 2004. The joint panel of NIH/CDC/IHV also drew up a strategic site development programme that month for the hospital.

Present international collaborators for the hospital projects are UNAIDS, APIN, HVTN, IAVI, CDC, AAVP and the IHV. Local collaborators are NIPRD, Abuja, NIMR, Lagos, UCH, Ibadan, UMTH, Maiduguri, Plateau Hospital, Jos, JUTH, Jos and the CDC Assisted Laboratories (Kano, Nnewi, Benin and the National Hospital).

Development of country specific candidate HIV vaccine: The Gede AIDS and Infectious Diseases Research Institute (GAIMI) is stepping up its effort in the development of novel drugs and vaccines for HIV. Tremendous efforts have been put into building its clinical trial facilities with good laboratory and clinical practices. In addition, the Institute has started its community preparedness studies for awareness and cohort development. The centre has developed a candidate vaccine construct specific for the prevalent HIV vaccine strain and this construct is presently undergoing preclinical (animal model) studies. There are substantial international collaborations on the project and these include the Aeras Global TB Vaccine Foundation, Maryland, USA; Large Scale Biology Inc, California, USA; NIH, Bethesda, USA; National Cancer
Institute, USA; CDC Atlanta, USA; Federal University of Rio de Janeiro, Brazil; University of Regensburg, Germany and the University of Milan, Italy.

Some local collaborators are the National Public Health laboratory, New Owerri General Hospital, Abakaliki, Ebonyi state; Federal Medical Center, Azare, Bauchi State; Aminu Kano Teaching Hospital, Kano, Kano State; Ministry of Health, Federal Capital Territory, Abuja; Federal Medical Center, Yola, Adamawa State; Kano State Ministry of Health, Kano, Kano State; Hope Worldwide, Lagos; Mother Welfare, Kaduna, Kaduna State; Maitama General Hospital, Abuja and the Primary Health Center Gwagwalada, Abuja.

National microbicide research and development

**Phase III 6% cellulose sulphate trials**: Cellulose sulphate is a fusion inhibitor. The product contains a synthetic polymer that binds to the HIV virus, thereby disrupting binding of the virus to target cells. The gel probably works in a similar fashion to block chlamydia and HSV-2 (herpes) infections.

This multi-center phase III trial is a masked, randomised placebo controlled trial to determine the effectiveness and safety of the product as a vaginal gel for the prevention of male to female vaginal transmission of HIV infection among women of high risk. This would be assessed by the incidence of HIV-1 and HIV-2 infection as determined by detection of HIV antibodies from oral mucosal transudate (OMT) specimens.

The trial also has a secondary objective which is to determine the effectiveness of cellulose sulphate gel in preventing male-to-female transmission of gonorrhea and chlamydia among women at high risk of sexually transmitted infections. This will be assessed by Incidence of genital gonorrhea or chlamydia as determined by DNA probe technology from self-administered vaginal swabs.

The trial is being conducted in two centres in Nigeria (LUTH and University of Port Harcourt Teaching Hospital) and would be recruiting 2,160 HIV antibody negative women aged 19 – 35 years who are already sexually active, healthy but with high risk behaviour. Half the number of participants will be randomly assigned to use the 6% cellulose sulphate gel. The gel would be inserted into the vagina before intercourse. The other half will be given a placebo, that is, a gel that looks just like the cellulose sulphate gel but has no active ingredient in it.

The trial which would span 26 months (starting March, 2004) - 12 months of participant recruitment; 12 months of product use for each participant; 26 total months in the field including screening and close-down. The study is being funded by USAID, sponsored by CONRAD, USA and implemented by FHI, USA with local partners.

In-country ethical approval for the study was obtained from the study centers as well as from NAFDAC. Both sites recruited participant advocates, independent of the trial, to advocate for the trial participants recruited for the trials so as to ensure that the
volunteer concerns are addressed. In addition, the LUTH trial site has put a number of structures in place to ensure preparation of the community in readiness for the trial. This includes advocacy visits and sensitisation programmes for community members on the trial as well as mobilisation of civil society in the trial location to support the trial. Also, all HIV positive volunteers diagnosed during the study period would be enlisted on the PEPFAR antiretroviral programme as well as referred to a liasing home based care and support project centre for psychological support.

**Phase III savvy trials:** Savvy is a surfactant that disrupts the outer surface of pathogens. This phase III trial would also be a randomised placebo controlled trial to determine the effectiveness and safety of the product as a vaginal gel for the prevention of male to female vaginal transmission of HIV infection among women of high risk.

The trial is being conducted in two centres (NIMR, Lagos and UCH, Ibadan) and would be recruiting 2,140 HIV antibody negative women between the ages of 19 – 35 years who are already sexually active, healthy but with high risk behaviour. Half the number of participants will be randomly assigned to use the savvy gel. The gel would be inserted into the vagina before intercourse. The other half will be given a placebo, that is, a gel that looks just like the savvy gel but has no active ingredient in it.

The trial would span 26 months (starting March, 2004). The study is being funded by USAID, sponsored by Biosyn, USA and implemented by FHI, USA with local partners.

In-country ethical approval for the study was obtained from the study centers as well as from NAFDAC. Both sites recruited participant advocates, independent of the trial, to advocate for the trial participants recruited for the trials so as to ensure that the volunteer concerns are addressed.

**The use of lime as a microbicide:** There is an ongoing study on the use of lime as a microbicide at the University of Jos. However, efforts made to obtain information about the study proved abortive.

**Tmc120 microbicide studies:** TMC120, a dianilinopyrimidine (DAPY) derivative, is a novel, non-nucleoside reverse transcriptase inhibitor (NNRTI) with equipotent *in vitro* activity against wild-type HIV-1 and NNRTI-resistant variants. When administered twice daily at doses of 50 and 100 mg for 7 days, it is found to be safe and a potent antiretroviral agent. The agent demonstrates good anti-viral activity in cellular and cervical explant models, and shows no toxicity at therapeutic levels, making it a good candidate microbicide. It is able to completely prevent HIV infection making it a promising potentially sterilizing microbicide.

**Other New HIV prevention technology research and development**

**Phase II oral prophylactic use of tenofovir:** Tenofovir is an anti-HIV drug that works by inhibiting an important enzyme in the HIV life cycle, called nucleotide reverse transcriptase. By doing so, tenofovir stops HIV from invading cells that have not yet been infected with the virus. It is taken in the form of a pill, it is long lasting, it has
relatively few side effects, and HIV is slow to develop resistance to it. There is a phase II clinical trials presently going on in UCH, Ibadan on the prospect of using tenofovir as an oral prophylaxis against HIV infection. This is in view of its prospects as a cheaper alternative to current treatment regimens, the possibility of reduction of the drug related toxicity when used as a prophylaxis and the possibility of preventing the spread of HIV until the disease is naturally burnt out.

This phase II trial is part of a clinical trial being conducted in three African countries to determine the safety and effectiveness of daily oral Tenofovir to prevent HIV among heterosexual women at high risk of infection. A randomized blind placebo trial which would involve Nigerian participants who are HIV negative, aged 18-35 years, already sexually active and healthy. Half the number of participants will be randomly assigned to take Tenofovir; the other half will be given a placebo, that is, a pill that looks and tastes just like Tenofovir but has no medicine in it.

