



Y.R.G. CARE

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Research Projects
1994 - 2004

COMPLETED RESEARCH PROJECTS

<i>PROJECT NO.</i>	<i>YEAR</i>	<i>TITLE</i>	<i>PAGE NO.</i>
01	1994-95	Prevalence of HIV1 and HIV2, in Tamil Nadu, India: a sero-surveillance study.	1
02	1995	Detection of mycobacterium tuberculosis and atypical mycobacteria in AIDS patients using PCR.	2
03	1996-97	Analysis of Risk factors and Evaluation of HIV testing in saliva and blood samples.	3
04	1997-98	Seroprevalence of HIV infection among hospital population in Chennai, India.	4
05	1997-98	Seroprevalence / risk factor analysis of HIV in partners of patients with HIV in Chennai, India.	5
06	1999-2000	Dried Blood Spots (DBS): A valuable tool for HIV surveillance in developing or tropical countries.	6
07	1999-2000	Lower genital tract infections (LGTI) in HIV positive women.	7
08	1999-2003	Scaling Up of Affordable and Appropriate Care and Support Services for people living with HIV/AIDS in South India.	8
09	2000-01	Prevention of mother to child transmission using AZT and 3TC	10
10	2000-01	Knowledge, attitudes and perceptions towards acceptability of vaginal microbicides.	11
11	2000-02	Training Health Care Providers in Southern India in HIV Medicine.	12
12	2000-01	Pathogenic profile of chronic diarrhea in persons with HIV in South India.	13
13	2002-04	Prevalence and risk factors of HBV and HCV in persons attending voluntary counselling and HIV testing center.	14
14	2002-04	Neuro-psychosocial manifestations among HIV seropositive patients in Chennai, South India.	15
15	2002-04	Comparative research study of the Reality female condom and Version 4 of the modified Reddy female condom.	16
16	2002-04	HIV Prevention Preparedness Study - HPTN 033	17
17	2002-04	Prevalence and incidence of sexually transmitted infections (STI) and HIV in high risk men and women in South India - HPTN033 substudy.	18
18	2002-04	Reliability, validity and acceptability of assessment of adherence to ART in Chennai.	19
19	2002-04	Drug resistance strains in Antiretroviral naïve HIV positive individuals attending YRG CARE clinic. Version 1.1	20
20	2003-04	Prevalence of Sexually Transmitted Diseases - In general population and in high-risk sub-population groups in Tamil Nadu.	21

ON-GOING RESEARCH PROJECTS

<i>PROJECT NO.</i>	<i>YEAR</i>	<i>TITLE</i>	<i>PAGE NO.</i>
01	2000	NIMH Collaborative HIV/STD Prevention Trial	22
02	2002	A randomized controlled clinical trial of structured intermittent therapy vs continuous therapy in HIV-positive patients in South India.	24
03	2002	Evaluation of cost effective laboratory markers to monitor HIV-infected persons in South India.	25
04	2002	A longitudinal study on HAART associated body composition, metabolic and quality of life changes. (substudy of Project No. 2)	27
05	2003	A longitudinal study on the bone composition changes in HIV positive individuals on HAART and controls - (Supplement to Project No. 4) [2003 ongoing]	28
06	2003	Religion and health beliefs and practices among Indian men and women with HIV.	29
07	2004	Behavioral Secondary HIV prevention in Chennai.	30
08	2004	Socio anthropological approach to HIV transmission from mother to child in India: The case of breast feeding.	31
09	2004	HPTN 052 - A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 In Serodiscordant Couples	32
10	2004	AACTG 5175 - A Phase IV, Prospective, Randomized, Open-label Evaluation of the efficacy of Once-Daily Protease Inhibitor and Once-Daily Non-Nucleoside Reverse Transcriptase Inhibitor-Containing Therapy combinations for Initial Treatment of HIV-1 Infected Individuals from Resource-Limited Settings (PEARLS) Trial	33

RESEARCH PROJECTS AWAITING CLEARANCE FROM HEALTH MINISTRY STEERING COMMITTEE

<i>PROJECT NO.</i>	<i>TITLE</i>	<i>PAGE NO.</i>
01	Understanding factors inhibiting access to HIV VCT in Chennai, India and measure impact of capacity building in improving access.	34
02	Stigma in Health Care Settings in South India.	35
03	Randomized Controlled Trial of 6% Cellulose Sulfate Gel and the effect on vaginal HIV transmission.	36
04	Neurocognitive Consequences of HIV/AIDS in South India.	37

Completed Research Projects



Y.R.G. CARE

PROJECT - 01	DESCRIPTION
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Title of the Project	Prevalence of HIV1 and HIV2, in Tamil Nadu, India: a sero-surveillance study. (1994)
Principal and Co-investigators' names	Dr. Suniti Solomon
Duration / Time period	1994 - 1995
Objective	To study the factors associated with the prevalence of HIV-1 and HIV-2 infection in the urban and rural areas of Tamil Nadu, India.
Outcome/s	HIV-1 is the predominant strain in Tamil Nadu. The prevalence of HIV infection in urban and rural areas was 7.2% among high risk population.
Publications	<i>Suniti Solomon, N. Kumarasamy, A.K. Ganesh, R. Edwin Amalraj. Prevalence and risk factors of HIV-1 and HIV-2 infection in urban and rural areas in Tamilnadu, India. Int. J STD & AIDS 1998; 9: 98-103.</i>
Methodology	100 samples from high risk and low risk groups from 5 urban and 5 rural areas of Tamil Nadu were collected after obtaining informed consent for this study. A detailed proforma was filled in consisting of their demographics and risk factors for HIV. ELISA for screening and Western Blot for confirmation of HIV antibody were done. The sample size was 1000.
Collaboration	Agency for Co-operation in International Health, Japan.
Financial Assistance	Agency for Co-operation in International Health, Japan - US \$ 14,100
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	One of the first studies in India which helped to identify prevalence of HIV in the rural areas of Tamil nadu. HIV-2 prevalence was also documented and recorded as low.

PROJECT - 02	DESCRIPTION
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Title of the Project	Detection of mycobacterium tuberculosis and atypical mycobacteria in AIDS patients using PCR. (1995)
Principal and Co-investigators' names	Dr. S.K. Kamatchiammal
Duration / Time period	1995
Objective	To find simple techniques to screen for mycobacterium tuberculosis.
Outcome/s	Salient findings: This simple sample processing method could be used to screen all blood samples quickly for mycobacterium using the genus PCR and only those positive for mycobacteria need to be tested for M.tuberculosis.
Publications	<i>S.Kamatchiammal, D.Saravanakumar, N.Kumarasamy, Suniti Solomon, Manjula, V.Sritharan.</i> A simple method for inhibition free PCR amplification of target DNA directly from clinical specimens. <i>Indian Journal of Clinical Biochemistry, 1997, 12 (1), 78-80.</i>
Methodology	Blood samples collected in an eppendorf tube from patients attending the YRG CARE clinic with symptoms of pulmonary tuberculosis using PCR.
Collaboration	YRG CARE, Centre for Biotechnology, Anna University, Chennai, National Environmental Engineering Research Institute, CSIR, Chennai, Baylor College of Medicine, Texas, USA, Dept. of Animal Science, School of Life Sciences, Hyderabad.
Financial Assistance	No foreign funding
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	The working of a simple method for inhibition for PCR amplification was proved.

PROJECT - 03	DESCRIPTION
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Title of the Project	Analysis of Risk factors and Evaluation of HIV testing in saliva and blood samples. (1996)
Principal and Co-investigators' names	Dr. Suniti Solomon
Duration / Time period	1 Year; 1996 - 1997
Objective	To study the sensitivity of HIV antibody testing using saliva and blood sample.
Outcome/s	Usefulness of Saliva for HIV serology with a sensitivity of 98.1% and specificity of 100%.
Publications	<i>Suniti Solomon, N.Kumarasamy, SP Martin, R. Pandian, K. Sathyamoorthy, SP Thyagarajan. Analysis of Risk factors and Evaluation of HIV testing in Saliva and Blood samples. Journal of Infection. 34/1 (1997), p.85-86.</i>
Methodology	Persons attending the VCT center (N=87; males - 59 and females - 28) were recruited for the study using a standard proforma. Saliva was collected using Omai SAL kit; sera was separated from the blood collected. Testing done by Biochem DETECT HIV EIA kit. Repeat test for positive samples by a different ELISA kit.
Collaboration	None
Financial Assistance	No foreign funding
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	Validated saliva testing for HIV.

PROJECT - 04	DESCRIPTION
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Title of the Project	Seroprevalence of HIV infection among hospital population in Chennai, India. (1997-98)
Principal and Co-investigators' names	Dr. N. Kumarasamy, Dr. Geeta Gopalakrishnan
Duration / Time period	1997 - 1998
Objective	To study the seroprevalence of HIV among hospital population in Chennai.
Outcome/s	2% of the patients attending a public hospital in Chennai were HIV+.
Publications	<i>Geetha Gopalakrishnan, N.Kumarasamy, Rogers M, Mc Garvey S, Dickenson B, Haridoss, Flanigan T, Suniti Solomon.</i> HIV Seroprevalence and Associated Risk Factors in Tamilnadu, India. Infectious Diseases Society of America-36th Annual Meeting. Nov 12-15, 1998. Denver, Colorado. <i>Abstract no: 395 Fr.</i>
Methodology	Patients referred to the Biochemistry department for various investigations from clinics of internal medicine, obstetrics and gynecology, general surgery, neurology, neurosurgery, diabetics, ophthalmology and dermatology are included in this study. The sample size was 1000. ELISA for screening and Western Blot for confirmation of HIV antibody was done.
Collaboration	AIRTP-Fogarty program of Brown University, Providence, RI.
Financial Assistance	No financial assistance. Training provided by AIRTP-Fogarty program of Brown University, Providence, RI.
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	The prevalence of HIV among those attending a public hospital in Chennai was noted.

