

Poster presentation

P14-01. Care and treatment for volunteers in IAVI-sponsored HIV vaccine clinical trials in India

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Background

International AIDS Vaccine Initiative and its global partners have or are conducting 22 preventive AIDS vaccine trials in 940 participants in 11 countries. The initiation of clinical trials in India prompted to examine referrals, care and treatment (CT) national guidelines to be offered to vaccine trial or HIV-infected volunteers.

Methods

National consultations and discussions were held by IAVI in India to define policy for CT of trial participants within national guidelines.

Results

CT guidelines formulated and implemented in clinical trials include the following provisions: for volunteer with adverse events or disabilities due to vaccination, provision of comprehensive care, diagnosis and treatment without charge; for volunteer becoming HIV-infected during the trial, IAVI ensures access to free anti-retroviral therapy (as per national guidelines) for 5 years after treatment initiation, unless free of charge from other sources. Volunteers HIV-infected at screening are referred to reliable HIV treatment centers. As personal medical insurance is uncommon, volunteers are provided with medical insurance for vaccine-unrelated medical events for duration of trial period. The trial centers provide free of cost consultations, diagnostic tests, contraceptives and medicines for common ailments whose annual cost is estimated to \$1960. Cost for insurance is \$60/volunteer/year. IAVI maintains global insurance policy which provides uniform liability

coverage for volunteers injured through participation in global clinical trials.

Conclusion

IAVI care and treatment policy has become the "Reference Standard" for the Ministry of Health. It ensures volunteers in IAVI-sponsored research treated according to highest ethical standards.