One thousand two hundred women would be recruited as participants in the study over a 6 months period. The trial participants would then be seen once a month for at least 12 months to find out how well they are doing in taking a pill every day, and how their sexual behaviour may be changing.

At each visit, participants will undergo an HIV test and a pregnancy test for women; physical examinations and blood test to check how the Tenofovir and placebo pills may be affecting them. The pills will be stopped if participants become infected or pregnant or there is evidence of developing health problems.

At the end of the research, researchers will compare how many HIV infections occurred in subjects who took Tenofovir and those who took placebo when they did not use condoms.

The study in being conducted in UCH, Ibadan, Nigeria and is being sponsored by Gilead Sciences, located in Foster City, California, the manufacturers of Tenofovir Disproxil Fumarate and Bill and Melinda gates Foundation. It is been implemented by FHI, USA with local partners.

Other HIV prevention technologies: Presently, there is no active national or international collaborative research going on in the country on new methods for preventing mother to child transmission and for developing highly sensitive and specific rapid HIV tests kits.

Key players and institutions

Table I to 3 outline the various key scientists and institutions involved in the various ongoing researches on new HIV prevention technologies in the country.
Table 1: Microbicide Trials Sites, September 2004

<table>
<thead>
<tr>
<th>Trial</th>
<th>Dates</th>
<th>Int’l Partner Institutions</th>
<th>Int’l partners</th>
<th>Local Institution</th>
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<td>Savvy Phase III</td>
<td>Jun 04 – Jun 06</td>
<td>FHI, Biosyn</td>
<td>Linda McNeil Vera Grigorieva</td>
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<td>Linda McNeil Vera Grigorieva</td>
<td>University College Hospital, Ibadan (UCH)</td>
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<td>Cellulose Sulphate Phase III</td>
<td>Sep 04 – Sep 06</td>
<td>FHI, Conrad</td>
<td>Lagos University Teaching Hospital (LUTH)</td>
<td>Port Harcourt University Teaching Hospital</td>
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<td>Use of lime as a microbicide</td>
<td>October 2003</td>
<td>Venture Strategies</td>
<td>Professor Malcolm Potts Daniel Perlman Mairo Mandara Ndola Prata</td>
<td>A NGO - Girl Child Concerns</td>
<td>O Obunge</td>
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<td>for Health and Development; The Bixby Program; The Center for Entrepreneurship in Health and Development of the School of Public Health, University of California, Berkeley</td>
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<td>Technology</td>
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<td>Principal Investigators</td>
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<td>Cellulose Sulphate Phase I</td>
<td>Dec 01 – Jun 03</td>
<td>WHO; Conrad; Institute of Tropical Medicine, Belgium</td>
<td>Uganda: Prof. Florence Mirembe; Dr Clemesia Nakabiito; Dr Bina Pandey</td>
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<td>India: Dr Chander Puri; Dr Kamal Hazari; Dr Shanta Chitlange</td>
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<td>Nonoxynol 9 study</td>
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*Principal investigators in Nigeria
### Table 2: HIV Vaccine Research and Development Sites, September 2004

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<td>Asokoro Hospital, Abuja</td>
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### Table 3: Other New HIV Prevention Technology Trials Site, September 2004

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<th>Trial</th>
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<td>Phase II trial on the use of tenofovir as prophylaxis against HIV infection</td>
<td>August 2004 – Jan 2006</td>
<td>FHI, Gilead</td>
<td>University College Hospital, Ibadan</td>
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*Principal investigators in Nigeria*
Regulatory procedures

**HIV Vaccine:** For any clinical HIV vaccine research to be conducted in Nigeria, there are basic regulatory procedures that need to be observed. The proposal needs to be submitted to the Vaccine working group for review for its technical integrity before implementation. In addition, NACA could make a request for such proposals and protocols to be reviewed by the WHO/GPA Steering Committee on Vaccine Development and when applicable, by other funding agencies. These technical reviews would be done in addition to that done by the Ethical Committee of NAFDAC to ensure the safety of the research process and ensure that the individual rights of volunteers are protected. The institutional review boards of the investigators’ institutions and the WHO Ethical Review Committee would also undertake the review of the research protocol (item 7.5 draft document).

**Microbicide:** The regulatory process for microbicide research in Nigeria is not spelt out explicitly as has been done for HIV vaccine research. However, all microbicide researches been undertaken in Nigeria had received approval from the institutional review boards of the investigators’ institutions as well as from the Ethical Committee of NAFDAC.

Civil Society involvement

**a. Cohort formation:** Cohort development is essential especially for vaccine trial sites. These are cohorts of individuals with high risk of infection with HIV. There are a number of cohorts being followed up at the University of Jos. However, the university students’ cohort study serves to determine which recruitment method may be apt for recruiting university students into vaccine trials. The cohort also helps to determine their sociodemographic features and HIV risk behaviour. This group were followed up for two years. Cohorts are also being followed up in UCH, Ibadan.

**b. Community involvement:** Community involvement in new HIV prevention technologies research and development ensures advocacy and education which is needed to ensure political commitment, resource mobilisation, production, distribution, acceptance and delivery of products. Unfortunately in Nigeria, community involvement in HIV vaccine and microbicide has been limited to the efforts of the research teams. So also are the present efforts to create awareness about the ongoing phase III microbicide trials in the country. The efforts of the research teams have been limited to communities where recruitments of possible trial participants could be identified. Presently, NGOs like Stopaids, Health Matters and Community Health Information Education Forum (CHIEF) have been recruited.
Situation Report on New HIV Prevention Technologies in Nigeria

by the individual research teams undertaking phase III microbicide trials as participant advocates (See glossary). For the research teams involved with HIV vaccine research, all efforts have been towards the creating of awareness on prevention and control of HIV/AIDS.

**NHVMAG’s efforts:** The Nigerian HIV Vaccine and Microbicide Advocacy Group was established in 2003. It is a coalition with 84 members operating through five semi independent committees. The organizations activities are coordinated by the steering committee which is constituted by the heads of the committees and the two coordinators. It is an organisation directly involved with advocating and mobilising communities for HIV vaccine and microbicide research and development. Its vision is to ‘accelerate HIV/AIDS policy formulation and ensure programme implementation and accountability in the context of HIV/AIDS vaccine and microbicide development in Nigeria’. Its mission is ‘to halt the spread of HIV/AIDS in Nigeria by ensuring the availability of safe, effective, acceptable, accessible and affordable HIV vaccine and microbicide products for all Nigerians when developed’. The objectives of the organization are:

1. Promote public understanding and support for the participation of Nigeria in the international HIV vaccine and microbicide development efforts
2. Promote early involvement of Nigeria into phases of a number of HIV vaccine and microbicide trial efforts relevant to her HIV/AIDS control efforts
3. Mobilize active participation of Nigeria and her nationals in vaccine and microbicide research and development activities worldwide
4. Ensure access by all Nigerians to a safe, effective and affordable HIV vaccine and microbicides when developed
5. Collaborate with other institutions and organizations locally and internationally for the rapid development of a safe and effective HIV vaccine and microbicide for all humanity

Since its inception, the organisation has been able to bring together a number of key relevant stakeholders in new HIV prevention research and development. This includes scientists, youths, policy makers, PLWHA, interested individuals and NGOs/civil society. There have been a lot of efforts by the coalition to ensure information sharing and dissemination, to dialogue about challenges in research and advocacy and to define ways to move the process of HIV vaccine and microbicide research forward. The coalition has also brought on board a number of journalists who are presently actively involved in printing and broadcasting about HIV vaccine and microbicides thereby disseminating information to the public. In addition, it has worked towards increasing the participation of NGOs in HIV vaccine and microbicide advocacy, sensitisation and awareness creation.

