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*** Contents

MINIREVIEW: GCLP in Clinical Trials

OPINION: High Prevalence of HIV/AIDS in Cameroon - Partly Attributed to Certain Cultural Practices?

Research Highlights

Clinical Trials ^{News}

Top Review Articles

HIV/STD Guidelines ^{New}

Funding Opportunities

Upcoming Scientific Events

YRG CARE Academic Programmes

YRG CARE Forthcoming Events

YRG CARE Past Events

YRG CARE Recent Publications



From the Director's Desk

Greetings from YRG CARE!

The Third National Science Symposium (HIV SCIENCE 2010) in August and the GCLP Workshop in June 2010, organized by YRG CARE were well attended and appreciated. It is my pleasure to thank the speakers, faculty, co-sponsors and delegates for their active participation. This encourages us to plan for the next International HIV Science Symposium to be announced shortly.

The establishment and maintenance of GCLP in laboratories has become an essential component to good patient care; and its consistent application is cardinal to the success of any clinical trial. Many a times, clinical trial data are laboratory-derived, as study endpoints or participant safety. In the event of inconsistent GCLP practice, there is a risk of data becoming inaccurate, even rendering the entire clinical trial a failure. The very informative mini-review article on the GCLP in this issue, addresses various aspects of principles and implementation strategies of GCLP in health-care settings.

In the forthcoming months we have annual symposia - the CART 2011, TYBS 2011 and HANS 2011 coming up. Detailed information on these events is available in this newsletter and on our website. We look forward to seeing you there!

We hope that this edition of the newsletter will contribute to the growing success of the series and to that end we continue to look forward to your ideas, suggestions and feedback.

Sincerely,
Prof. Suniti Solomon, MD, FAMS
Editor-in-Chief

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MINIREVIEW Clinical Trial

GCLP in Clinical Trials

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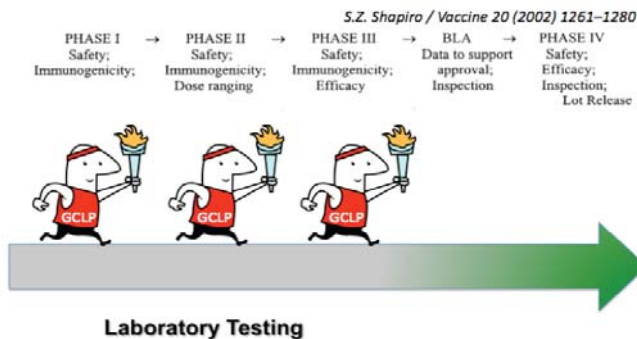
A crucial pre-requisite to the conduct of clinical trial research is adherence to the principles of Good Clinical Practice (GCP). GCP is an international quality standard provided by the International Conference for Harmonization (ICH) for the conduct of clinical trials and for protecting the rights of trial subjects [European Medicines Agency, ICH Topic Guidelines GCLP, 1996]. In contrast to the universally recognized GCP principles, there are no globally accepted standards applying to laboratories conducting tests on specimens from human clinical trials. One cannot apply Good Laboratory Practice (GLP) guidelines [Code of Federal Regulations, 21 CFR Part 58 GCLP, 2005] because GLP applies only to pre-clinical studies. Stiles *et al.* (British Association Research Quality Assurance-BARQA) merged GCP with GLP to develop Good Clinical Laboratory Practice (GCLP) guidelines to promote the validity of test results generated by analytical laboratories in support of clinical trials [Stiles *et al.*, 2003]. These types of tests include protocol-mandated safety assays, blood processing, and cellular and serological immunogenicity assays performed on specimens for phase I - III human clinical trials.

GCLP is designed to provide general guidelines on the "gray area" (see Figure) covering the conduct of laboratory testing for phase I - III human clinical trials. These general guidelines are prone to a wide array of interpretation by laboratories and organizations implementing them. Recognizing this issue, the US National Institute of Allergy and Infectious Disease, Division of AIDS (DAIDS) expanded the existing knowledge on GCLP and published comprehensive GCLP guidelines [Ezzelle *et al.*, 2008; DAIDS Guidelines for GCLP, 2009] incorporating elements of Clinical Laboratory Improvement Amendments (CLIA) [CFR Part 493, 2005], College of American Pathologists (CAP) [CAP, 2009], and International Organization for Standardization (ISO) [ISO 15189, 2003]. The latter GCLP guidelines (NIAID GCLP) provided a much-needed practical approach to the implementation of GCLP in laboratories conducting safety and immunogenicity testing for human clinical trials. GCLP is the minimal requirement for clinical research laboratories of all DAIDS-funded clinical trials. The World Health Organization/Special Programme for Research & Training in Tropical Diseases (WHO/TDR) acquired the copyright to the GCLP guidelines that were originally published by BARQA (BARQA GCLP), and set them as standards for compliance by laboratories involved in the analysis of samples from TDR-supported clinical trials [WHO/TDR, 2009]. In India, the Indian Council of Medical Research adopted and widened the scope of GCLP as a standard "to be followed by medical laboratories involved in clinical research and/or patient care" [ICMR Guidelines for GCLP, 2008]. The South African National Accreditation System currently provides GCLP accreditation to South African laboratories conducting tests on human clinical specimens [South African National Accreditation System].

GCLP has now been adopted by multiple organizations in many research medical fields (HIV-1, malaria, TB, cancer), but it has not yet been upgraded to a universal standard. When laboratories need to apply GCLP as a quality standard, they must decide which GCLP they should follow. This is particularly important when clinical laboratories are located in distant geographical sites and the results of their tests need to be standardized and compared within and across networks.