PROJECT - 05	DESCRIPTION
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Title of the Project	Seroprevalence / risk factor analysis of HIV in partners of patients with HIV in Chennai, India (1997-1998)
Principal and Co-investigators' names	Dr. N. Kumarasamy, Dr. Maya Rogers
Duration / Time period	2 Years
Objective	To study the HIV prevalence and risk factors among couples attending the YRG CARE VCT center.
Outcome/s	100 couples studied; 34% were sero-discordant. Higher mean viral load (1,415, 564 vs 1,323,998) was seen in concordant index patients. Lower mean CD4 count (193 vs 224) was seen in concordant index patients. Greater than 95% women partners of male index patients reported their husbands as their only risk factor for HIV. Only 11% of women always used condoms during sexual relations.
Publications	<i>Geetha Gopalakrishnan, N.Kumarasamy, Rogers M, McGarvey S, Dickenson B, Flanigan T, Mayer K and Solomon S.</i> Seroprevalence and riskfactors for HIV in partners of HIV positive patients in Chennai, India. <i>5th Asia Pacific AIDS conference'99, Kuala Lumpur. Abstract No:182/PSCD106.</i> <i>M. Chatterjee Rogers, G. Gopalakrishnan, N.Kumarasamy, T.P. Flanigan, C.C.J. Carpenter, K. H. Mayer, S Solomon.</i> HIV in couples in South India; Implications for prevention. <i>Int J STD & AIDS; 2004 (In press)</i>
Methodology	Married couples attending the YRG CARE VCT center were included in this study. The sample size was 100. A detailed questionnaire consisting of demographics and risk factors for HIV was filled-in for each couple. ELISA for screening and Western Blot for confirmation of HIV antibody was done. Pre- and post-test counseling were offered to the couples.
Collaboration	AIRTP-Fogarty program of Brown University, Providence, RI.
Financial Assistance	No financial assistance. Training provided by AIRTP-Fogarty program of Brown University, Providence, RI.
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	Demonstrated the need for couple counseling to prevent transmission of HIV from the index partner to the spouse.

PROJECT - 06

DESCRIPTION

Title of the Project	DESCRIPTION
Principal and Co-investigators' names	Dr. Sunil Solomon, Dr. Suniti Solomon
Duration / Time period	1999 - 2000
Objective	Study the stability of DBS in the hot and humid field conditions in tropical countries. Compare the sensitivity and specificity of DBS vs. Serum by ELISA and Western Blot.
Outcome/s	DBS testing results demonstrate reliability and stability. DBS emerges as a convenient, cost effective technique for surveillance and does not need refrigeration and sample processing facilities.
Publications	<p><i>Sunil Solomon, Suniti Solomon, Irma I Rodriguez, Stephen T McGarvey, AK Ganesh, SP Thyagarajan, Anish Mahajan, Kenneth Mayer. Dried blood spots (DBS): a valuable tool for HIV surveillance in developing/tropical countries. Int'l Journal of STD & AIDS 2002; 13:25-28.</i></p> <p><i>Sunil Solomon, Suniti Solomon, Irma I Rodriguez, Stephen T McGarvey, AK Ganesh, SP Thyagarajan, Anish Mahajan, Kenneth Mayer. Dried Blood Spots (DBS): a valuable tool for HIV surveillance in developing/tropical countries. Oral presentation. XIII International AIDS Conference, Durban, South Africa. July 9-14, 2000.</i></p> <p><i>Sandeep Pullimi, Sunil Solomon, Irma Rodriguez, Kenneth Mayer, KG Murugavel, SK Satishkumar, A K Ganesh, Suniti Solomon. Utility of fingerstick dried blood spots as a tool for HIV epidemiology studies in resource constrained settings. XIV International AIDS Conference 2002, Barcelona July 7-12, 2002. Abs. Ref# 9994.</i></p> <p><i>Sunil S Solomon, Sandeep Pulimi, Irma I Rodriguez, Sreekanth K Chaguturu, S K Satish Kumar, Kenneth H Mayer, Suniti Solomon. Dried blood spots are an acceptable and useful HIV surveillance in a remote developing world setting. Int J of STD and AIDS 2004: 15 (10) 658-661.</i></p>
Methodology	12 blood spots were prepared for each positive sample on Guthrie cards. 6 blood spots were prepared for each negative sample. These were air dried after labeling and left at room temperature and humidity. Every 24 hours the 2 positive and 2 negative samples were stored in the refrigerator. The last DBS for each individual would be kept at room temperature of 35.8°C and a humidity of 73% for 6 days. Finally DBS was eluted with PBS and screened for HIV antibodies using ELISA kits.
Collaboration	Brown University, Providence, RI, USA
Financial Assistance	Brown University, Providence, RI, USA. US \$ 10,461 for training and diagnostic kits.
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	Demonstrated a cost effective technique for surveillance in areas with poor infrastructure.

PROJECT - 07	DESCRIPTION
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Title of the Project	Lower genital tract infections (LGTI) in HIV positive women. (1999-2000)
Principal and Co-investigators' names	Dr. Purnima Madhivanan
Duration / Time period	1999 - 2000
Objective	<p>To determine the prevalence of LGTI among HIV seropositive women in a tertiary care center in TN, South India.</p> <p>To determine factors associated with LGTI among the same group of women.</p>
Outcome/s	There is a need for better diagnosis and management of lower genital tract infections through regular gynecological examinations and health education for women in resource-limited settings.
Publications	<p><i>Purnima Madhivanan, Susan Cu-Uvin, Mira Govindarajan, Kenneth Mayer, Kate Wilson, Joseph Harwell, R Hemalatha, Suniti Solomon.</i> Prevalence of cervical dysplasia among women attending an HIV care center in Chennai, South India. <i>J Obstet Gynecol Ind, Vol. 53, No. 4: July/August 2003.</i></p> <p><i>Purnima Madhivanan, Susan Cu-Uvin, SP Thyagarajan, Kate Wilson, Kenneth Mayer, Hemalatha R, Suniti Solomon.</i> "Prevalence of Lower Genital Tract Infections among Women Attending an HIV Care Center in South India". <i>VIICAAP, Melbourne, October 2001, Abstract 0431, Pg. 446.</i></p> <p><i>P. Madhivanan, S. Cu-Uvin, S. P. Thyagarajan, K. Mayer, K. Wilson, S. Solomon.</i> Prevalence of lower genital tract infections among women attending an HIV care clinic in Chennai, India. (Submitted).</p>
Methodology	One-time prevalence study of 100 HIV positive women, previously and newly diagnosed patients who receive primary care from YRG CARE.
Collaboration	Miriam Hospital, Brown University, Providence, RI, USA,
Financial Assistance	Miriam Hospital, Brown University, Providence, RI, USA. US \$ 21,367 for training and diagnostic tools
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	An association between HIV and LGTI was established among women in South India

PROJECT - 08	DESCRIPTION
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Title of the Project	Scaling Up of Affordable and Appropriate Care and Support Services for people living with HIV/AIDS in South India. (1999-2003)
Principal & Co-investigators' names	Dr. Suniti Solomon
Duration / Time period	1999 - 2003
Objective	<p>Component 1: a. Quality of Life To better understand the affordability and appropriateness of an existing integrated care and support model to meet the needs of PLHA and to improve their QoL. To examine the process and costs of scaling up this model through a strategy of concept replication in varied settings in South India.</p> <p>b. Burden on Households, Institutional Costs, Client Willingness to Pay, and Financing Services Estimate the direct and indirect costs of treatment and services and the Burden on Households. Measure the costs of treating illness episodes and explore changes in costs over a period of time. Examine the financial coping strategies adopted by the households to meet treatment costs.</p> <p>Component 2: Scaling Up of 4 NGOs in South India on Care and Support for PLHA. Study the process, costs and feasibility of transferring and adapting the model.</p>
Outcome/s	<p>Component 1a: QoL of PLHA can improve with comprehensive, client-centered, confidential, effective, and affordable services with or without ART even in advanced stages of disease. Counseling facilitates disclosure of status.</p> <p>Component 1b: A majority of the YRG CARE clients are willing to pay higher fees for the services they receive, but this may result in higher household indebtedness. The social mission of YRG CARE suggests that the free care option will be maintained. User fees will not be high enough to cover total cost of services. To be sustainable, NGOs providing care and support services cannot rely on user fees as their sole source of revenue. Hence YRG CARE will continue to rely on in-kind and monetary donations and subsidy from other activities.</p> <p>Component 2: Selection of appropriate partners with shared vision and commitment is essential. As collaboration and networking intensified referrals grew and care options increased. More paid staff and volunteers were mobilized to support expanded care. documentation, monitoring and reporting Provider attitudes shifted from a focus on clinical aspects to patient-centered care Increased availability of care was associated with higher demand for prevention and care services. Stigma of PLHA and their families required attention in all sites. Much can be accomplished through locally led capacity building.</p>
Publications	<i>Please see next page</i>
Methodology	<p>Component 1a: Documentation of the base model to describe the program's conceptual and operational models and procedures and systems for maintaining standards of care. Economic analysis of YRG CARE services and the potential for cost recovery. Cohort of 341 HIV-positive participants in the YRG CARE program from various stages of disease; asymptomatic, moderate and advanced stages. Followed for up to 18 months (4/2000 to 1/2002)</p> <p>Component 1b: Data from a cohort of HIV/AIDS clients of YRG CARE. 153 Clients who had completed R-I and R-III tools for data collection. A structured pre-tested questionnaire used to collect out-of-pocket expenditure on treatment and services, loss of income and workdays, and source of finance over a six-month reference period</p> <p>Component 2: Baseline and end-of-project data collection: situation assessments, process documentation, and in-depth interviews with scale up partner staff (n= 24). Interviews with male and female clients (n=39) at end of project only.</p>
Collaboration	Horizons, Population Council and HIV/AIDS Alliance.
Financial Assistance	Horizons, Population Council and HIV/AIDS Alliance. INR 87,78,848.
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	Counseling services are important and more initiatives have to be taken urgently to decrease stigma and discrimination at the community level. Improved quality of life helps in the disease management of the patient; returning to gainful employment and reduction in household stigma. The direct and indirect costs of treatment decrease with early onset of the person living with HIV presenting for clinical care and management.

