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

Completed Projects

Sr. No	Name of the Project	Year of completion	Implemented by
1.	Preventing Cervical Cancer in India through self-sampling. (PCCIS)	2022	Dr. Gauravi Mishra, Dr. Sharmila Pimple, Dr. MandanaVahabi, Dr. Josephine Wong, Dr. Aisha Lofters, Dr.Amita Maheshwari, Dr.Shylashree T S, Dr. Sanjay Biswas, Dr. Vasundhara Kulkarni, Dr. KavitaAnand
2.	Strengthening of Clinical Trial Unit for Conduct of COVID-19 Vaccine Trials among Cancer Patients and Healthy Volunteers	2022	Dr. Manju Sengar, Dr. Sharmila Pimple, Dr.Gauravi Mishra, Dr. GirishChinnaswamy, Dr. Sheela Sawant, Dr. PriyaRanganathan,Dr. Vasundhara Kulkarni, Dr. HeenaShaik, Dr. ManojGorade, Dr. Shilpushp Bhosale, Dr. Sandeep Tandon.
3.	Acceptability and validity of self-sampling for high risk HPV detection among women in Maharashtra	2021	Dr. Gauravi Mishra, Dr. Sharmila Pimple Dr. Kavita Anand, Dr.Rohini Kelkar.
4.	Narrow band imaging observed oral mucosa microvasculature as a tool to detect early oral cancer	---	Dr. Deepa Nair, Dr.Pankaj Chaturvedi, Dr. Munita Bal, Dr. Sudhir Nair, Dr. Gauravi Mishra, Dr. Sharmila Pimple, Dr. Manish Mair.
5.	Performance of HPV DNA Test in presence of co-infection with	2022	Dr. Sharmila Pimple, Dr. ReenaWani, Dr. Savita Karnad, Dr. KavitaAnand.

	common RTIs.		
6.	Cervical Cancer Screening Tutorials for skills development of Auxiliary Nurse Midwives (ANMs), Accredited Social Health Activists (ASHAs) and Primary Health workers (PHWs)	---	Dr. Gauravi Mishra, Dr. Shylasree T S, Prof Santosh Noronha.
7.	Comparative Evaluation of Efficacy of Different Methods of Tobacco Cessation Interventions among BEST Employees in Mumbai: A Randomized Controlled Trial	2019	Dr. Gauravi Mishra; Dr. Sharmila Pimple Mrs. Parishi Majmudar and Dr. Sheetal Kulkarni
8.	A Pilot Study on Comparative Evaluation of Results of Pap Smears and HPV Hybrid Capture 2 performed on Cervical Samples before and after Application of Acetic Acid.	---	Dr. Gauravi Mishra, Dr. Sharmila Pimple, Dr. KavitaAnand, Dr. Surendra Shastri
9.	Compliance, perceptions and attitudes of Bus employees and commuters towards smoke free bus policy (as part of smoke free public places) in Mumbai, India.	---	Dr. Sharmila Pimple, Dr. Gauravi Mishra, Dr. A M Singal, Mrs. Parishi Majmudar
10.	Impact of smoke free cabs (as part of smoke free public places) on cab drivers in Mumbai, India	---	Dr. Gauravi Mishra
11.	A mixed methods study to assess compliance for Gutkha, Pan masala ban and Section 5 and 6	---	Dr. Sharmila Pimple, Dr. Gauravi Mishra, Dr. Kriti Patel, Dr. Sandeep Gunjal, Mrs. Parishi Majmudar, Dr.

	of COTPA in Thane District, Maharashtra and Stakeholder views on challenges, barriers and opportunities for effective implementation of Tobacco Control legislation in District Tobacco Control Program.		Surendra Shastri
12.	Detection of dysplasia in leukoplakia and erythroplakia of the oral cavity using conventional cytology and liquid based cytology – comparative study.	---	Dr. Shubhada Kane, Dr. Sandeep OjhaBilkis, Dr. Neelam Prabhu Desai, Dr. Asawari Patel, Dr. Munita Pal, Dr. Gauravi Mishra, Dr. Pankaj Chaturvedi
13.	Evaluation of the diagnostic performance of HPV E6/E7 mRNA versus oncogenic HPV DNA as a secondary triage test for VIA positive women in cervical cancer screening program.	2019	Dr. Sharmila Pimple, Dr. TanujaTeni, Dr. Gauravi Mishra, Dr. SurendraShastriand Dr. K. M Mohandas
14.	Interventional Study to Determine the Effectiveness of Medium Intensity Versus Low Intensity Tobacco Use Prevention and Cessation Intervention in the Unorganized Sector of Zari Work in Mumbai.	---	Dr. Sharmila Pimple, Dr. Gauravi Mishra; Mrs. Parishi Majmudar
15.	Assessment of Impact of 'Gutkha and Pan Masala ban' in the state of Maharashtra on users.	---	Dr. Gauravi Mishra, Dr. Sharmila Pimple, Mrs. Parishi Majmudar, Dr. Sandeep Gunjal, Mrs. Subhadra Gupta

16.	A short duration pilot cohort study to assess the level of compliance in undertaking Breast Self- Examination (BSE) among women attending Preventive Oncology Clinic.	2011	Dr. Ketaki Karnik, Dr. Gauravi Mishra
17.	Restaurant Airborne Nicotine Monitoring in Mumbai, India: A Feasibility Study.	---	Dr. Surendra Shastri, Dr. Rachel Schwartz, Dr. Gauravi Mishra
18.	An interventional study to evaluate the impact of direct and surrogate advertising and compliance with the bill with respect to the sale of tobacco products around the educational institutes.	---	Dr. Sharmila Pimple, Dr. Gauravi Mishra, Mrs. Parishi Majmudar
19.	Acceptability and feasibility study of HPV vaccination	2010	Dr. Gauravi Mishra, Dr. Sharmila Pimple
20.	Prevalence of Human Papilloma Virus infection in migrant female sex workers and the risk of cervical intraepithelial neoplasia, in Mumbai, India.	---	Dr. Sharmila Pimple, Dr.Surendra Shastri
21.	Feasibility Study On Concurrent Evaluation Of The Three Methods Viz. Naked Eye Visual Examination, Examination Using Velscope And Examination With Toluidine Blue As Screening	2008	Dr.Surendra Shastri, Dr. Gauravi Mishra, Dr.Pallavi Uplap, Dr.Shubahda Kane, Dr.DevendraChauka

	Techniques Performed By Trained Primary Health Workers For The Early Detection Of Oral Neoplasia In Mumbai, India		
22.	A phase IIIB, Double Blind, Randomized, Controlled Study to Evaluate the Immunogenicity and Safety of HPV-16/18 L1 VLP/ASO4 Vaccine Administered Intramuscularly According to a 0, 1, 6 Months Schedule in Healthy Indian Female Subjects aged 18-35 Years.	---	Dr.SurendranathShastri, Dr. Sharmila Pimple
23.	Tobacco Control Among Business Process Outsourcing (BPO) Employees.	2008	Dr. Gauravi Mishra, Mrs. Parishi Majmudar, Dr.Nilesh Ingole
24.	Cervix Cancer Screening by two step (VIA & HPV DNA Tests) Technique, among low socio-economic population in Mumbai, India.	2008	Dr. Sharmila Pimple, Dr.Surendra Shastri, Dr. Gauravi Mishra, Dr. G. Amin, Dr. R Kelkar, Dr. K Deodhar, Dr. S Patil, Dr. J S Malliga.
25.	Cervical Cancer Prevention Project (Osmanabad-Barshi)	---	Funded by Bill and Melinda Gates Foundation through the IARC, Lyon, France
26.	Early Detection of Common Cancers in Women in India. (TMCUOP project)	---	Dr.Rajendra Badwe, Dr.Gauravi Mishra, Dr. Indraneel Mittra
27.	Tata Memorial Centre Workplace	---	Dr. Gauravi Mishra, Dr. PallaviUplap,