We made the first effort to harmonize the BARQA GCLP with the NIAID GCLP by organizing a "Workshop on GCLP Guidelines for International Clinical Trials: Interpretation and Implementation" [2007, Raleigh, North Carolina] with experts in phase I-III HIV clinical trials, GCLP, GLP and GCP. The results of the workshop, which were published in 2009, focused around four critical elements of GCLP: Training, Auditing/Accreditation, Assay Validation, and Proficiency Testing. Harmonization was reached for three out of the four-selected GCLP elements [Sarzotti-Kelsoe *et al.*, 2009]. However, the issue of GCLP accreditation was not harmonized since accreditation is not globally provided by regulatory agencies, and there is no governing body overseeing this process.

Phases of Clinical Trials



A practical application of our GCLP harmonization efforts is provided by the Collaboration for AIDS Vaccine Discovery/Comprehensive Antibody-Vaccine Immune Monitoring Consortium (CAVD/CA-VIMC) (sponsored by the Bill and Melinda Gates Foundation), which uses a combination of BARQA GCLP and NIAID GCLP to standardize its international laboratory sites in the performance of a validated Neutralizing Antibody Assay for HIV-1 (TZM-bl assay), and provides accreditation following an extensive training, assay implementation and auditing process. An encouraging result of our GCLP harmonization efforts is the fact that audits performed by the CAVD/CA-VIMC have been acknowledged and accepted by vaccine networks following the BARQA GCLP (such as the International AIDS Vaccine Initiative) as well as those following the NIAID GCLP (such as the HIV Vaccines Trials Network).

With the first successful HIV-1 vaccine clinical trial conducted in Thailand, the establishment of GCLP-compliant laboratories performing the same validated immune monitoring assay will become essential for testing clinical trial specimens. Acknowledging the importance of GCLP standardization, the CAVD/CA-VIMC laboratory directed by Dr. P. Balakrishnan at YRG CARE, Chennai, was one of the first international laboratory sites accredited to perform the TZM-bl assay for human clinical trials, in GCLP compliance. In support of these efforts, YRG CARE recently organized a GCLP Training Workshop to offer comprehensive guidance for those professionals associated with clinical laboratory management and accreditation [YRG CARE GCLP Workshop, 2010].

The CAVD/CA-VIMC also developed and recently launched the first International Proficiency Testing program to qualify laboratories performing the Neutralizing Antibody TZM-bl assay for HIV/AIDS vaccine clinical trials. This program is jointly sponsored by the NIH/DAIDS and the CAVD and it is open to all laboratories performing the TZM-bl assay. Currently, all of the domestic and international laboratories accredited by the CAVD/CA-VIMC to perform the TZM-bl assay in GCLP compliance have successfully completed two rounds of proficiency testing provided by this program. With the first effective HIV-1 vaccine trial conducted in Thailand [Rerks-Ngarm *et al.*, 2009], the establishment of a network of GCLP-compliant laboratories consistently performing the same validated immune monitoring assay will become essential for testing clinical trial specimens.

Acknowledgments

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August 2010

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OPINION

Social Issues

High Prevalence of HIV/AIDS in Cameroon - Partly Attributed to Certain Cultural Practices?

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Cameroon is situated in west and central Africa, a region from where the HIV pandemic is thought to have disseminated to other parts of the world [Bailes *et al.*, 2003; Gao *et al.*, 1993; Wolfe *et al.*, 2004; Cohen, 2000]. Cross-sectional studies conducted to elucidate the virologic origin of the pandemic from 14 remote villages of Cameroon showed the existence of tremendous genetic diversities of HIV-1 strains. The study hypothesized that the viral strains in remote Cameroon largely represented the pre-epidemic stage of HIV evolution [Wolfe *et al.*, 2004]. Cameroon is widely known as "Africa in miniature," largely owing to her rich cultural diversity. Some of the cultural practices in Cameroon are now believed to be partially responsible for the increasing number of HIV cases (5.1%) in the region. These practices vary from place to place within the country but share a common phenomenon being the involvement of blood between humans or animals.

African bush meat consumption: A cause of concern.

Hunters in eastern Cameroon poach monkeys, chimpanzees and even gorillas for food, commonly known as bush-meat see figure. The tradition of consuming these primates is risky for humans as primates are known to harbor similar viruses (e.g. simian immunodeficiency virus, SIV) that have been shown to have jumped into Homo sapiens, and after multiple phases of mutations, the HIV virus was originated [Bailes *et al.*, 2003; Gao *et al.*, 1993]. Interestingly, I have witnessed the consumption of raw bush meat by hunters in the field, a move to exercise human dominance over primates. There are indications that man is still being infected directly from primates today as shown by a study by [Plantier *et al.*, 2009]. They found a new HIV in a Cameroonian woman which was closely related to the gorilla SIV and showed no evidence of recombination with other HIV-1 lineages [Plantier *et al.*, 2009].

Polygamy in remote Cameroon.

Polygamy is a cultural practice widely observed in some parts of Cameroon and many other regions in Africa, especially in the rural communities [http://en.wikipedia.org/wiki/Polygamy_in_Cameroon 2010]. One man with more than one wife puts the group at risk if one amongst the spouses contracted the virus at some point in time. More interestingly, infidelity amongst the wives has been reported ~60% of polygamous homes studied and the percentage is



proportional to the number of wives per husband. More spouses logically means less time devoted on each of them. This may prompt the spouses to seek sexual satisfaction externally and thereby putting the family at risk.

Witch-clinic and traditional medicine: Taking innocents for a ride!