Publications:

Scaling Up of Affordable and Appropriate Care and Support Services for people living with HIV/AIDS in South India. (1999-2003)

Duraisamy Palanigounder, Celine Daly, Praneeta Varma, Rick Homan, Suniti Solomon, D Sathiyavan, Christopher Castle. "Cost And Burden Of Treatment For Persons Living With HIV/AIDS In South India?" VI International Congress on HIV/AIDS in Asia and the Pacific, Melbourne, October 2001, Oral Poster, Abstract 0489, Pg. 357

AK Ganesh, Rick Homan, Caroline West, Duraisamy Palanigounder, Suniti Solomon, Benjamin. "Estimating the Cost of Integrated Prevention and Care and Support Services: Sometimes More is Less". VI International Congress on HIV/AIDS in Asia and the Pacific, Melbourne, October 2001, Pg. 0505, Pg. 396

Shirley Thomas, Suniti Solomon, Gladston Xavier, Rebecca George, Benjamin Franklin, Christopher Castle, Celine Daly. "Lessons learned from Scaling Up HIV/AIDS Care and Support Services in South India". VI International Congress on HIV/AIDS in Asia and the Pacific, Melbourne, October 2001, Oral Presentation, Abstract 0509, Pg. 445.

Praneeta Varma, Suniti Solomon, Lisanne Brown, Celine Daly. "The Quality of Care of HIV Positive Patients: Before and After First Visit to YRG CARE, Chennai, India". VI International Congress on HIV/AIDS in Asia and the Pacific, Melbourne, October 2001, Oral Presentation, Abstract 0479

"Teach a man to fish, you feed him for a lifetime": an approach for scaling up HIV/AIDS care and support. XIV International AIDS Conference 2002, Barcelona July 7-12, 2002. Abs. Ref# 7227

How people living with HIV/AIDS in South India cope with the costs of treatment. XIV International AIDS Conference 2002, Barcelona July 7-12, 2002. Abs. Ref# 7266

The cost and sustainability of care and support services for people living with HIV/AIDS in South India. XIV International AIDS Conference 2002, Barcelona July 7-12, 2002. Abs. Ref# 7175

"How PLHAs rate importance of NGO care and support services" XIV International AIDS Conference 2002, Barcelona July 7-12, 2002. Abs. Ref# 7293

Care and support in India: Special Focus on YRG CARE. Horizons Report, HIV/AIDS Operations Research. Dec 2002. Horizons Program, Population Council. www.popcouncil.org/horizons/newsletter/horizons_report.html

Summary Report: Expanding Care and Support in South India: Scaling up YRG CARE's Patient-Centred Approach. YRG CARE, International HIV/AIDS Alliance, Horizons Program. Jan 2004.

P. Duraisamy, C. Costello Daly, R.K. Homan, A.K. Ganesh, N. Kumarasamy, P. Sripriya, C. Castle, P. Varma, V. Mahendra, S. Solomon. Burden on households and coping strategies of PLHA in south India. [MoPeD3855] Poster. XV Intl. AIDS Conf, Bangkok, 11-16 July 2004

A.K. Srikrishnan, C. Castle, C. Costello Daly, S. Swarnalakshmi, A.K. Ganesh, S. Solomon. Client experiences with stigma and discrimination. [WePeD6444] Poster. XV Intl. AIDS Conf, Bangkok, 11-16 July 2004

S. Swarnalakshmi, A.K. Ganesh, N. Kumarasamy, A.K. Srikrishnan, C. Castle, C. Costello Daly, S. Solomon. Barriers to strengthening and expanding care and support. [D12425] CD pub: Social and Economic Issues. XV Intl. AIDS Conf, Bangkok, 11-16 July 2004.

PROJECT - 09	DESCRIPTION
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Title of the Project	Prevention of mother to child transmission using AZT and 3TC (2000)
Principal and Co-investigators' names	Dr. Purnima Madhivanan
Duration / Time period	2000 - 2001
Objective	To study the effectiveness of AZT+ 3TC in the last 4 weeks of pregnancy in reducing MTCT.
Outcome/s	All babies tested negative except for two who tested HIV positive.
Publications	<p><i>Suniti Solomon, Purnima Madhivanan, AK Ganesh.</i> Mother to Child Transmission of HIV: Situation in India and Programme Implications. <i>Proceedings of the Sixth Round Table Conference, "HIV/AIDS in India", Ranbaxy Science Foundation, New Delhi, April 2000</i></p> <p><i>Solomon S, Ganesh AK.</i> Role of nongovernmental organisations in the prevention and care of HIV disease in women and children. It makes a difference. <i>Annals of New York Academic Science; (2000); 918:22-26.</i></p> <p><i>Brown H.W, Vallabhaneni S., Solomon S, Mothi SN, McGarvey ST, Jackson TJ, Putcha M, Brenner SE, Mate KS, Cu-Uvin S.</i> "Attitudes towards Prenatal HIV-testing and treatment among pregnant women in Southern India" <i>International Journal of STD and AIDS June 2001 Vol 12 Issue 6, pg. 390-394</i></p> <p><i>Sheila Shyamprasad, Purnima Madhivanan, Mitra Dhanraj, Geetha Durgabai, Suniti Solomon, Susan Cu-Uvin, Kenneth Mayer.</i> AZT, 3TC, NVP & Caesarean Section in prevention of vertical transmission in Chennai, India. <i>XIV Int AIDS Conference 2002, Barcelona July 7-12, 2002. Abs. ThPpD2145.</i></p> <p><i>Purnima Madhivanan, Amudha Hari, N.Kumarasamy, A.Geetha, Kausalya, JS. Lambert, Suniti Solomon.</i> Profile of HIV-infected pregnant women and the interventions used in the prevention of perinatal transmission of HIV at a tertiary HIV care center in South India. <i>The Journal of Obstetrics and Gynaecology of India, Vol 52, No. 2, Mar-Apr 2002, 43-47.</i></p>
Methodology	30 pregnant mothers who were HIV positive were recruited for this study after obtaining informed consent. From the last 4 weeks of pregnancy the study participants received zidovudine 300 mg twice daily and lamivudine 150 mg twice daily till delivery. All women underwent C-section. The infants received zidovudine and lamivudine for 1 week after birth. All infants received artificial formula.
Collaboration	Fogarty-Brown University. USA.
Financial Assistance	Fogarty-Brown University. USA. US \$ 17,500
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	Studying different protocols are needed for the prevention of mother to child transmission. Success stories need to be documented for streamlining the program.

PROJECT - 10	DESCRIPTION
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Title of the Project	Knowledge, attitudes and perceptions towards acceptability of vaginal microbicides. (2000-2001)
Principal and Co-investigators' names	Dr. Suniti Solomon
Duration / Time period	2000 - 2001
Objective	To assess the acceptance and attitudes of men and women towards the use of topical microbicides and other vaginal products.
Outcome/s	Consistent condom use and women's ability to negotiate condom use remain low in the community. Male acceptability of microbicides with regular or married partners is low. Majority held that they were not at risk of HIV which raises the most critical question of all, "Would they then use microbicides?"
Publications	<p><i>Suniti Solomon, Kathleen Morrow, AK Srikrishnan, Easter Thamburaj, Rochelle Rosen, AK Ganesh, Rochelle D'Souza Yephthomi, Kenneth H Mayer. "Is Our Community Sufficiently Prepared for Microbicides?" VI International Congress on HIV/AIDS in Asia and the Pacific, Melbourne, October 2001, Oral Presentation, Abs 0487, Pg. 78.</i></p> <p><i>AK Srikrishnan, Kate Morrow, AK Ganesh, Sethulakshmi Johnson, Easter Thamburaj, Rochelle Rosen, Kenneth H Mayer, Suniti Solomon. "Same Risks, Disparate Perceptions: Challenges To Microbicide Acceptability in the Chennai Community". VI International Congress on HIV/AIDS in Asia and the Pacific, Melbourne, October 2001, Oral Presentation, Abstract 0777, Pg. 355.</i></p> <p><i>Suniti Solomon, Kathleen Morrow, Jessica Buck, Sreekanth Chaguturu, Rochelle Rosen, AK Srikrishnan, Rochelle D'Souza Yephthomi and Kenneth Mayer. HIV knowledge, risks behaviours, and microbicide acceptability in Chennai, India. (Under review)</i></p>
Methodology	Questionnaires and focus group discussions with high and low risk populations in South India.
Collaboration	Brown University, Fogarty Grant. USA
Financial Assistance	Brown University, Fogarty Grant. USA. US \$ 19,825
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	Showed that the perception of risk among housewives was very low. Proper education and intervention are required in order to encourage high risk women as well as women with low perception of their risks to use microbicides as an women initiated option (when available) for HIV and STD prevention.

PROJECT - 11	DESCRIPTION
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Title of the Project	Training Health Care Providers in Southern India in HIV Medicine. (2000-2002)
Principal and Co-investigators' names	Dr. Suniti Solomon
Duration / Time period	2000 - 2001
Objective	To develop knowledge and clinical competence among health professionals (physicians, nurses, mental health and paramedical professionals) in the southern states to identify (i.e. pre and post-test counseling and risk reduction referrals) and care for persons living with HIV and AIDS.
Outcome/s	The CME sessions, counselling programmes and educational programs on infection control and waste management for physicians, nurses and paramedics respectively have given rise to requests for in-house training on medical-related HIV issues. Such mentorship programs through the YRG CARE medical and counselling center can discuss issues related to the care and management of HIV disease, counselling and psychosocial support of people infected with and affected by HIV/AIDS and other related issues like prophylaxis, universal precautions and waste management.
Publications	<p><i>AK Ganesh, Purnima Madhivanan, Kenneth H Mayer, Olivier P Humblet, Grace Macalino, R Hemalatha, Suniti Solomon. "Knowledge, Attitudes and Beliefs Regarding HIV, and Attitudinal and Structural Barriers to Care among South Indian Physicians". VI International Congress on HIV/AIDS in Asia and the Pacific, Melbourne, October 2001, Abstract 1625, Pg. 80.</i></p> <p><i>Olivier P Humblet, Purnima Madhivanan, Kenneth H Mayer, Grace Macalino, R Hemalatha, AK Ganesh, Suniti Solomon. "Knowledge, Attitudes and Beliefs Regarding HIV among South Indian Obstetrician /Gynecologists". VI International Congress on HIV/AIDS in Asia and the Pacific, Melbourne, October 2001, Abstract 1624, Pg. 445</i></p> <p><i>S Solomon, AK Ganesh, O Humblet, P Madhivanan, G Macalino, R. D'Souza Yephthomi, KH Mayer. Journal of The Association of Physicians of India. Physicians' Knowledge and Attitudes towards care of HIV/AIDS Patients in South India. (Under review).</i></p>
Methodology	Series of training of trainers workshops in South India.
Collaboration	World AIDS Foundation
Financial Assistance	World AIDS Foundation, US \$ 69,986 for training.
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	Updated information and training on HIV disease management and follow-up training reduces clinicians inhibitions in care and support of people living with HIV and improves their quality of life. It also helps clinicians to be aware of post exposure prophylaxis and the need for universal precautions.

