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NEWS

“Africa Must Own and Set Her Agenda in HIV Vaccine Development”- Mme Kagame



The First Lady of Rwanda and High Representative for AAVP, Mme. Jeannette Kagame recently urged African governments to make good on their commitments to support the development of an AIDS vaccine through technical,

financial and political resources. In a speech delivered at the 59th Session of the WHO Regional Committee for Africa Consultations held in Kigali in September, Mme. Kagame stated: “It is imperative for us to own this process and truly begin to set our own agenda in the fight against HIV and AIDS.” She urged Africa to be more relevant in HIV vaccine research and development efforts and to raise awareness of Africa-specific concerns

on the international stage.

The High Representative appealed to the delegates to ensure that the opportunity to save future generations is not squandered. She remarked that a safe and effective HIV vaccine, when used in combination with other HIV prevention strategies, has the potential to end the AIDS pandemic.

While appreciating the challenges and costs associated with developing an AIDS vaccine, Mme. Kagame called on all players to refrain from downplaying the gravity of the AIDS pandemic by equating it to ‘a chronic disease’. Such an attitude may deny the vaccine development process the urgency it deserves.

The High Representative asked African leaders to offer incentives and a conducive environment to African scientists working towards developing an HIV vaccine in Africa and for Africans.

“Let us dare to imagine an African continent and a world without AIDS,” she stated.

Commitments Made at Previous AAVP Forums

Over the past eight years, AAVP has convened four forums where recommendations and commitments have been made. Below are summaries of statements from each of the previous forums.

June 2002: The 1st AAVP Forum, Cape Town, South Africa: Develop strategies and plans to support the on-going efforts to develop multiple HIV vaccine trial sites in Africa.

June 2003: 2nd AAVP Forum, Addis Ababa, Ethiopia: Need for the development of ethical, legal and regulatory frameworks in support of the development of HIV vaccine trial sites.

October 2005: 3rd AAVP Forum, Yaoundé, Cameroon: Need to better define Africa’s role and contribution to the global efforts for the development of safe, effective and affordable HIV vaccines for African countries.

November 28th -30th 2007: 4th AAVP Forum, Abuja, Nigeria: Commitment by African leaders to support AAVP.

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Uganda Hosts the 5TH AAVP Forum

The 5th African AIDS Vaccine Programme Forum is in Kampala, Uganda, from December 13 - 15, 2009. The theme for the Forum is "Africa needs an AIDS vaccine: Building a common platform for prevention research in Africa." Previous forums have been held in Cape Town, 2002; Addis Ababa, 2003; Yaounde, 2005 and Abuja, 2007.

Her Excellency, Mrs. Janet Museveni, the First Lady of Uganda, is scheduled to open the Kampala Forum on 13 December. Also in attendance will be Her Excellency Mme. Jeannette Kagame, the First Lady of Rwanda and AAVP High Representative, AAVP Co-Chairs - Dr. Alash'le Abimiku and Dr. Pontiano Kaleebu. Dr. David K. Apuuli will chair the Forum.

The Kampala Forum brings together scientists, advocates, community and policy leaders, and other stakeholders supporting Africa's contribution to the development of an AIDS vaccine. During the Forum, stakeholders will update one another on the progress being made in AIDS vaccine research and development, as well as build stronger linkages and collaboration.

This year's Forum will also discuss the relocation of the AAVP secretariat to Africa, governance structures, and participation in vaccine research. The secretariat's host country in Africa will also be announced.

The AAVP Forum was instituted to create an opportunity to network within Africa and address issues unique to the continent. The main objective is to identify what is new and interesting in vaccine research in Africa. The Forum's intention is to ensure that governments are involved and commit their technical, financial and political support to the search for an AIDS vaccine.