Belief in witch-healing is still a common practice in certain rural and urban parts of modern day Cameroon. Currently, the use of traditional herbs is the second-line option for treatment of common diseases. Although the witch-healers proclaim to 'treat' HIV in various 'ways' the most dangerous act is through the use of razor blades that pierces into the body through which their concoctions are administered. Further, an entire house-hold may periodically visit a witch-healer to seek for fortune or deliverance. The witch-healer in most instances in the past had a single razor that is as lengthy as it could create openings he wanted to, in a given patient. Using one razor for a month can mean distributing blood contents to as many as 100 - 300 people. HIV prevalence in Cameroon is estimated to be 5.1%, which implies the use of a singly razor to create cuts on a house-hold of 20 members is a high probability of transmitting HIV to some of them.

Scalp-shaving: A 'closed-shave' for innocents of a household?

North West province of Cameroon observes a tradition whereby, the family members of a deceased individual offers to shave hairs from tip to toe down from the scalp using one single 'sacred' razor or in some poor homes, sharp pieces from a broken glass bottle. This practice is commonly followed by cuts and bruises from which blood with possible HIV infection could be transmitted from the infected individual to all other 'unlucky' individuals of the family undergoing a subsequent scalp-shave with the same razor.

Female genital mutilation.

The *Ejagham* tribe of the South West Province, the *Haoussas*, *Arapshouas* in the Northern part of Cameroon illegally practice female genital mutilation [http://www.fgmnetwork.org/articles/arrey_cameroon.php]. This desperate act is a cultural practice handed down for generations still prevailing in the aforementioned tribal populations. In rural areas, the clitoris, the labia minora and the labia majora are excised with no prior using crude metal instruments. This could lead to excessive bleeding and the most important point to note here is the usage of the same instrument without proper sterilization for all the other females of the house-hold, which predisposes to potential transmission of HIV infection and sexually transmitted pathogens.

Bizarre belief from unknown sources.

Infected people were made to believe that having sex with a virgin was sufficient to cure them of HIV. To 'test' this young girls were raped by HIV positive men wherein they became infected and the patient could never cure of the disease either. The meaning of AIDS (Acquired Immune Deficiency Syndrome) was modified to *America's Idea to Discourage Sex*. This notion was bought by a handful of people, a belief that handicapped almost all the efforts put by the government to sensitize the public. People became reckless with their sex life, an act that contributed to a few more people being infected.

HIV/AIDS awareness education has penetrated communities thanks to vigorous and aggressive programs put in place by governmental and non-governmental organizations. The idea that HIV/AIDS patients suffer from recurrent infections with constant hospitalizations and weight loss has been used by others as a diagnostic tool within their remote communities. Faced with desperate situations or temptations, groups of individuals make decisions as to whether one is positive or not by physical examinations for the above observations. HIV/AIDS prevalence in Cameroon stands at 5.1% as of 2008 in a population of about 18 million inhabitants. Over half a million people walk the streets carrying the virus and thanks to anti-retro viral therapy, viral replication and disease progression has tremendously been reduced over the years. AIDS patients have regained weight and strength they no longer frequent hospitals and are able to function normally. This makes it difficult therefore, to predict who may have been infected or who may not. Hence by all means having unprotected sex with an individual simply because the individual looks healthy could prove detrimental.

Culture is an important aspect that makes a group of people unique in some way. It is known to be an identity in a group of people. With the rapid changes and developments in our societies to day, certain circumstances have it difficult

to follow our cultures or practices in the same way as ever. This has therefore forced several communities to readjust their practices to suit the circumstances that prevail. In case of HIV for example, some of the above mentioned practices or habits should be abolished or modified for the best interest of the people loyal to the culture. HIV is a disease transmitted through blood and cultural practices that involve the exchange of blood between man and man or man and primates should be abolished or checked to make sure that people are not infected.

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RESEARCH HIGHLIGHTS

Alcoholic Beverages Tighten the Noose Further: Accelerates HIV Disease Progression!

Baum and colleagues from the US have shown that frequent alcohol intake could accelerate HIV disease progression. A 30-month prospective study conducted on 231 adult HIV positive patients concluded that alcohol (defined as two or more drinks daily) consumption had a direct deleterious effect on CD4+ T cells and that the accelerated decline in CD4+ T cell counts was not always due to poorer adherence to ART in the study population. The study also went on to show that frequent alcohol users were 2.91 times more likely to present a decline of CD4+ T cells to ≤ 200 cells/ μ L. Notably, frequent alcohol users who were not on antiretroviral therapy also increased their risk for CD4+ T cell decline to ≤ 200 cells/ μ L. Hence the study has confirmed the common notion that frequent intake of alcohol could intensify the rate of disease progression due to HIV infection [Baum, MK et al, *AIDS Res Hum Retroviruses*. 2010, 26: 511 - 518. © Mary Ann Liebert, Inc., Publishers, USA].

Could Cancer Drugs Break the HIV-1 Bails?

Clouser and colleagues from the University of Minnesota have identified two anti-cancer drugs that could serve as an effective treatment for HIV infection. The drugs, decitabine and gemcitabine were already approved by US-FDA for the use of cancer treatment, and have been recently shown to be effective against HIV infection. The anti-HIV activities were proved to be effective in a mouse model by causing the virus to mutate itself to death. The anti-HIV activities of these two drugs have been promising when the drugs were administered in a combination, when the viral infectivity was dramatically reduced by 73%. Besides inhibiting virus growth and replication like the currently available anti-HIV drugs, the described new drug combination in the study forces the virus to mutate faster necessitating the virus to undergo a lethal mutagenesis.