	Tobacco Cessation Programme in rural Maharashtra.		Mrs. Parishi Majmudar, Dr.Shrirang Pakhale

1. "Preventing Cervical Cancer in India through Self-Sampling" (PCCIS)

IEC Project No.	:	3786
PI	:	Dr. Gauravi Mishra, Dr. Sharmila Pimple, Dr.Mandana Vahabi,Dr. Josephine Wong, Dr Aisha Lofters.
Co-PI	**:**	Dr.Amita Maheshwari, Dr.Shylashree T S, Dr. Sanjay Biswas, Dr.Vasundhara Kulkarni, Dr.KavitaAnand
IEC Approval Date	:	23.08.2021
Funding Source	:	Extra mural- The Fund for Innovation and Transformation (FIT) Administered by the Manitoba Council for International Co- operation (MICC) has awarded funding to Ryerson University, Canada who is collaborating research with Tata Memorial Centre.
Project Status	:	Completed in October 2022

Project Summary:

In this community-based intervention, focused on underserved women in rural India, the study aimed to improve women's health by addressing HPV and cervical cancer disparities. It consisted of two components: education and access to screenings. A total of 120 women aged 30-69 and 120 males from three villages in Palghar district, Maharashtra, were enrolled based on cervical cancer incidence rates. The study aimed to increase sexual health literacy, reduce stigma related to cervical cancer and screenings, and explore the feasibility of HPV self-sampling for early detection. Participants completed pre-data collection surveys, received sexual health education, and then completed post-data collection surveys. A movie matinee was organized, where participants indicated their choices through colored ribbons. Based on their responses, women were divided into two cohorts: Cohort A (willing to use HPV self-sampling) and Cohort B (not willing or opting for Pap/VIA test). Further tests and referrals were made based on positive results. Focus group discussions were conducted with women from both cohorts to gather their

experiences, suggestions, and explore barriers and attitudes towards screening. Additionally, focus group discussions were held with local healthcare providers to gather their perspectives on HPV self-sampling and recommendations for practice and policy.

The duration of the study was 1 year 9 months. Study started on 02.02.2022 and completed on 31.10.2022. Target accruals of study were 240. Total screened were 1529. Screen failures were 1289. Total Enrolled were 240.

Results:

- All 120 women along with their male partners demonstrated a significant increase in knowledge of cervical cancer, HPV and screening modalities for cervical cancer (Pap, VIA) after participation in the study SHE session.
- The improvement in attitude towards pap and VIA screening tests was significantly higher among men than women.
- The mean scores for stigma among women were significantly higher than their male partners during pre and post intervention which supports that women are more inclined to be influenced by social stigma about STIs than their male partners.
- No significant difference was observed in gender equity scores from pre and post-intervention.
- Sustainability strategy discussion with stakeholders and groundwork for PCCIS brought out the need of ASHA workers as effective outreach personnel. Hence, training provided to 451 ASHA workers would enable them to promote cervical screening in these areas as per WHO mandate.

2. "Strengthening of Clinical Trial Unit for Conduct of COVID-19 Vaccine Trials among Cancer Patients and Healthy Volunteers"

IEC Project No	:	Not applicable
PI	:	Dr. ManjuSengar
Co-I	:	Dr. Sharmila Pimple, Dr.Gauravi Mishra, Dr. Girish Chinnaswamy, Dr.Sheela Sawant, Dr. Priya Ranganathan,

		Dr. Vasundhara Kulkarni, Dr. Heena Shaikh, Dr. Anuprita Daddi, Dr. Manoj Gorade, Dr. Shilpushp Bhosale, Dr. Sandeep Tandon
IEC Approval Date	:	Not applicable (Date of Sanction - 25.03.2021 from BIRAC)
Funding	:	Biotechnology Industry Research Assistance Council, a Government of India Enterprise (BIRAC)
Project Status	:	Completed on 30.09.2022

Project Summary:

The aim of the proposal was to establish the necessary infrastructure and capacity to conduct large-scale trials for evaluating COVID-19 vaccine candidates in Phase II/III. These trials would involve randomized or non-randomized approaches to assess the safety, immunogenicity, and efficacy of the vaccines in preventing primary COVID-19 infection and its severe complications. The target population for these trials would include both cancer patients and healthy individuals from the community.

Objectives:

1. Capacity Building

On-site availability of equipment for trial conduct and development of functional laboratory for bio specimen collection, processing and cold chain facility for storage of vaccines and bio-samples. Recruitment of man-power and completion of training of newly appointed staff under this grant: GCP/ BLS/ DGCT 2019 Good Clinical Practice / Basic Life Support, New Drugs and Clinical Trials Rules, 2019.

2. Volunteer Database Development

A. Research project was conducted as per the SOPs of TMH-IEC. The ICH-GCP guidelines were adhered to for conducting this research project. All members including Principal Key Investigator, Key Investigators and team members had undergone mandatory Good Clinical Practice training and continued with re-training at regular intervals. The IEC members and Investigators were responsible for protection, safety, rights and confidentiality of the research subjects. A set of uniform SOPs was developed addressing all aspects of COVID-19 vaccine trial conduct.

B. As part of quality control and quality check, retraining was conducted based on the performance assessment. There was mandatory annual training and assessment for the research team and administrative personnel involved in the clinical trial.

C. Planning was done for preparation of Information, Education and Communication.

3.To make the site ready for Clinical Trial Conduct

Gap analysis was conducted, and critical SOPs were developed for COVID-19 vaccine trials. The clinical trial center was developed, including the clinical examination room, consenting rooms, sample collection facility, trial pharmacy, participant observation rooms, data management and record-keeping facility. SOPs were developed for managing and reporting adverse events following immunization and managing medical emergencies. Referral and inpatient management protocols were established for trial participants in case of serious adverse events (SAEs). An audio-visual consenting facility was provided. Site assessments were performed by industry/third-party representatives to assess readiness for conducting clinical trials, conducted through audit visits from vaccine manufacturers. Subsequently, service agreements were signed.

3. "Acceptability and Validity of Self-Sampling for High Risk HPV Detection among Women in Maharashtra"

IEC Project No	:	1686
PI	:	Dr. Gauravi Mishra
Co-PI	:	Dr. Sharmila Pimple
Co-I	:	Dr.Kavita Anand, Dr.Rohini Kelkar
IEC Approval Date	:	02.03.2017
Project Started Date	:	01.03.2021
Funding	:	Terry Fox Research Institute.
Project Status	:	Completed

Project Summary:

This is a community-based interventional study, whose objectives were to determine the test characteristics (sensitivity, specificity, positive predictive value, false positivity rates, false negativity rates) of health personnel collected and self-collected for hybrid capture explained by

two different methods of HPV samples. In addition, to evaluate the agreement between self-collected HPV samples and health personnel-collected HPV samples for Hybrid capture with two different methods of education. Along with that, to study the attitudes, acceptability and barriers to self-collection of specimens for HPV-DNA testing in the Indian population and determine the predictors of self-sampling preference.