**National and international networking**

There has been a significant international and national collaborative effort on HIV vaccine and microbicide research and development. Most of these efforts international and national networking efforts are significantly more visible in relation to HIV vaccine research and development efforts.
During the process of developing the National HIV vaccine plan, there was significant input and drive from the international community. UNAIDS and WHO facilitated the development of the National HIV vaccine plan. The AAVP provided the template for the development. As enumerated above, there is significant and substantial networking between organisations involved with HIV vaccine research in the country as well as international institutions such as Institute of Human Virology, University of Maryland and Robert Koch Institute Germany and organisations like AIDS Prevention in Nigeria (APIN), IHVU, CDC, National Cancer Institute and NIH (see table 1).

Most of the networking there is on microbicide research are presently limited to international organisations especially the funding, sponsoring and collaborative institutions such as WHO, FHI, Conrad, Biosyn and Institute of Tropical Medicine (see table 1). National networking efforts on microbicide research and development seems to be limited to the relationship that exists between the research organisations, the NGOs employed as participant advocates for the trials and NHVMAG.
5

Fact sheet on HIV vaccine and microbicide research in Nigeria

Success of current response

Government and policies

During the 1st national advocates meeting on new HIV prevention technologies in Nigeria, which held on May 26th – 27th 2004 in Abuja, participants identified that the presence of a strong political will and commitment of the national Government to supporting HIV issues is a ‘plus’ for the pursuit of research and the development of new HIV prevention technologies relevant to Nigerians. The existence of a National HIV vaccine plan also put Nigeria ahead of many other countries in terms of its preparedness for international HIV vaccine research efforts. During the visit of members of the South African AIDS Vaccine Initiative (SAAVI) to Nigeria on the 16th – 18th of June 2004, the visitors (see report of visit on www.nhvmag.org) noted that the existence of a National HIV vaccine Plan was a plus for the country in terms of preparedness for HIV vaccine research and this puts it ahead of South Africa in terms of HIV vaccine research and development related policies.

The existence and role of NACA as a coordinating body is also laudable. This body could also be highly functional in ensuring the overall coordination and streamlining of all activities related to new HIV prevention technology research and development efforts in the country so as to ensure that all efforts are focused towards achieving a nationally set objective.

Research and Development

The research and development process for new prevention technologies is a truly global enterprise. Scientists and product developers come from both developed and developing countries, and answers to critical scientific questions will emerge more rapidly as these global partnerships expand and mature.

Nigeria’s involvement in the development of new HIV prevention technologies would help in improving its national research capacity, strengthen its research systems, and it will educate advocates on research issues. Nigeria is also amassing field-workers, policy-makers, media and community advocates who are involved in conducting, monitoring or advocating around the research and will be knowledgeable advocates in a few years.

The various trainings the Nigerian researchers undertake to equip them for the various trial phases makes them readily available resource materials for such future trials. They become assets for the country and can be easily consulted in future in the design and planning of various phases of human trials.

During the National advocates meeting, it was also identified that the existence of committed institutions involved and interested in the development of New HIV
Situation Report on New HIV Prevention Technologies in Nigeria

prevention technologies such as Gede Foundation, Asokoro Hospital, NIPRD and other research institutes like NIMR, LUTH, UCH and UPTH as successes for the country. These institutions’ capacity can always be harnessed for future research efforts as presently, as a result of the present research efforts, individual capacities are being built and structures are put in place.

Laboratory facilities

The country has reference laboratories that have the facilities to carry our HIV serology, screening and confirmation tests. In addition, the laboratories can do CD4 counts, DNA and RNA (RT) PCR, viral load, STI diagnosis and management with adequate storage facilities. The laboratory in Gede foundation in addition, has the capacity for vial isolation and culture, DNA sequencing, HLA typing and facilities for the analysis of cell immune response. These laboratories all have adequate facilities for transportation and communication for fieldwork with highly trained laboratory and field staff. These laboratories located at the University of Jos, University of Ibadan and the Gede Foundation in Abuja also maintain linkages to other international and national laboratories across the country. With the network and linkages, laboratory facilities in the country can adequately conduct and monitor immune responses to various immune stimulants especially those related to HIV vaccine development. The Biomedical Working Group of the AAVP in its 2003 report, adjudged Nigeria as having almost adequate capacity to conduct vaccine trials.

Existence of NHVMAG

Participants at the national advocates’ meeting also identifies the existence of NHVMAG and its ability to bring stakeholders together and ensure their active participation as commendable and an important organization facilitating the country’s involvement in global research and development drive for new HIV prevention technologies. Its existence has enhances the commencement of community sensitization on HIV vaccine and microbicide research thereby filling a vacuum otherwise left by the national government.

In one example, Dr Ogunsola recounted that while the phase III Cellulose Sulphate trial protocol was being reviewed by NAFDAC and there were some problems, a newspaper article was published describing the benefits of microbicides and explaining the research. This, she said, helped her case and she was impressed and thankful to media in particular, for this. These media reports had all being facilitated by NHVMAG.

Gaps in current response

International policies

Presently, efforts are underway to develop other policy models and agreements in areas that will play a key role in facilitating rapid access once products are shown to be safe and effective. The delivery of the developed product would depend on a range of key policies along side capacities in-country. These include incentives related to excise taxes and import requirements, measures to ensure technology
transfer and enhance local production and manufacturing capabilities, differential pricing of products by pharmaceuticals and ensuring that delivering new prevention technologies are given priority by international donors and in national health budgets. Many countries which belong to the European Union are already putting structures in place to ensure these. The country need to prepare even for these new technologies before they are developed. Countries need to start addressing International Property Rights and tiered-pricing now. For example, the European Union regulation was introduced in May 2003 that prevents the re-importation of reduced-price pharmaceuticals into Europe.

Presently, the Nigeria Government is not involved or putting measures in place to address these various issues. These are crucial issues that need to be addressed long before product development and formulations. International collaborations to help define regulations and policies in this respect are highly needed. There seems to be no efforts presently in this direction.

Government policies and involvement

At the policy level, the focus of the Nigerian Government is on scaling up existing interventions so as to prevent new infections. It continues to emphasise prevention while moving rapidly to treat those already infected. Unfortunately it does not explicitly address research into new technologies as part of their national strategies for combating AIDS.

At present, there are no national documents in the country that makes reference to microbicide. The 2003 revised edition of the national HIV/AIDS policy as well as the HEAP made no reference to microbicide. Neither did the 1996 National Health policy, the 2001 National Policy on Reproductive Health, the 2001 draft National policy on Women, The 2001 draft National Policy on Population and sustainable Development and the 1995 National Adolescent Health Policy highlight ways of promoting the research and development of new HIV prevention technologies in the country. The concept of microbicide is new to the various stakeholders and policy formulators in Nigeria. During the first advocate’s meeting on HIV prevention technology in Nigeria which held on the 26-27 of May, 2004, many advocates were learning about microbicides and its various potentials on controlling the HIV epidemic for the first time as well as other direction efforts for developing new HIV prevention technologies in the country and around the world. This apparent ignorance about efforts in developing a microbicide and other new HIV prevention technologies may have created the lapses noted. However, the government and various stakeholders had been
involved with HIV vaccine research and development efforts since 1999 through the involvement of country representatives in the AAVP programme. The continued oversight in integrating this agenda into all HIV related document may not be unrelated to the low priority the government gives to research.