Interestingly, the study has also shown that the proposed drug regimen have no noticeable toxic side effects heretofore, which has encouraged researchers currently working on drug development against HIV infection [Clouser, CL et al, *J Virol*. 2010, 84: 9301 - 9309. © American Society of Microbiology, USA].

Could Pooling Method be a Boon in Resource-limited Settings?

Plasma viral load monitoring during antiretroviral therapy is not currently being performed in many resource-constrained settings largely because of the underlying costs involved. The investigators, May and colleagues from the University of California at San Diego have shown that pooling strategies could be used to significantly reduce the cost compared with individual testing methods

and also make such monitoring aspects feasible in resource-constrained settings. The methodology included in this study was based on the simulations, which were used to generate sample values of viral loads that represent a population of patients on ART. They had demonstrated a variety of algorithms and pool sizes that can incorporate available quantitative viral load data and data on how pooling methods can be used efficiently and accurately to monitor for virologic failure in patients receiving ART. [May, S et al, *J Acquir Immune Defic Syndr*. 2010, 53: 194 – 201. © Lippincott Williams & Wilkins, USA].

Genetically Engineered Live Bacteria as Potential Microbicides!

Lactobacillus sp. are ideal candidates for live microbicide development as they are the predominant bacterial species in the female genital tract. Investigators from the San Raffaele Scientific Institute, Italy have engineered a human vaginal isolate of *L. jensenii* capable of producing certain anti-HIV-1 proteins, such as RANTES and C1C5 RANTES. Full length wild-type RANTES and C1C5 RANTES secreted by *L. jensenii* were purified to homogeneity and were shown to adopt a correctly folded conformation. Both RANTES variants were shown to have strong activity against HIV-1 isolates of different genetic subtypes. [Vangelista, L et al, *Antimicrob Agents Chemother*. 2010, 54:2994 – 3001. © American Society of Microbiology, USA].

HIV DOT Supports Better Survival: Research Outcome!

Directly observed therapy (DOT) is a treatment strategy commonly used for tuberculosis, in which a health-care worker ensures that medication is taken by patients at health care facilities to improve drug adherence. The first randomized controlled trial of patient-nominated treatment-supporters providing partial DOT in resource-limited settings was conducted at University of Cape Town, South Africa. The researchers analysed data from 274 adult patients initiating antiretroviral therapy (ART) and these patients were randomised to treatment-supporter DOT-ART or self-administered ART. In the DOT group, patients selected someone from their own personal network such as a family member or friend to observe at least one medication dose every day and provide support. DOT-ART patients and supporters received baseline plus follow-up training and monitoring.

The study concluded that although virologic outcome was poor, the CD4 cell count increased at the 6th-month follow up. Importantly, the researchers found that mortality rates were lower among DOT patients (n=9) than among self-monitored ART (n=20). [Nachega, JB et al, *AIDS*. 2010, 24: 1273 – 1280. © Wolters Kluwer, USA].

POC CD4 Estimation Test: Waiting in the Wings for Use in Resource-limited Settings!

Stybayaeva and colleagues from the Department of Electrical Engineering, University of California has developed a "lab-on-a-chip" microarray holographic imaging device for CD4 testing. This microfluidic device uses antibodies to "capture" CD4+ and CD8+ T cells and also detects the levels of cytokines released by the cells. It consists of a polymer film imprinted with an array of miniature spots. Each spot contains antibodies specific to the CD4+ and CD8+ T cells. When the blood flowed across the antibody spots, the specific T-cells stopped, and they stick onto the spots. Each T cell type is captured next to antibody-spots specific for the cytokines that they might produce. When the specific antibodies activated the cells, spots adjacent to the cells captured the cytokines they secreted. This connected a specific T cell subset to its secreted cytokines. The visible colour intensity of antibody spots revealed differences in cytokine production by T cells.

This method takes only seconds to complete, and could be a potentially useful tool for use in resource-limited settings. [Stybayaeva, G et al, *Anal Chem*. 2010, 82: 3736 – 3744. © American Chemical Society, USA].

Now the Novel Peptides Walk on Egg Shells: Promising New HIV Treatment Strategy in the Pipeline!

Israeli researchers have developed a new treatment for HIV that kills human cells infected with the virus but not damaging healthy ones. New therapeutic approaches and new anti-viral agents are being continuously developed to obtain a better management of HIV disease. However, once the viral cDNA is integrated into the host chromosome it is almost impossible to terminate viral multiplication process and cure the disease. HIV-1 infected cells, unlike cells infected by other retroviruses, bear only 1 - 2 copies of integrated viral cDNA per cell and this is despite the presence of numerous copies of unintegrated viral cDNA. Recently Levin and others have developed a novel approach to specifically and significantly eradicate HIV-1 infected cells and eliminate infectious virions from cultured cells. Addition of integration-stimulating peptides to cells infected by wild type HIV-1 significantly increased the appearance of new virions during the first 6-8 days post infection. But from the eighth day post-infection, a decrease in virus production was observed. Almost complete eradication of virions was obtained and this eradication was probably due to promotion of cell death by apoptosis. [Levin, A et al, *AIDS Res Ther*. 2010, 7: 31 © Levin A].

Nutritional Supplements Show Modest Benefits in HIV Infected Patients!

Swaminathan and her colleagues conducted a prospective six-month study in southern India to test the hypothesis whether nutritional supplementation with added calories and fat would improve the overall health of patients and slow down the disease progression in HIV patients. One group of patients received nutritional counseling and standard care, whereas another group of patients additionally received a macronutrient providing 400 cal and 15 g of protein daily. Study outcomes were changes in anthropometry, body composition, blood chemistry, and CD4 count at 6 months. Totally 636 ART-naive patients were enrolled in the study and 361 completed 6 months of follow-up, of which 282 received supplements and 79 received standard care. The mean age was 31 years and mean weight was 50 kg. The investigators concluded that macronutrient supplementation did not significantly result in increased weight gain when compared with standard care among patients with moderately advanced HIV disease. [Swaminathan, S et al, *Clin Infect Dis*. 2010; 51: 51 – 57. © The University of Chicago Press, USA].

