Research Projects by Department of Preventive Oncology, Tata Memorial Hospital, Mumbai.

Ongoing Projects

Sr. No	Name of the Project	Year of implementation	Implemented by
1.	Women Empowerment-Cancer Awareness Nexus (We-CAN): An Implementation Research Study of Cervical Cancer Prevention through HPV Self-sampling and Education in India	2023	Dr. Gauravi Mishra, Dr. Mandana Vahabi
2.	Incidence of Human Immunodeficiency Virus (HIV) among Indian Men who have Sex with Men (MSM)	MoU in process	Dr. Sharmila Pimple, Prof. Shaesta Mehta, Dr. Prachi Patil, Dr. Alexandra Hernandez, Dr. Gauravi Mishra, Dr. Joel Palefsky
3.	Prevention and Screening Innovation Project toward Elimination of Cervical Cancer. PRESCRIP- TEC	2022	Dr. Jaap Koot, Dr. Keerthana Prasad, Dr. Sharmila Pimple, Dr. Gauravi Mishra
4.	Investigating Human Papillomavirus (HPV) Infection and HPV-associated Disease in Indian Men who have Sex with Men who are HIV-positive.	MoU in process	Dr. Sharmila Pimple,Dr. Gauravi Mishra, Dr. Joel Palefsky, Prof. Shaesta Mehta, Dr. Prachi Patil, Dr. Alexandra Hernandez
5.	Primary screening of high risk HPV DNA by a low cost	2020	Dr. Sharmila Pimple, Dr. Gauravi Mishra, Dr. Kiran

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	molecular HPV test for early detection of cervical pre cancers and cancers among women in urban and rural community of Maharashtra.		Munne, Dr. Anushree, Dr. Kedar Deodhar, Dr. Rohini Kelkar, Dr. Jayanti Mania, Dr. Suchitra Surve, Dr. Shahin Begum, Dr. Vrushali Palayekar, Dr. Abhijit Chavan, Dr. Pranjali Patil, Dr. Deepti Tandon, Dr. Sanjay Chauhan
6.	Prevalence of Human Papilloma Virus in Spouses of Men Diagnosed with Oral and Oropharyngeal Cancer.	Funding awaited	Dr. Gauravi Mishra, Dr.Richa Bansal, Dr. Rohini Kelkar, Dr. Manoj Mahimkar, Dr. Munita Bal, Dr. Kedar Deodhar, Dr. Sharmila Pimple, Dr.Sudhir Nair, Dr. Vasundhara Kulkarni, Dr. Shakthi Dorai.
7.	Collaborative Action for Control of Cancer and Other Non-Communicable Diseases among Mumbai Police Personnel	2019	Dr. Gauravi Mishra, Dr. Sharmila Pimple, Dr. C. S. Pramesh and21 Co investigators
8.	Molecular Genetic Analysis of Clinically High-Risk Oral Leukoplakia to Identify Potentially High-Risk Lesions.	2018	Dr. Manoj B Mahimkar, Dr. Sharmila Pimple, Dr. Prathamesh Pai, Dr. Pankaj Chaturvedi, Dr. Asawari Patil, Dr. Swapnil Rane, Dr. Munita Bal, Dr. Poonam Gera, Dr. Neha Mittal, Dr. Gauravi Mishra, Mrs. Sadhana Kannan
9.	A Phase-II/III, Partially Double-blind, Randomized, Active-	2018	Dr. Sharmila Pimple**,** Dr. Gauravi Mishra, Dr. Amita

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	controlled, Multicentric Study to Assess the Immunogenicity and Safety of SIIPL's qHPV Vaccine Administered Intramuscularly in Healthy Volunteers According to a Two-dose Schedule to Cohort 1 (Girls and Boys Aged 9-14 years) and a Three-dose Schedule to Cohort 2 (Women and Men Aged 15-26 years) as Compared to Merck's HPV6/11/16/18 vaccine (Gardasil®)		Maheshwar, and Dr. Nirmalya Roy Maulik
10.	A Pilot Study on HPV and Cervical Cancer Screening in India.	2023	Dr. Gauravi Mishra, Dr. Sharmila Pimple, Dr. Vasundhara Kulkarni
11.	Randomized trial of 2 versus 3 doses of HPV vaccine in India - Extended follow-up of the participants of IARC-India HPV vaccination study to evaluate the effectiveness of one, two and three doses of Quadrivalent HPV vaccine in preventing cervical neoplasm	2010	Dr Partha Basu, Dr. Sharmila Pimple, Dr. Gauravi Mishra.

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1. **"Women Empowerment-Cancer Awareness Nexus (We-CAN): An Implementation Research Study of Cervical Cancer Prevention through HPV Self-sampling and Education in India"**

IEC Project No : 3826

List of PI's

1. **CIHR**
   a. PI Canada : Dr. MandanaVahabi
   b. PI India : Dr. Gauravi Mishra

2. **Collaborating centres and PI:**
   a. Mangalore :Dr. Abhay Nirgude
   b. Trivandrum :Dr. Kalavathy Mathur Chennath
   c. Calcutta :Dr. Ranajit Kumar Mandal
   d. Gujarat :Dr. Amol Dongre
   e. Visakhapatnam :Dr. Umesh Shetty
   f. Guwahati :Dr. Srabana Bhagabaty
   g. Punjab :Dr. Ashish Gulia

IEC Approval Date : 27/03/ 2023(IEC-II)

Funding source : ICMR and CIHR

Collaborating centers : BBCI Guwahati, HBCHRC Vizag, HomiBhabha Cancer Hospital-Punjab, Chittaranjan Cancer Institute-Calcutta, Yenepoya Medical College-Mangalore, Regional cancer Center-Trivandrum and Bhaikaka University-Gujarat

Project Status : Ongoing

Project Summary:

Aim:

To address the socio-cultural, economic, and healthcare system challenges, we propose an innovative, evidence based, and community-engaged intervention, Women Empowerment-Cancer Awareness Nexus (We-Can). The overarching goal of WE-CAN is to reduce the avoidable health disparities associated with HPV and cervical cancer among low-income UNS women in India.