PROJECT - 12	DESCRIPTION
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Title of the Project	Pathogenic profile of chronic diarrhea in persons with HIV in South India. (2000-2001)
Principal and Co-investigators' names	Dr. N.Kumarasamy
Duration / Time period	2000 - 2001
Objective	To study the etiology of chronic diarrhea in persons with HIV in South India.
Outcome/s	Cryptosporidium parvum is the most common organism responsible for chronic diarrhea in HIV-infected persons in South India
Publications	<p><i>A.Mahajan, Vandana Reddy, N.Kumarasamy, T.Flanigan, M.Rogers, K.Mayer, Suniti Solomon. Pathogenic profile of chronic diarrhea in HIV/AIDS patients in South India. 5th Asia Pacific AIDS conference '99, Kuala Lumpur. Abstract No: 540/SAB02-03.</i></p> <p><i>N.Kumarasamy, Timothy Flanigan, Anish Mahajan, R.Edwin Amalraj, Kenneth Mayer, Suniti Solomon. Comparative study of chronic diarrhea in persons with HIV in South India. XIII International AIDS Conference, Durban, South Africa. July 9-14, 2000. Abstract: MoPeB 2268.</i></p>
Methodology	Patients attending the YRGCARE clinic with chronic diarrhea were included in the study. The sample size was 30. Also 30 matched controls were included who were HIV+ without diarrhea. Stool was collected from both the groups and was sent for microbiological examination to study the organisms.
Collaboration	AIRTP-Fogarty program of Brown University, Providence, RI.
Financial Assistance	AIRTP-Fogarty program of Brown University, Providence, RI. US \$ 15, 758
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	This study clearly demonstrated that cryptosporidium parvum is the most common pathogen in chronic diarrhea.

PROJECT - 13

DESCRIPTION

Title of the Project	DESCRIPTION
Principal and Co-investigators' names	Dr. Maya Rogers & Dr. N. Kumarasamy
Duration / Time period	2002 - 2004
Objective	To study the prevalence and risk factors of HBV and HCV in persons attending the HIV VCT center of YRG CARE.
Outcome/s	Low HIV/HCV/HBV co-infection rates in Chennai. Suggested screening for HBV and HCV in HIV patients with significant clinical suspicion. Unsterile medical injections and non-traditional exposure to blood borne diseases may be associated with HIV transmission.
Publications	<i>Maya Chatterjee Rogers, N. Kumarasamy, Sreekanth K. Chaguturu, Timothy P. Flanigan, Kenneth H. Mayer, P. Balakrishnan, and Suniti Solomon. Hepatitis B, Hepatitis C and Human Immunodeficiency Virus Co-Infection in Chennai, India. 11th Conference on Retroviruses and Opportunistic Infections. Feb 8-11th, 2004, San Francisco USA. Abstract no: V 60</i>
Methodology	A cohort of 250 men and 250 women in both the HIV positive and the HIV negative arms, who come into YRG CARE for voluntary HIV testing. Blood samples drawn will be analyzed for HIV, HCV and HBV with hepatitis C ELISA, hepatitis B surface antigen, hepatitis B antibody and hepatitis B core antibody, and will be labelled and stored for future analysis. Basic demographic data, as well as detailed data on injection practices and exposure to needles, will be collected. HBV and HCV seroprevalence rates will be assessed and correlated with HIV seroprevalence data and with data obtained on the questionnaire.
Collaboration	AIRTP-Fogarty program of Brown University, Providence, RI.
Financial Assistance	AIRTP-Fogarty program of Brown University, Providence, RI. Funds: US \$ 17,865 for training and diagnostic kits.
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	This study showed low prevalence of HBV / HCV among patients attending HIV VCT center. HBV / HCV need not be done routinely for HIV patients in Southern India.

PROJECT - 14	DESCRIPTION
Title of the Project	Neuro-psychosocial manifestations among HIV seropositive patients in Chennai, South India. (2002-2004)
Principal and Co-investigators' names	Dr. Tokugha Yepthomi
Duration / Time period	2002 - 2004
Objective	To study the neurological manifestations of HIV disease in South India. To study the disease progression of persons with neurological manifestations. To study the psychosocial factors associated in persons with neurological complaints. To correlate the neuro-psychosocial manifestations with immunological and virological parameters.
Outcome/s	Patients who present with neurological complaints in this cohort present with advanced HIV infection and a broad range of diagnoses. High rates of T. gondii seropositivity and infection underscore the importance of prophylaxis.
Publications	In process
Methodology	50 participants were serially recruited of those complaining of headache (severe or persistent for more than 2 weeks), seizures, or mental status change at YRG CARE, an HIV referral center in India from June 2001 to May 2002 they received immunological, radiological and plasma/CSF serological testing.
Collaboration	Brown University, Providence, RI, USA.
Financial Assistance	Brown University, Providence, RI, USA. US \$ 19,900 for training and lab monitoring tests.
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	In HIV management, it is important to note that this study documented a high rate of toxoplasmosis which suggests the importance of chemoprophylaxis among patients with low CD4 cell counts.

PROJECT - 15	DESCRIPTION
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Title of the Project	Comparative research study of the Reality female condom and Version 4 of the modified Reddy female condom. (2002-2004)
Principal and Co-investigators' names	Dr. Suniti Solomon
Duration / Time period	2002 - 2004
Objective	The primary objective of this research study is to assess acceptability and functional performance of the modified Reddy female condom (Version 4) in comparison with the Reality female condom.
Outcome/s	Among measures of acceptability, participants did not indicate a clear preference for either of the two condom types. There were no statistically significant differences in any of the performance measures between the modified Reddy Female Condom Version 4 and the Reality female condom. The general feeling was that the condom kept moving and was uncomfortable and intrusive during sexual intercourse. This was attributed in part to the outer ring/frame displacement during use.
Publications	<p><i>Rochelle D'Souza Yephthomi, Priscilla Kabeer, Marianne Callahan*, A.K. Srikrishnan, A.K. Ganesh, Suniti Solomon.</i> Role of men in studies involving female-controlled preventive strategies. YRG CARE, Chennai, INDIA. *CONRAD, USA. <i>Microbicides 2004, London. March 28 31, 2004.</i></p> <p><i>A. Kalamalini, R. D'Souza Yephthomi, P. Kabeer, S. Solomon, A.K. Srikrishnan, A.K. Ganesh, M. Callahan.</i> Women at low risk also require education on HIV and female controlled preventive strategies. [ThPeC7407] Poster. <i>XV Intl. AIDS Conf, Bangkok, 11-16 July 2004.</i></p> <p><i>R. D'Souza Yephthomi, P. Kabeer, M. Callahan, A.K. Srikrishnan, A.K. Ganesh, A. Kalamalini, S. Solomon.</i> The role of men in studies on female-controlled preventive strategies. [C10934] CD pub: <i>Epidemiology and Prevention. XV Intl. AIDS Conf, Bangkok, 11-16 July 2004.</i></p> <p><i>Joshi S, Joglekar N, D'Souza Yephthomi R, B Kishore Kumar, Callahan M, Solomon S, Mehendale S.</i> Comparative Acceptability study of the Reality Female condom and the version 4 of the Modified Reddy Female Condom in India. <i>Under review.</i></p>
Methodology	30 monogamous couples; low risk to HIV, randomly assigned to one of two use sequence groups of the Reality female condom and Version 4 of the modified Reddy female condom to be used over a three week period. Use of survey forms and questionnaires after use of each product.
Collaboration	NARI, Pune, FHI, USA and CONRAD, Virginia, USA.
Financial Assistance	Dept. of Biotechnology, Govt. of India. INR Rs. 2,78,000/-
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	Inspite of decades of condom promotion, consistent condom use is low. This study demonstrated that modified Reddy female condom was more acceptable than the Reality female condom. Women need to be given preventive options as men's consistent condom use is low. The female condom is one such option that could be used in counseling and intervention programs. Practicality and cost of such products are essential issues.