Swedish Team Links Suppressor T-cell Expansion with Possible Immune Abrogation in HIV Infection!

Swedish scientists led by Marie Larsson at the Linköping University points out to the ability of HIV-1 to induct suppressor T cells armed with certain negative costimulatory molecules namely PD-1, CTLA-4 and TRAIL which leads to possible immune abrogation, the hallmark of HIV disease. This raises the possibility that immune dysfunctions seen in HIV infection is attributed to suppressor T cells, which in addition to inducing hyper-immune activation could initiate a cascade of negative T cell stimulation that ultimately leads to inhibition of salubrious T cell responses. T cell priming in lymphoid tissues of HIV-infected individuals occurs in the presence of HIV-1. Dendritic cells present, activate T cells and disseminate viruses to newly activated T cells. The scientists studied the effects of HIV-1 on DC-naïve T cell interactions and found a dramatic decrease in the primary expansion of naïve T cells when cultured with HIV-1 exposed DCs. CD4+ and CD8+ T cells expressed high levels of TRAIL and PD-1, whereas CTLA-4 expression was observed on CD4+ T cells. T cells primed in the presence of HIV-1 also suppressed priming of other naïve T cells in a contact-dependent manner.

The researchers pointed out the concrete role of CTLA-4, TRAIL and PD-1 in the immunosuppression pathways; blocking these negative costimulatory molecules restored T cell proliferation to a greater extent. The study concluded that the



presence of HIV-1 during DC priming produced cells with inhibitory effects on T cell activation and proliferation, i.e. suppressor T cells, a mechanism that could contribute to the enhancement of HIV-1 pathogenesis. [Che, KF *et al*, *Eur J Immunol*. 2010; 40: 2248 – 2258. © 2010 2010 WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim, Germany].

US-FDA Approves a New 4th Generation HIV Test'

On June 18, 2010, FDA approved "4th Generation", the first HIV diagnostic test (ARCHITECT HIV Ag/Ab Combo test manufactured by ABBOTT Laboratories, ABBOTT Park, Illinois), that simultaneously detects both antigen and antibodies for the HIV. This single, automated test is a highly sensitive chemiluminescent microparticle immunoassay intended to be used for an early diagnosis of HIV-1/HIV-2 infection. It is specific for the detection of the HIV-1 p24 antigen, as well as antibodies to HIV-1 groups M and O, and antibodies to HIV-2. The median detection time was demonstrated to be 7 days earlier (range 0 to 20 days) compared to 3rd generation ELISA antibody tests to which they were compared.

While the assay is not intended to be used for routine screening of blood donors, it is approved as a donor screening assay for HIV-1/HIV-2 infection in urgent situations where licensed blood-donor screening tests are unavailable or their usage is impractical.

CLINICAL TRIAL *News*

Adenovirus Type 5 HIV-1 Gag Therapeutic Vaccine: Safe!

An NIH funded randomized, placebo-controlled and double blinded phase clinical trial (ACTG 5197) has shown that the vaccine was generally safe and very well tolerated. Despite a trend favouring viral suppression among vaccine recipients observed, differences in HIV-1 RNA levels did not meet the pre-specified level of significance.

The primary goal of this study was to determine whether patients on anti-HIV medications can stop taking those medications if they receive an HIV vaccine. The study hypotheses were: 1) the week 12 and week 16 post-ART interruption geometric mean HIV-1 RNA levels will be lower among participants, who had received MRK Ad5 vaccine prior to ART interruption than among participants who received placebo and 2) the time averaged area under the curve of the log₁₀ HIV-1 RNA copies/mL versus day function in the 16 week post-ART interruption step will be lower among participants, who received the MRK Ad5 vaccine prior to ART interruption than among participants who receive placebo. Although the vaccine benefit trends were seen for both primary end points, they did not reach a pre-specified significance level.

The researchers concluded that the future immunogenicity studies should require a substantially higher immunogenicity threshold before an analytical treatment interruption is contemplated. [Schooley RT, *et al*, *J Infect Dis*. 2010; 202: 705 – 716. © University of Chicago Press, USA].

First Therapeutic Vaccine Trial from GeoVax!

The AIDS Research Consortium of Atlanta (ARCA) has recently received approval to begin enrolment for the first ever therapeutic trial conducted using a promising HIV vaccine candidate from GeoVax, a US based biotechnology company in the mission of developing an effective and safe vaccine against HIV-1. ARCA worked together with GeoVax to design the protocol for the Phase I clinical trial.

