

<b>1) To understand community and health care providers' perspective on male controlled biological options in India (An ICMR task-force study)</b>	
<b>Principal Investigator</b>	Dr. Seema Sahay, NARI
<b>Co-Principal Investigator(s)</b>	Dr. Anju Sinha (ICMR)
<b>Other Investigator(s)</b>	Site PIs: 1) Dr. S. Kholkutte (RMRC, Belgaum) 2) Dr. Shalini Bharat (TISS, Mumbai) 3) Dr. Abhilasha Gupta/ Dr. Rukma Idnani (HRRC, Meerut) 4) Dr. Sibnath Deb, (Calcutta University, Kolkata)
<b>Category / Nature</b>	Community based multicentric qualitative research
<b>Collaboration / Participating Centers</b>	RMRC (Belgaum), TISS (Mumbai), HRRC (Meerut), Calcutta University (Kolkata)
<b>Funding Agency(ies) / Sponsors</b>	Indian Council of Medical Research
<b>Budget</b>	INR:1953203/-[NARI site]
<b>Study Period</b>	2009-2011
<b>Objectives</b>	This study aimed at understanding community and health care providers' perspectives, concerns and prospective role in relation to male controlled biological option especially the circumcision (MC) in India in the context of HIV prevention and control program.
<b>Description</b>	A four centre qualitative study was conducted at Belgaum, Kolkata, Meerut and Mumbai cities in India, and a total of 134 in-depth interviews were conducted. Of these, 62 in-depth interviews were conducted among representatives of circumcising and non-circumcising communities (CC & NCC respectively) which comprised of medically and traditionally circumcised men, parents of circumcised children, spouses of circumcised men, and religious leaders. In all, 72 general and pediatric surgeons, pediatricians, STD practitioners, traditional circumcisers, general

	practitioner, and operation theatre nurses were also interviewed
<b>Current Status</b>	Completed
<b>Publications</b>	Seema Sahay <sup>1*</sup> Archana Verma <sup>1</sup> , Sanjay Mehendale <sup>2</sup> . Care providers' attitude towards male circumcision as an option for HIV prevention: a qualitative study from India. Accepted for book chapter, 2013.
<b>Presentations</b>	<p>Seema Sahay<sup>1*</sup>, Vidisha Kanthe<sup>1</sup>, Neelam Joglekar<sup>1</sup>, Bijesh Kumar<sup>1</sup>, Amit Nirmalkar<sup>1</sup>, Sibnath Deb<sup>3</sup>, Shalini Bharat<sup>4</sup>, Shripad Bhatt<sup>5</sup>, Abhilasha Gupta<sup>6</sup>, Anju Sinha<sup>7</sup>, Nomita Chandhiok<sup>7</sup>, Sanjay Mehendale<sup>2</sup>. Male circumcision as an HIV prevention option: A socio-cultural perspective. <i>ISSRF Conference, 2011, NIRRH, Mumbai</i></p> <p><u>Seema Sahay</u>, Anju Sinha, Neelam Joglekar, Vidisha Kanthe, Sanjay Mehendale, Sibnath Deb, Shalini Bharat, Abhilasha Gupta, Shripad Bhat. Male circumcision as HIV prevention Option: Perspectives from circumcising and non circumcising communities in India. <i>Poster presentation at M2012, Sydney, Australia</i></p> <p><u>Seema Sahay</u> , <u>Karikalán Nagarajan</u>, <u>Sanjay Mehendale S</u>, <u>Deb S</u>, <u>Gupta A</u>, <u>Shalini Bharat S</u>, <u>Bhatt S</u>, <u>Bijesh A</u>, <u>Kanthe V</u>, <u>Sinha A</u>, <u>Chandhiok N</u>. A multicentric qualitative study about male circumcision practices in India from the perspectives of community and health care providers. <i>Poster # MOPE155, IAS 2013, KualaLampur, Malaysia</i></p>