In addition, unlike many countries, the nation has a developed and adopted a National HIV Vaccine Plan that took 3 years (2001-2003) to develop. Unfortunately, the contents of this well articulated document which highlights the research priorities and development process for a country relevant vaccine development process is not specifically referred to in the context of broader national HIV/AIDS plans and strategies. In the 2003 national policy on HIV/AIDS, the part IV of the document wrote two paragraphs on vaccine development. The paragraphs made no reference to the existing National Vaccine plan and its proposed framework of activities (section 10 of the draft National Vaccine Plan). On the contrary, it highlights the need to undertake a process that had earlier been undertaken by the formulation of the National HIV Vaccine Plan (page 41). Neither does the HIV/AIDS Emergency Action Plan (HEAP), the national ‘battle plan’ in the fight against HIV/AIDS, make any reference to HIV vaccine research and development. Worse still none of the national documents on HIV/AIDS in Nigeria makes any reference to research and development of microbicides or any other possible HIV prevention technology.

Despite the seemingly slow pace of the efforts of the Nigerian government in actively supporting research and development efforts for new HIV prevention technologies in the country, there is an apparent increased focus on HIV vaccine research and development process in the country. This seemingly interest in HIV vaccine development may have arisen from the past experience and controversy on the development of an HIV vaccine by Dr J Abalaka in the years 1999-2002. The heated debates and controversy surrounding his highly published discovery of a HIV vaccine and those of other non scientists and the public administration of this product must have lead to the significant national government investment and facilitation of the development of national guidelines for HIV vaccine development. That development may have facilitated the national government interest and involvement in HIV vaccine research and development. The existing structures and policy are however not strong enough to facilitate any significant progress in HIV vaccine research and development for despite the presence of an HIV vaccine plan, there are no strategies defined for its operationalisation.

Research and development

a. Poor research infrastructure: Except for the reference laboratories located in Abuja, Jos and Ibadan, the laboratories in other research institutions are in a poor state of disrepair. A recent report by a consultant to the Global Campaign Microbicide (GCM) noted they resilience of the Nigerian research community to work in the conditions they do. The report pointed out that from brief visits, it appears that the teaching hospital, research institutions and public health laboratories were kept in poor conditions, with severe infrastructural problems including electricity outages, manpower shortages, poor internet access, limited monetary resources and buildings in disrepair. One informant told the consultant that “It’s even worse than it looks or seems…” The report reflects that this poor
infrastructure may pose limitations to the integrity of the research and could possibly compromise the research and hence affect the results of such research. The consultant comments that individual interests and enthusiasm of the researchers and their willingness to make sacrifices appear to be the driving force for the continuity. It is the reason that such researches of international magnitude have hope of success in spite of existing poor facilities.

b. Changing agendas: Also, apparently, there has been little continuity of leadership within and without the research institutions leading to there being changes of research agendas, un-enforced policies, poor commitment and limited access to resources. This destabilises systems and prevents expansion of the institutional research portfolio which also has its resultant effects on the research processes conducted in the institutions.

c. Inexperienced researchers: The negligence of the educational and research institutions by the government over the last two decades had led to brain drain to Western countries. Thus there are very few older, more experienced researchers/scientists working in those entities and so the “core of experience is not there”.

d. Social science and acceptability research: Social science researches are important for the understanding of uptake, use and acceptability of products. These researches facilitate the understanding of the community in which the researchers are to work thereby enhancing the scientific research process. It would also guide future regulatory and access advocacy plans. Unfortunately, there are very few of these country specific researches and information on the few done is poorly disseminated.

One possible reason for poor information exchange is that the country does not have regular fora for the exchange of research information and findings. Others include the lack of local funding for simple science research.

National Review Structures

a. National Agency for Food, Drug Administration and Control (NAFDAC): Presently, there has not been any scientifically approved clinical trial of candidate HIV vaccine products. However the various phase I and III microbicide trials as well as the phase II trial of the possible use of ARV as prophylaxis had to get NAFDAC approval before they could be start off. The need to get approval from the National drug and food agency was a prerequisite stated by the international partnering collaborators. There are presently no approval processes outlined by any government agencies for trials of potential new HIV prevention technologies in the country.

The researchers who had to receive approvals for their various research protocols expressed significant difficulties in obtaining approval from NAFDAC. NIMR had an extremely difficult time getting its phase III Savvy trial approved. This difficulty may have arisen because NAFDAC is focused on drug control, not involved in ‘new’ research. It has also never regulated clinical trials of a product not approved
anywhere and do not have the appropriate knowledge to review such research - especially new HIV prevention technologies trials with such complicated ethical issues.

Some of the worries of the Ethical Committee of NAFDAC as expressed by the researchers who had to have their research protocol approved was that the trial “was promoting promiscuity, using Nigerians as guinea pigs”. There was also “religious biases.” The content of the protocol “offended their sensibilities.” One informant commented that NAFDAC is a good pharmaceutical monitor but needs continuous education regarding new research.

Because of the inability of NAFDAC’s Ethical Review Committee to adequately undertake the review of these protocols, there were significant delays with the review processes. It took 12 months of advocacy to get the Phase III Savvy trial approved. The phase I cellulose sulphate trial also had the same delay. Political pressure was needed to push it through and USAID and FHI got involved at ‘high levels.’ One researcher noted that “the trials was easily passed after the committee realised the trials would focus on sex-workers - as they were not as worried about that population”. For the phase I 6% cellulose sulphate trial in Sagamu, they had to apply for trial approval of microbicides as a cosmetic as the NAFDAC application forms had no place for seeking approval trials of products that were not drugs or cosmetics.

b. The Nigerian Ethical Review Board (NERB): The Nigerian Ethical Review Board (NERB) is a dormant national entity. It has no terms-of-reference, is not active and has no legitimacy. NACA facilitated its development and created its’ working structure. It is meant to operate as an autonomous body that will develop simple guidance document for institutional review boards/ethical review committees in the country which will spell out what is meant by good science and ethics in the Nigerian environment amongst other objectives. However, the formation of this board must be approved directly by government. There is a presently a draft bill going through the Senate and the Senate will then officially constitute it as a legitimate Board. This process has however being slow and delayed. Its eventual animation as being an important step in improving the ethical review structure in the country as it would enhance the constitution and function of ethical committees all research institutions as well as equip members with the capacity to function optimally.

