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Promising developments in vaccine research, development of a vaginal gel and PrEP lead to calls for a combination of biomedical and non biomedical approaches to HIV prevention policy

Monday, 18 July, 2011 (Rome, Italy) - Researchers speaking in the first plenary session of the 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2011) have today offered insights into current and future HIV prevention research and discussed how biomedical developments over the past two years are beginning to shape debate on the future of HIV prevention policy.

The presentations reflect the breadth of expertise among the more than 5,000 researchers, clinicians and community leaders attending the conference, which runs from 17-20 July in Rome.

“We appear to be at a watershed in terms of HIV/AIDS science,” said IAS 2011 International Chair and International AIDS Society President, Elly Katabira. “It is a sign of how far the HIV/AIDS community has come in three decades that we are now beginning to discuss how to best combine traditional ways of preventing HIV such as condoms, needle exchange and testing with biomedical approaches such as a vaginal gel, early antiretroviral treatment and PrEP.”

“The developments in biomedical science over the past few years are very encouraging but at the same time only reinforce the need to maintain a robust HIV/AIDS research agenda,” said Stefano Vella, IAS 2011 Local Co-Chair and Research Director at the Istituto Superiore di Sanità (ISS).

The Changing Face of HIV Vaccine Research

In his plenary remarks, Gary Nabel, (United States) Director of the Vaccine Research Center at the National Institute of Allergy and Infectious Diseases (NIAID) said that despite the fact that an AIDS vaccine posed an exceptional research challenge, and progress had been slow, two recent developments have renewed optimism for the prospects of a vaccine.

Firstly, though efficacy was modest, the RV144 efficacy trial conducted in Thailand provided a proof of concept that a vaccine can prevent HIV infection in humans. The fact that a vaccine can prevent infection rather than simply controlling viremia has significant implications for its potential public health impact.

Secondly, it has become clear that broadly neutralizing antibodies are made in a substantial number of HIV-1 infected subjects (10-25%). Exceptionally, broadly neutralizing antibodies have

been derived from these subjects by several groups in the past year. Using structure-based rational vaccine design, Nabel and his team at the Vaccine Research Center identified a human antibody, termed VRC01, which neutralizes more than 90% of naturally circulating viruses. This antibody recognized the highly conserved CD4bs of the viral envelop required for entry.

The molecular details of how this antibody recognizes the virus have been discovered, and researchers have identified a class of antibodies with related properties. With this knowledge, it has been possible to trace how these antibodies are generated in humans. These advances provide critical insight into the design of an AIDS vaccine and open the door to new immune prevention strategies.

Nabel concluded by saying that the urgency for an effective AIDS vaccine has never been greater, and that it will become increasingly difficult to conduct efficacy trials in the future. By taking advantage of the recent scientific advances and coupling them with efficient clinical trial designs, the search for an effective AIDS vaccine can and must be accelerated.

Managing HIV Treatment in 2011

Giovanni Di Perri (Italy), from the School of Medicine, University of Turin, discussed how a number of high-standard clinical trials have put in a place a hierarchy of therapeutic solutions available today. Consequently, this has given the actual impression that no dramatic changes will take place in the near future.

Although the currently available therapeutic guidelines indicate that the management of HIV infection would appear straightforward, Di Perri pointed out that in the real world a series of variables (often at an individual level) frequently require the adoption of non-conventional drug combinations.

Variables such as tolerability and /or toxicity together with the increasing pressure on cost reduction are driving discussion around the clinical use of alternative therapeutic regimens.

These regimes have not been fully validated by adequately sized (statistically powered) and designed clinical trials. Nevertheless, the applied knowledge of some specific pharmacologic properties of antiretrovirals – as well as a closer consideration of single patient profiles (including pharmacogenomics) -- might help to better tailor antiretroviral therapy at the individual level, an intention fully justified by the need of lifelong therapy.

The Combined Approach to Preventing HIV Infection

Robin Shattock, (United Kingdom), Professor of Mucosal Infection and Immunity at Imperial College in London, argued that the time is now right to consider a combination of biomedical and non-biomedical strategies to prevent HIV infection.

Combinations of non-biomedical strategies aimed at individual behavioral change and community intervention to reduce HIV risk and vulnerability have been applied for nearly three decades, with differing success. These include sexually transmitted infection (STIs) diagnosis and treatment, HIV education and knowledge of HIV serostatus, condom social marketing, rights-based behavioural change, prevention of mother-to-child transmission, needle exchange, blood safety, infection control in healthcare, and legal protection for people living with HIV.

However, a number of new biomedical tools (or prevention technologies) have demonstrated variable success in randomized controlled trials (RCT) including:

- medical male circumcision (MMC) (57%);
- daily oral tenofovir (TDF) plus emtricitabine (FTC) used as pre-exposure prophylaxis (oral-PrEP) by HIV-negative men who have sex with men (MSM) (iPrEX study) (44%);
- 1% tenofovir gel (microbicide) applied vaginally before and after sex by HIV-negative women as topical pre-exposure prophylaxis (CAPRISA 004 study) (39%);
- a prime-boost HIV vaccine regimen (RV144 study) (31% effectiveness);
- early use of antiretroviral treatment (ART) (treatment for prevention (T4P)) by an HIV-infected individual has been shown to reduced heterosexual transmission to an uninfected partner by 96% (HPTN052)

Approaches that could be studied now include focused assessment of medical male circumcision combined with microbicide gels for men's female partners. A second combination to evaluate would be T4P for the infected partner combined with antiretroviral (ARV) PrEP for the HIV-negative partner. At least 18% of sexual transmissions in the HPTN052 trial may have been acquired from partners outside the primary relationship. Thus the offer of ARV PrEP for the HIV-negative partner together with T4P for the infected partner may provide a more cost-effective option per infection averted.

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Online Coverage of IAS 2011 at www.ias2011.org

The online Programme-at-a-Glance, available through the website, includes links to abstracts, as well as session slides with audio and speeches (all abstract findings are embargoed until date and time of delivery at the conference). Additional online programming is provided by IAS 2011's two official online partners: Clinical Care Options and NAM. Reporters and others can also follow key developments on the IAS 2011 blog at <http://blog.ias2011.org> or on Twitter at www.twitter.com/ias2011.

About the IAS 2011 Organizers

IAS: The [International AIDS Society](http://www.iasociety.org) (IAS) is the world's leading independent association of HIV professionals, with over 16,000 members from more than 196 countries working at all levels of the global response to AIDS. Our members include researchers from all disciplines, clinicians, public health and community practitioners on the frontlines of the epidemic, as well as policy and programme planners. The IAS is the custodian of the biennial International AIDS Conference and lead organizer of the IAS Conference on HIV Pathogenesis, Treatment and Prevention, which is currently being held in Rome, Italy.

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ISS: The [Istituto Superiore di Sanità](http://www.iss.it) (ISS) is the leading technical and scientific body of the Italian National Health Service. Its activities include research, clinical trials, and control and training in public health. It also serves as a major national clearing-house for technical and scientific information on public health issues. Among other things, the Institute conducts scientific research in a wide variety of fields, from cutting-edge molecular and genetic research,

to population-based studies of risk factors for disease and disability, to Global Health research.

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