PROJECT - 16	DESCRIPTION
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Title of the Project	HIV Prevention Preparedness Study - HPTN 033 (2002-2004)
Principal and Co-investigators' names	Dr. Suniti Solomon
Duration / Time period	2002 - 2004
Objective	To evaluate the impact of risk reduction by counseling on sexual behaviour among high risk population. To estimate rates of HIV seroincidence among persons targeted for inclusion in future HIV Prevention Trials Network (HPTN) studies of HIV prevention interventions.
Outcome/s	Counseling was found to be an effective method in reducing risk behaviour. Reduction in the sexual behaviour and treatment of STIs help in the prevention. The study recorded a retention rate of 90%
Publications	<p>Manuscripts in progress.</p> <p><i>A.K. Srikrishnan, J. Easter Thamburaj, R. Singal, K.M. Mayer, S. Solomon. Cohort retention - Findings from a study in Chennai, India. [WePeE6749]. Poster. XV Intl. AIDS Conf, Bangkok, 11-16 July 2004.</i></p> <p><i>S. Anand, A.K. Ganesh, A.K. Srikrishnan, S. Solomon. Data Management-supportive role in research. [WePeE6805] Poster. XV Intl. AIDS Conf, Bangkok, 11-16 July 2004.</i></p> <p><i>E.J. Thamburaj, A.K. Srikrishnan, R. Singal, K.M. Mayer, S. Solomon. Challenges in recruitment for research study at a Community-based Health Center in South India. [WePeE6806] Poster. XV Intl. AIDS Conf, Bangkok, 11-16 July 2004.</i></p>
Methodology	Prospective Cohort study where participants were followed for one year.
Collaboration	US National Institute of Allergy and Infectious Diseases / US National Institutes of Health.
Financial Assistance	YRG CARE medical centre and the Stanley Govt. Hospital STD clinic, Chennai. Division of AIDS, US National Institute of Allergy and Infectious Diseases/US National Institutes of Health. US \$ 211,963
Current Status of research	Completed
HMSC Clearance Status	2002
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	First study to measure incidence following a cohort over 12 months. Demonstrated risk reduction attributed to one-to-one counseling at frequent intervals.

PROJECT - 17	DESCRIPTION
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Title of the Project	Prevalence and incidence of sexually transmitted infections (STI) and HIV in high risk men and women in South India - HPTN033 substudy (2002-2004)
Principal and Co-investigators' names	Dr. N.Kumarasamy
Duration / Time period	2002 - 2004
Objective	To study prevalence and incidence of STIs among HIV negative men attending STD clinic of Govt Hospital, Stanley Medical College and sero-negative wives of HIV infected male patients attending VHS-YRG CARE. - HPTN033 study.
Outcome/s	STIs are common in those at increased risk of HIV infection. Trials of STI diagnosis and prophylaxis are warranted in this community to decrease the spread of HIV. High prevalence and incidence of HSV2 in South India suggest a need for suppressive therapy to reduce both HSV2 and HIV transmission.
Publications	<p><i>N.Kumarasamy, P.Balakrishnan, Sreekanth Chaguturu, AK Srikrishan, Suniti Solomon, Kenneth Mayer. Prevalence of Sexually Transmitted Infections among individuals at high risk for HIV in Chennai, India- Implications for HIV Prevention. ISSTD Congress, July 27-30, 2003. Ottawa, Canada. Abstract no: 355.</i></p> <p><i>N Kumarasamy, P Balakrishnan, S Solomon, J Anitha Cecelia, A K Srikrishnan, S Chaguturu, K H Mayer. Prevalence and Incidence of Sexually transmitted infections among individuals at high risk for HIV in Chennai, India -Implications for HIV prevention. XV International AIDS Conference, Bangkok, Thailand, 11-16 July 2004.</i></p>
Methodology	Participants of HPTN033 study were included for this study. Various STIs (Syphilis, Trichomonas, Chlamydia, HSV, HBC, HCV and Gonococcus) were screened every 6 months and were treated with the standard of care. These participants were follow up for 12 months to study the incidence of STIs.
Collaboration	AIRTP-Fogarty Program of Brown University, Providence, RI.
Financial Assistance	A substudy of HPTN 033.
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	<p>High prevalence and incidence of HSV-II antibodies seen among HIV negative high risk individuals.</p> <p>Hypothesis on "HSV-II suppressions prevent HIV acquisition" should be studied.</p>

PROJECT - 18	DESCRIPTION
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Title of the Project	Reliability, validity and acceptability of assessment of adherence to ART in Chennai. (2002-2004)
Principal and Co-investigators' names	Dr. Steven Safren / Dr. N.Kumarasamy
Duration / Time period	2002 - 2004
Objective	<p>To establish support capable of undertaking Antiretroviral Therapy (ART) adherence in Chennai, India.</p> <p>To lay the necessary formative research for adapting U.S. based adherence interventions and assessment methodology for use in ART studies and clinical care in India.</p>
Outcome/s	Data analysis under process.
Publications	<p><i>N Kumarasamy, S Safren, R Raminani, R Pickard, J Romola, S Solomon, KH Mayer. A qualitative study of cultural dimensions regarding adherence to antiretroviral therapy among patients with HIV in Chennai, India. XV International AIDS Conference, Bangkok, Thailand, 11-16 July 2004</i></p> <p><i>S.A. Safren, N. Kumarasamy, R. James, S.R. Raminani, S. Solomon, K.H. Mayer. ART adherence, demographic variables, and CD4 outcome among HIV-positive patients on antiretroviral therapy in Chennai, India. XV Intl. AIDS Conf, Bangkok, 11-16 July 2004. [WePeB5766]. Poster.</i></p>
Methodology	The qualitative study will be a series of individual interviews and focus group discussions among different risk-groups of patients with HIV infection, taking ART and who have not yet initiated ART. Semi-structured facilitation guides consisting of open-ended questions will be used.
Collaboration	AIRTP-Fogarty Program of Brown University, Providence, RI.
Financial Assistance	AIRTP-Fogarty Program of Brown University, Providence, RI.
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	96% adherence was found among patients on HAART at YRG CARE. Cost and non disclosure of HIV status to family members are indicators of poor ART adherence.

PROJECT - 19	DESCRIPTION
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Title of the Project	Drug resistance strains in Antiretroviral naïve HIV positive individuals attending YRG CARE clinic. Version 1.1 (2002 - 2004)
Principal and Co-investigators' names	Dr. P. Balakrishnan
Duration / Time period	2002; 2 Years
Objective	To determine the pattern drug resistance strains in ART naïve population attending STD clinic.
Outcome/s	6% and 14% of patients have mutations at NRTI and/or NNRTI resistance position respectively.
Publications	In process
Methodology	50 plasma samples collected from ARV naïve subjects in South India examined for their resistant pattern. The HIV RNA was extracted using Qiagen kit. The RT-PCR amplification done using clade C specific primers (designed at Brown University) for amplification of protease and RT gene. The amplified products were sequenced using specific primers (designed at Brown University) and analyzed to identify the HIV-1 drug resistance mutations.
Collaboration	Technical support from Brown University and Stanford AIRTP, USA.
Financial Assistance	No financial assistance
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	This study indicates the usefulness of baseline genotyping before starting ART.

PROJECT - 20	DESCRIPTION
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Title of the Project	Prevalence of Sexually Transmitted Diseases - In general population and in high-risk sub-population groups in Tamil Nadu. [2003-2004]
Principal and Co-investigators' names	Dr. Suniti Solomon
Duration / Time period	2003 - 2004
Objective	The main goal of this study is to determine the STD prevalence in general population and high-risk populations (CSW, Truck drivers and helpers) in southern districts in South India.
Outcome/s	Prevalence of STDs in rural and urban areas of 6 districts in Tamil Nadu were reported.
Publications	-
Methodology	The study was done with the study population from six different districts in Tamilnadu, which were randomly selected. The specimens (blood and genital specimens) were screened for different STDs by microbiological and molecular biological techniques.
Collaboration	YRG CARE with APAC-VHS (USAID)
Financial Assistance	YRG CARE with APAC-VHS (USAID) INR 43,68,633/-
Current Status of research	Completed
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	The knowledge on the prevalence of STD in general and high-risk populations will play a major role in planning HIV prevention strategies and implementing policies.

On-going Research Projects



PROJECT - 01	DESCRIPTION
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Title of the Project	NIMH Collaborative HIV/STD Prevention Trial (Jan 2000; 5 years)
Principal and Co-investigators' names	Dr. Suniti Solomon
Duration / Time period	2000, 5 Years
Objective	The key objective is to conduct a two-arm behavioral efficacy trial, involving adapting, translating and testing community-level, community popular opinion leader (CPOL) preventive intervention in the five international sites chosen. This is an ideal HIV/STD prevention program for low resource settings.
Outcome/s	Study in progress
Publications	<i>Please see next page</i>
Methodology	Behaviour change communication to high-risk individuals from slum communities, wine shops and women in prostitution; using community popular opinion leaders (CPOL) model of intervention.
Collaboration	Johns Hopkins School of Public Health, USA.
Financial Assistance	National Institutes of Health, USA. Total amt in US \$ 1,736,565
Current Status of research	Ongoing
HMSC Clearance Status	Cleared May 2000.
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	Word of mouth dissemination of prevention messages is a low cost sustainable behaviour change model and establishes very strong community linkages. Any prevention effort that involves top down approach faces a certain level of resistance to change that may not occur in this model, as it involves social networks, based on the theory of diffusion of innovation. For Indian settings, this may be an ideal model to replicate and this may eventually identify potential opinion leaders in the communities who could be used as health care behavior change agents.

Publications:

NIMH Collaborative HIV/STD Prevention Trial (Jan 2000; 5 years)

Carl Latkin, AK Srikrishnan, Vivian F. Go, Suniti Solomon, Sudha Sivaram, Sethulakshmi Johnson, Margaret E. Bentley, David Celentano. "Risk and Social Groups among Slum Dwellers in Chennai, India". VI International Congress on HIV/AIDS in Asia and the Pacific, Melbourne, October 2001, Abstract 1395, Pg. 424

AK Srikrishnan, Sudha Sivaram, Sethulakshmi Johnson, Margaret E. Bentley, Vivian F. Go, Carl Latkin, David Celentano, Suniti Solomon. "Talking about Sex Communication, Personal Networks and HIV Prevention Among Urban Slum Women and Men in Chennai, India." VI International Congress on HIV/AIDS in Asia and the Pacific, Melbourne, October 2001, Abstract 1181, Pg. 425

Vivian F. Go, Sethulakshmi Johnson, Margaret E. Bentley, Sudha Sivaram, Srikrishnan AK, Carl Latkin, David D. Celentano, Suniti Solomon. Violence against women in Chennai, India: Heightened Vulnerability to HIV/AIDS. VI International Congress on HIV/AIDS in Asia and the Pacific, Melbourne, October 2001, Abs. 1411, Pg. 224.