One of the highlights of the draft document developed and yet to be made public is defining criteria for the assessment of protocols that design multicentered clinical trials and studies. It also defined the rights and responsibilities of researchers and institutions including the issues of intellectual property rights as well as the role of IRB/ERBs. These roles include the monitoring of research processes and evaluation of the outcome researches it approves. This role has not been implemented by research institutions in the country. As noted by the chairman of the IRB of UCH, Ibadan (Prof AG Falusi) during the 2003 edition of the APIN funded National Ethics Workshop in Ibadan, the UCH IRB had not been monitoring its approved researches because of poor funding and unavailable manpower.
Although there is no documented approval process for the research into and the development of new HIV prevention technologies in Nigeria except for HIV vaccines, the draft National ethics and operational guidelines of the NERB did spell out the process for ethical approval of health research including clinical trials in Nigeria which can be applicable to all new HIV prevention technology research protocols. This well developed document would help facilitate protocol review processes to ensure that uniform procedures are followed for the review of all protocols as well as ensure that the rights of all clinical trial participants are aptly protected. The inept attitude of the national government to ensuring the take of and functioning of NERB is therefore not a positive development in view of many ongoing and future trials of new HIV prevention technologies in humans.

c. Institutional Review Process: Most research institutions do not have constituted review boards. Where they exists, many are non functional or sub-optimally functional. For example, when FHI invited LUTH to partner in the phase III cellulose sulphate microbicide research, the trial had to be approved by the institution’s ERB in line with FHI’s standards and requirement. However LUTH’s ERB was not registered and not functioning in line with FHI’s requirements. Dr Ogunsola, the principal investigator of the LUTH based phase III cellulose sulphate trial had to register the ERB with the FWI and also provided the ERB members with all the documentation necessary to review the trial. “I created the panel which in turn grilled me…” see noted.

As noted by Dr Ogunsola above, most members of ERB/IRCs are not conversant nor do they have current and up to date information about ethical issues on the subject matter. Sourcing of information is also very difficult and so review of protocols are often based on rules of the thumb and obsolete information. Optimal review processes are not undertaken. Usually, many of these suboptimal review processes are undertaken in line with the demands of international collaborators. These routine processes then become cumbersome on the long run as the required process is not routinely done. As noted by Dr Ogunsola, every change made on the consent form or in the trial design must pass through the ERB but, the ERB is getting fed-up of reviewing every small change and this is slowing the process down. "Our ERBs do not work like those in West....". This observation may have unfortunately led to compromises in the thoroughness of the research design, implementation and its monitoring and evaluation. There is a need to strengthen ethical review boards’ capacity and understanding of ethical issues involved in clinical trials.

Regulation of products

A number of other policy strategies are equally important to speed up research and prepare for introducing new prevention technologies into any country. For example, national regulatory agencies in several developing countries are engaging with partner groups to define appropriate review criteria and strategies that balance rigorous analysis with expedited review that reflects the urgent need for additional prevention strategies. This is critical, given the global influence of the European Agency for the Evaluation of Medicinal Products (EMEA) and the U.S. Food and
Drug Administration in regulatory matters and given that the criteria they may establish for approval and introduction in Europe and the U.S. are unlikely to appropriately reflect the differential risk/benefit of introducing even partially effective prevention methods in high-incidence settings. In an effort to provide regulatory review that reflects the urgent health need of diverse populations worldwide, the European Parliament and the Council passed Article 58, a regulation under legislation 726/2004, whereby the EMEA would provide technical scientific review of products intended primarily for use in developing countries, but would not include marketing authorisation. This process would be initiated on request from WHO with in-country national regulatory agencies making the final licensing decision.

Working with European agencies, including the EMEA, and international organisations such as WHO that can provide technical support and help broker discussions, the national regulatory agencies can take a leadership role in defining new approaches that reflect the urgent need for additional prevention strategies among their populations. It is then expected that governments of interested nations should play the important role of influencing the priorities of key intergovernmental organisations like WHO to ensure that they focus on critical activities, such as strengthening and building the capacity of national regulatory agencies. Presently, NAFDAC is the recognised national regulatory agency.

In the lecture delivered by the Director General of the Agency during the Interactive Seminar on development and clinical trials of vaccines and drugs for HIV/AIDS and other infectious diseases organized by the Gede foundation, Abuja on May 25, 2004, the agency did not highlight or recognize this possible role in the drive to ensure new HIV Prevention products for Nigerians. The mandate of NAFDAC as established by Decree No 15 of 1993 (as amended in 1999), is ‘to control and regulate the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, chemicals/detergents, medical devices and packaged water including all drinks.’ This functional scope of the agency may need to be redefined to enable the agency function as a regulatory agency for the research and development of new products including vaccines and microbicides in the country as presently, it is focused on drug control.

Presently, the capacity of NAFDAC to function effectively in defining regulatory issues for new HIV prevention technologies in Nigeria is limited and there is a need for capacity building to enable the agency play its full role as a regulatory body for HIV vaccine and microbicide research and development in Nigeria.

**Ensuring product availability**

Apart from the need to document processes for national involvement in developing new prevention technologies which are highly relevant for the control of the HIV epidemic in the country, it is also critically important that the government examine how they can offer guarantees that new products will be available at the lowest possible price when developed. This may entail the removal of any taxes and tariffs on such products. There is presently no effort in that direction in the country.
Poor health systems

The Health infrastructure in the country is poor. Life expectancy increased from 36 years in 1963 to 53 years in 1991. It however decreased to 46.8 years and 48.2 years for males and females respectively in 1999. The disability adjusted life expectancy (DALE) concept introduced by WHO, which aims to capture the quality of life in terms of the presence or absence of disability alongside longevity puts the value for Nigeria at 38.3 years. The country ranks 163 among 191 countries in 1999 – far behind smaller countries like Congo, Gambia, Ghana, Togo and Benin. Several efforts to improve the performance of and reform the health sector had met with a lot of challenges. These include the operation of the National Health Scheme, making the Primary Health care system the cornerstone of the national health system and establishing a national health information management system. All these initiatives have had little successes in reshaping the health system. Yet, good health infrastructures are needed for large scale trials especially phase III trials of candidate HIV vaccines products.

Community involvement, mobilisation and preparedness

The success of new prevention technology research depends on the successful completion of human clinical trials in countries around the world. Tens of thousands of altruistic and courageous individuals will need to provide informed consent to participate in trials of experimental products, and millions of people in the communities where these trials take place will need to appreciate the importance of this research, have trust in ongoing research efforts, and support the research process.

This research cannot be viewed as something done to or for willing communities; rather it is something done with these communities. This research will be a long-term effort, one in which multiple studies will provide complex and disappointing – as well as hopeful – data and in which controversy can be expected.

An important way of demonstrating commitment to the communities where clinical trials are carried out is to ensure that trials provide an immediate public health benefit to communities, through health education or improved counselling or clinical treatment capacity. This lays the foundation for subsequent delivery of proven products and leaves participating communities better off, irrespective of whether the candidate product is shown to be efficacious.

The capacities of community groups, women’s organisations, the media and government programmes working in the area of HIV/AIDS, reproductive health and general development can be harnessed in providing information and mobilising volunteers. Such partnership will help to assess and shape current attitudes and awareness about HIV vaccines, microbicides and other developing HIV prevention options, by helping people understand the role these new technologies might play in controlling the epidemic and by addressing their apprehensions and fears. These partnerships would improve current efforts, support future trials, and begin to develop informed users for these technologies once they are proven.
Key print and broadcast journalists covering HIV/AIDS could also play an extremely important role in raising awareness about the potential of new prevention technologies. Their stories highlight the impact that such technologies could have in ameliorating the epidemic’s effects in their countries and the critical role of national governments and populations in facilitating and participating in research. As noted by participants at the 1st national advocates meeting which held on the 26th-27th of May 2004 in Abuja, there is a misconception, lots of ignorance and suspicion about HIV vaccine and microbicide research in the community. Unfortunately, the Nigerian government is presently doing very little in ensuring that the capacities of these crucial stakeholders are harnessed to ensure community mobilisation (involvement and preparedness) and support for the entire process. There is low awareness about ongoing microbicide research in the country. Neither is there any nationally supported central coordinating body mobilising the community to support HIV vaccine development process.