- The goal of the study was to recruit 1600 participants from three communities that were urban slum area of Mumbai City, urban non-slum area of Mumbai City, and rural area of Raigad/Thane district. The duration set for the study was 18 months.
- 1600 participants were enrolled in the study. Informed consent was obtained from willing participants, after detailed explanation, participants were interviewed to collect the baseline KAP (knowledge, attitude, and practice) regarding cervical cancer, screening, and HPV.
- Half of the women in each group were invited for health education and distribution of self-sampler while the other half were provided an information booklet on how to use self-samplers at home then similar interviews were conducted for both groups.
- During the visit to collect the samples, social workers interviewed about their experience of collecting the samples at home and to assess their acceptability of self-sampling for HPV detection. Those who refused to do self-sampling were interviewed to understand the barriers. HPV testing was performed with Hybrid Capture System II (Digene), which detects 13 different high-risk HPV types (16,18,31,33,35,39,45,51,52,56,58,59,68).
- HPV determination was quantitative and women with samples producing readings of one or more times the positive control were considered as HPV test positive. The reports of self-sampling HPV were distributed to the women after 15 days. The women who tested positive on either test was contacted personally by staff and offered free preventive oncology check-up, colposcopy, and necessary workup at TMH. Those who were not willing were referred to nearby municipal or private hospitals offering these services.

Results: The overall acceptance of HPV-SS was 97% (485) in the target population. The acceptance of HPV-SS was 100% (250) in the health education arm and 94% (235) in the pamphlet arm for all those receiving the instructions in both formats. The agreement

between the HPV-PHW sample and the HPV-SS was demonstrated to be 94.69% (232) and 95.61% (196) in the health education arm and pamphlet arm, respectively. Overall, the agreement rate was 95.11% (428). The kappa value demonstrated moderate agreement between the two samples readings by the HC2 test, $k = 0.55$ (95% CI = 0.34–0.77), $p < 0.001$.

4."**Narrow Band Imaging Observed Oral Mucosa Microvasculature as a Tool to Detect Early Oral Cancer"**

IEC Project No	:	1767
PI	:	Dr. Deepa Nair
Co-PI	:	Dr.Pankaj Chaturvedi
Co-I	:	Dr.Munita Bal, Dr. Sudhir Nair, Dr. Gauravi Mishra, Dr. Sharmila Pimple, Dr. Manish Nair
IEC approval Date	:	12.12.2016
Project Status	:	Completed

Project Summary:

Narrow band imaging (NBI) is a novel method with the potential to improve the diagnostic capability of white-light

Methods:

A prospective observational study of 50 consecutive patients, with suspicious malignant/premalignant lesions. White-light images were assessed as suspicious for malignancy/negative for malignancy, whereas NBI images were classified based on the IPCL patterns. All lesions underwent biopsy and accuracy was compared with the histopathology.

Results:

25 lesions (49%) were positive for malignancy, 2 (3.9%) lesions showed severe dysplasia, and 24(47%) were considered negative on histopathology. The sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of white light and NBI in detecting invasive carcinoma was 74.07%, 79.17%, 80.00%, 73.08% and 76.47%, and 92.67%, 90.16%, 92.56%, 91.67% and 92.16% respectively. The NBI group had a significantly better sensitivity and specificity to white light. The inter-observer concordance was $\kappa = 0.881$.

Conclusion:

NBI is a highly effective tool to detect invasive carcinomas amongst suspicious lesions of the oral cavity.

5. "Performance of HPV DNA Test in Presence of Co-infection with Common RTIs"

IEC Project No	**:**	1671
PI	**:**	Dr. Sharmila Pimple
Co-PI	**:**	Dr. ReenaWani, Mrs. Dr. Savita Karnad, Dr.Kavita Anand
IEC Approval Date	**:**	14.06.2016
Funding Source	**:**	Intramural
Project Status	**:**	Completed in 13.12. 2022

Project Summary:

Aims:

To study whether the presence of clinical cervicitis or co-infections with lab diagnosed RTIs interfere with the test result of HPV-DNA by HC2 method.

Objectives:

Primary objective

- To study whether the presence of clinical cervicitis /or co-infections with lab diagnosed RTIs interfere with the result of HPV-DNA testing by HC2 method.

Secondary Objective

- To determine the prevalence of HPV infection in women with and without clinically diagnosed cervicitis.
- To determine prevalence of HPV infection in women with lab diagnosed RTIs. (Gonococcal, Non- Gonococcal infections, Bacterial Vaginosis, Candida).

Methodology:

A total of 508 women, 254 women with clinical cervicitis and 254 asymptomatic women without cervicitis were enrolled as cases and control respectively. The duration of the project was 6 years 6 months. A baseline cervicovaginal swabs for RTIs and HC2 test samples were collected for all women enrolled in the study. All women in case arm received syndromic treatment for cervicitis while women in control arm received no treatment. A repeat cervicovaginal swab and HC2 test were collected for all women enrolled in the study after 7-14 days.

Results:

508 participants were enrolled in the study. Out of these 18 were lost to follow-up and rest had completed the intervention. This study demonstrated that the overall detection rates of HPV by the HC2 test improved by 4.5% among women treated for mucopurulent cervicitis. After controlling for biological and behavioral determinants through modeling, the study revealed the influencing role of mucopurulent discharge associated with cervicitis on the test results of the HC2 test**.**

6. "Cervical Cancer Screening Tutorials for Skills Development of Auxiliary Nurse Midwives (ANMs), Accredited Social Health Activists (ASHAs) and Primary Health Workers (PHWs)"

IEC Project No **:** 1605

PI **:** Dr Gauravi Mishra,

Co-PI **:** Dr Shylasree T S, Prof Santosh Noronha

IEC Approval Date **:** 28.01.2016

Funding Source **:** IIT Mumbai and Intramural TMH

Project Status **:** Completed

Project Summary:

This study aimed at creating video-based tutorials for developing skills in performing cervical cancer screening using VIA for the Auxillary Nurse Midwives (ANMs), Accredited Social Health Activists (ASHAs) and Primary Health Workers (PHWs). Cervical cancer screening was mainly done by the following three methods: Visual inspection with acetic acid (VIA), Cervical

Smear Cytology (PAP) and HPV- DNA test. VIA is a low cost, low resource cervical cancer screening method and especially useful for low middle income countries (LMICs) like India.

It was proposed to develop video-based tutorials, such that the ANMs/ASHAs/PHWs could be trained in performing and interpreting VIA with the use of this tutorial. The ANMs/ASHAs/PHWs have important roles in delivering health in rural/ semi urban areas and they were trained using this tutorial.

The video-based tutorials were made according to the 'Spoken Tutorials' methodology, developed at IIT Bombay. Video-based Tutorials has given skills based training to over 2 lakh students in the past four years on IT based topics. The tutorials were made available online free of cost. They were designed to be used without the need of an expert being physically present.

Results:

The video based tutorials prepared in ten modules were tested for validation among fifty ANMs and LHVs. Data was captured in a structured questionnaire and analyzed in SPSS version18. There was significant increase in the knowledge regarding cervical cancers, risk factors, signs and symptoms, HPV, methods of screening and early detection in the post intervention period compared to the pre-intervention period. Satisfaction levels regarding the video training was assessed based on likert scale. 98% trainees strongly agreed that they were happy with the video mode of learning, they felt that videos and animations were engaging and pleasure to watch, topics were better understood because of animation and that the videos were arranged in a logical manner.