A.K. Srikrishnan, Sudha Sivaram, Sethulakshmi Johnson, Vivian F. Go, Margaret E Bentley, Carl Latkin, Suniti Solomon, David D. Celentano. Identifying Peer Opinion Leaders: Key partners in HIV prevention among urban slum communities in Chennai, India. XIV Intl AIDS Conf 2002, Barcelona July 7-12, 2002. Abs. Ref# 10083

Suniti Solomon, KG Murugavel, David Celantano, P Balakrishnan, AK Srikrishnan, Vivian F. Go, Sudha Sivaram, Kenneth H. Mayer. Low HIV/STI infection and risks in Chennai (India) Slums. XIV International AIDS Conference 2002, Barcelona July 7-12, 2002. Abs. Ref# 10128

AK Srikrishnan, Suniti Solomon, CK Vasudevan, Priscilla Kabeer, AK Ganesh, Roberta Singal, Kenneth H Mayer. Community Advisory Boards. XIV International AIDS Conference 2002, Barcelona July 7-12, 2002. Abs. Ref # 24000.

Vivian F. Go, C. Johnson Sethulakshmi, Margaret E. Bentley, Sudha Sivaram, AK Srikrishnan, Suniti Solomon, David D. Celantano. When HIV-Prevention Messages and Gender Norms Clash: The Impact of Domestic Violence on Women's HIV risk in Slums of Chennai, India. AIDS and Behaviour, Vol 7, No. 3, Sept 2003.

Vivian F. Go, AK Srikrishnan, Sudha Sivaram, G Kailapuri Murugavel, Noya Galai, Sethulakshmi C Johnson, Teerada Sripaipan, Suniti Solomon and David D. Celantano. "High HIV Prevalence and Risk Behaviours in Men who have sex with men in Chennai, India". JAIDS, Vol 35, # 3, March 1, 2004; (Epidemiology and Social Science).

Sudha Sivaram, Aylur K Srikrishnan, Carl A Latkin, Sethulakshmi C Johnson, Vivian F Go, Margaret E Bentley, Suniti Solomon and David D Celentano. Development of an opinion leader-led HIV prevention intervention among alcohol users in Chennai, India. AIDS Education and Prevention, 16(2), 137-149, 2004.

Sudha Sivaram, AK Srikrishnan, KG Murugavel, Kenneth H Mayer, S Anand, David D Celentano, Suniti Solomon. Ethical issues in the epidemiological assessment of HIV risk in Chennai, India. (Submitted Feb 2004).

D.D. Celentano, A.K. Srikrishnan, S. Sivaram, P. Balakrishnan, T. Sripaipan, S. Johnson, V.F. Go, K. Mayer, S. Solomon. The HIV epidemic in Chennai (southern India) remains concentrated in high risk groups. [MoPeC3469] Poster. XV Intl. AIDS Conf, Bangkok, 11-16 July 2004

D.D. Celentano, S. Sivaram, A.K. Srikrishnan, C.A. Latkin, S. Anand, T. Sripaipan, S. Solomon. Is alcohol use associated with risky sexual behavior among men: Findings from Chennai, India. [MoPeC3478] Poster. XV Intl. AIDS Conf, Bangkok, 11-16 July 2004.

S. Panchanadeswaran, S. Johnson, V. Go, A.K. Srikrishnan, M.E. Bentley, S. Solomon, S.S. Sivaram, D.D. Celentano. Partner violence and HIV sexual risk behaviors among alcohol users in India. [WePeD6299]. Poster. XV Intl. AIDS Conf, Bangkok, 11-16 July 2004.

S.A. Safren, C. Martin, A.K. Srikrishnan, S. Menon, M. Mimiaga, S. Solomon, K.H. Mayer. A survey of MSM outreach workers in Chennai, India. [C11062]. CD pub: Epidemiology and Prevention. XV Intl. AIDS Conf, Bangkok, 11-16 July 2004

S. Panchanadeswaran, A.K. Srikrishnan, S.S. Sivaram, S. Johnson, V. Go, K. Mayer, S. Solomon, D.D. Celentano. Gender differences in STD prevalence and health seeking behavior in a random sample in India. [C11146] CD pub: Epidemiology & Prevention. XV Intl. AIDS Conf, Bangkok, July 2004



PROJECT - 02	DESCRIPTION
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Title of the Project	A randomized controlled clinical trial of structured intermittent therapy vs continuous therapy in HIV-positive patients in South India. (2002 - ongoing)
Principal and Co-investigators' names	Dr. N. Kumarasamy
Duration / Time period	2002 - ongoing
Objective	<p>Primary Objective: To compare the immunological and virological effects of structured intermittent HAART versus continuous HAART in subjects with HIV-1 infection on treatment with CD4+ T cell count > 300 cells/mm³ and plasma viral load (PVL) < 400 copies/ml.</p> <p>Secondary Objective: To compare toxicity and side effects of structured intermittent HAART versus continuous HAART in subjects with HIV-1 infection.</p>
Outcome/s	Study in progress
Publications	<i>N. Kumarasamy, T. Flanigan, S. Solomon, J. Anitha Cecelia, P. Balakrishnan, S. Chaguturu, K.H. Mayer. Rapid Viral load suppression following generic HAART in South Indian HIV-infected patients. XV Int. AIDS Conf, Bangkok, Thailand, 11-16 July 2004.</i>
Methodology	This is a randomized controlled study of antiretroviral naïve subjects with HIV-1 infection designed to evaluate the efficacy of structured intermittent HAART in maintaining CD4+ T cell count > 200 cells/mm ³ . This study will begin as a pilot investigation with 20 patients in each HAART group as planned sample size. The study population will consist of adult subjects above 18 years of age with documented HIV-1 infection fulfilling the criteria outlined in the project proposal.
Collaboration	AIRTP-Fogarty Program of Brown University, Providence, RI and CIPLA.
Financial Assistance	AIRTP-Fogarty Program of Brown University, Providence, RI and CIPLA. US \$ 1,33,106
Current Status of research	Ongoing
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	The study will enable us to determine if we can reduce the cost and toxicity of HAART

PROJECT - 03

DESCRIPTION

Title of the Project	Evaluation of cost effective laboratory markers to monitor HIV-infected persons in South India. (2002- ongoing)
Principal and Co-investigators' names	Dr. P. Balakrishnan
Duration / Time period	2002 - ongoing
Objective	To study the correlation CD4 lymphocyte counts by standard assay (flow cytometry) vs low cost technology (Guava) in persons with HIV. The correlation of Plasma Viral Load (Roche) with CAVIDI assay is also being evaluated.
Outcome/s	Correlation between the flow cytometry and low cost for CD4 T+ lymphocyte count is being assessed. The reproducibility and inter- and intra-personal variation is being evaluated.
Publications	<i>Please see next page</i>
Methodology	PPV, NPV, sensitivity and specificity for CD4 count <200 cells is assessed against gold standard. Also the aged sample for the enumeration of CD4 is in progress. The low cost viral load assay is in progress.
Collaboration	Australia-India Council
Financial Assistance	No funding.
Current Status of research	Ongoing
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	The costs of ART have come down yet HIV monitoring by standard method is expensive and not affordable for patients in developing countries. The low cost technology will reduce the cost of HIV monitoring. Currently, YRG CARE is evaluating manual Coulter Assay and Guava Technology for CD4 and CavidI Assay for viral load testing.

Evaluation of cost effective laboratory markers to monitor HIV-infected persons in South India. (2002-ongoing)

Publications:

N.Kumarasamy, Anish Mahajan, Timothy Flanigan, R.Hemalatha, Kenneth Mayer, Charles Carpenter, SP. Thyagarajan, Suniti Solomon. The Total Lymphocyte count (TLC) is a useful tool for Opportunistic infection prophylaxis in India and other resource-constrained countries. *JAIDS* 2002; 31:378-383.

N.Kumarasamy, Timothy Flanigan, Anish Mahajan, R.Hemalatha, Kenneth Mayer, Charles Carpenter, Suniti Solomon. Monitoring HIV treatment in the developing world. *The Lancet-Infectious Diseases Vol2 Nov 2002*; 656-657.

Mahajan AP, Hogan JW, Snyder B, Kumarasamy N, Mehta K, Solomon S, Carpenter CC, Mayer KH, Flanigan TP. Changes in Total Lymphocyte Count as a Surrogate for Changes in CD4 Count Following Initiation of HAART: Implications for Monitoring in Resource-Limited Settings. *JAIDS* 2004 Apr 20; 36(1): 567-575.

Balakrishnan P, Mandy Dunne, N.Kumarasamy, Suzanne Crowe, Subbulakshmi G, Ganesh AK, Cecelia AJ, Patricia Roth, Kenneth H. Mayer, Thyagarajan SP, Suniti Solomon. An inexpensive, simple and manual method of CD4 T- cell quantitation in HIV infected individuals for use in developing countries. *JAIDS (under review).*

P.Balakrishnan, N.Kumarasamy, S.Vidhya, Sreekanth Chaguturu, KG. Murugavel, J.Anitha Cecelia, Timothy Flanigan, Kenneth Mayer, SP.Thyagarajan, Suniti Solomon. A simple monitoring of antiretroviral therapy with a signal amplification-boosted HIV-1 p24 antigen assay with heat-denatured plasma - An inexpensive marker alternative to tests for viral RNA PCR. (*submitted*).