<b>2) Adolescent Reproductive and Sexual Health Education An Intervention Study [ICMR task force study]</b>	
<b>Site Principal Investigator [Pune site]</b>	Dr. Seema Sahay, NARI
<b>Other Investigator(s) [Pune]</b>	Dr. S.M. Mehendale, Deputy Director [SG]; Mrs. Suvarna Sane, Research Assistant
<b>Category / Nature</b>	Intervention study
<b>Funding Agency(ies) / Sponsors</b>	Indian Council of Medical Research
<b>Budget</b>	INR: 1192250/-
<b>Study Period</b>	2003-06-11
<b>Objectives</b>	To develop feasible model for providing Reproductive and Sexual Health Education to school going adolescents in different parts of India
<b>Description</b>	The study was conducted between 2003 and 2006 and curriculum was finalized in the year 2011 after testing during the study. It was an intervention study conducted on 9th and 11th standard students. Parents/ teachers questionnaire and students' baseline questionnaire were developed in consultation with investigators from all sites and ICMR. Structured questionnaire with 33 items were developed for parents and teachers. Students' questionnaire had 123 items at baseline and 127 items at end line. Informed consent was developed by NARI. Data was collected only once from parents/ teachers or guardians. Baseline and end line data was collected from students.
<b>Current Status</b>	Completed
<b>Publications</b>	<ul style="list-style-type: none"> <li>• <i>Sahay S, Mehendale SM.</i> Adolescent ReproductRSHE module. Publishers:NARI,ICMR. 2011</li> <li>• <i>Sahay S, Nirmalkar A, Sane S, Verma A, Reddy S Mehendale S.</i> Correlates of Sex Initiation among School Going Adolescents in Pune,</li> </ul>

	India. Indian J Pediatr DOI 10.1007/s12098-013-1025-8, 2013
<b>Presentations</b>	<ul style="list-style-type: none"> <li>• Dissemination of study findings. July 2011, New Delhi ARSHE module release by Secretary, DHR, DG, ICMR, Dr.V. M.Katoch at New Delhi, 2011</li> <li>• Neelam Joglekar, Seema Sahay, Sanjay Mehendale. Adolescents' perspective of their own reproductive and sexual health needs. <i>International Conference on Fundamental and Translational Research on HIV/ AIDS: Global perspectives</i>. 5-8 October 2008, Mumbai, India.</li> <li>• Seema Sahay. Adolescent Reproductive and Sexual Health Education: Impact of ICMR Education Module on Rural and Urban School Going Adolescents in Pune, India. <i>International Conference on Fundamental and Translational Research on HIV/ AIDS: Global perspectives</i>. 5-8 October 2008, Mumbai, India.</li> </ul>

<b>3) A Phase I Double-Blind, Placebo-Controlled, Randomized Trial to Evaluate the Safety and Immunogenicity of TBC-M4, a multigenic MVA HIV Vaccine vs. ADVAX, a multigenic DNA HIV Vaccine followed by TBC-M4, a multigenic MVA HIV Vaccine (P001)</b>	
<b>Principal Investigator</b>	Dr. S. M. Mehendale
<b>Co-Investigator(s)</b>	Dr Seema Sahay, Dr Madhuri Thakar
<b>Category / Nature</b>	HIV prevention Research
<b>Collaboration / Participating Centers</b>	NARI, Pune and NIRT, Chennai
<b>Funding Agency(ies) / Sponsors</b>	International AIDS Vaccine Initiative, NY, USA.
<b>Budget</b>	Rs. 2,85,00,000/-
<b>Study Period</b>	2 years
<b>Objectives</b>	<p>Primary : To evaluate the safety of intramuscularly administered ADVAX DNA HIV vaccine at time 0 and 1 month, followed by TBC-M4 at months 3 and 6, compared with TBC-M4 administered intramuscularly at 0,1,and 6 months.</p> <p>Secondary : To evaluate the immunogenicity of intramuscularly administered ADVAX DNA HIV vaccine at time 0 and 1 month, followed by TBC-M4 at months 3 and 6, compared with TBC-M4 administered intramuscularly at 0, 1, and 6 months.</p> <p>Other: To examine the safety &amp; immunogenicity of the construct in the presence of pre-existing immunity against vaccines, if any participants have such immunity.</p> <p>Study design: Randomized, double blind, placebo controlled, Prime Boost trial using ADVAX, a DNA vaccine and TBC- M4, a MVA vaccine</p>
<b>Description</b>	Comparison of safety and immunogenicity between two groups, DNA/MVA