Welcome to the 5th African AIDS Vaccine Programme (AAVP) Forum

This year Uganda hosts the 5th AAVP Forum in Kampala, December 13 – 15, 2009, with the theme “Africa Needs an AIDS Vaccine: Building a Common Platform for Prevention Research in Africa”

We are all aware that Africa continues to bear the highest burden of HIV and AIDS, with about 67% of the total number of HIV infections globally occurring on the continent. Though efforts have been made to increase awareness on prevention, and to provide treatment and care for those infected and affected, more needs to be done. We need additional new prevention tools to complement what is currently available. In this regard, we support the global effort to discover new HIV prevention technologies, including an efficacious and affordable HIV vaccine capable of controlling the pandemic.

The theme for the Forum in Kampala was selected to underscore the need for all those engaged in research into new prevention technologies to work together, in order to maximise on the available resources available and to prepare for challenges involved in conducting multiple intervention studies.

In 2000, representatives of African scientists who met in Nairobi created the AAVP and issued a declaration - “An African Appeal for an AIDS Vaccine”. AAVP aims to ensure that African communities and Africans participating in the HIV vaccine development process are adequately supported, well-represented globally, and are equal partners in global HIV vaccine development efforts.

AAVP has strengthened the network of African HIV vaccine stakeholders committed to HIV vaccine development for Africa through research, advocacy and partnership, and has contributed to capacity strengthening and policy development.

The road to the development of an HIV vaccine thus far has not been an easy one, nor is it expected to be. This year brought renewed hope after the results of a large clinical trial in Thailand indicated, for the first time, a modest efficacy of a candidate vaccine. We need to build on this new momentum, and Africa provides definitive and unique opportunities to assist in the continued search for a safe and efficacious vaccine.

We are hosting this Forum at a time when AAVP is transitioning to become an independent, autonomous organization based in Africa. This Forum is an important landmark, and we hope to discuss the strategies needed to make this transition a success.

On behalf of the National Organizing Committee, we thank all those who have contributed to the preparation of this Forum. We thank the local and international organizing committees. We sincerely thank those who have given financial support to make this Forum possible.

Finally, we applaud the continued support from H.E. Mme. Jeannette Kagame, the AAVP High Representative and the support received from the Government of Uganda.

We look forward to a very successful meeting.

Dr. David Kihumuro Apuuli
Co-chair National Organizing Committee

Dr. Pontiano Kaleebu
Co-chair National Organizing Committee
and Conference chair

AAVP transition: The Journey from Europe to Africa

Following recommendations made at the 4th Forum, AAVP is embarking on a relocation and re-engineering process that will see it set up its Secretariat in Africa. The aim of the relocation is to give AAVP a clearer identity and enhance Africa's ability to participate in the global HIV vaccine research and development process.

A Transition Advisory Panel set up to facilitate the process engaged the international consultancy firm PriceWaterhouseCoopers (PWC) to design a business plan for AAVP. The firm was also to develop selection criteria for the host country and institution. A Call for Applications was posted internationally, upon which eight institutes from six countries expressed interest in hosting the AAVP secretariat. Applications were received from institutes in Senegal, Botswana, Uganda, Mozambique, Burundi and Tanzania. Two applications were received from the Republic of South Africa.

Following an assessment of the applications, three institutions have been pre-selected: the Aurum Institute in Johannesburg, South Africa; Botswana-Harvard Partnership, Gaborone, Botswana; and Uganda Virus Research Institute, Entebbe, Uganda. The advisory panel has conducted site visits to assess the suitability of the interested institutions, and to interact with the government representatives in the various countries.

The Secretariat's host institution will be announced at the 5th AAVP Forum, in Kampala, Uganda.

Charting a New Pathway to

At the AIDS Vaccine 2009 conference co-hosted by the Global HIV Vaccine Enterprise and the French National Institute for Research on AIDS (ANRS) in Paris this October, data presented from the RV144 trial conducted in Thailand offered the first proof of concept that it may be possible to confer protection against HIV infection with a vaccine regimen.