7. "Comparative Evaluation of Efficacy of Different Methods of Tobacco Cessation Interventions among BEST Employees in Mumbai: A Randomized Controlled Trial"

IEC Project No	**:**	1368
PI	**:**	Dr. Gauravi Mishra; Dr. Sharmila Pimple
Co-I	**:**	Mrs. Parishi Majmudar Dr. A.M. Singhal
Mentor	:	Dr S S Shastri
IEC Approval Date	**:**	16th February 2015
Funding	**:**	Not Applicable

Project Status : Completed in 30/01/2019

Project Summary:

Objectives:

The objective of this study was to assess the knowledge, attitude, and practices (KAP) regarding the harmful effects of tobacco among the staff of public transport buses. The study aimed to educate them about the importance of smoke-free legislation and the health risks associated with tobacco use. Additionally, the study aimed to provide support for tobacco cessation, conduct oral cancer screenings and assist in further management as required for BEST Employees.

Materials and methods:

Around 4000 public transport bus employees in Mumbai were enrolled after explaining the programme and obtaining informed consent. They were interviewed and their KAP regarding tobacco was recorded. The employees were then given detailed health education. They were screened for oral cancers and counseled for tobacco cessation. The screen positive employees were referred to Nodal Hospital for diagnostic evaluation and management.

Results:

4000 public transport bus employees were enrolled. Amongst them 1691 (42.28%) were tobacco users. Smokeless form of tobacco use was dominant, 1561 (92.31%). All 4000 employees participated in oral cancer screening and were enrolled for tobacco cessation counselling. 743 employees were screened positive, 592 complied with referral for diagnostic evaluation and 534 employees were clinically diagnosed with oral pre-cancers.

Conclusions:

Tobacco use and oral pre-cancers were high among the public transport bus employees in Mumbai. Hence, awareness of oral cavity screening and tobacco cessation counseling were recommended to incorporate within their annual health check-up.

8. "A Pilot Study on Comparative Evaluation of Results of Pap Smears and HPV Hybrid Capture 2 Performed on Cervical Samples Before and After Application of Acetic Acid."

IEC Project No : 1413

PI : Dr. Gauravi Mishra, Dr. Sharmila Pimple

Co-I : Dr. Kavita Anand, Dr. Surendra Shastri

IEC Approval Date : 14.01.2015

Funding Source : Intramural Funds

Project Status : Completed

Project Summary:

Aim:

To assess the feasibility of triaging VIA (Visual inspection with Acetic Acid) positive women with a test with higher specificity, either Pap or HPV-DNA test (Human Papilloma Virus) in the same sitting at community level. This strategy if successful shall prevent unnecessary referrals to tertiary care in resource constrained settings and also increase the programmatic yield.

Objective:

To investigate, whether the 5% acetic acid, used in VIA screening will compromise the cellularity of Pap test or results of HPV-DNA test.

Materials/ Methods:

Fifty women were randomised to either HPV test arm or Cytology test arm. The 25 women in HPV- DNA arm underwent a HPV-DNA HC2 test before and five minutes after application of 5% acetic acid. In cytology arm, 25 women underwent Pap test before and five minutes after application of 5% acetic acid.

Results:

- The Pap smear of one woman was reported inadequate both before & after application of acetic acid (VIA). Among the remaining 24 women, 71% women had adequate cellularity on smears both before & after VIA test, while in 29% women with adequate smears before application of VIA, were reported to have inadequate smears after application of the test. There was statistically significant difference in proportion of women reporting the cell adequacy on Pap smear before and after VIA test using acetic acid. (p=0.008)
- The application of acetic acid (VIA test) did not alter interpretation of ASCUS smear, while a smear reported as LSIL before VIA test was reported as normal after VIA test.

Colposcopy & Histopathology confirmed the findings as CIN I. (cervical intraepithelial neoplasm grade 1)

- Concordance was seen in results of 24 women (2 positive result and 22 negative results) before & after application of acetic acid (VIA). Only one woman whose test was negative before VIA was reported in grey zone after VIA test. (RLU of 0.8 to 1.2) An overall agreement of 96% was observed in HC2 results. There was no statistically significant difference in proportion of women with HPV-DNA test results before and after application of acetic acid. (p=0.317)

Results: According to the results of this study, 5% acetic acid affected the cellularity of cytology smears and may affect interpretation of dysplastic smears. HPV-DNA test results remained unaffected by acetic acid. These results suggest that HPV HC2 may perhaps be a better triage test for VIA positive women. However, this needs confirmation with a larger sample size. These findings were extremely crucial in the scenario that National Cancer Control Programme in many low-income countries including India are adopting VIA based screening and there is unavailability of resources to handle the large number of false positives emerging from positive VIA test.

9."**Compliance, Perceptions and Attitudes of Bus Employees and Commuters towards Smoke Free Bus Policy (as part of smoke free public places) in Mumbai, India**."

IEC Project No	**:**	1369
PI	**:**	Dr. Sharmila Pimple, Dr. Gauravi Mishra
Co- I	**:**	Dr. A. M.Singal, Ms. Parish Majmudar
IEC Approval Date	**:**	22.12.2014
Funding Source	**:**	Nil
Project Status	**:**	Completed

Project Summary:

Three years since the Smoke Free Mumbai campaign and six years since the ban on smoking in public places were implemented. It is necessary to review the situation at this point, in time, so

that corrective actions if necessary can be taken. Hence, this study is planned to understand the perceptions and attitudes of commuters and bus employees (drivers, conductors and ticket checkers) regarding the law, its implementation, reactions from the commuters, violations observed, violations reported.

This study will help evaluate the implementation of provision of prohibiting smoking in public places and help understand how to increase the compliance. The results will inform enforcement and public health agencies about where to target enforcement and public education resources.

10. "Impact of Smoke Free Cabs (as part of smoke free public places) on Cab Drivers in Mumbai, India"

IEC Project No : 1378
PI : Dr. Gauravi Mishra
IEC Approval Date : 03/12/2014
Project Status : Completed
Project Summary:
Objectives:

The objective of this study was to address the significant public health threat posed by the tobacco epidemic, which claims the lives of approximately seven million people every year. While smoke-free public places, legislation had been implemented in India, making cabs smoke-free environments, a considerable number of cab drivers remained addicted to tobacco. Therefore, this study aimed to assess the knowledge and opinions of cab drivers regarding tobacco, examine the patterns of tobacco usage among them, help and support to quit tobacco, conduct oral cancer screenings, evaluate the effectiveness of the smoking ban in cabs, and gain insights into the perceptions of cab drivers regarding the tobacco ban.

Methods:

The intervention study was carried out among cab drivers in Mumbai from 2015 to 2018. Various cab unions in Mumbai were approached, and a total of 400 cab drivers were recruited and interviewed for the study. Over the period of one year, the enrolled cab drivers received

health education, regular oral cancer screenings, and assistance for tobacco cessation at scheduled intervals.

Results:

64%of cab drivers used tobacco, mainly in smokeless forms (80%). 94% intended to quit, 66% had made previous quit attempts and 70% expressed need of assistance for quitting tobacco. 62% had displayed a 'No Smoking' sign in their cab and 75% expressed full compliance by passengers to the ban. 30% of cab drivers had oral precancerous lesions and one cab driver was diagnosed with invasive oral carcinoma. 32% of cab drivers had quit tobacco by the end of nine months and 36% of cab drivers had reduced their tobacco consumption.

Conclusions:

The implementation of smoke-free laws was crucial in minimizing cab drivers' exposure to second-hand smoke. Nevertheless, it was observed that a significant number of cab drivers were struggling with tobacco addiction and required assistance to quit. In this study, we successfully demonstrated the implementation of a comprehensive tobacco control and cessation program to support the effectiveness of smoke-free laws.