Objectives:

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- Promote open dialogue and health literacy about cervical cancer prevention in the family and community (knowledge).
- Reduce gendered stigma of HPV and cervical cancer (attitudes).
- Increase cervical cancer screening uptake by enabling women to self-sample using HPV kits in the privacy of their own home and at a time that is convenient for them (behavior).

Methodology:

Study were guided by the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework to evaluate the contextual processes and outcomes of implementing our WE-CAN intervention in India.

- Examine the reach of the target populations (i.e low-income UNS women in rural and urban settings and supportive men in these women's lives).
- Evaluate the effectiveness of the WE-CAN intervention.
- Gauge support for the cultural adoption of WE-CAN among stakeholders (community partners, organizations, decision-makers).
- Evaluate implementation, including intervention fidelity, processes, contextual factors, and outcomes.
- Understand the requirements, including the complex contexts for the maintenance, or sustainability of HPV and cervical cancer literacy as well as sustainable adoption of self-sampling as cervical cancer prevention at the individual, organizational and community levels.

Current Status:

Recruitment and training of the staff is complete and study has been initiated.

2. "Incidence of Human Immunodeficiency Virus (HIV) among Indian Men who have Sex with Men (MSM)"

IEC Project No **:** 3451

PI **:** Dr. Sharmila Pimple

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Co- I	**:**	Prof. Shaesta Mehta, Dr. Prachi Patil, Dr. Alexandra Hernandez, Dr. Gauravi Mishra, Dr. Joel Palefsky
IEC Approval Date	**:**	04/05/2022
Funding Source	**:**	Extramural Funds
Project Status	**:**	MoU in process

Project Summary:

Aim:

The one-year incidence of HIV will be at least 4%.

Objective:

- To determine the one-year incidence of HIV among high-risk MSM in India.
- To test the feasibility and acceptability of recruiting a sample of 150 high-risk HIV-uninfected MSM using respondent-driven sampling (RDS) and following them every six months for one year.
- To produce preliminary descriptive data on:
  - **a.** The prevalence and incidence of HPV infection and HPV-associated disease, and STIs other than HPV in HIV-seronegative MSM in India.
  - **b.** Sexual risk behaviours with men and women, as well as data on other potential confounders

Methodology:

This is a prospective, longitudinal cohort study with 150 Indian MSM participants. Respondent-driven samplings (RDS) will be used for participant recruitment, starting with six well-connected seed participants who will recruit additional participants using coupons. The coupons will contain project information and contact details for screening appointments. Enrolled participants will be registered online using the AMC Advantage e-Clinical system. Eligibility criteria will be assessed prior to enrolment, and participants not meeting the criteria will be offered alternative treatment or follow-up screening.

Current Status:

The project is approved by the IEC and MoU is in process.

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3. "Prevention and Screening Innovation Project toward Elimination of Cervical Cancer" PRESCRIP- TEC

IEC Project No : 3835

International centers : India, Bangladesh, Uganda and Slovakia

National centers :

- Tata Memorial Hospital, Mumbai
- Manipal Academy of Higher Education, Manipal (MAHE)
- St. John's National Academy of Health Sciences (SJNAHS), Bengaluru
- Sri Dharmasthala Manjunatheshwara College and Hospital of Ayurveda, Udupi (SDMCHAU)
- Tata Medical Center (TMC), Kolkotta
- Chittaranjan National Cancer Institute (CNCI), Kolkota
- Sikkim Manipal University, Sikkim

PI's:

PI EU : Dr Jaap Koot

PI India : Dr Keerthana Prasad

Collaborating centers: PI

- Dr. Sharmila Pimple : TMH
- Dr. Gauravi Mishra : Co-I, TMH
- Dr. Kirthana : Manipal Academy of Higher Education, Manipal (MAHE)
- Dr Kiran Kulkarni : St. John's National Academy of Health Sciences, (SJNAHS), Bengaluru
- Dr Mamatha K.V. : Sri Dharmasthala Manjunatheshwara College and Hospital of Ayurveda, Udupi (SDMCHAU)
- Dr Sonia Mathai : Tata Medical Center (TMC), Kolkotta
- Dr Ranjan Mandal : Chittaranjan National Cancer Institute (CNCI), Kolkota
- Dr NasrinBanuLaskar : Sikkim Manipal University, Sikkim

IEC Approval Date : 02/12/2021

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Funding Source : Horizon 2020-DBT

Project Status : Ongoing

Project Summary:

Aims:

To analyse both patient-related and health services-related facilitators and barriers for uptake of cervical cancer screening in LMICs and in vulnerable groups in Central and Eastern Europe. Building on existing screening protocols in the four countries as a starting point, this study will introduce

- Interactive information with communities via mobile devices and social media, in addition to traditional means of communication applied in resource-poor settings
- Client-friendly, community-based strategies, with self-test for high-risk HPV infection, allowing for selection of women who need further gynaecological examination; and
- Artificial intelligence in gynaecological examination. The use of artificial intelligence (AI) built into mobile devices aims to provide high quality diagnostics in resource-poor settings, and consequently could allow for task shifting in the future with screening provided by lower-level trained cadres.