The Thai trial was a great logistical and global effort, involving partners from different parts of the world and more than 16,000 trial volunteers. This is the type of collaboration that underpins any successful AIDS vaccine R&D effort. No one scientist, research group, country or continent can go it alone.

Ensuring that AIDS vaccine research is as focused and as productive as it needs to be will require expanded funding, and even greater global collaboration and partnership between AIDS research institutions and funders.

To move forward, we must first agree on where we are going and how best to get there. The 2010 Scientific Strategic Plan of the Global HIV Vaccine Enterprise will provide this direction.

More than 100 scientists from every part of the world and every field of HIV vaccine research are working now to put together bold recommendations to advance the field.

Clinical trials are crucial to advancing AIDS vaccine research, according the pipeline of promising candidates and ideas under investigation. Many of these trials must be conducted in Africa, where the disease is most widespread, and where a vaccine will be most broadly used.

Young people are essential to future progress in this field. Early-career and young investigators from other areas of science must be encouraged to enter HIV vaccine research and be mentored to ensure

HIV Vaccine Discovery and Development

their success. The promise of these young minds is great, but supporting them to realize their full potential requires supporting education, and the development and maintenance of research facilities. The latter helps African researchers work in the continent to find solutions to diseases that affect predominantly Africans.

Africa demands, rightly so, to be a full partner in AIDS vaccine research. Today, the continent's capacity to play a critical role in HIV vaccine research has been clearly demonstrated – and its expertise is needed to expand AIDS vaccine research efforts. We must continue to empower African scientists to contribute to and to drive HIV vaccine research efforts. And we must also invite and encourage African governments to fund this research.

The African AIDS Vaccine Programme (AAVP) shows how North–South collaboration can move AIDS vaccine research forward. This African-led initiative works with developed world funders to build the capacity of African researchers and laboratories to conduct vaccine trials and the socio/behavioral research needed to support HIV prevention efforts. AAVP's focus on the ethical conduct of vaccine trials is particularly important in places in which there is the potential for misunderstanding or suspicion about the goals and conduct of biomedical research.

Twenty-eight years into the AIDS epidemic, nearly 3 million people, most of them in sub-Saharan Africa, are newly infected with HIV every year. This situation is unacceptable, not just for Africa, but for the world.

We must all work together, in partnerships of mutual support and respect, to ensure that Africa is a full partner in the global effort to end this pandemic.

In September this year, the world heard the results from the Thai prime-boost AIDS vaccine efficacy trial. The initial announcement reported that the vaccine had reduced HIV risk by approximately 30 percent in volunteers who received any or all of the full course of six immunizations. Further data released in October 2009 added layers of complexity to this initial finding. Today, the AIDS vaccine field and the broader world of HIV prevention are working hard to understand what these findings mean and to identify next steps. AVAC has developed a number of materials to help guide advocates through the data and has released *“Understanding the Results of the Thai Prime-Boost Vaccine Trial, RV144”*. This document is a guide to the key questions and answers that have arisen since the results were announced. This document and additional trial and results coverage is available at www.avac.org/thaitrial.htm).

Article by The Global HIV Vaccine Enterprise

What Is The Thai Prime-Boost Trial?

The Thai prime-boost test-of-concept trial, also known as RV144, began in 2003 and enrolled more than 16,400 HIV-negative Thai men and women between the ages of 18 and 30. It was conducted by the Thai Ministry of Public Health, sponsored by the US Army Surgeon General, managed by the US Military HIV Research Program and funded by the Division of AIDS of the National Institute of Allergy and Infectious Diseases, NIH, and the US Army Medical Research and Materiel Command. The trial tested a combination of two vaccines: ALVAC HIV vaccine (the prime) and AIDSVAX B/E vaccine (the boost). The trial was designed to evaluate whether this vaccine regimen reduced risk of HIV infection and/or whether participants who received the vaccine and went on to acquire HIV had lower viral loads than participants who received the placebo and acquired HIV.