The ongoing microbicide researches taking place in four sites in the country (together they would be recruiting 4,300 aged 18 – 35 years) do not have community preparedness activities incorporated into the research protocols. Most of the researchers had very little experience and in-depth understanding of how to conduct large scale clinical trials and researches of national significance; they were not conversant with the intricacies involved with designing clinical trials. The in-country principal investigators’ of these trials were not involved with the writing and designing of the research protocols and they made very little input to the whole protocol. The trial designs therefore initially had little components on community mobilisation. With updates and information, subsequent review of the protocols took cognisance of this need and therefore the phase III 6% cellulose sulphate and savvy trials have now incorporated elements of community sensitisation and preparedness into the trial design. These efforts are however still limited and focused on the trial sites.

Community preparedness is very much needed for: community understanding of research processes, site preparation, volunteer mobilization, community ownership and protection from harm. Where community preparedness is not undertaken properly and effectively, the research may be compromised. One informant as reported in the GCM assessment, was especially worried about how this would affect real informed consent, reliability and continuity of trial participants in research process, and that there would be no community ownership of the process. She opined that “the pressure to meet up with target dates and recruitments of such large number of volunteers may make the researchers compromise on the integrity of volunteer recruitment procedure. Such is likely where the community is not adequately prepared and mobilized for the research process thereby making recruitment procedure difficult....”

Some are also worried about credibility of the ongoing microbicide researches if “it continues as it is (with poor community preparedness and mobilization) ...” - because without thorough ethical consideration and community preparedness - not only for the trial but for future access - it will fail and “we can’t have another failed oral polio vaccination process...”
Nigeria HIV Vaccine and Microbicide Advocacy Group (NHVMAG)

The Nigeria HIV Vaccine and Microbicide Advocacy Group (NHVMAG) sees itself as a popularly owned campaign, with its members, supporters and partners as the driving force. It has been actively involved in advocating for increased government and community involvement in HIV vaccine and microbicide research and development with a desire to see the research processes being a community owned and driven initiative.

However, many identify gaps in its present operations with informants (members & non-members) saying that NHVMAG “NHVMAG needs to prepare the ground for legislative relevance e.g. getting the FDA to understand the science & ethical issues involved.” The organization needs to advocate with the drug regulation board for future access and to make drug trials more welcome. The coalition also

“… needs to advocate with the ministry folk……”

In addition individual and organizational members of the group are not fully integrated into the organisation’s activities and updated about events in the light of the comments of the members

“It’s all on paper but not sure who is really in which group and what is actually going on. It seems to be run with just two people’s ideas and focuses on their efforts.”

It was also noted that “It (NHVMAG) only involves and focuses on South-West Nigeria – we need to involve research and advocacy groups from other parts.”

Challenges for research and development of new HIV prevention technology in Nigeria

Developing a broad based national policy for research and development of new HIV prevention technologies

The National government had expended a lot of time and energy to develop a national HIV vaccine plan. At the time the country was focusing on HIV vaccine, other new HIV prevention technologies were unfolding. Others would still unfold in the future. It may therefore be wise and more cost effective if the government, in developing policies and action plans, be proactive in its concept. Rather than focusing on existing concepts of products, it would be wider to address the whole evolving concept of New HIV prevention technologies and therefore develop policies, guidelines and action plans to focus on all these

Strengthening regulatory bodies

For large scales trials such as would be needed for HIV vaccine studies, there is a need for appropriate regulatory oversights. The structure and capacity of NAFDAC needs to be strengthened so as to ensure it can perform its anticipated role as a truly regulatory body for new HIV prevention technologies in Nigeria. Presently, the capacity of NAFDAC is limited in terms of understanding of all related issues and
Situation Report on New HIV Prevention Technologies in Nigeria

possibly the needed manpower to help address the issues. NAFDAC would need to work closely with the government to ensure its capacity in this area is properly built especially with the understanding that WHO would readily provide support for this process. In addition, it needs to start working with customs and excise duty department of the Ministry of Immigration to ensure that taxes and tariffs of these new prevention technologies are removed when finally developed so as to ensure access and affordability of the products for its citizens.

**Strengthening ethical review boards**

The capacity of ERB of all research institutions in the country need to be build as they are all potential research sites for new HIV prevention technologies. These bodies need to learn to pay attention to critical ethical issues in these various research protocols especially the need to pay attention to standard of care issues for research participants, the issue of voluntary and understood consent, ensuring that participating communities benefit from the research process, ensuring that the Community Advisory Boards for projects are set up and are functional; ensuring community mobilisation and preparedness for such large scale trials.

**Community mobilisation and preparedness**

The need for community ownership/partnership to ensure successes of trials and future use of research products cannot be overemphasied. There is an increasing need to advocate to all at the top and at the bottom for increased support for research and development of new HIV prevention technologies to ensure an increase in choice options and complement the existing ranges of prevention alternatives.

Community mobilization and preparedness efforts for clinical trials involve updating all stakeholders about these research processes. This makes the whole process transparent and more easily acceptable by the community. There are many complaints from the media/NGOs that details on the various trials process are kept secret and until the recent 4th National HIV/AIDS conference. This information had never been made public. This process would also help communities to overcome prejudices they have about research especially clinical trials.

To ensure wholesome community mobilization and involvement in trial efforts, efforts should be directed at increasing the enlightenment of the public to the implications and import of the trials. Existing structures within the community should be used to reach the community. These structures should be used to integrate knowledge about new HIV prevention technologies into HIV prevention messages so as to ensure community recognise these research processes as part of the broader HIV prevention effort thus ensuring support for the process. This would also entail engaging private/public sector participation as well as professional bodies and policy makers. The media should also need to be adequately mobilised to ensure reporting and coverage of the research and development process as well as using the media for advocacy and education to enhance greater government involvement in the processes. But then, if media are to understand and be able to accurately report on research, then the scientists need to de-jargonise their language when
talking to media. For example, a very experienced journalist who has been reporting on HIV for many years said that when he hears one of the lead vaccine research scientist talk, he tunes off because he always speaks so technically. “I don’t feel I can report on him accurately or interestingly…”

**Information sharing**

To ensure that the whole research process is transparent, information sharing should be bidirectional; from the community to the researchers and vice versa. It is important to ensure adequate and appropriate a bidirectional feedback process from the community to the researchers and scientific community and vice versa. This ways, lessons learnt could be shared and community perspectives could be taken cognizance off in research design and implementation. There is also the need for the creation of more fora for the sharing of scientific information within the scientific community thereby preventing the duplication of efforts and enhancing lesson sharing. One other veritable tool to ensure information dissemination and knowledge acquisition about new HIV prevention technologies identified during the recent national advocates’ meeting is the inclusion of these issues and discussions in school curricula, especially medical school curricula. Also, counsellors, educators could include this information in their information package to clients.

**Research efforts**

There is a need for conducting more basic and formative research in the country to ensure that these research efforts are culturally appropriate and take cognizance of the cultural issues peculiar to Nigeria. These include conducting need assessment research, and defining appropriate communication strategies for these various messages.