11. "A Mixed Methods Study to Assess Compliance for Gutkha, Pan Masala Ban and Section 5 and 6 of COTPA in Thane District, Maharashtra and Stakeholder Views on Challenges, Barriers and Opportunities for Effective Implementation of Tobacco Control Legislation in District Tobacco Control Program"

IEC Project No	**:**	1271
PI	**:**	Dr. Sharmila Pimple
Co-PI	**:**	Dr. Gauravi Mishra
Co – I	**:**	Dr. Kriti Patel, Dr. Sandeep Gunjal, Mrs. ParishiMajmudar, Dr. Surendra Shastri
IEC Approval Date	**:**	03.11.2014
Funding Source	**:**	PHFI

Project Status : Completed

Project Summary :

Cigarettes and other tobacco products act 2003 (COTPA) is the principal law governing tobacco control in India. Government of Maharashtra is one of its landmark decisions also banned manufacturing, sale and distribution of gutka and pan masala since July 2012. The desired impact and level of enforcement of the COTPA legislation and the gutka and pan masala ban in Maharashtra State, however, needs assessment. Among the many provisions within COTPA, the present study seeks to assess compliance to implementation and enforcement of Section 5 and 6 of COTPA including compliance to gutka and pan masala ban in Mumbai, India.

Methodology: Six educational institutes (EI) within the Mumbai metropolitan region were selected in a two stage random sampling process. Area around each EI was manually mapped and all the tobacco products selling outlets within the 100 yards distance were listed by trained Field Social Investigators and were observed to determine compliance for Section 5 and Section 6 of the COTPA legislation and for gutka and pan masala ban. The vendors/shop owners managing these outlets were also interviewed for their personal sociodemographic details, self-tobacco use, awareness and perception about ill-effects of tobacco and existing tobacco control legislation in the country.

Results: A total of 222 tobacco retail outlets were listed within 100 yards of the EI in violation to the provisions of Section 6 of COTPA, of which 72 (32.4%) were selling tobacco products on mobile structures. About 53.2% of the tobacco vendors were also users of some form of tobacco. Whereas, nearly 217 (97.7%) vendors were aware about the gutka and pan masala ban in the state, only 48.2% were aware about the existence of COTPA legislation. None of the EI had a display board prohibiting the sale of tobacco products within a radius of 100 yards of their EI. Only 56.3% tobacco outlets had complied with the mandatory warning display boards indicating tobacco products will not be sold to people below 18 years of age. With regards to point-of-sale advertisement, only 25.2% compliance was noted for display of health warning boards at the point-of-sale. Nearly, 48.6% tobacco outlets exhibited >2 display boards and another 43.2% exhibited hoardings with brand pack photo, brand name in violation to the provision under Section 5. Violation by visible stacking and open display of tobacco products for sale was

observed at 51.3% of tobacco outlets. While 41% of tobacco outlets were found displaying gutka and pan masala packets in violation to the ban.

Conclusions: Enacting of the law without robust measures for enforcement has led to widespread noncompliance to the provisions with in the tobacco control legislation in the metropolitan city of Mumbai. Strong and sustainable measures needs to be incorporated both by civic administration and public health departments for its forceful implementation.

12. "Detection of Dysplasia in Leukoplakia and Erythroplakia of the Oral Cavity using Conventional Cytology and Liquid Based Cytology – Comparative Study"

IEC Project No	**:**	1142
PI	**:**	Dr. Shubhada Kane
Co-I	**:**	Dr. Sandeep Ojha, Dr. Bilkis, Dr. Neelam Prabhudesai, Dr. Asawari Patel, Dr. Munita Pal, Dr. Gauravi Mishra, Dr. Pankaj Chaturvedi
IEC Approval Date	**:**	30.05.2013
Funding Source	**:**	Trivitron health care Pvt. Ltd & Intramural funding
Project Status	**:**	Completed

Project Summary:

Total accrual: 100 patients, Time duration: 12 months and enrollment is completed.

13. "Evaluation of the Diagnostic Performance of HPV E6/E7 mRNA versus Oncogenic HPV-DNA as a Secondary Triage Test for VIA Positive Women in Cervical Cancer Screening Program."

IEC Project No	:	1103
PI	:	Dr. Sharmila Pimple
Co-PI	:	Dr. TanujaTeni

Co-I	:	Dr. Gauravi Mishra, Dr. Surendra Shastri and Dr. K. M Mohandas
IEC Approval Date	:	11th February 2013
Funding Source	:	DBT (Department of Biotechnology)
Project Status	:	Completed in 13th October 2019

Project Summary:

The objective of this study was to develop and standardize a methodology/algorithm for testing E6/E7 mRNA for HPV genotypes 16, 18, 31, 33, and 45 using Real-Time RT-PCR in cervical samples. The study also aimed to compare the performance of this HPV E6/E7 mRNA assay with HPV DNA testing using HC II as a secondary screening test, using colposcopy with biopsy as the reference standard. This comparison aimed to triage women who tested positive in the primary screening test using VIA. Additionally, the study sought to determine the number of false positives in the primary screening test after testing VIA-positive samples with a known high-specificity secondary screening test (HPV DNA HC II) compared to HPV E6/E7 mRNA testing.

Methodology:

A total 3839 women in the age group of 30-65 years attending cancer-screening clinic were screened with the primary screening test VIA between May 2012 to December 2014. VIA test, positive women were further offered secondary screening tests viz Hybrid Capture-II (HC-II) and HPV E6/E7 mRNA test. The reference standard for final disease status was colposcopy-guided histopathology.

Result:

The sensitivity and specificity of HPV-DNA and HPV E6/E7 mRNA testing was 0.89 (95% CI: 0.65-0.99), 0.60 (95% CI: 0.36-0.81) and 0.78 (95% CI:0.70-0.85), 0.88 (95% CI:0.80-0.93) respectively. The false positive rate of HPV-DNA was 0.22(95% CI: 0.15-0.30) and that of HPV E6/E7 mRNA was 0.12 (95% CI:0.07-0.20)

Conclusion:

The E6/E7 mRNA test was found to be less sensitive but showed similar test characteristics as HC-II. HC-II therefore could be used as a triage to help reduce the excess false positive burden and cost on health care system where the services for histopathology confirmation were nonexistent.

14. "Interventional Study to Determine the Effectiveness of Medium Intensity versus Low Intensity Tobacco Use Prevention and Cessation Intervention in the Unorganized Sector of Zari Work in Mumbai."

IEC Project No	:	979
PI	:	Dr. Sharmila Pimple,
Co-PI	:	Dr. Gauravi Mishra;
Co-I	:	Mrs. Parishi Majmudar
IEC Approval Date	:	3rd January 2013
Funding Source	:	Intramural funds
Project Status	:	Completed

Project Summary:

This study aimed to investigate tobacco use among informal sector workers of the Zari Industry. It assessed the feasibility and acceptability of prevention and cessation strategies through a programmatic approach. The interventions involved assessing knowledge, attitudes, and perceptions of tobacco use before and after the intervention, providing education and cessation support, and evaluating changes in attitudes and quit rates among tobacco users.

Introduction and Objectives:

This study was conducted as a part of a broader research project on tobacco cessation for Zari Workers by Department of Preventive Oncology, Tata Memorial Hospital, and Mumbai.

The specific objectives of this study were as follows: to evaluate the socio-demographic characteristics of Zari Workers in Mumbai, to assess tobacco usage among this population, to determine the reasons given by participants for using tobacco, and to raise awareness about the health risks associated with tobacco.