Presentations:

N.Kumarasamy, Suniti Solomon, R.E.Amalraj, B.Ravikumar, J.Biswas, S.P.Thyagarajan. Correlation between CD4/CD8 and Total Lymphocyte cell counts to Opportunistic infections in Persons with HIV/AIDS in Chennai (Madras), India. *12th World AIDS Conference, Geneva. June 28- July 3, 1998. Abstract. No: 42189.*

N.Kumarasamy, A.Mahajan, J.Allsworth, A.Geetha, T.Flanigan, K.Mayer, Suniti Solomon. Correlation between CD4 count and Total Lymphocyte Count in HIV-positive patients in South India. *5th Asia Pacific AIDS conf '99, KL.Abs538/PSAB005.*

Timothy Flanigan, Anish Mahajan, N.Kumarasamy, R.Hemalatha, Kenneth Mayer, Suniti Solomon. Cost effective strategies to monitor HIV therapy in the developing world. *6th International Congress on AIDS in Asia Pacific, Oct 4-10, 2001, Melbourne, Australia. Abstract no: 1142*

T.Flanigan, A.Mahajan, N.Kumarasamy, R.Hemalatha, C.Carpenter, K.Mayer, S.Solomon. Total Lymphocyte count as a surrogate for CD4 count to initiate and monitor HAART in resource limited countries. *9th Conference on Retroviruses and Opportunistic infections, Feb 24-28, 2002, Seattle, USA. Abstract no: 456W.*

N.Kumarasamy, P.Balakrishnan, J.Anitha Cecelia, Suniti Solomon, Sreekanth Chaguturu, Kenneth H Mayer, Timothy P Flanigan. Low cost strategies to monitor highly active antiretroviral therapy in resource-limited settings. *CROI, Feb 2004. San Francisco, USA.*

PROJECT - 04	DESCRIPTION
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Title of the Project	A longitudinal study on HAART associated body composition, metabolic and quality of life changes. (substudy of Project No. 2) (2002 ongoing)
Principal and Co-investigators' names	Ms. Suneeta Saghayam
Duration / Time period	2002 - ongoing
Objective	To study whether the use of HAART (PI + 2 NRTI or NNRTI + 2 NRTI), brings about any change in the body composition, nutritional status, body shape, quality of life and metabolic changes as compared to ART naïve patients and HIV-negative controls over a period of 2 years.
Outcome/s	Study in progress
Publications	<p><i>S. Saghayam, N. Kumarasamy, S. Solomon, J. Anitha, S. Chaguturu, K. Mayer, T. Flanigan, and C. Wanke. Weight and Body Shape Changes Associated with Antiretroviral Therapy in South India - Initial Prospective Analysis. CROI, Feb 2004. San Francisco, USA.</i></p> <p><i>Suneeta Saghayam, Sreekanth K. Chaguturu, N. Kumarasamy, Suniti Solomon, Kenneth H. Mayer, Christine Wanke. Lipoatrophy is the Predominant Presentation of HIV-associated Lipodystrophy in Southern India. CID 2004; 38 (1 June); 1646-7 (Correspondence).</i></p> <p><i>S. Saghayam, N. Kumarasamy, S. Solomon, J. Anitha Cecelia, T. Flanigan, K. Mayer, C. Wanke. Metabolic and body shape changes in a ART naïve-cohort initiating generic HAART in South India. [WePeB5923]. Poster. XV Intl. AIDS Conf, Bangkok, 11-16 July 2004.</i></p>
Methodology	<p>A prospective longitudinal study (24 months) following a total of 100 HIV positive patients, not previously on HAART; 20 participants from each of the five groups matched based on age, sex and CD4 count.</p> <p>Patients on continuous PI HAART therapy; Patients on continuous NNRTI HAART therapy; Patients on interrupted NNRTI HAART therapy. ART naïve patients; HIV-negative controls.</p> <p>Use of a proforma consisting of demographic details, medical history, body weight, body composition, body shape, dietary intake, laboratory and quality of life details would be filled in by the nutritionist for each study subject. Details of the antiretroviral therapy and any other medications would also be included.</p>
Collaboration	AIRTP-Fogarty program of Brown University, Providence, RI, USA. Tufts University, Boston, USA,
Financial Assistance	AIRTP-Fogarty program of Brown University, Providence, RI, USA. Tufts University, Boston, USA, US \$34,448
Current Status of research	2002 - ongoing
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	This first prospective study in India would throw light on the natural history of the lipodystrophy syndrome and the factors responsible for the body shape and metabolic complications following HAART, so that prevention or treatment measures can be undertaken in the future.

PROJECT - 05	DESCRIPTION
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Title of the Project	A longitudinal study on the bone composition changes in HIV positive individuals on HAART and controls - (Supplement to Project No. 4) [2003 ongoing]
Principal and Co-investigators' names	Ms. Suneeta Saghayam
Duration / Time period	2003 - ongoing
Objective	To study whether the use of HAART causes any changes in the bone composition.
Outcome/s	Study in progress
Publications	-
Methodology	Dual Energy X-ray Absorptiometry (DEXA) to study bone composition done annually, and use of proforma consisting of demographic details, sexual functioning and reproductive history administered to each of the study subjects at each visit.
Collaboration	None
Financial Assistance	None
Current Status of research	Ongoing
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	This study would help observe if there is a loss in bone mineral content and density in HIV infection and whether this is worsened by HAART as compared to controls. In future, this would help supplement their diet with required nutrients to prevent fractures.

PROJECT - 06	DESCRIPTION
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Title of the Project	Religion and health beliefs and practices among Indian men and women with HIV. (2003 - 2004)
Principal and Co-investigators' names	Dr. Nalini Tarakeshwar
Duration / Time period	2003 - 2004
Objective	The project trains research associates at YRG CARE in conducting individual elicitation interviews and focus group discussions to evaluate the influence of religion and culture on the health-related beliefs and practices of men and women with HIV/AIDS and their health care providers. Based on these, a culturally sensitive, individual counseling intervention will be developed which can be integrated with the existing counseling modules at YRG CARE.
Outcome/s	Study in progress
Publications	-
Methodology	<ol style="list-style-type: none"> 1. Individual, semi structured elicitation interviews with 30 men and 30 women with HIV/AIDS. 2. One focus group with 10 HIV health providers (male and female). 3. Individual, semi-structured elicitation interviews with 5-10 healthcare providers at YRG CARE.
Collaboration	YRG CARE with Yale University School of Medicine, Yale New Haven Hospital, CT 06511. Fogarty International Center, NIH.
Financial Assistance	Yale University School of Medicine, Yale New Haven Hospital, CT 06511. Fogarty International Center, NIH, US \$ 13016
Current Status of research	Ongoing
HMSC Clearance Status	N/A
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	The power of counseling as a prevention tool has been well established and scientifically proven in HIV incidence studies. Religion certainly plays an integral part in our social lives and this study strives to establish the positive co-factors that may help restructure the counseling. This study conducted by trained ethnographers would identify the right inputs that could be added to the existing counseling modules at YRG CARE and could be replicated at other VCT centers too, with appropriate training.

PROJECT - 07	DESCRIPTION
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Title of the Project	Behavioral Secondary HIV prevention in Chennai [2004-2005]
Principal and Co-investigators' names	Dr. Suniti Solomon
Duration / Time period	2004 - 2005
Objective	To establish infrastructure and administrative support capable of evaluating current practices and potential impediments around secondary HIV prevention efforts targeting persons infected with HIV in Chennai India; To identify through qualitative methods (i.e. interviews and focus groups) barriers to, and facilitators of, HIV testing and safer sexual behaviors, and secondary HIV prevention needs in the risk-groups; To utilize the local derived qualitative data coupled with quantitative models of HIV transmission risk behaviors established and tested in the U.S., to lay the groundwork for culturally specific interventions for prevention programs in Chennai.
Outcome/s	Study in progress
Publications	-
Methodology	Formative qualitative study involving individual interviews among the risk groups of persons (IDU, Truck Drivers / Men who travel on business only, Sex workers, Married men, Married women) with HIV in Chennai, India. This will be followed by a quantitative study.
Collaboration	Fogarty International Center, NIH through Brown Center For AIDS Research (CFAR), Brown University, Providence, RI, USA
Financial Assistance	Fogarty International Center, NIH through Brown Center For AIDS Research (CFAR), Brown University, Providence, RI, USA
Current Status of research	Ongoing
HMSC Clearance Status	Cleared on 12th March 2004
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	This study will address the barriers and factors affecting HIV testing especially since the HIV epidemic has reached the general population. The quantitative and qualitative results will help to develop a structured intervention to prevent further secondary HIV infection. This is a vital national need and has a strong case for national level replication.

PROJECT - 08	DESCRIPTION
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Title of the Project	Socio anthropological approach to HIV transmission from mother to child in India: The case of breast feeding [2004-2007]
Principal and Co-investigators' names	Ms. Sethulakshmi C Johnson
Duration / Time period	2004 - 2007
Objective	<p>The study of breast feeding in the context of the HIV/AIDS infections.</p> <p>(a) the understanding of the mothers and their social milieu in context of the risk of HIV transmission through breast feeding.</p> <p>(b) the influence of their husbands and of the surrounding sociocultural groups on issues relating to alternatives for extended breast feeding.</p> <p>(c) the consequences of the relation established between the women and the medical and political authorities.</p> <p>(d) the consequences of the social construction of the disease and the existence of discriminatory and stigmatising behavior towards people infected with HIV.</p> <p>(e) the influence of the insertion of the women or their surroundings in new social milieu (life style changes, insertion in an association, migratory networks, relations with the medical staff, therapeutic resources etc.).</p>
Expected Outcome/s	To document the sociocultural issues regarding biographical components of HIV positive women, their cultural and social representations, and the medical and prevention context in which this occurs.
Publications	-
Methodology	<p>Survey based on interviews of 25 - 30 HIV positive women in a psycho sociological framework, on the basis of a qualitative analysis.</p> <p>An ethnographical study about breast feeding practices among rural communities in Tamil Nadu.</p>
Collaboration	French Institute of Pondicherry, Group of Research Innovations and Societies (GRIS), Dept. of Sociology, University of Rouen, Mont Saint Aignan Cedex, France and YRG CARE, Chennai. French Ministry of Foreign Affairs, Paris, France.
Financial Assistance	French Institute of Pondicherry, Group of Research Innovations and Societies (GRIS), Dept. of Sociology, University of Rouen, Mont Saint Aignan Cedex, France and YRG CARE, Chennai. French Ministry of Foreign Affairs, Paris, France. Euro 7,200.
Current Status of research	In preparatory phase
HMSC Clearance Status	Cleared on 12th March 2004
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	It is an established factor that an HIV infected mother breast feeding her new born is risky though there have been very strong citations on how formula food causes hygiene related risks to the infant and does not provide the sufficient immune inputs. This study analyses the socio-anthropological factors. Considering the active role Government of India has been taking on PMTCT, this is a vital study to determine the right intervention that needs to be implemented at the grass root level for a positive behavior change.