**The Nigeria HIV Vaccine and Microbicide Advocacy Group**

NHVMAG needs to maintain and increase it present partnership and not just limits its partnership to CBOs, media and scientists. It needs to engage more PLWHA and stakeholders like the public sectors and other researchers and scientists in the advocacy process. The coalition would also need to educate its members so as to ensure they are veritable advocate tools in the community mobilising all segment of the community effectively and disseminating correct and factual information. While the coalition focuses on policy makers, it needs to also define strategies to address grassroots involvement in the process researching and developing new HIV prevention technologies research.

**Coordination of efforts**

Participants at the national advocates’ meeting identified the need for a national coordination process for new HIV prevention technologies research and development efforts. They advocated for NACA to act as a coordinating body to ensure community preparedness for new HIV prevention technologies’ research and development and that the FMOH should provide resources for research and should also mobilize for collaborations. These institutions could also ensure the introduction of new HIV prevention technologies awareness and sensitization efforts into all community based projects now.
The way forward

Combination Prevention – the need for more options

No single drug or medical approach is effective in treating a person with HIV. Similarly, a combination approach and an enabling environment are needed to help people prevent HIV transmission. Strategies must offer real choices for people, including people with HIV, which meet their different and changing needs and that address the contexts in which decisions can be made and acted upon. Prevention responses should include activities such as: voluntary counselling and testing; reducing mother-to-child transmission; improving blood safety; prevention and treatment of sexually transmitted diseases; behavioural change communications with youth and other vulnerable groups; male and female condom social marketing and use; and preventing transmission through injection drug use.

A few countries have seen HIV prevention successes, including Thailand, Senegal and Uganda. The latter has demonstrated that a combination of prevention efforts that offer appropriate choices can reduce HIV incidence if they are properly funded, implemented and sustained as part of a broader response to HIV and AIDS. Early community mobilisation, efforts to address HIV stigma and discrimination backed by visible political leadership and relatively high funding, underpinned an HIV prevention strategy that lowered incidence and reduced prevalence from 15% to 5% between 1991 and 2001. The key elements of this strategy, often referred to as ‘ABC’, include; Abstinence (or delaying first sexual activity); Being faithful (mutual fidelity) and; Condom use. All three are promoted together as part of a broader HIV and AIDS response.

Providing a range of options makes sense. Prevention choices may conflict with personal, community, religious or cultural priorities or beliefs. Similarly, the circumstances and priorities of individuals change overtime. Even an ABC approach has its limitations; abstinence provides little protection where people change their minds, where childbearing is important or where sex occurs without mutual consent; partner reduction can be achieved in some settings but may be difficult to sustain or replicate in others; condoms may be religiously unacceptable on one hand and perceived to inhibit intimacy or sexual pleasure on the other. Increasing the range of available prevention options will increase the likelihood that people will be able to adopt a strategy appropriate to their needs and situation. New HIV prevention technologies like vaccines and microbicides would be significant prevention options in themselves, but they would also add significantly to the overall effectiveness of HIV prevention strategies more generally.
Recommendations

The need to articulate research explicitly in the national HIV/AIDS programme and agenda

Many explicitly address research into new technologies as part of their national strategies for combating AIDS. Brazil – among the world leaders in providing comprehensive treatment to its population – has always positioned treatment as part of a comprehensive response that also emphasises primary prevention and continued research into new approaches to prevention and treatment. Indeed, many of the countries dealing with the epidemic most successfully – including Brazil, Thailand and Uganda – have addressed primary prevention not only by using the approaches available today, but also by looking to the future and making development and access to new prevention technologies an explicit priority. Moreover, these countries have articulated research priorities specifically in the context of broader national HIV/AIDS plans or strategies.

India, where the epidemic is emerging rapidly, has also made explicit reference to the importance of developing and testing new prevention technologies. It has demonstrated its commitment to this priority by providing leadership and investment within the National AIDS Research Institute (NARI) and the Indian Council of Medical Research (ICMR). In South Africa, the government and its Medical Research Council created and support both the South African AIDS Vaccine Initiative (SAAVI) and the South African Microbicides Research Initiative (SAMRI). Even before these new technologies are proven, international agencies, donors and product developers are developing plans to assure reasonable pricing and widespread availability as soon as products are approved for use. The experience of polio vaccine development in the USA – where the more than 200 clinical trial sites became the first immediate access points for the vaccine once it was licensed – is an important historical lesson on linking clinical trials to the subsequent distribution and use of a product.

The Nigerian government needs to learn from these success stories. Initiatives for the control of the HIV epidemic in the country need to be comprehensive and proactive. The country cannot afford to act retrospectively as it has done since the beginning of the HIV epidemic. An upstream approach is needed to help end this epidemic on time and stop the staggering effects on its citizen. The national government may need to:

- Research should be explicitly articulated in the national HIV/AIDS programmes and agenda
- Establish and build the capacity of regulatory bodies especially those that would be involved with the regulation and licensing of products such as NAFDAC
- Encourage and maximize international collaborative efforts especially those that ensure entails programmes that complements the national strategy
- Harness the potentials of community participation to facilitate process
- Ensure comprehensive response to the HIV/AIDS epidemic by being proactive; work ahead of present initiatives
a. Broaden the concept of the national HIV vaccine working group and rather have a national working group on new HIV prevention technologies in Nigeria. The Group can then have working committees focusing on each emerging new HIV prevention technology. The committees can then help to make input into the development and reviews of a national guideline for new HIV prevention technology studies in the country. It would also help to identify research priority activities related to new HIV prevention technologies for the country and help to coordinate all such related research activities.

b. Empower and enhance the functioning of this national working group on new HIV prevention technology in the country

c. Incorporate issues on new HIV prevention technologies’ development into various national policy documents being developed or undergoing reviews such as the Workplace policy been developed by FMOL, the NLC HIV Policy, the National policy on Prisons and Immigration and Education. The FMOH HIV/AIDS strategic plan as well as the ongoing revision of HEAP should also proactively strategically incorporate plans for new HIV prevention technology development into their agenda

Capacity of NAFDAC needs to be built

The need to build the capacity of NAFDAC to effectively function in its role as a regulatory body for new HIV prevention technologies cannot be overemphasised. The organisation needs to first identify itself as a crucial body to facilitate this agenda in the country. It then needs to take stock of its existing capability to play its role and then define strategies for building up its capacity to function in this capacity. The process of capacity building can be facilitated by WHO with the support of the national government.

Establishment of a National Ethics Review Board

The establishment and functioning of a National Ethics Board would help build the capacity of ERBs in the country in all potential research institutions in the country. The NERB in providing guidance, training and support to IRB/ERCs in the country, would also audit and accredit their practices thereby providing a means to assure the public the ethical review of research proposals is carried out according to established standards.

Harnessing potentials for scaling up access of PLWHA to treatment and ensuring future access to developed products

As the national government has made increasing commitments to provide treatment for people with HIV infection and AIDS, these clinical research can provide resources and sites for exploring the most appropriate and feasible clinical and logistical approaches to providing such treatment. The Nigerian Government can harness the potentials of these research processes by working with the various product developers and trial sponsors to support the provision of HIV treatment, care and support – including antiretrovirals when recommended by agreed
treatment guidelines – to participants in clinical trials who become infected with HIV during the trial. Through the necessary planning, capacity building, resourcing and consultation, the country can devise ways to deliver such services and link them with the broader country efforts to improve HIV-related treatment, care and support.