Materials and Methods:

In Dharavi and Govandi, the owners of Zari Work Units were contacted and approached for participation. Workers who gave their consent and whose unit owners granted permission were included in the study. As a result, the first 300 workers from each area were selected as participants. On average, each unit consisted of 7 to 8 workers. A Pre-Intervention questionnaire was administered to all participants. Health talks on the health risks associated with tobacco use and counseling sessions were conducted in each unit, even for those who did not participate in the study.

Results:

The study population consisted entirely of male Zari Workers with low levels of education. The majority had migrated from Bihar and 95% lived and worked in the same location, often in cramped places with colleagues. Nearly 60% reported working long hours. More than 70% reported using tobacco, with smokeless tobacco being the most common form. The majority of tobacco users attributed their use to the unsuitable working conditions.

Conclusion:

The study found a high prevalence of tobacco use among Zari Workers, which may be largely attributed to the unsuitable working and living conditions. These findings highlight the need for tobacco control efforts targeting unorganized labor.

15. "Assessment of Impact of 'Gutkha and Pan Masala Ban' in the State of Maharashtra on Users"

IEC Project No	:	912
PI	:	Dr. Gauravi Mishra, Dr. Sharmila Pimple;
Co-I	:	Mrs. Parishi Majmudar, Dr. Sandeep Gunjal, Mrs. Subhadra Gupta
Mentor	:	Dr. Surendra Shastri
IEC Approval Date	:	27th October 2011
Funding Source	:	Nil
Project Status	:	Completed

Project Summary:

Since July 19, 2012, the Government of Maharashtra has implemented a ban on the manufacture, storage, distribution, and sale of gutka and pan masala. Maharashtra was the first state in India to ban pan masala in addition to gutka. In light of this ban, this trial was proposed to evaluate the awareness of gutka and paan masala users regarding the prohibition and its impact on both users and tobacco vendors.

Objectives:

The objective of this study was to determine the impact of the ban on gutkha and pan masala on its users and vendors.

Methodology:

A cross-sectional study was conducted among gutkha and/or pan masala users and tobacco vendors in the selected area of Mumbai city, 4-6 months after the implementation of the ban. The parameters study included knowledge regarding the ban, usage or discontinuation of use of the banned products, product availability, withdrawal symptoms among quitters, etc.,

Results:

A total of 68 users and 5 tobacco vendors were enrolled in this study. Although all users were aware about the ban on gutkha, very few knew about the ban on pan masala. Only 5.9% of users knew that currently the ban had been declared for only 1 year. Electronic media was the main source of information regarding the ban as reported by 45.6% users. All users and vendors were in favor of the ban. After the ban, 23.53% gutkha users quit their habit while 55.88% reduced their gutkha consumption. Non-availability of gutkha was the most important reason stated by the gutkha users for quitting or reducing the consumption. In spite of the ban, gutkha was still available in the market, but at an increased cost or in a different form.

Conclusion:

Nearly 23.53% of gutkha users had quit their habit post-ban despite its availability through illegal sources.

16. "A Short Duration Pilot Cohort Study to assess the Level of Compliance in Undertaking Breast Self Examination (BSE) among Women Attending Preventive Oncology Clinic".

IEC Project No **:** 827

PI **:** Dr. Ketaki Karnik

Co-PI **:** Dr Gauravi Mishra

IEC Approval Date **:** 12.11.2010

Funding Source **:** Nil

Project Status **:** Completed in 2011

Project Summary:

Breast cancer is the most common cancer among women residing in majority of the urban areas in India. The deaths due to breast cancer are mainly a result of late presentation of the symptoms due to lack of awareness of the signs and symptoms of the disease and lack of knowledge of performing BSE. The BSE technique can be a good tool for improving the awareness about the symptoms of breast cancer. Hence, we propose a pilot study of short duration (3 months follow-up), to assess the level of compliance to BSE and assess the various reasons for non-compliance. Based on the results of this study a long term cohort study was planned with similar objectives.

Detailed description

This is an observational cohort study about BSE among women attending the Preventive Oncology (PO) Clinic, TMH. All women attending for screening of common cancers at the Preventive Oncology OPD at TMH are demonstrated the technique of BSE and advised on when, how and why to perform BSE.

Women attending the PO clinic and who had mentioned their residential address as Mumbai and provided contact number were invited to participate in the study. They were explained the study protocol and those who were interested in participating were offered informed consent forms. The women who sign the informed consent form were enrolled into the trial.

The data regarding the socio-demographic details and level of knowledge, attitude and practice (KAP) about breast cancer and BSE were collected from the participating women. They were asked if they have any doubts regarding the technique of BSE and their willingness to perform BSE. Thereafter, a follow-up period of 3 months, the women were contacted telephonically to collect the data to assess the level of compliance to BSE and the reasons for non-compliance, if any. Also, the women were asked if they have observed any abnormal changes in their breasts and have they visited the clinician for the same. And subsequently, their health care seeking behavior was studied.

The data collected before and after the follow-up were entered in the SPSS software and analyzed using simple statistical tests like mean, chi-square, t-test and univariate and multivariate analysis.

17. "Restaurant Airborne Nicotine Monitoring in Mumbai, India: A Feasibility Study"

IEC Project No **:** 785

PI **:** Dr. Surendra Shastri, Dr. Rachel Schwartz

Co-I **:** Dr. Gauravi Mishra

IEC approval Date **:** 24.06.2010

Funding Source **:** Global Health Institute at the University of Southern California and Johns Hopkins School of Public Health

Project Status **:** Completed

Project Summary:

This trial aimed at measuring levels of indoor air nicotine through passive and particulate matter (PM2.5) monitoring in restaurants in Mumbai in an effort to generate evidence for advocacy of stronger smoke-free laws.

18. "An Interventional Study to Evaluate the Impact of Direct and Surrogate Advertising and Compliance with the Bill with Respect to the Sale of Tobacco Products around the Educational Institutes."

IEC project No **:** 647

PI : Dr. Sharmila Pimple, Dr. Gauravi Mishra

Co – I : Mrs. Parishi Majmudar

Mentor : Dr.Surendra Shastri

IEC Approval Date : 12.01.2010

Funding Source : Nil

Project Status : Completed

Project Summary:

The project aimed at enlisting the outlets selling tobacco in any form and enlisting the tobacco based advertisements (Direct and Surrogate) directed towards the community, within 100 yards of the selected educational institutes and studying their impact on the students of that institute. This will further be followed by an intervention program directed at the outlet owners, which entails creating awareness about the harmful effects of tobacco and the existing bill and thereby assessing any change in Knowledge, Attitude and Practice. The results thus obtained will facilitate implementation of the existing Bill.

Intervention Details:

Behavioral: Health Education

a. Implementing the intervention programme designed for creating awareness about harmful effect of tobacco (smoked and smokeless forms) and the current regulation to the shop-owners.
b. Administering the questionnaire to objectively assess the impact of direct/ surrogate tobacco advertisements influencing student behavior and perception about tobacco and tobacco products.
c. Implementing the intervention programme designed for creating awareness about harmful effects of tobacco (smoked and smokeless forms) and the current regulation to the students through interactive sessions with students in their respective educational institute.