The trial based on the achievement of excellent post-vaccine viral control in animal studies conducted in recently infected non-human primates at the Yerkes National primate research Center, affiliated with Emory University. To be eligible for the study, the person should have had a negative HIV test followed by a positive test up to 6 months later, and ART should have been

initiated on these patients within 6 months of diagnosis. The study will last for up to 77 weeks. All patients will be followed closely for safety and for the ability of the vaccine to elicit protective immune responses in vaccinated participants. [Source: http://www.geovax.com/newsroom/arca_final_27may10.pdf]

HAART in Pregnancy & Breast-feeding Mother: *Mma Bana* Study

NIH sponsored clinical NCT00270296 has shown the lowest rate (1.1%) of mother-to-child transmission recorded, in a study from Africa among breastfeeding infants. This study was the first randomized clinical trial to compare highly active antiretroviral therapy (HAART) regimens used during pregnancy or breastfeeding. The study compared the HIV viral suppression in mothers at delivery and throughout breastfeeding among women assigned to receive one of three treatment regimens. In total, 730 HIV-1 infected pregnant women were enrolled in the study and of which 560 women were with CD4 count of > or = 200 cells/μL received coformulated abacavir, zidovudine, and lamivudine (NRTI group) or lopinavir-ritonavir plus zidovudine-lamivudine (PI group) from 26 to 34 weeks' gestation through planned weaning by 6 months post partum. The remaining 170 women were with CD4 counts of less than 200 cells/μL received nevirapine plus zidovudine-lamivudine (the observational group). Infants received single-dose nevirapine and 4 weeks of zidovudine. Almost all women achieved viral suppression by delivery, and their viral levels remained undetectable throughout breastfeeding.

The investigators also found that the HAART regimens used in the study were safe and generally well-tolerated. The *Mma Bana* Study findings have already significantly influenced the recent guidelines by WHO on the use of HAART to prevent mother-to-child HIV transmission. [Shapiro, RL *et al*, *N Engl J Med*. 2010 ; 17; 362: 2316 – 2318. © Massachusetts Medical Society, USA].

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Funding Opportunities / Fellowships

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WHO-TDR Short Course in Tropical Medicine. Organised by the London School of Hygiene & Tropical Medicine. 4 Oct to 12 Nov 2010. <http://www.who.int/tdr>. eMail: philip.gothard@uclh.nhs.uk

Upcoming Scientific Events 2010 - 11

October - November '10

3rd National Conference of AIDS Society of India. Oct 29 – 31, 2010. Marriott Convention Centre, Hyderabad, India. www.asicon2010.com/

22nd Australasian HIV/AIDS Conference 2010, Oct 20 – 22, Sydney Convention Centre, Sydney, Australia. <http://www.hivaidsconference.com.au/>

2nd International Workshop on Adverse Drug Reactions & Co-morbidities in HIV Nov 4 – 6, London, UK. <http://www.intmedpress.com/lipodystrophy/>

41st Union World Conference on Lung Health – TB, HIV, Lung Health, Nov 11 - 15, Berlin, Germany. <http://www.worldlunghealth.org/confBerlin/>

January - November '11

The YRG CARE Bioethics Symposium (TYBS 2011). Jan 6-7, 2011. Chennai, India. <http://www.yrgcare.org/>

Chennai ART Symposium (CART 2011). Jan 8 - 9, 2011. Chennai, India. <http://www.yrgcare.org/>

HIV/AIDS Nursing Symposium (HANS 2011). Jan 7 , 2011. Chennai, India. <http://www.yrgcare.org/>

1st International Workshop on HIV & Women. Jan 10 – 11, 2011. Washington DC, USA. <http://www.virology-education.com/>

Conference on Translational Research in HIV/AIDS in India. Jan 12 - 15, 2011, Vivanta by Taj - Goa, India. <http://health.usf.edu/research/aitrip/trai.html>

14th Bangkok International Symposium on HIV Medicine, Jan 19-21, 2011. Bangkok, Bangkok, Thailand. <http://www.hivnat.org/bangkoksymposium>

International Conference on Emerging Frontiers & Challenges in HIV/AIDS Research. Feb 5 – 8, 2011. Mumbai, India. http://icmr.nic.in/icmrnews/nirrh_conference.pdf

3rd International Conference on Drug Discovery & Therapy, Feb 7 – 10, 2011, Dubai, UAE. <http://www.icddt.com/>

CROI 2011 (Conference on Retroviruses & Opportunistic Infections). Feb 27 – Mar 2, 2011. Boston, MA, USA. <http://www.retroconference.org/>

6th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment & Prevention, July 17 – 20, 2011, Rome, Italy. <http://www.ias2011.org/>

10th International Congress on AIDS in Asia and the Pacific (ICAAP10), Aug 22 – 26, 2011. Busan, South Korea. <http://www.icaap10.org/html/main.html>

13th European AIDS Conference / EACS. Oct 12 – 15, 2011. Belgrade, Serbia <http://www.eacs-conference2011.com/>

16th International Conference on AIDS and STI in Africa (ICASA). Dec 4 – 8, 2011. Addis Ababa, Ethiopia. <http://www.icasa2011addis.org/>

5th International Workshop on HIV Persistence: The Reference Workshop on HIV Reservoirs, Dec 6 – 9, 2011, St Martin, West Indies. <http://www.hiv-workshop.com>



RENEWAL OF THE 365 GOOD FRIENDS CALENDAR!



YRG CARE is raising funds from 365 Good Friends. Rs 2000/USD 45 will support costs for children at our medical centers in 2011. In appreciation of the donation from the 365 Good Friends, we shall develop a calendar with the person's name on a

particular specified date of the year. Local donations receive 80% tax exemption while donations from the USA are also tax deductible on filing the Federal Tax form 1040. For more information, please log on to <http://yrgcare.org/icare/index.htm#365goodfriends> or write to info@yrgcare.org.

Friends from USA can please mail cheques to Dr Michael Gaitonde, 7240 Winnipeg Court, Gainesville, VA 20155.

YRG CARE

Academic Programmes



PhD Degree Course

Applications for PhD degree course in Medical Microbiology (affiliated to the University of Madras) at YRG CARE are invited from candidates who have completed their Post Graduate degree in Medical Microbiology /Applied Microbiology / Molecular biology / Biotechnology. Applicants should have passed the national entrance tests for independent fellowships under CSIR /ICMR/ DBT.