Objectives:

- To measure accessibility, acceptability and adherence to the enhanced cervical cancer screening programme among the target population eligible for cervical cancer screening
- To measure the availability and readiness of the health system for the enhanced cervical screening programme (including hrHPV testing and AI-DSS systems)
- To assess service availability, readiness and quality during the expansion and full implementation period
- To pilot-test the selected instruments to measure client-related or health system-related factors
- To evaluate if artificial intelligence offers the healthcare worker (HCW) reliable management decision support in the interpretation of cervical lesions during screening with visual inspection with acetic acid
- To measure feasibility and implementation fidelity of the improved screening protocol

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- To evaluate the impact of the enhanced screening module on the uptake and coverage of cervical cancer screening in the target area
- To evaluate the impact of the enhanced screening module on the uptake of early treatment of precancerous lesions
- To measure cost-effectiveness of the enhanced screening programme

Methodology:

RE-AIM framework

1. Reach: uptake, coverage, and contributing factors

- % of eligible women aware of cervical cancer and screening
- % of eligible women screened
- Scores on trust and cancer awareness

2. Effectiveness: adherence to follow-up and referrals

- % of hr HPV women coming for VIA or Pap smear
- % of women receiving early treatment
- % of women referred for advanced care

3. Adoption: implementation fidelity and stakeholders involvement

- % of health professionals implementing standard procedures including AI-DSS
- Involvement of authorities in implementation of screening programme

4. Implementation: implementation fidelity

- Scores in the SARA-cervical cancer surveys

5. Maintenance: commitment of governments, NGOs and funding agencies to continue the improved protocol

- Adoption of improved national screening guidelines
- Adoption of AI-DSS

Current Status:

Awacan (African women awareness of Cancer) survey for 100 females and 100-decision maker has been done in month of Feb 2022. Total Human resources trained under the project for Cancer

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awareness-60, no of awareness session -17, no of people awared-630. Total no. Participant recruited for Self Sampling (hrHPV)-500 VIA by AI Device done – 12.

4. "Investigating Human Papillomavirus (HPV) Infection and HPV-associated Disease in Indian Men who have Sex with Men who are HIV-positive."

IEC Project No	**:**	3450
PI	**:**	Dr. Sharmila Pimple
Co-PI	**:**	Dr. Gauravi Mishra, Dr. Joel Palefsky
Co-I	**:**	Prof. Shaesta Mehta, Dr. Prachi Patil, Dr. Alexandra Hernandez
IEC Approval Date	:	16/09/2021
Funding Source	:	Extramural, awaiting funds from ICMR
Project Status	:	Ongoing (MoU in process)

Project Summary:

Aim:

The prevalence of high-grade anal intraepithelial neoplasia (HGAIN) will be at least 15%. The prevalence of high-grade penile intraepithelial neoplasia will be lower than that of HGAIN.

Objectives:

- To determine the prevalence of HPV associated premalignant lesions in the anus and penis in Indian HIV seropositive men who have sex with men (MSM).
- To describe risk factors for prevalent premalignant lesions in the anus and penis in Indian HIV seropositive MSM.
- To describe the incidence and prevalence of penile and anal HPV infection in Indian HIV-seropositive MSM.

Methodology:

This is prospective longitudinal cohort study. Participants will be recruited from among identified HIV-seropositive MSM who are being seen for support and counselling or who are referred by HIV counsellors. Men who had previous positive HIV test prior to enrolment will be considered. Trained outreach workers will recruit participants through their established networks.

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They will also use targeted advertising in the form of posters and flyers to be distributed in locations known to be frequented by the MSM community. The study will not be advertised in any way that would compromise the confidentiality of participants and will not mention HIV, HPV, or MSM. In addition, any potential participants who test positive for HIV as part of AMC-093 enrolment procedures will be invited to enrol in this study. The investigator or designated individual will review the potential participants' laboratory results, and if the criteria are met, they will begin informed consent procedures. Participants who sign the informed consent form and meet all eligibility and screening criteria will be invited to participate in this protocol. If participants do not meet eligibility criteria, they will be informed and offered appropriate alternative treatment and/or follow-up screening.

Current Status:

The project is approved by the IEC but has not yet started as waiting for the funds to receive from the ICMR.

5. **"Primary Screening Of High Risk HPV DNA By a Low Cost Molecular HPV Test for Early Detection of Cervical Pre Cancers and Cancers Among Women In Urban and Rural Community of Maharashtra."**

IEC Project No	**:**	3361
PI	**:**	Dr. Sharmila Pimple
Co-PI	**:**	Dr. Gauravi Mishra, Dr. Kiran Munne, Dr. Anushree
Co-I	**:**	Dr. Kedar Deodhar, Dr.Rohini Kelkar,Dr. Jayanti Mania, Dr. Suchitra Surve, Dr. Shahin Begum, Dr. Vrushali Palayekar, Dr.Abhijit Chavan, Dr. Pranjali Patil, Dr. Deepti Tandon, Dr. Sanjay Chauhan
IEC Approval Date	**:**	13/11/2019
Funding Source and	**:**	Department of Health Research, Ministry of Health Family Welfare. New Delhi
Collaborating centers	**:**	1) TMH 2) ICMR-NIRRH

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Project Status **:** Ongoing

Project Summary:

Aims:

Primary screening of high risk HPV DNA by a low cost molecular HPV test for early detection of cervical pre-cancers and cancers among women in urban and rural community of Maharashtra.