19. "Acceptability and Feasibility Study of HPV Vaccination"

IEC Project No : 655

PI : Dr. Gauravi Mishra, Dr. Sharmila Pimple

Mentor : Dr.Surendra Shastri

IEC approval Date : 20.10.2009

Funding Source : TMH Intramural

Project Status : Completed in 2010

Project Summary:

The trial aimed at determining the acceptability and feasibility of introducing a population based HPV Vaccination programme and understanding the key individual and community factors that would determine the potential acceptability of the vaccine.

20. "Prevalence of Human Papilloma Virus Infection in Migrant Female Sex Workers and the Risk of Cervical Intraepithelial Neoplasia, in Mumbai, India"

IEC Project No : 358

PI : Dr. Sharmila Pimple

Co-I : Dr. SurendraShastri

IEC Approval Date : 28.09.2007

Project Status : Completed

21. "Feasibility Study on Concurrent Evaluation of the Three Methods Viz. Naked Eye Visual Examination, Examination Using Velscope and Examination with Toluidine Blue as Screening Techniques Performed by Trained Primary Health Workers for the Early Detection of Oral Neoplasia in Mumbai, India"

IEC Project No : 391

PI : Dr SurendraShastri

Co-I : Dr Gauravi Mishra, Dr Pallavi Uplap, Dr Shubahda Kane, Dr. Devendra Chaukar

IEC Approval Date : 11.09.2007

Funding Source : American Cancer Society through Emory University

Project Status : Completed in 2008

Project Summary:

This oral cancer screening trial aimed at evaluating the feasibility and efficacy of performance of the three oral cancer screening tests viz. i) naked eye unaided examination ii) examination using Velscope iii) naked eye visual examination after application of Toluidine Blue by trained primary health workers; and estimating the test characteristics of each of the three oral cancer screening techniques.

22. "A phase IIIB, Double Blind, Randomized, Controlled Study to Evaluate the Immunogenicity and Safety of HPV-16/18 L1 VLP/ASO4 Vaccine Administered Intramuscularly According to a 0, 1, 6 Months Schedule in Healthy Indian Female Subjects aged 18-35 Years"

IEC Project No : 316

PI : Dr.Surendra Shastri

Co-PI : Dr. Sharmila Pimple

IEC Approval Date : 03.04.2007

Recruitment : 24

Time Frame : 2007-08

Funding Agency : GSK Biologicals (GlaxoSmithKline)

Project Status : Completed

Project Details:

Brief Summary:

Human papillomavirus infection has clearly been recognized as the cause of cervical cancer. Indeed, the infection of the cervix by certain oncogenic types of HPV, if not cleared, can lead over time to cervical cancer in women. This study will evaluate the immune response induced by the HPV-16/18 L1/AS04 vaccine and the safety of the vaccine.

The Protocol Posting has been updated in order to comply with the FDA Amendment Act, Sep 2007.

Aim: India has the highest number of annual incident cases and mortality rates for cervical cancer worldwide. This study was conducted to assess the immunogenicity and safety of human papillomavirus (HPV)-16/18 AS04-adjuvanted cervical cancer vaccine in healthy Indian women aged 18-35 years old.

Methods: This double-blind, randomized (1:1), controlled and multicenter trial with two parallel groups, the Vaccine and Placebo groups, included 354 subjects in four centers across India. Subjects were given GlaxoSmithKline's HPV-16/18 AS04-adjuvanted cervical cancer vaccine or aluminum hydroxide placebo according to a 0, 1 and 6 month schedule and followed up until month 7. Serum samples were drawn at pre-vaccination and at month 7. Safety data were collected throughout the study.

Results: A total of 330 subjects completed the study. One month post-Dose 3, all initially seronegative subjects in the vaccine group had seroconverted for HPV-16 and HPV-18 antibodies with anti-HPV-16 and anti-HPV-18 geometric mean titer levels of 10226.5 EL.U/ml (95% confidence interval: 8847.1-11821.0) and 3953.0 EL.U/ml (95% confidence interval: 3421.8-4566.8), respectively. Initially, seropositive subjects also showed an increase to similar geometric mean titer levels. Six serious adverse events (two in the vaccine group and four in the placebo group), all unrelated to vaccination, were reported. Commonly reported solicited local (injection-site pain) and general (fatigue, headache and fever) symptoms were similar in both groups. Compliance to the three-dose vaccination course was >97%.

Conclusions: The AS04-adjuvanted HPV-16/18 cervical cancer vaccine was highly immunogenic and generally well-tolerated making it a potential tool for prevention and control of cervical cancer in India.

23. "Tobacco Control among Business Process Outsourcing (BPO) Employees."

IEC Project No	**:**	351
PI	**:**	Dr. Gauravi Mishra
Co-I	**:**	Mrs. Parishi Majmudar, Dr.Nilesh Ingole,
Mentor	**:**	Dr. Surendra Shastri
IEC Approval Date	**:**	23.03.2007
Funding Source	**:**	TMH Intramural
Project Status	**:**	Completed in 2008

Project Summary :

The Business Process Outsourcing BPO industry has been rapidly expanding in India over the last 10 years. There was a concern regarding issues of health and safety that are unique to this new and developing industry. The lack of reliable and relevant information on which to base the response to this concern poses a challenge for safeguarding the health of BPO employees. Elevated stress levels, shift duties, high work targets, lofty income may force many towards addictions to keep them going.

Use of tobacco, which is very common addiction in India, is associated with several health hazards. Anecdotal evidence suggests that smoking and other forms of addictions are at its peak in the BPO industries. We are conducting a research on the tobacco habits among Business Process Outsourcing (BPO) employees to understand the prevalence of different forms of tobacco addiction and the reasons for initiation and continuation of the habit. We will also offer different interventions as a measure of tobacco cessation.

Study Methodology:

This was a four arm randomized controlled trial among Business Process Outsourcing (BPO) employees working in four different BPO units. The trial was undertaken with the objective to explore the prevalence of tobacco use in its various forms along with factors responsible for initiation and continuation of the habit. This trial also aimed to study the change in the

knowledge, attitudes and practices among BPO employees after intervention with different tobacco cessation strategies.

Four BPO units with work force of approximately 200 employees each, with the management and employees that consent to participate in the study were selected for the trial. The aim and purpose of the study were explained and a written informed consent form in English was offered. The employees who were willing to participate in the trial, were recruited after signing the informed consent form.

The subjects involved in the research were expected to answer a few questions about their socio-demographic, occupational, medical, risk factor history and some questions to assess their knowledge, attitude and practice regarding tobacco use. Following this the tobacco users were offered one of the tobacco cessation interventions to help them quit tobacco.

Regular follow-up visits were conducted throughout the period of the study. The same questionnaire as the pre intervention was repeated post intervention, ten months later to assess change in their knowledge, attitude and practice regarding tobacco use.

Results: The prevalence of tobacco dependence was 41%, mainly cigarette smoking. The tobacco quit rate was similar (nearly 20%) in the 3 intervention arms. Significantly higher reduction in tobacco consumption of 45% was seen in Arm 4 with the use of pharmacotherapy. BPO employees change jobs frequently, hence follow-up remains a major challenge**.**

24. "Cervix Cancer Screening by two step (VIA & HPV DNA Tests) Technique, among low socio-economic population in Mumbai, India"

IEC Project No	**:**	264
PI	**:**	Dr. Sharmila Pimple, Dr.Surendra Shastri
Co-I	**:**	Dr. Gauravi Mishra, Dr. G. Amin, Dr. R Kelkar, Dr. K Deodhar, Dr. S Patil, Dr. J S Malliga
EC Approval Date	**:**	07.04.2006
Funding Source	**:**	American Cancer Society
Project Status	**:**	Completed in 2008

Project Summary:

The primary objectives of this trial was to determine the test characteristics of VIA and to determine the number of false positives in primary screening test (i.e. VIA) by testing the VIA positive women by a secondary screening test (i.e. HPV HC 2).