The trial results were first released on September 24th 2009 stating that the prime-boost combination of ALVAC HIV and AIDSVAX B/E lowered the rate of HIV infection by 31.2% compared with placebo. The vaccine had no effect on viral load.

On 20 October 2009, the trial team presented expanded analyses at the AIDS Vaccine 2009 Conference. These data were also published in the *New England Journal of Medicine*; the scientific article along with an accompanying editorial can be downloaded for free at the NEJM website: <http://content.nejm.org/>.

What's the bottom line? The Thai prime-boost trial showed a modest reduction in risk of HIV infection in those participants who received the vaccine regimen (ALVAC plus AIDSVAX). Although a modest result, it's one that needs to be explored and better understood through additional data analyses and future research. One of the most important facets of the Thai data is that all three analyses of the data showed the same trend. In each case, there were fewer infections in the vaccine arm as compared to the placebo arm. While only one analysis reached a level of statistical significance (which means that the observed difference is very likely due to the effect of the vaccine), the fact that all analyses trend in the same direction provides strong evidence that there was a modest vaccine effect.

The results from the Thai trial are the first indication in humans that an AIDS vaccine can be protective. However, the excitement about the result is due to the sense of possibility that it brings to AIDS vaccine research—not the sense that this specific product would be made available. It is important to remember that clinical trials of other AIDS vaccine candidates are continuing and can also generate important information. (For an overview of AIDS vaccine clinical trials, visit <http://www.avac.org/ht/d/sp/i/324/pid/324>.)

The Thai prime-boost results are part of a larger AIDS vaccine discovery effort that is continuing on multiple fronts including basic science, clinical research, non-human primate research and many related disciplines.

Thai Trial Statistics

Trial duration: 2003-2009
Total participants: 16,402

Infections:

74 out of 8,198 volunteers who received placebo immunizations became infected with HIV compared to 51 out of 8,197 volunteers who received the vaccine regimen of ALVAC vCP1521 and AIDSVAX B/E.

Strengthening Capacity for Ethical

The AAVP Ethics, Law, and Human Rights Collaborating Centre (ELH) situated at the University of KwaZulu-Natal's School of Psychology, Pietermaritzburg, South Africa, works to facilitate the ethical conduct of HIV vaccine trials in selected African countries.

In 2009 ELH secured funding from the European and Developing Countries Clinical Trials Partnership (EDCTP) to strengthen African Research Ethics Committees' capacity for ethical review of HIV prevention research protocols. To achieve this, ELH will sponsor five African Research Ethics Committee members each year for the next three years to attend two intensive training modules on Institutionalising

First Round of HIV Prevention Research Advocacy Fellowship Announced

AVAC and the Global Campaign for Microbicides (GCM) recently launched a new Fellowship program that pairs emerging leaders in advocacy and activism with existing organizations to develop and execute creative, context-specific projects focused on HIV prevention research. Fellowship projects are focusing primarily on advocacy around biomedical HIV prevention research (such as clinical trials of vaccines, microbicides, pre-exposure prophylaxis) or rollout of male circumcision for HIV prevention. Fellows receive training, full-time financial support, and technical assistance to plan and implement a targeted one-year project within host organizations focused on HIV/AIDS.

The inaugural group of HIV Prevention Research Advocacy Fellows were announced in November. From over 100 applications from around the world, eight inaugural fellows were selected, all of whom are based in Africa. Additional fellows may be confirmed by the end of 2009. The Fellows were selected by an independent review committee of advocates, activists and other HIV prevention research stakeholders. AVAC and GCM will provide joint technical support and coordination for the entire program. The host organizations, to which the Fellows are closely tied, will provide additional support and structure for their work. The Fellows will focus on a variety of issues, including male circumcision for HIV prevention; involvement of gay men and other men who have sex with men in sub-Saharan African HIV prevention research; journalist and media engagement; trial results dissemination; vaccines; microbicides; and pre-exposure prophylaxis. Another round of Fellowships will be awarded in 2010. To learn more about the Fellowship program and to find out about upcoming rounds of Fellowships visit: www.avac.org/fellows.htm and www.global-campaign.org/Fellows.htm.