Objectives:

This study is planned with the following objectives:

- To estimate the prevalence of high-risk HPV infection for early detection of cervical pre-cancers and cancers by care HPV and Hybrid Capture 2 (HC2) test among women aged 30-59 years in the selected urban and rural community
- Comparative performance evaluation of primary HPV screening tests: careHPV and HC2 for point of care testing
- To determine the optimal triage strategies for primary screening by HPV detection i. Triage with PAP ii. Triage with VIA
- Comparative evaluation of In-house NIRRH HPV PCR test with that of the Gene Xpert HPV test (Principle- PCR based)

Methodology:

This is a Cross-sectional implementation study in the urban slum population of Mumbai. The eligible women under Abhyuday Nagar Community Clinic (NIRRH, Mumbai) and Ashagad PHC was selected. Women of 30-59 years of age with the following inclusion criteria were included in this study over the period of 3 years.

With the proposed budget, we have divided the total sample size (n=3457) into urban (n=1750) and rural (n=1750) component. After fulfilling the inclusion/ exclusion criteria and obtaining the informed consent to participate in the study, a detailed demographic and clinical history will be recorded in the case report form. After speculum examination, Pap smear will be collected from the participant. An endocervical specimen will be taken using care Brush (Qiagen). After the cervix is fully exposed, the secretions will be wiped from the surface and a specimen brush will be inserted to a 1-cm depth into the cervical canal. The specimen brush will be rotated 2-3 turns

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clockwise before being removed. Endocervical specimen will be collected for care HPV and HCII test by respective collection device into respective collection tubes. Samples will be preserved in respective Collection Medium (CCM) and kept at room temperature, and each vial will be labelled with corresponding identification numbers. Collected specimen may be shipped and stored at room temperature (15–30°C) for 14 days or at 2–8°C for 30 days. It was followed by Visual Inspection of cervix with acetic acid (VIA).The samples positive for high risk HPV DNA will be tested for NIRRH HPV PCR test and Gene Xpert HPV test for genotyping.

In this community based study we will screen the urban slum community by low cost molecular careHPV test. Comparative performance evaluation of care HPV will be done for point of care testing using HC2 as reference gold standard test. Also the efficacy of indigenous NIRRH HPV PCR detection method will be compared with and Gene Xpert test. Those who are screened positive by any of the screening tests will be followed up at Preventive Oncology Department, TMH and colposcopy evaluation with/without Biopsy will be done. Management of precancerous lesions will be done as per the standard protocol.

Current Status:

Currently, total of 1543 participants are enrolled in the study including 1024 patients from the Mumbai camp site and 519 participants from the Dhanu camp site. Recruitment is complete and follow-up is ongoing.

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6. "Prevalence of Human Papilloma Virus in Spouses of Men Diagnosed with Oral and Oropharyngeal Cancer."

IEC Project No	:	3239
PI	:	Dr. Gauravi Mishra
Co-PI	:	Dr. Richa Bansal
Co-I	:	Dr. Rohini Kelkar, Dr. Manoj Mahimkar,
		Dr. Munita Bal, Dr.KedarDeodhar, Dr.Sharmila Pimple,

		Dr. Sudhir Nair, Dr.Vasundhara Kulkarni, Dr. Shakthi Dorai
IEC Approval Date	:	03/05/2019
Funding Source	:	CSR funds/ Intramural
Project Status	:	Awaited funding support.

Project Summary:

This is a cross-sectional study, will include all men with newly diagnosed, histologically confirmed oral and oropharyngeal squamous cell carcinoma and their spouses. The study group will approximately include 250 men with HPV-associated oral and oropharyngeal cancer and their spouses. While control group will include 500 men with HPV- negative oral and oropharyngeal cancer and their spouses. The study will be conducted in a tertiary cancer center in western India over the period of 2 years.

The hypothesis is that prevalence of high-risk HPV infection in the cervix is higher in the spouses of patients with HPV-associated oral and oropharyngeal cancer as compared to the prevalence in spouses of men with HPV-negative oral and oropharyngeal cancer.

Husband and wife pair will be invited to participate in the study and informed consent obtained. The data will be collected and recorded. HPV status of the tumour will be determined from p16 immunohistochemistry analysis on paraffin-embedded tumor samples from the diagnostic biopsy. P16-positive samples will further undergo PCR from slides of tumor samples for confirming HPV DNA in the tumor. P16-positive and PCR-positive cases were regarded as HPV-positive tumours.

Cytobrush scrapping oral samples will be collected from all study participants and their spouses. In addition, cytobrush scrapings from the cervical mucosa of women and the distal part of the urethral mucosa of men from both groups will be collected and tested for HR HPV. All women in the study will undergo screening with a Pap smear. The spouse will be offered VIA/Pap smear and clinical breast screening as part of the preventive medicine registration protocol.