The Nigerian Government could also possibly develop relationships and partner with some of the leading agencies working to develop new prevention technologies, such as the International AIDS Vaccine Initiative (IAVI) and the International Partnership for Microbicides (IPM), who are oriented explicitly to supporting product development and delivery for developing country populations. Usually, these agreements that support product development include explicit terms to facilitate affordable pricing and availability in countries hit by the epidemic such as Nigeria. Such agreements are complemented by programmatic efforts to build capacity in developing countries for widespread and rapid product introduction, access and use. Unfortunately, the Nigerian Government is presently not tapping into such possible potentially benefiting relationships that would help facilitate the access to developed products despite its investments and committed human and financial resources to the research process.

Harnessing the potentials of community participation

The country, with the number of past, ongoing and prospect for future researches on HIV vaccine and microbicides and other new HIV prevention technologies, needs to work actively to creating an enabling environment for clinical testing. Successful implementation of new prevention technology clinical trials, particularly large-scale trials, requires scientists, policy makers, community groups, and the media to develop and implement a common agenda. Ideally, this agenda situates research in the broader context of health activities and services, for example, by implementing widespread voluntary HIV counselling and testing; building sufficient community health infrastructure; and promoting policies and capacity that support rapid regulatory review.

International, national and local political commitment and consensus can streamline the regulatory approval process. In Uganda, growing political commitment to AIDS vaccines as part of the country’s comprehensive response to the epidemic led to implementation of an effective system for regulatory approvals and cut approval time from more than two years for the first trial to less than six months for the second trial. Similarly, strong political commitment and support in Rwanda led to the first AIDS vaccine clinical trial protocol being approved in two months.

Harnessing the potentials of NHVMAG

NHVMAG is in a good position to prevent any problems that are often attributed to media – misconstruing and sensationalising issues – as the group has good media outreach and can conduct adequate training. They also have the opportunity to sensitise researchers on the appropriate language to use when dealing with media and the public as there would be an increasing need for researchers to relate with the community in which they work. A cross-training between media and scientists, and the scientists and community workers would facilitate these processes so that “everyone can see everyone’s issues” and possibly address this identified gap.
Looking Ahead

Leadership in policy, science and activism around new prevention technologies is coming increasingly from within developing countries. It is critical that such efforts be expanded and supported through global partnerships and funding. Specifically, efforts in the following key areas should be strengthened:

- New prevention technology research cannot be seen as something done to or for willing communities; rather it should be seen as something done with these communities.

- Engagement of community members, policy makers, political leaders and media to create an enabling environment of trust and open discussion is essential to support the development of new prevention technologies.

- The global community should commit to determining a prioritised portfolio of products that can be tested rapidly and in parallel. The Nigerian government, scientists and communities should play a more direct role in establishing, implementing and monitoring this overall research strategy for Nigeria and Nigerian.

- High-quality clinical trials can be conducted in resource-limited settings like Nigeria, given sufficient investment and training to build additional clinical trial capacity and, as appropriate, administrative and technical support for ethics committees and national regulatory authorities. A conscientious effort should be geared towards enhancing the capacity of these sectors and their ability to participate actively in the global efforts to develop new HIV prevention technologies and help drive the Nigerian agenda.

- In developing new technologies, a considerable number of activities will support prevention research while simultaneously providing immediate public health benefits to communities where research will take place. Country and community preparedness activities should provide a long-term, sustainable infrastructure and build capacity for research, prevention, care and treatment. Structures must be put in place to ensure that clinical trials must leave participating communities better off, irrespective of whether the candidate product is shown to be efficacious.
7

Conclusion

Investing in future success

The current challenges to effective HIV prevention make clear that new prevention options are needed. The benefits that vaccines, microbicides and other possibly other new HIV prevention technologies would offer in addition to existing prevention technologies means that their introduction and integration into broader HIV/AIDS strategies could provide powerful means to reduce HIV transmission rates significantly, providing valuable support for both treatment and care and impact mitigation efforts. In the best case, a highly effective and widely available HIV vaccine could repeat the unique successes of vaccination against smallpox and other communicable diseases, and bring an end to the epidemic.

After twenty years since the discovery of HIV, only one microbicide and one vaccine have been fully tested in clinical trials, both with disappointing results. However, scientists agree that, given sufficient investment and focused collective effort, microbicides and HIV vaccines are possible. Efforts to accelerate the next generation of candidate products into clinical trials are underway, but more could be done. The potential health and social dividends of R&D investment are enormous, extending well beyond a single individual, country or generation. Despite this, the commercial returns on preventive technologies, particularly those that will have most impact in developing countries, are uncertain. Consequently, large pharmaceutical and biotech companies have generally invested little of their own capital in either of these fields. This need to change and opportunities to encourage greater private sector contributions are needed. However, in all cases, public sector support including the active mobilization of the community to ensure that the research and development efforts is viewed as a community owned process, will be fundamental to the successful development of these new technologies and to their future introduction and use, particularly in developing countries like Nigeria.

A truly comprehensive response to HIV/AIDS requires both breadth and long-term vision if the efforts to scale up today are to be complemented by the necessary means to end the epidemic tomorrow.
Glossary

**Microbicide:** Microbicides refers to a range of different products that share one common characteristic: the ability to prevent the sexual transmission of HIV and other sexually transmitted diseases when applied topically. A microbicide could be produced in many forms, including gels, creams, suppositories, films, or as a sponge or ring that releases the active ingredient over time. Scientists are currently testing many substances to see whether they help protect against HIV and/or other STDs, but no safe and effective microbicide is currently available to the public. However, scientists are seriously pursuing almost 60 product leads, including at least eleven that have proven safe and effective in animals and are now being tested in people. If one of these leads proves successful and investment is sufficient, a microbicide could be available in five to seven years.

**HIV vaccine:** A vaccine is a substance that teaches the body to recognize and defend itself against bacterial and viruses that cause diseases. A vaccine causes the body’s defense system to produce a response, which enables it to fight and overcome the bacterial or virus when exposed to it at a later date. Vaccines have long been established as the most effective way to change the natural destructive courses of diseases. The best long term hopes for controlling HIV/AIDS is the development and widespread distribution of a safe, effective and affordable vaccine, which prevent primary infections. Currently, there is no effective HIV vaccine available. However, there are several possible vaccines that may work. Some are already undergoing clinical trials while others are still undergoing animal trials. The development of a vaccine takes a while. This is so as to ensure it is safe and effective. An effective HIV vaccine would teach the body to recognize the human immunodeficiency virus (HIV) that causes AIDS and will cause the body’s defense system to overcome the virus when it enters the body.

**Participant advocate:**

**NHVMAG:** NHVMAG (pronounced ‘navmag’) is an acronym for the Nigerian HIV/AIDS Vaccine And Microbicide Development Advocacy Group. It is a civil society group committed to mobilising public support for HIV vaccine and microbicide research and development in Nigeria. Its mission is to halt the spread of HIV/AIDS in Nigeria by ensuring the availability of safe, effective, acceptable and affordable HIV vaccine and microbicide products for all Nigerians when produced. NHVMAG works to ensure the proactive participation of Nigeria and Nigerians in global efforts for the development of HIV vaccine and microbicides. It recognizes that there is an ethical imperative to seek, as urgently as possible, an effective and accessible vaccine to complement other existing and emerging prevention strategies.
References


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