AAVP Advocacy Strategy Taskforce Set Up

AAVP has established a taskforce that will oversee the design and implementation of a strategy to serve the advocacy and communication interests of AAVP and its partners. The taskforce will provide the AAVP Steering Committee with independent evaluation of strategic and technical aspects of advocacy and communication. It will also review AAVP's collaboration with the Global HIV Vaccine Enterprise partners and advise on priority advocacy activities related to vaccine research and development.

The taskforce membership is drawn from AVAC: Global Advocacy for HIV Prevention, African Microbicides Advocacy Group (AMAG), International AIDS Vaccine Initiative (IAVI), and the National Institute for Allergies and Infectious Diseases (NIH-NIAID) and the US Agency for International Development (USAID) among others. AAVP needs to develop an advocacy strategy to dispel myths and misconceptions on HIV vaccine trials, to improve public knowledge and attitudes toward HIV vaccine development, to foster an environment that supports HIV vaccine research and clinical trials, and to address the concerns of most affected communities as well as treatment groups.

The HIV vaccine research and development process is ever-changing, hence the need to sustain the focus of all partners and stakeholders. HIV prevention involves a diverse array of strategies that need to be presented as a whole package. As such, greater coordination and consistency in advocacy and communication messages is needed. Furthermore, sharing competencies and information, as well as implementing joint advocacy and communication, makes the best use of the scarce resources available.

Review of HIV Prevention Research

Institutional Review Boards and Ethical issues in HIV Vaccine Trials. The modules have been developed and are hosted by the South African Research Ethics Training Initiative (SARETI) at the University of KwaZulu-Natal.

This year's successful applicants were Dr Alaba Oni (Nigeria), Ms Catherine Machyo (Kenya), Dr Rekha Kumar (Botswana), Dr Samuel Malamba (Uganda), and Prof Tsehayneh Kelemu (Ethiopia).

Further information on scholarships to attend these modules in 2010 can be obtained from Nicole Mamotte at aavp1@ukzn.ac.za.

Article by The AAVP Ethics, Law, and Human Rights Collaborating Centre



ABOUT AAVP

AAVP envisions an AIDS-free Africa through an effective vaccine. Its mission is to promote HIV vaccine development for Africa, through research, advocacy, partnership, and contribution to capacity strengthening and policy development. With encouragement and support from WHO and UNAIDS, AAVP has become a strong network of African HIV vaccine stakeholders, committed to HIV vaccine development for Africa.

Structure & Activity Implementation:

AAVP is structured to maximize the efforts of the network of African HIV stakeholders committed to HIV vaccine research and development. AAVP's structure is comprised of: (a) the AAVP Steering Committee, which provides overall guidance on activities; (b) four AAVP Centres of Excellence (the Coordinating and Resource Facilities) at African research institutions, which act as the principle mechanism for implementation of AAVP's activities; and (c) a secretariat. All of AAVP's structures work together in an integrated fashion to achieve AAVP's objectives and shared strategic directions and to carry out 5 distinct areas of work.

Strategic Directions and Work Areas:

To address the challenges in developing an effective HIV vaccine as well as work with global partners involved in HIV vaccine R&D, AAVP has a 5 year Strategic Plan (2007-2011) that is guided by five strategic directions: (1) capacity strengthening; (2) advocacy; (3) policy development; (4) increased community involvement; and (5) networking. There are five work areas that address these strategic directions, namely: (a) country-based strategic planning; (b) regulatory issues; (c) biomedical research; (d) communication and media; and (e) ethics, law and human rights.

AAVP Co-Chairs are Dr. Alash'le Abimiku and Dr. Pontiano Kaleebu.

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