Methodology:

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This is a cross-sectional study. Husband and wife pairs will be invited to participate in the study. Information will be collected from both partners, including demographic details, education level, medical and sexual history, habits, socioeconomic status, and HPV status. The study and control groups will be formed based on tumor HPV status. Oral and cervical samples will be collected and tested for HR HPV using Hybrid Capture 2 assay and genotyping. A total of 750 couples will be included in the study.

Objectives:

Primary Objective:

To determine if there is an increased prevalence of genital HPV infection in spouses of men with HPV-associated oral and oropharyngeal cancer as compared to the spouses of men with HPV-negative oral and oropharyngeal cancer.

Secondary Objectives:

- To asses if there is a site-specific association of the HPV infection among different body sites of the oral cavity and the genital area (cervix and penis) in the husband and wife pair.
- To assess the acceptance of the study intervention by the women in both groups.
- Concordance of HPV positivity with tumour p16 positivity and Hybrid capture 2 done with oral brush sampling

Duration of the study:

The study will be conducted in a tertiary cancer center in western India over the period of 2 years.

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7. "Collaborative Action for Control of Cancer and Other Non- Communicable Diseases among Mumbai Police Personnel"

IEC Project No	:	3231
PI	:	Dr. Gauravi Mishra
Co–PI	:	Dr. Sharmila Pimple, Dr. C. S. Pramesh,
Co- Investigators	:	21 Co-Investigators
IEC approval Date	:	26/02/2019

Funding Source : Extramural and Intramural

Status of Project : Ongoing

Project Summary:

Introduction:

The Police service has been identified as a stressful occupation because of long working hours, irregular dietary habits, irregular sleep patterns, lack of regular exercise and addiction to tobacco and alcohol, predisposing them to several health risks.

Considering the special risk of Police personnel to NCDs including cancers and as only limited data on health status of policemen in India is currently available, we propose to conduct a research project and collect the socio-demographic and risk factor data, screen the police personnel for common cancers and NCDs, facilitate referrals, diagnostics and management and form a Model Demonstration Project for Prevention and Control of NCDs and Common Cancers among the police personnel in Mumbai that can be replicated at other places in the country. The traffic police being at increased risk of respiratory morbidities will in addition be screened for Obstructive Airways Disease.

Aim:

To formulate a demonstrable and sustainable model on prevention, control and early detection of NCDs including common cancers among the Police personnel and their families in Mumbai and among Railway Police (RPF and GRPF), Maharashtra Police working in Mumbai, Maharashtra Police working in different districts of Maharashtra and MSF (Maharashtra Security Force) working in Mumbai and all districts of Maharashtra that can be replicated in other parts of India.

Objectives:

- To identify the risk factor exposure to NCDs including common cancers among the Mumbai Police and their families, Railway Police, Maharashtra Police and MSF
- To create awareness among the police personnel and their family members regarding prevention and early detection of common cancers and NCDs.

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- To determine the prevalence of common cancers in this group by conducting screening of common cancers; Breast, Uterine Cervix and Oral Cavity Cancers for women Police personnel and oral cavity cancers for men police personnel and also screen their spouses and family members using low cost and effective technologies.

- To estimate the prevalence of certain NCDs by conducting screening for Diabetes, Hypertension and Obesity using simple and effective standard techniques.

- To estimate the prevalence of respiratory morbidities among the Mumbai traffic police by screening them for Obstructive Airways Diseases.

- To formulate the referral linkage of all screen positive cases for cancer screening to the Department of Preventive Oncology, Tata Memorial Hospital, Mumbai for diagnostic confirmation and further management and identify the compliance for the same and the factors affecting it.

- To formulate the referral linkage of all screen positive cases for other Non-Communicable Diseases such as Diabetes, Hypertension, Obesity, Obstructive Airways Diseases to the Police Hospital, Nagpada, Mumbai Central, Dr. Babasaheb Ambedkar Hospital, Byculla, Mumbai, respective police hospital in all districts and ESIS Hospital, identify the compliance for the same and the factors affecting it.

- To provide professional assistance for tobacco and alcohol cessation at the camp site during the first visit and thereafter through referral services to the Tobacco Cessation Clinic at the Department of Preventive Oncology, Tata Memorial Hospital, Mumbai.

- To strengthen Institutional capacity of the Police medical and health teams for implementing awareness and screening of common cancers and NCDs.

Time Frames:

Mumbai & Traffic Police	:	24 months
Railway Police	:	12 months
Maharashtra Police (Phase -1)	:	18 months

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Maharashtra Police (Phase -2) : 36 months

Maharashtra Police (Phase -3) : Ten Years

Maharashtra Security Force : 12 months

- Phase 1: One and half year– to cover 10,566 Maharashtra Police and 4,000 MSF posted in Mumbai.
- Phase 2: Three years – to cover 16,215 Maharashtra Police in Navi Mumbai, Thane and Mira Bhayander districts and around 3,000 MSF in these districts.
- Phase 3: Ten years – to cover 1,04,617 Maharashtra Police in other districts and 8 zones and around 8,000 MSF staff.