YRG CARE

Forthcoming Events



HIV Testing Counselling Training

YRG CARE is organizing two day training course on Pre and Post-HIV Test Counselling in January 2011 (dates to be announced). The training course is based on the National AIDS Control Organization (NACO) guidelines to ensure uniformity in counseling and testing services across the country. It is also a requirement from the National Accreditation Board of Laboratories (NABL) to have laboratory staff trained and certified for providing Voluntary Counseling and Testing (VCT) services. For more details please write to VCTtraining@yrgcare.org



Chennai ART Symposium

CART 2011 will be organized on 8th and 9th, January 2011 with an objective to provide the latest clinical updates on the management of HIV infection and current concepts of antiviral therapeutics. Several experts from national and international institutes will deliver talks on the pathogenesis of HIV disease, principles of antiretroviral therapy, toxicities, immune reconstitution syndrome, drug resistance, newer drugs, management of co-infections and opportunistic infections, ART in pregnancy, management of paediatric HIV infection, and laboratory diagnosis of HIV. Clinicians involved or interested in HIV care and interested researchers are invited to participate in the symposium. For more details on the symposium, please write to cart@yrgcare.org.



The YRG CARE Bioethics Symposium

The YRG CARE Bioethics symposium will be organized on 6th and 7th of January 2011. This symposium will explore ethical issues in research involving human participants. Faculty includes national and international experts in the field of bioethics. For details on registration, write to tybs@yrgcare.org



HIV/AIDS Nursing Symposium

HANS2011- the Nursing symposium will be organized on 7th January 2011 and in this event, experts/faculties will speak on various aspects of HIV/AIDS pertaining to nursing. Participation is on first-come; first-served basis. For more details, please write to hans@yrgcare.org

YRG CARE

Past Events

Expansion of Infectious Diseases Laboratory Wing at YRG CARE

YRG CARE dedicated the 2nd floor in the new block at the Voluntary Health Services Hospital Campus, Taramani for the expansion of clinical and research laboratory activities. Thiru. V. Y. Gaitonde, Trustee, YRG CARE inaugurated the facility on 4th June, 2010.



Photograph: Thiru. V. Y. Gaitonde, Trustee, YRG CARE dedicated the extension of laboratory wing. Dr. P. Balakrishnan, Mr. A. K. Ganesh, Prof. Solomon, Mr. K. Murugan and Dr. Sunil Solomon are in the photograph.

3rd National HIV SCIENCE Symposium - Marks Discussions on Advancements in HIV Research Priorities

YRG CARE organized a 2-day, third national science symposium on HIV/AIDS on 30-31 August 2010 at the Vigyan Auditorium, Council of Scientific and Industrial Research (CSIR) campus, Taramani, Chennai. The symposium was co-sponsored by the Indian Council of Medical Research (ICMR), New Delhi, Department of Biotechnology (DBT), New Delhi and Council of Scientific and Industrial Research (CSIR), New Delhi.

Four hundred and eight delegates from various states of India participated in the symposium. Seven participants were awarded with scholarships in order to encourage them to endorse research on HIV disease. Poster sessions were held on both the days of the symposium that provided a platform for the participants to update the ongoing research activities. An expert review committee adjudged five abstracts for best research poster awards that were given away by Prof. Solomon and Prof. S. P. Thyagarajan at the closing ceremony.

The scientific program contained a rich mix of formats, with sessions featuring well-known and thought-provoking speakers from esteemed institutions and highly interactive discussions followed each of the scientific sessions. The scientific content ranged from basics to the most advanced development in the field of HIV and STDs.



Photograph: Lighting of Kuthuvilakku at the Inaugural ceremony of HIV SCIENCE 2010. **From the left:** Thiru. Shambhu Kallollikar (Project Director, TANSACS, Chennai), Prof. S. P. Thyagarajan (Former Vice-Chancellor, University of Madras & Pro-Chancellor (Research), Sri Ramachandra Medical University, Chennai), Dr. Rajat Goyal (Country Director, IAVI, New Delhi), Dr. Ramesh S. Paranjape (Director, NARI, Pune) and Prof. Solomon.

Former Tennis Ace Vijay Amritraj Visits YRG CARE

Mr. Vijay Amritraj, a prominent philanthropist who served as a U.N. Messenger of Peace and formerly a tennis champion visited YRG CARE facilities on 22nd September, 2010. He is the founder of the Vijay Amritraj Foundation, a charity organisation with a mission to help and care for the under-privileged people in India.



Photograph: Mr. Vijay Amritraj is in the picture during his visit to YRG CARE facility and Ms. Jabin Sharma, Dr. Shirley Pradeep, Prof. Suniti Solomon and Ms. Rochelle D' Souza are in the picture. Brown Fogarty Scholars Ms. Krutika Kuppalli and Ms. Samara are also seen.

GCLP Workshop Concludes with Approaches Aimed at Improving Labs to International Standards

YRG CARE organized a 3-day GCLP workshop on 18-20 June, 2010 at the TICEL Bio-Park in Taramani, Chennai, co-sponsored by the Indian Council of Medical Research, New Delhi. Several national and international faculties facilitated the programme and interacted with the participants.



Photograph: Lighting the kuthuvilakku at the inaugural ceremony. **From the left:** Ms. Estelle Piwowar (Deputy Director, HPTN Network Laboratory, Johns Hopkins University, Baltimore, USA), Prof. Solomon, Prof. S. P. Thyagarajan (Former Vice-Chancellor, University of Madras/ Pro-Chancellor (Research), Sri Ramachandra Medical University, Chennai), and Dr. Reba Kanungo (Laboratory Program Advisor, CDC-GAP-India, American Consulate, Chennai) are in the photograph.

