1. Patterns of disclosure of HIV diagnosis to adolescents/ children: A facility based exploratory study	
Principal Investigator	Dr. Seema Sahay, NARI
Other Investigator(s):	Mrs. N. Joglekar, Mrs. R. Brahme, Dr. M Ghate, Mr. R. Yadav
Category / Nature:	Care and support study Observational cross section study
Collaboration / Participating Centers:	Nil
Funding Agency(ies) / Sponsors:	Intramural
Budget:	Rs. 6,78750/-
Study Period:	2012-2014
Objectives :	To identify the proportion of children who have knowledge of their serostatus and factors associated with disclosure in HIV-infected children registered for ART or on HAART. To conduct qualitative study to understand perspective of caregivers (parents, teachers and health care providers) for disclosure among children and concerns around issue of adherence to ART.
Description :	As first step, formative research which was community based, was conducted among infected, affected and uninfected adolescents, parents of the three groups of adolescents, teachers, health care providers, NGO/ CBO representatives and program official. Based on the content analysis, structured questionnaire has been developed to understand patterns of disclosure among children by (ranging from no disclosure to complete disclosure) by parents and doctors. It also includes survey among children attending our facility. This focuses on children's awareness about their health problems and their perceptions regarding their health status, their coping mechanism and psychological stressors
Current Status :	Ongoing Project

Publications:	Nil
Presentations:	Nil

2. A 5282: A Randomized, Phase II Trial to Compare an HPV Test-and-Treat Strategy to a Cytology-based Strategy for Prevention of CIN 2+ in HIV-infected Women	
Principal Investigator	Dr. Sheela Godbole MD
Co-Principal Investigator(s):	Nil
Other Investigator(s):	Dr. Usha Katti, Dr. Arati Mane, Dr. M Ghate, Dr. Prachi Athavale Local Consultants: Dr. Girija Wagh, Dr. N. Karandikar, Dr. Manju Talathi (Bharati Vidyapeeth Hospital)
Category / Nature:	Care and treatment
Collaboration / Participating Centers:	India, Peru, Malawi, south Africa, Haiti, Botswana, Zambia and Zimbabwe.
Funding Agency(ies) / Sponsors:	The study is being funded by the National Institutes of Health of the US government through AIDS clinical trial group and Family Health International; funded by the Division of AIDS.
Budget:	Nil
Study Period:	Nil

Objectives :	**Primary objectives:** • To evaluate the effectiveness of immediate cryotherapy in HIV-infected women with hr-HPV compared to a cytology-based strategy by comparing cumulative CIN2+ rates. **Secondary objectives:** • To evaluate the safety and tolerability of cervical cryotherapy (Arm A) in HIV infected women. • To compare between arms the presence of cervical cytological abnormalities during the study. • To assess study discontinuation rates and reasons for discontinuation between arms. • To compare time to development of CIN2+ between those women with and without detection of hr-HPV by a HPV at 26 weeks, and those women with and without cervical cytological abnormalities after cervical cryotherapy in Arm A.

	• To assess detection frequencies of cervical HPV types (by DNA PCR) and the rates of hr-HPV by careHPV at study entry. • To evaluate baseline/screening characteristics (detection of various HPV types, CD4, CD4 nadir, and HIV RNA) associated with cytological abnormalities at baseline.

Brief description: (one paragraph)	**Study design:** Multicenter, Phase II, randomized clinical trial that will compare a human papillomavirus (HPV) test-and-treat-strategy with a cytology-based strategy. **Study rationale:** Cervical cancer is the second most common cancer among women worldwide. Nearly 80% of these cases are in developing countries where screening programs are not well established and awareness about the disease is low. HIV-infected women appear to be at increased risk of cervical cancer both in resource rich and resource limited areas. Cervical cancer screening programs are traditionally based on cervical cytology as the initial screening test. It is challenging to establish and sustain cytology-based screening programs in resource limited settings. Such programs require trained cytotechnologists and qualified pathologists to interpret the results. An alternative strategy that has been proposed relies on testing for cancer-causing or "high-risk" types of HPV (hr-HPV) as the screening test for cervical cancer. The underlying principle is that hr-HPV infection is a necessary cofactor for the vast majority of cervical cancers. If hr-HPV is present, women undergo ablative treatment of the transformation zone with same-visit cryotherapy to treat presumptive CIN2+ and/or areas of hr-HPV infection without actual CIN2+. **Study Population:** HIV-infected women 18 years of age or older. Eligible participants should have no history of major cervical procedures or suspicion of cervical, vaginal, or vulvar cancer. See Section 4.0 for specific eligibility criteria. **Sample Size:** The study will randomize 280 hr-HPV-positive women to Arms A and B and enroll approximately 170 women in Arm C for a total study sample size of up to 450 participants.

	Study duration: Participants in Arms A and B will be followed up for about 2.5 years while participants in Arm C are followed up for 6 months. **Treatment Regimen:** Arm A: Cervical cryotherapy. Arm B: Cytology-based strategy Arm C: Participants with cervical lesions inappropriate for cryotherapy are not eligible for randomization but will be eligible to register to Arm C. Participants without hr-HPV will also be eligible to register to Arm C if lesions were seen on the screening colposcopy or if the screening cytology shows HSIL. **NARI Study status:** As of 31st March 2013, we had screened 77 women for high risk HPV and other inclusion criteria and enrolled 7 women in Arms A 6 women in Arm B and 2 in Arm C.
Current status	Ongoing
Publications	Nil
Presentations	Nil

3. Pediatric neurocognitive study	
Principal Investigator	Dr. Manisha Ghate
Category / Nature	Intramural study

Collaboration / Participating Centers	Nil
Funding Agency(ies) / Sponsors	Nil
Budget	Nil
Study Period	2013-2014
Objectives	To study the neurocognitive aspects in HIV infected children before and after ART initiation
Description	Total 50 HIV infected and 50 uninfected children will be enrolled. Their cognitive and behavioral assessment will be done using Indian Child Intelligence Test (ICIT). The follow up will be done after 6 months of ART initiation to study the effect of ART on neurocognition.
Current Status	Ongoing
Publications	Nil
Presentations	Nil

Title	A case control study to understand determinants and biomarkers associated with immunologic non response [INR] as well as to assess quality of adaptive and innate immune responses in patients with INR in Pune
PI and Co-PIs	Principal Investigator: Dr. Ashwini Shete, Co-PI: Dr. Sampada Dhayarkar, Co- Investigators: Dr. Madhuri Thakar, Dr. R.R.Gangakhedkar
Funding/Sponsoring agency	NACO
Category	Care and Treatment Research
Study period	2015-2018
Broad Objective	To understand the determinants and biomarkers associated with Immuno-virologic discordance in HIV infected patients taking ART at NACO ART center in Pune
Approved Budget	Rs. 45,04,920/
Current status	Ongoing
No. of publications with titles and/or abstracts presented	Nil