PROJECT - 09	DESCRIPTION
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Title of the Project	HPTN 052 - A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 In Serodiscordant Couples
Principal and Co-investigators' names	Dr. N.Kumarasamy
Duration / Time period	In preparatory phase
Objective	The purpose of this study is to determine whether antiretroviral therapy (ART) can prevent the sexual transmission of HIV-1 in HIV-1 serodiscordant couples.
Outcome/s	In preparatory phase
Publications	-
Methodology	The study is a Phase III, two-arm, randomized, controlled, multi-center trial. A run-in period is planned prior to fully enrolling the study participants. HIV serodiscordant couples in which the HIV-infected partner is ART-naïve and has a CD4+ cell count of 300-500 cells/mm ³ .
Collaboration	Family Health International and Fenway Community Health, USA
Financial Assistance	National Institutes of Health, USA
Current Status of research	In preparatory phase
HMSC Clearance Status	Approved by HMSC. Submitted by NARI, Pune (on behalf of YRG CARE as both NARI and YRG CARE are trial sites of the HPTU Network).
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	This study tests the hypothesis: 'ART can prevent sexual transmission of HIV.'

PROJECT - 10	DESCRIPTION
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Title of the Project	AACTG 5175 - A Phase IV, Prospective, Randomized, Open-label Evaluation of the efficacy of Once-Daily Protease Inhibitor and Once-Daily Non-Nucleoside Reverse Transcriptase Inhibitor-Containing Therapy combinations for Initial Treatment of HIV-1 Infected Individuals from Resource-Limited Settings (PEARLS) Trial
Principal and Co-investigators' names	Dr. N. Kumarasamy
Duration / Time period	In preparatory phase
Objective	To demonstrate the non-inferiority of a once-daily PI- and a once-daily NNRTI containing regimen as compared with standard twice-daily ARV therapy for the initial treatment of individuals infected with HIV-1 from diverse areas of the world.
Outcome/s	In preparatory phase
Publications	-
Methodology	The study is a Phase IV, randomized, multicenter trial involving 1520 participants in a two arm treatment regimen.
Collaboration	Adult AIDS Clinical Trial Group
Financial Assistance	The National Institute of Allergy and Infectious Diseases NIAID, NIH U.S.A., US \$ 355,153
Current Status of research	In preparatory phase
HMSC Clearance Status	Approved by HMSC. Submitted by NARI, Pune (on behalf of YRG CARE as both are trial sites of the AACTG).
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	This study tests the usefulness of simplified HAART regimens with once daily regimen. Also this study will describe the long term toxicity of HAART, adherence related issues, ARV resistance, immune reconstitution syndrome and changing spectrum of HIV disease.

Research Projects
awaiting clearance from
Health Ministry Steering Committee



Y.R.G.CARE

PROJECT - 01	DESCRIPTION
Title of the Project	Understanding factors inhibiting access to HIV VCT in Chennai, India and measure impact of capacity building in improving access.
Principal and Co-investigators' names	Dr. Suniti Solomon
Duration / Time period	1 Year
Objective	<p>To conduct a baseline survey in fifty select private HIV testing services in Chennai City on the factors that impact or inhibit access to HIV Voluntary Testing and Counseling in the case of various population groups - IDU, CSW, general population men and women.</p> <p>To develop and offer a core curriculum in HIV VCT based on CDC guidelines to twenty-five laboratories at Chennai City which are currently testing for HIV antibodies (mostly without, or with inadequate, pre and post-test counseling) and to compare the outcomes by the end of the project period with the baseline.</p>
Methodology	50 laboratories will be selected in the city and an in-depth interview will be conducted to understand actual practices that may seriously challenge access to VCT. Based on the information obtained from this survey 25 participating laboratories would be selected and YRG CARE will provide technical assistance to their counselors to develop skills in counseling process.
Collaboration	Dr. Kenneth Mayer, Prof. of Medicine and Community Health, Brown University, USA.
Financial Assistance	Center for AIDS Research (CFAR), USA.
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	The study would lead to capacity building in improving access that are culturally relevant to the Indian context. VCT is a valuable component of a comprehensive HIV/AIDS program. VCT is an entry point for care and support for HIV. Private testing providers are increasing in numbers each day. Their role could be more constructive. This project will serve as a pilot for broadbasing findings at a national level.
Date of submission to ICMR	August 21, 2002.
Details of acknowledgement from ICMR	No. INDO/FRC/439(I)/2002/IFC dated 3/9/2002 No. HIV/51/64/2002-ECD-II dated 13/6/2003
Comments from ICMR	Letter No. HIV/51/64/2001-ECD-II, dated 13/8/04, that the project was not approved as PI's reply was not found satisfactory by the HMSC.

PROJECT - 02	DESCRIPTION
Title of the Project	Stigma in Health Care Settings in South India.
Principal and Co-investigators' names	Dr. Suniti Solomon
Duration / Time period	3 Years
Objective	<p>To explore what creates and influences HIV stigma in individuals, families, communities and health care settings in South India.</p> <p>To examine the psycho-social impact of HIV stigma on South Indian Individuals.</p> <p>To analyze situations where stigma is less prevalent in South India.</p> <p>To determine how HIV stigma affects care and access to care in South India.</p> <p>To disseminate findings in an Indo-USA working group on stigma focusing on informing the development of interventions to reduce stigma.</p>
Methodology	<p>A total of 450 participants will be enrolled from 2 cities and 2 towns and interviewed over a period of 2 years. Participants will comprise of patients, family members, physicians and surgeons, nurses and paramedical workers from medical centers. They will be administered in-depth, semi-structured qualitative interviews individually. The interviews will follow a standard guide with broad open-ended questions following probes to elicit further information.</p>
Collaboration	Dr. Kenneth Mayer, Prof. of Medicine and Community Health, Brown University, USA.
Financial Assistance	Fogarty International Center, National Institute Of Health, USA US \$ 162,000
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	<p>Stigma seriously challenges access to prevention, testing and care. This is a global trend and widely prevalent in India as well. The project will help us understand the determinants and possible solutions to this problem. The findings will be shared in a national level workshop which will provide a framework for interventions and planning of future steps.</p>
Date of submission to ICMR	November 11th, 2003
Details of acknowledgement from ICMR	June 24th, 2004
Comments from ICMR	Letter No. HIV/51/86/2003-ECD-II, dated 13/8/04 that the project is not approved.

PROJECT - 03	DESCRIPTION
Title of the Project	Randomized Controlled Trial of 6% Cellulose Sulfate Gel and the effect on vaginal HIV transmission.
Principal and Co-investigators' names	Dr. Suniti Solomon
Duration / Time period	40 Months
Objective	<p>Primary Objective: To assess the effectiveness of CS gel (3.5 ml) compared to placebo gel (3.5 ml) in preventing vaginal male-to-female transmission of HIV.</p> <p>Secondary Objective: To assess the effectiveness of CS gel (3.5 ml) compared to placebo gel (3.5 ml) in preventing vaginal male-to-female transmission of HIV.</p>
Methodology	A total of 2574 HIV negative women will be recruited in several African countries and in India. Participants will be randomly assigned to CS or the placebo gel in a 1:1 allocation ratio. Each participant will be followed for 12 months and the scheduled visits will include a screening visit, an enrollment visit and 12 monthly follow-up visit.
Collaboration	Drs. Henry L. Gabelnick, Marianne Morse Callahan, Lut Van Damme, Contraceptive Research and Development (CONRAD), Arlington, USA.
Financial Assistance	CONRAD
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	If successful, the product will serve as a barrier measure which is women initiated and controlled to prevent STI and HIV infection.
Date of submission to ICMR	June 24, 2004.
Details of acknowledgement from ICMR	Not yet received
Comments from ICMR	Awaiting comments

PROJECT - 04	DESCRIPTION
Title of the Project	Neurocognitive Consequences of HIV/AIDS in South India.
Principal and Co-investigators' names	Dr. Tokugha Yephthomi
Duration / Time period	2 Years
Objective	<p>To establish infrastructure and administrative support capable of evaluating cognitive and neuroimaging aspects of HIV, and the impact of treatment of HIV on these variables.</p> <p>To examine relationships between disease severity, performance on cognitive tests (eg., memory, attention, motor speed) and images of brain structure on magnetic resonance imaging.</p> <p>To examine the impact of HIV treatment on cognitive function and neuroimaging changes associated with HIV.</p>
Methodology	<p>A total of 50 individuals with HIV and whose CD4 cell counts < 200 at baseline will be examined in the study. A total of 100 healthy controls matched to the HIV group for gender, age and education will be recruited. The healthy controls will be asked to complete the cognitive tests and undergo MRI or lab tests. Clinical and laboratory assessments including demographic data, medical history, current antiretroviral treatment history, CD4 count and viral load, duration of HIV infection, neuroimaging, neurological examination, neuropsychological examination and blood draw.</p>
Collaboration	Drs. Timothy Flanigan, Robert Paul, David Tate, Center for AIDS Research (CFAR), Brown University, Providence, Rhode Island, USA
Financial Assistance	National Institutes of Health (NIH) through CFAR, Brown University.
Usefulness of the study in terms of interventions / HIV / AIDS prevention strategy	<p>We expect that the study will significantly contribute to our understanding of cognitive difficulties associated with HIV by:</p> <p>Identifying the nature and severity of cognitive difficulties prior to therapy.</p> <p>Identifying the specific changes in brain structure associated with cognitive difficulties in HIV.</p> <p>Describe the resolution of the cognitive and neuroimaging abnormalities with treatment of HIV.</p> <p>The study would also lead to the development of valuable cognitive tests translated in languages native to Southern India, and modified for cultural relevance. These tests can be employed in multiple clinical settings to identify individuals with cognitive difficulties, and the efficacy of interventions to improve cognitive function.</p>
Date of submission to ICMR	May 31, 2004.
Details of acknowledgement from ICMR	Not yet received
Comments from ICMR	Awaiting comments



Y.R.G.CARE
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