Mother Teresa Memorial Award to Prof. Solomon

Education Today (Tamil Monthly) and Teacher Kuppuswamy Educational Trust jointly organised Mother Teresa Birth Centenary function on 5th September 2010 at Stella Maris College Auditorium, Chennai. In this event, Prof. Solomon was conferred with Mother Teresa Memorial Award for her education and humanitarian services.



Photograph: Mother Teresa Memorial Award was presented to Prof. Solomon Dr. T. Suryakumar (Dy. Registrar, IIT, Chennai and Advisor, Education Today), Honorable M. Ravindran (Addl. Solicitor General of India, High Court of Madras) and Dr. D. Janaki (Former Vice-Chancellor, Mother Teresa Women's University) are in the photograph.

TANSA 2009 Award Conferred on Prof. Solomon

The Tamilnadu State Council for Science and Technology (TNSCST) Award was conferred on Prof. Solomon on 25th August 2010 at the Vivekananda Auditorium, Anna University, Chennai for her research contribution in the field of medical sciences in Tamilnadu.





Photograph: Dr. K. Ponmudi, Hon' ble Minister for Higher Education, Government of Tamilnadu, presenting the TANSA 2009 award to Prof. Solomon. Thiru K. Ganesan, IAS, Principal Secretary to Government of Tamilnadu (Higher Education), Dr. P. Mannar Jawahar, Vice- Chancellor, Anna University, Chennai, Dr . G. Thiruvassagam, Vice-Chancellor, University of Madras and Dr. S. Vincent (Member Secretary, TNSCST) are also seen.

Visit of USA-Ambassador to YRG CARE Facility

Ms. Melanne Vermeer, Ambassador (USA State Department Office) for Global Women's Issues visited YRG CARE on 13th September 2010. Ambassador Ms. Vermeer coordinates foreign policy issues and activities relating to the political, economic and social advancement of women around the world. Ms. Anjana Chatterjee (USA Consulate, Political Analyst/Economic Specialist), Ms. Saba Ghori (Staff Assistant to Ambassador) and Mr. Matthew Beh (Political/ Economic Officer) also accompanied the Ambassador during this visit.



Photograph: Prof. Solomon, Dr. KG. Murugavel and Ms. Vermeer are in the picture during the visit to YRG CARE.

YRG CARE January – August 2010

Publications



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Factors associated with perpetration of sexual violence among wine-shop patrons in Chennai, India. Go VF, Srikrishnan AK, Salter ML, Mehta S, Johnson SC, Sivaram S, Davis W, Solomon S, Celentano DD. *Soc Sci Med.* 2010; 71(7):1277 – 84.

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SPECIAL NEWS

Tenofovir Gel: Safe & Effective in Preventing HIV Infection!

The Center for AIDS Programme of Research in South Africa (CAPRISA) announced successful results of a clinical trial testing an antiretroviral -based vaginal microbicide for its ability to prevent HIV infection in women at the 2010 International AIDS Conference at Vienna. The microbicide trial, named CAPRISA 004, showed that women who used a gel containing 1% tenofovir, an ARV commonly used to treat HIV, had a 39 % lower rate of infection compared to women who used a placebo gel. A double-blind, randomized controlled trial was conducted comparing tenofovir gel ($n= 445$) with placebo gel ($n = 444$) in sexually active, HIV uninfected women in urban and rural areas in South Africa and this study was conducted with monthly follow-up visits for 30 months. Women enrolled in this trial used a gel containing tenofovir up to 12 hours before and after sexual intercourse. HIV incidence in the tenofovir gel arm was 5.6 per 100 women-years compared to 9.1 per 100 women-years in the placebo gel arm with the incidence rate ratio = 0.61 ($p = 0.017$). The trial provides solid evidence that the use of 1% tenofovir -based microbicide gel can significantly reduce the risk of HIV and also genital herpes infection in women. The HIV incidence observed with high adherers (gel adherence >80%), intermediate adherers (gel adherence 50 to 80%) and low adherers (gel adherence <50%) were 54%, 38% and 28% lower, respectively. However, no increase in the overall adverse event rates was observed and there was no tenofovir drug resistance in HIV seroconvertors. Tenofovir gel could potentially fill an important HIV prevention gap, especially for women who are not able to successfully negotiate mutual monogamy or condom use. Source:http://www.caprisa.org/joomla/Micro/AbdoolKarim-07-23-10_EMBARGOED.pdf.

Invitation for Contributors

We welcome your contribution towards YRG CARE. Donations to YRG CARE are eligible for tax deductions under **Section 80G** of the Income Tax Act. The Foundation is registered with the Ministry of Home Affairs to receive Foreign Contributions under the Foreign Contributions Regulation Act (**FCRA**) vide registration No. 75900630/12 July 1991. Please mail us with the subject head 'Donations' with your contact details.

Ask the Experts

Readers are invited to send their queries on HIV/AIDS to newsletter@yrgcare.org, which will be answered by experts from YRG CARE.



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COST-EFFECTIVE HIV DIAGNOSTIC SERVICES

YRG CARE offers certified, quality assured and cost-effective HIV monitoring laboratory tests; CD4+ T-Cell Count by Beckman Coulter FlowCARE assay (Rs.300), HIV-1 Viral Load by ABBOTT RealTime PCR Assay (Rs. 2000) and HIV-1 Drug Resistance Homebrew Genotyping Assay (Rs. 4000 for RT drugs, Rs.6000 for RT and PI drugs).

The laboratory also offers various internationally certified STD testings such as, HIV, HSV-2, syphilis, trichomoniasis, chlamydia, and gonorrhoea.

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