Methodology:

This is a cross-sectional interventional study among police personnel working in Mumbai and Maharashtra. Female police in age group 30-65 years were eligible to participate in breast and cervical cancer screening. The exclusion criteria involved any acute or chronic health condition that may limit the ability of the potential participant to participate in the study. The various divisions and sub-divisions and zones of the city police were identified. After getting necessary approvals, the camps were set up. Registrations of all eligible participants were done after explaining the procedure and Informed consent is obtained followed by health awareness by Medical social worker and screening by Health assistants for NCDs and common cancers.

In addition, Traffic Police were screened for Obstructive Airway Diseases using Breath CO (Breath Carbon Monoxide), PEFR (Peak Expiratory Flow Rate), FOT (Forced Oscillation Technique) and Spirometry. Screen positives for NCDs are referred to Nagpada hospital (Mumbai Police and their family members), Dr. Babasaheb Ambedkar Hospital (Railway Police), Respective district hospitals (Maharashtra police) and ESIS Hospital (MSF) for further treatment and management and screen positive for Oral cavity, Breast and Cervix are referred to Department of Preventive Oncology, Tata Memorial Hospital for further treatment and management. For confirmed negative participants regular follow-up is done.

Results:

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39,672 police personnel will be contacted and invited and 30,291 (76.4%) enrolled. 30,290 (100%) participated in health awareness program. (1251 clinically and 60 histologically confirmed) oral pre-cancers, 58 cervical pre-cancers, 01 breast and 10 oral cavity cancers were be diagnosed. They all availed diagnostic and treatment services at the Tata Memorial Hospital. Totally, 4867 (16.1%) police will be detected with diabetes, 5897 (19.5%) with hypertension and 13, 710 (45.3%) with obesity.

Current Status: Screening is ongoing for Thane, Navi Mumbai Police, Maharashtra Security Force and Railway police.

8. "Molecular Genetic Analysis of Clinically High-Risk Oral Leukoplakia to Identify Potentially High-Risk Lesions."

IEC Project No	:	900268
PI	:	Dr. Manoj B Mahimkar
Co-PI	:	Dr. Sharmila Pimple
Co-I	:	Dr. Prathamesh Pai, Dr. Pankaj Chaturvedi, Dr. Asawari Patil, Dr. Swapnil Rane, Dr. Munita Bal, Dr. Poonam Gera, Dr. Neha Mittal, Dr. Gauravi Mishra, Mrs. Sadhana Kannan
IEC Approval Date	:	02/04/2018
Funding Source	:	Terry Fox
Project Status	:	Ongoing

Project Summary:

Study is to analyze altered chromosomal loci/ underlined genes in clinically high-risk oral leukoplakia, which will help in better stratification of the high-risk lesions, which have potential to transform. The proposed analysis will be carried out by using Nano String and these results will be validated by real-time PCR. Our proposed approach will help in ascertaining the high-

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risk leukoplakia more objectively. As the oral carcinogenesis is a multifactorial process, in which both environmental and genetic factors contribute in the disease development.

Primary objective is to carry out molecular genetic analysis of the chromosomal loci, in clinic pathologically well annotated high-risk leukoplakia lesions to ascertain the disease progression and to identify high-risk lesions that can potentially transform. Secondary objective is to document and estimate risk associated with lifestyle factor such as use of tobacco and alcohol in development of OPLs (Oral Premalignant Lesion).

The sample size estimates are based on our results of a CGH and FISH where we observe 58% of leukoplakia exhibit gain of 8q24.3 locus with 95% confidence level. Considering 20%, attrition total sample size of 500 clinically detected leukoplakia will form the study group.

Study duration is 9 years; Study will be carried out in 2 phases:

- **Phase 1** (Duration 5 years): First 3 years of active accrual and follow-up of 2 years. We are planning to accrue 200 OPL participants per year for first 2 years and 100 OPL patients in 3rd year. These OPL participants will be actively followed up for 2 years
- **Phase 2**(Duration 4 years): All the cases will be actively followed-up for 4 years.

Summary of work done till date:

Target leukoplakia samples are 500, till now 405 leukoplakia samples (Pre-cancerous lesions) along with blood collection done. H & E staining and blinded grading with two pathologists initiated. Completed grading of 346 samples. Discrepancy between both the pathologists resolved for 264 samples. DNA/RNA extraction of 371 leukoplakia samples is completed. Detection of HPV through Nested PCR in 371 leukoplakia samples is done. (None of the leukoplakia samples was HPV positive)

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1. Follow up of patients:

1st Follow up - Total: 314					
Free of	Persistence of	Recurrence at same	Transformation	Carcinoma at	Dead

disease	lesion	/ other site	to OSCC	diagnosis	
138	155	6	5	6	4
2nd Follow up - Total: 235					
Free of disease	Persistence of lesion	Recurrence at same / other site	Transformation to OSCC	Carcinoma at diagnosis	Dead
136	89	7	2	0	1
3rd Follow up - Total: 154					
Free of disease	Persistence of lesion	Recurrence at same / other site	Transformation to OSCC	Carcinoma at diagnosis	Dead
98	56	0	0	0	0

9. "A Phase-II/III, Partially Double-blind, Randomized, Active-controlled, Multicentre Study to Assess the Immunogenicity and Safety of SIIPL's qHPV Vaccine Administered Intramuscularly in Healthy Volunteers According to a Two-dose Schedule to Cohort 1 (Girls and Boys Aged 9-14 years) and a Three-dose Schedule to Cohort 2 (Women and Men Aged 15-26 years) as Compared to Merck's HPV6/11/16/18 vaccine (Gardasil®)"

Department of Preventive Onco

IEC Project No	**:**	3051
PI	**:**	Dr. Sharmila Pimple
CO-I	**:**	Dr. Gauravi Mishra, Dr. Amita Maheshwar, and Dr. Nirmalya Roy Maulik
Date of IRB approval	**:**	28/06/2018
Funding Source	**:**	Serum Institute of India Pvt. Ltd. (SIIPL), Pune
Responsible CRO	**:**	Diagno Search Life Sciences Pvt. Ltd.