25. "Cervical Cancer Prevention Project (Osmanabad-Barshi)"

Recruitment : 1,43,000

Time Frame : 2000-10

Funding Agency : Bill and Melinda Gates Foundation through the IARC, Lyon, France

Project Status : Completed

Project Details:

Objective:

To determine the factors associated with participation in cervical cancer screening and follow-up treatment in the context of a randomized controlled trial. The trial was initiated to evaluate the efficacy and cost effectiveness of visual inspection with acetic acid, cytological screening and testing for human papillomavirus in reducing the incidence of and mortality from cervical cancer in Maharashtra, India.

Methods:

Between October 1999 and November 2003 women, aged 30–59 years were randomized to receive one of the three tests or to a control group. Participation was analysed for all three intervention arms. The differences between those who were screened versus those who were not was analyzed according to the sociodemographic characteristics of the 1,00,800 eligible women invited for screening. Those who were treated versus those who were not were analysed according to the sociodemographic characteristics of the 932 women diagnosed with high-grade lesions. Participation in screening and compliance with treatment were also analysed according to the type of test used.

Findings:

Compared with women who were not tested, screened women were younger (aged 30–39), better educated and had ever used contraception. A higher proportion of screened women were married and a lower proportion had never been pregnant. Of the 932 women diagnosed with high-grade lesions or invasive cancer, 85.3% (795) received treatment. Women with higher levels of education, who had fewer pregnancies and those who were married were more likely to comply with treatment. There were no differences in rates of screening or compliance with treatment when results were analyzed by the test received.

Conclusion:

Irrespective of the test being used, good participation levels for cervical cancer screening can be achieved in rural areas of developing countries by using appropriate strategies to deliver services. Communication methods and delivery strategies aimed at encouraging older, less-educated women, who have less contact with reproductive services, are needed to further increase screening uptake.

26. "Early Detection of Common Cancers in Women in India" (TMCUOP project)

IEC Project No.	:	1996-I
PI	:	Dr.Rajendra Badwe
Co-I	:	Dr.Gauravi Mishra, Dr. Indraneel Mittra
IEC Approval Date	:	August 1996, project started in May 1998
Funding Source	:	National Institutes of Health.
Project Status	:	Completed

Project Summary:

This is a cluster-randomized trial where twenty slum clusters in Mumbai, India were selected by simple random sampling consisting of over 151,538 participants. Ten slum clusters consisting of 75,360 participants were randomized into intervention arm to receive four rounds of intervention (Health Education Program followed by breast and cervix cancer screening) followed by four rounds of active surveillance. Another 10 slum clusters consisting of 76,178 participants were randomized to control arm to receive one-time health education program in the first active

surveillance followed by seven rounds of active surveillance only. Every round is of 24 months duration.

The primary aim of this trial was among urban slum women, aged 35-64 years, in Mumbai, India. To investigate the efficacy of cancer education and screening, using affordable, sustainable and culturally acceptable techniques, i.e. Clinical Breast Examination (CBE) and Visual Inspection with 4% Acetic Acid (VIA), performed by trained female primary health workers (PHWs) in the: 1) Early detection and down staging of breast and cervical cancer, 2) Reduction in breast and cervical cancer mortality 3) Reduction in cervical cancer incidence.

Results:

1. Cervical cancer screening results published in Journal of the National Cancer Institute, JNCI.

They recruited 75,360 women from 10 clusters in the screening group and 76,178 women from 10 comparable clusters in the control group. In the screening group, they achieved 89% participation for screening and 79.4% compliance for diagnosis confirmation. The incidence of invasive cervical cancer was 26.74 per 1,00,000 (95% confidence interval [CI] = 23.41 to 30.74) in the screening group and 27.49 per 1,00,000 (95% CI = 23.66 to 32.09) in the control group. Compliance to treatment for invasive cancer was 86.3% in the screening group and 72.3% in the control group. The screening group showed a statistically significant 31% reduction in cervical cancer mortality (RR = 0.69; 95% CI = 0.54 to 0.88; P = .003).

2. Breast cancer results Published in British Medical Journal, The BMJ.

Breast cancer was detected at an earlier age in the screening group than in the control group (age 55.18 (standard deviation 9.10) v 56.50 (9.10); P=0.01), with a significant reduction in the proportion of women with stage III or IV disease (37% (n=220) v 47% (n=271), P=0.001). A non-significant 15% reduction in breast cancer mortality was observed in the screening arm versus control arm in the overall study population (age 35-64; 20.82 deaths per 100 000 person years (95% confidence interval 18.25 to 23.97) v 24.62 (21.71 to 28.04); rate ratio 0.85 (95% confidence interval 0.71 to 1.01); P=0.07). However, a post hoc subset analysis showed nearly 30% relative reduction in breast cancer mortality in women aged 50 and older (24.62 (20.62 to 29.76) v 34.68 (27.54 to 44.37); 0.71 (0.54 to 0.94); P=0.02), but no significant reduction in women younger than 50 (19.53 (17.24 to 22.29) v 21.03 (18.97 to 23.44); 0.93 (0.79 to 1.09);

P=0.37). A 5% reduction in all cause mortality was seen in the screening arm versus the control arm, but it was not statistically significant (rate ratio 0.95 (95% confidence interval 0.81 to 1.10); P=0.49).

27. "**Tata Memorial Centre Workplace Tobacco Cessation Programme in rural Maharashtra**."

IEC Project No **:** 458

PI **:** Dr. Gauravi Mishra

Co – I **:** Dr. Pallavi Uplap, Mrs. Pareshi Majmudar, Dr.Shrirang Pakhale

Mentor **:** Dr. Surendra Shastri

Funding Source **:** TMCROP budget through DAE

Project Status **:** Completed

Project Summary:

This trial aimed at studying the prevalence of tobacco use and oral neoplasia among the industrial employees and implementing the tobacco cessation activities at workplace and studying its impact by measuring tobacco quit rates. In addition, our objective was to develop man-power for Tobacco Control activities in the local area.

Brief Summary:

Aims: To assess the tobacco quit rates among employees, through self report history, and validate it with rapid urine cotinine test; compare post-intervention KAP regarding tobacco consumption with the pre-intervention responses and assess the tobacco consumption pattern among contract employees and provide assistance to encourage quitting.

Settings and Design: This is a cohort study implemented in a chemical industry in rural Maharashtra, India.

Materials and methods: All employees (104) were interviewed and screened for oral neoplasia. Active intervention in the form of awareness lectures, focus group discussions and if needed, pharmacotherapy was offered. Medical staff from the industrial medical unit and from a local

referral hospital was trained. Awareness programs were arranged for the family members and contract employees.

Statistical analysis used: Non-parametric statistical techniques and kappa.

Results: 48% of employees consumed tobacco. The tobacco quit rates increased with each follow-up intervention session and reached 40% at the end of one year. There was 96% agreement between self-report tobacco history and results of rapid urine cotinine test. The post-intervention KAP showed considerable improvement over the pre-intervention KAP. 56% of contract employees used tobacco and 55% among them had oral pre-cancerous lesions.

Conclusions: A positive atmosphere towards tobacco quitting and positive peer pressure assisting each other in tobacco cessation was remarkably noted on the entire industrial campus. A comprehensive model workplace tobacco cessation program has been established, which can be replicated elsewhere.