	<p>(group A) and MVA only (group B) was done in the trial. Overall both the vaccine candidates (ADVAX-DNA, TBC-M4- MVA) used in the trial were found to be safe and well tolerated without any significant difference in reactogenicity and adverse events from placebo recipients. Antibody response was found to be better in MVA only group in terms of magnitude, breadth, persistence as well as titres of neutralizing antibodies. T cell based response as assessed by ELISPOT assay was comparable in both the groups.</p>
<b>Current Status</b>	Completed
<b>Publications</b>	<p>Safety and immunogenicity of DNA and MVA HIV-1 subtype C vaccine prime-boost regimens: A phase I randomised trial in HIV-uninfected Indian volunteers. Sanjay Mehendale, Madhuri Thakar, Seema Sahay, Makesh Kumar, Ashwini Shete, Pattabiraman Sathyamurthi, Amita Verma, Swarali Kurle, Aparna Shrotri, Jill Gilmour, Rajat Goyal, Len Dally, Eddy Sayeed, Devika Zachariah, James Ackland, Sonali Kochhar , Josephine H Cox, Jean-Louis Excler, Vasanthapuram Kumaraswami, Ramesh Paranjape, Vadakkuppatu Devasenapathi Ramanathan. PLoS ONE. 2013; 8(2): e55831.</p>
<b>Presentations</b>	<p>Poster presentation in AIDS vaccine conference 2011 in Bangkok, Thailand. on “Safety and immunogenicity of DNA and MVA HIV-1 subtype C vaccine prime-boost regimens: A Phase I trial in HIV-uninfected Indian volunteers” S Mehendale, M Thakar, M Makesh Kumar, S Sahay, P Satyamurthy, A Verma, Swarali Kurle, Ashwini Shete, S Kochhar, J Gilmour, R Goyal, L Dally, JH Cox, JL Excler, P Fast, V Kumaraswami, R Paranjape, VD Ramanathan.</p>

## Anal HPV

<b>4) Prevalence of anal HPV infections and associated abnormalities in HIV infected women: A feasibility study</b>	
<b>Principal Investigator</b>	Dr. Sheela Godbole MD
<b>Co-Principal Investigator(s):</b>	Dr. Arati Mane MD
<b>Other Investigator(s):</b>	<ul style="list-style-type: none"> <li>• Dr. A Risbud</li> <li>• Dr. M Ghate</li> <li>• Dr. Mallika Alexander</li> <li>• Dr. Usha Katti</li> <li>• Dr. S Gupta (ICPO)</li> </ul>
<b>Category / Nature:</b>	Facility based Cross sectional Study
<b>Collaboration / Participating Centers:</b>	Nil
<b>Funding Agency(ies) / Sponsors:</b>	NARI-Intramural Study
<b>Budget:</b>	Nil
<b>Study Period:</b>	2 years September 2011-2013
<b>Objectives :</b>	<p>Objectives:</p> <ul style="list-style-type: none"> <li>• To establish feasibility of screening for Anal HPV and AIN in HIV infected women at NARI</li> <li>• To determine the prevalence of anal HPV infection in HIV infected women and describe the specific HPV types associated with anal infection among them.</li> <li>• To identify the risk factors associated with anal HPV infection in the study population.</li> <li>• To determine the association of anal HPV infection with concurrent cervical HPV infection.</li> </ul>
<b>Brief description: (one paragraph)</b>	High risk Human Papilloma Virus (HPV), the primary infectious agent of cervical cancer, is also associated with the development of anal cancers. Rates of cervical and anal HPV infection and abnormal cytology are high in

	<p>HIV-infected women. As HIV-infected women live longer with HAART, they continue to be at risk for HPV associated diseases including dysplasia and cancer of the cervix, vulva and anus. Although it is established that HPV infection can be transmitted to women through receptive anal intercourse, alternate routes of transmission may be possible. HIV infected women have at least 7 times greater risk of developing anal carcinoma or carcinoma-in situ compared to their HIV negative counterparts.</p> <p>Despite the considerable data on cervical neoplasia and HPV infection in HIV-infected women in India, there is limited data on anal neoplasia and anal HPV infection in this population.</p> <p>We therefore planned an exploratory cross-sectional study to assess the prevalence of anal cytologic abnormalities and type-specific anal HPV infection in HIV-infected women</p>
<b>Current status</b>	Completed
<b>Publications</b>	Nil
<b>Presentations</b>	Nil