Central Immunology Laboratory : Syngene International Ltd., Bangalore German Cancer Research Center (Deutsches Krebs for Schungszentrum, DKFZ), Germany.

Project Status : Ongoing

Project Summary:

Objectives:

To assess the reactogenicity and safety of SIIPL qHPV and Gardasil vaccines in 9-14 years cohort receiving 2 doses and 15-26 years receiving 3 doses of the vaccine.

Methodology:

This is a phase II/III research study to evaluate whether SIIPL qHPV vaccine administered intramuscularly (IM) to healthy Indian boys/girls and men/women of 9 to 26 years of age were safe and well tolerated (likelihood of causing less side effects) and produce an immune response (antibodies against the vaccine) as compared to already marketed Gardasil® vaccine.

Vaccine schedule:

COHORT I (9-14 years)-DAY 0, DAY 180

COHORT II (15-26 years)- DAY 0, DAY 60, DAY 180

Current Status:

Total 250 subjects are randomized. Total 58 subjects are recruited for phase II in which 49 participants completed their follow ups after vaccination. 09 participants discontinued from the study in follow up phase. The Phase II study was completed in 21st Jan 2022 with all participants all follow ups

In Phase III we have recruited 192 participants in which 58 participants completed their all follow ups total 25 participants discontinued the study and 109 participants are on Follow-up.

10. "A Pilot Study on HPV and Cervical Cancer Screening in India."

Department of Preventive Oncology, TMH, Mumbai

IEC Project No	:	1763
PI	:	Dr. Gauravi Mishra
Co-PI	:	Dr. Sharmila Pimple
Co- I	:	Dr. Vasundhara Kulkarni,
Consultants	:	Dr. Usha Menon, Dr. Laura A Szalacha
IEC Approval Date	:	02/03/2017
Funding Source	:	CSR funding (Lok Foundation)
Project Status	:	Ongoing

Department of Preventive Oncology, TMH Mumbai

Project Summary:

This trial will be a rigorous, systematic effort to describe HPV types in India by using innovative point of care testing and single visit approach (SVA). This will extend reach of critical health services to poor/ vulnerable women. By identifying different patterns of HPV infection in India (i.e. presence of HPV but not one of six genotypes identified through GeneXpert), we will be in position to move to next step of larger epidemiological study and potentially targeted vaccine development. This study is highly innovative since, it will test dissemination/ implementation design imperative for translational science and introduce new, cost-effective point of care technology.

Research Objectives:

The primary purpose of this proposed project is to introduce point-of-care HPV testing in a cancer screening program in Mumbai, India. The specific aims are:

- Test feasibility and acceptability of point of care HPV testing
- Describe HPV infection types in women screened
- Compare if the quality of HPV clinician- collected and self-collected samples are similar to detect HPV and cervical cancer precursor lesions.

- Compare agreement between HPV GeneXpert and HPV HC2 test on clinician – collected sample.

Methodology:

Study Setting:

Urban slum cluster in Mumbai

Study Design:

Community based interventional Pilot study

Sampling strategy:

This pilot study does not aim at assessing the efficacy of the SVA procedure nor of HPV testing. Sample size is based on the ability to fit predictive models of HPV infection and make reasonable comparisons with the national data that are available. A sample size of 227 would have 0.80 power to detect an effect size of 0.76 (Odd Ratio = 1.38). For this pilot study to enrol 227 women, expecting a compliance of 60%, we will need to enumerate 500 screening eligible women.Based on the estimation of approximately 12-15 women seen per day, enrolment of 227 women is completed.

Sample Size:

227 eligible women (sexually active, 30-55 years)

Research Methodology:

Study Procedure*:* An Urban slum cluster with around 3000 total population in Mumbai was selected, so as to enumerate around 500 eligible women between 30 to 55 years. The study was explained and informed consent was obtained. 227 women were enrolled and invited to the community based camps. The participants were interviewed to collect their baseline socio-demographic and risk factor history. They were given Health Education explaining the risk factors, signs and symptoms, methods of prevention, early detection, and importance of cervical cancer screening and also method of collection of HPV self-sample. The women were asked to collect their own cervical samples for HPV testing by GeneXpert. Thereafter, trained primary health workers (PHWs) collected two cervical samples from women with per speculum examination; viz one for HPV HC2 and other for HPV GeneXpert. This was followed by VIA

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screening for the women by PHWs. Focus Group Discussions was be held with the women in small groups to qualitatively assess acceptability of HPV testing using GeneXpert. If any of these tests are positive (VIA/ HPV self collected and tested by GeneXpert, HPV PHW collected and tested by GeneXpert or HPV PHW collected and tested by HC2), the women were referred to Tata Memorial Hospital (TMH) for further management.

Expected Outcomes:

The feasibility of HPV testing and it's cultural appropriateness, the prevalence and distribution of HPV genotypes, predictive model of HPV infection(s) predicted by sexual behaviour, sociodemographic and clinical characteristics of the women screened, the feasibility of self-sampling for GeneXpert, perceptions about self- collection, overall agreement between clinician- collected versus self-collected samples and agreement between HPV GeneXpert and HPV HC2 samples by health care provider.

Current Status: Data entry and analysis is ongoing.

11. "Randomized Trial Of 2 Versus 3 Doses of HPV Vaccine in India - Extended Follow-Up of the Participants Of IARC-India HPV Vaccination Study to Evaluate the Effectiveness of One, Two and Three Doses of Quadrivalent HPV Vaccine in Preventing Cervical Neoplasm"

IEC Project No	:	562
IARC	**:**	International Agency for Research on Cancer, Lyon, France
PI	**:**	Dr ParthaBasu,

List of PI's

Collaborating centres and PI's

1.	Dr. SharmilaPatil	:	Tata Memorial Center, Mumbai
	Dr. Gauravi Mishra (Co-I)	:	Tata Memorial Center, Mumbai
2.	Dr. Sylla G. Malvi	:	Tata Memorial Centre Rural Cancer Project, Nargis Dutt

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		Memorial Cancer Hospital, Barshi, India (NDMCH)
3. Dr. Smita Joshi	:	Jehangir Clinical Development Centre (JCDC), Pune, India
4. Dr. Pulikottil.O. Esmy	:	Christian Fellowship Community Health Centre, Ambilikkai, India CFCHC
5. Dr. Anand Shah	:	Gujarat Cancer & Research Institute (GCRI), M.P.Shah Cancer Hospital, Ahmedabad, India
6. Dr. Neerja Bhatla	:	All India Institute of Medical Sciences, Delhi, India(AIIMS)
7. Dr. Usha Rani Reddy Poli	:	India Institute of Public Health (IIPH) of Hyderabad, India
8. Dr. Maqsood Siddiqi	:	Cancer Foundation of India, Kolkata, India (CFI)
9. Dr. YogeshVerma	:	Sikkim Manipal University/STNM Hospital, Gangtok, India
10. Dr. Eric Zomawia	:	Civil Hospital Aizawl, Aizawl, India(CHA)
11. Dr. Devasena Anantharaman	:	Rajiv Gandhi Centre for Biotechnology, Trivandrum, India (RGCB)
IEC Approval Date	:	11/10/2008

IEC Approval for Extended follow-up 2 versus 3 doses of HPV Vaccine: 04/08/2017

Approval for Extended follow-up single dose of HPV vaccine amendment: 05/10/2021

Funding Source **:** International Agency for Research on Cancer, World Health Organization, Lyon, France

Collaborating centers **:** IARC **(**International Agency for Research on Cancer, Lyon, France)

Project Status **:** Ongoing

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Project Summary:

Aims:

The present study is a continuation of a previous study comparing two doses versus three doses of HPV vaccine.

This phase aims to periodically check the girls and women who participated in the original study over the next five years to assess if any of them get persistent HPV infection after marriage and develop cervical pre-cancers after the age of 25 years(if married in study time)

Objectives and Methodology:

1. Generate long-term robust data on HPV vaccine efficacy against persistent infection

Methods: 514 participants will be vaccinated in three different groups (Group 1: three doses, Group 2: two doses, Group 3: single dose), along with an unvaccinated genotype cohort. Yearly follow-ups will be conducted for 4 years, collecting cervical samples for HPV genotyping. Participants with new HPV infections in the fourth sample provided a fifth sample to assess persistence.

2. Estimate efficacy of HPV vaccine against histologically proven CIN 2+

Methods: Vaccinated participants and unvaccinated women in a genotype cohort will be screened using HPV detection tests as they reached 25 years of age. Colposcopy and biopsies will be conducted for screen positive women. HPV negative women underwent a second screening after 5 years. Persistent HPV positive cases received punch biopsies. The same protocol was followed for the second round of screening.

3. Assess long-term immunogenicity of recipients of a single dose of HPV vaccine

Methods: Blood samples will be collected from recipients of single, two, and three doses of HPV vaccine to assess antibody levels using ELISA and neutralization assays. Follow-up samples will be planned for 2025. Unvaccinated women will be also sampled for comparison.

4. Establish linkage with population-based cancer registries for long-term follow-up

Methods: The study cohorts will be linked with regional population-based cancer registries for long-term follow-up. Active participant follow-up and passive registry-based tracking will be employed to document HPV-associated cancer incidence.

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5. Conduct follow-up modelling exercise to assess potential effectiveness and return on investment of one-dose vaccination schedules.

Methods: Baseline modelling was conducted using available data to assess the potential effectiveness and return on investment of one-dose vaccination schedules. Ongoing data collection on vaccine efficacy, duration of protection, and local vaccination programs will inform an expanded modelling exercise to design sustainable one-dose HPV vaccination programs. The exercise will consider vaccine effectiveness, return on investment, and program resilience under different local conditions. Studies to monitor short-term impact and vaccination outcomes will also be designed based on modelling outcomes.

Current Status:

The project was initiated on August 3, 2009. 514 girls will be recruited. Currently extended follow-up of all vaccinated girls is on-going. Total vaccinated participant 514 out of them 490 girls on follow up. Among these, 182 girls are married and total of 286 cervical samples for Pap smear testing and 103 samples for hrHPV (HC2) are done.

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